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**THE SIMULATED OCULAR SURGERY (SOS) TRIALS:  
RANDOMISED-CONTROLLED TRIALS COMPARING INTENSE  
SIMULATION-BASED SURGICAL EDUCATION FOR CATARACT AND  
GLAUCOMA SURGERY TO CONVENTIONAL TRAINING ALONE IN  
EAST AND SOUTHERN AFRICA**



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2020

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Thesis submitted in accordance with the requirements for the Degree of:  
Doctor of Philosophy  
University of London



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## Abstract

Cataract remains the most common cause of blindness globally, and glaucoma is the third after uncorrected refractive error. Surgical management remains a priority, yet surgical training of ophthalmologists continues in the outdated apprentice model. Simulation-based surgical education is yet to be tested to the level of a randomised-controlled trial in ophthalmology.

We designed two separate and independent multi-centre multi-country investigator-masked randomised controlled educational-intervention parallel group efficacy trials. Post-graduate doctors in ophthalmology training programmes at collaborating institutions in five East and Southern African countries were assessed for eligibility for inclusion (not having performed the procedure as primary surgeon) into either the OLIMPICS (ophthalmic learning and improvement initiative in cataract surgery) or GLASS (glaucoma simulated surgery) trials. Fifty-one surgical trainees were recruited into the GLASS trial, and 50 into the OLIMPICS trial. Surgical competency was assessed by video recordings, which were double marked by independent experts who were masked to group assignment and timing of the assessment. The intervention was an intense simulation-based cataract or glaucoma surgical training course over 5 days. Primary outcome measure was surgical competency at three-months assessed with validated simulated surgical competency assessment rubrics, the Sim-OSSCARs (ophthalmic simulation surgical competency assessment rubric), for both trials. The trials were registered in March 2017 on the Pan-African Clinical Trial Registry (PACTR201803002159198) and are currently closed to recruitment.

Baseline characteristics of age, sex, year of training, baseline knowledge and competency scores were balanced between both arms, for both trials.

In total 1,361 surgical videos from across different time-points were independently graded by two separate graders in both trials.

In the OLIMPICS trial, 50 participants were recruited between November 2017 and May 2018 and 49 included in the final intention-to-treat analysis with one dropout from the control group. Intervention group participants increased mean simulated surgical competence scores from a baseline of 10.8 of 40 points (27.0%) to 33.7 (84.2%) at 3-months after the training

intervention, an increase of 212%. Control group participants' mean baseline scores were 12.8 (31.9%) and 3-month scores 17.9 (44.7%).

We found strong evidence (linear regression  $p < 0.0001$ ) that those in the intervention arm were estimated to have higher scores at three months than those in the control arm, after adjusting for baseline score. Among individuals with the same baseline score, those who received the training were estimated to have scores 16.6 points higher (95%CI 14.5 to 18.8) at three months, compared to those who had not received the training.

Intervention participants performed a mean of 22 cataract surgeries as primary surgeon in the one year following the training intervention, compared to 9 by control participants (Poisson regression  $p < 0.0001$ ). Surgical complications were reported for the one year period, and posterior capsule rupture (PCR) rates were 7.4% for the intervention group compared to 26.2% for controls ( $p < 0.0001$ ).

Confidence rating scores were assessed using a ten-point Likert scale anchored at 1='not confident at all', and 10='very confident'. Confidence as cataract surgeons increased from 2.2 (of 10) to 6.3 at three-months in the intervention group, compared to 3.4 at baseline to 4.2 for the control group. Among individuals with the same baseline confidence score, those receiving the training were estimated to have scores 2.7 points higher (95%CI 1.6 to 3.7) ( $p < 0.001$ ).

In the GLASS trial, 53 trainee ophthalmologists were assessed for eligibility, and 51 were enrolled and randomised. Forty-nine participants were included in the final intention-to-treat analysis: 23 intervention and 26 control, following two drop outs from the intervention group. Baseline surgical competency scores for intervention were a mean of 9.1/40 (22.6%) [median 7.3, IQR 5.4-12.1]; and for control: 8.7/40 (21.8%) [median 8.2, IQR 6.3-12.0] participants. Mean Sim-OSSCAR scores at three-months were 30.4 (76.1%) [median 30.3 IQR 27.8-33.5] and 9.8 (24.4%) [median 9.2 IQR 7.5-11.7] for intervention and control groups respectively. We found strong evidence (linear regression  $p < 0.0001$ ) that those in the intervention arm were estimated to have higher scores at three months than those in the control arm, after adjusting for baseline score as a fixed effect. Among individuals with the same baseline score, those who received the training were estimated to have scores 20.5 points (of 40) higher

(95%CI 18.4 to 22.6) at three months, compared to those who had not received the training (linear regression  $p<0.0001$ ).

Baseline mean self-reported confidence in glaucoma surgical skills was 3.0/10 for intervention and 3.2 for control participants. This increased to mean 6.4 and 3.7 at three months respectively ( $p=0.002$ ).

Trainee participants in the intervention group performed a mean of 3.1 live surgical trabeculectomies as primary surgeon over one year following training (median 2, range 0-15, IQR 0-4). Over the same period (and before their simulation training) the control group performed a mean of 0.15 (only one of the 26 control participants performed any glaucoma surgery, compared to 14 of the 23 intervention participants).

These are the first multi-centre ophthalmic simulation surgery educational-intervention randomised controlled trials ever conducted. Intense simulation training affords a rapid and sustained increase in surgical competence, confidence as a surgeon, and impacts the number of live surgeries performed. Simulation education in cataract surgery affords a striking benefit in terms of patient safety.

## Declaration

I, William Henry Dean, declare that this work presented in this thesis is my own. All information and contributions from others is acknowledged within the thesis.

Signed

A solid black rectangular box used to redact the signature of the author.

15 December 2020

## Format of the thesis

This thesis is submitted in the form of published work. All published papers include lists of co-authors involved in the study.

The introduction chapter comprises a more detailed overview of cataract and glaucoma management, surgical education, simulation-based surgical education and educational theory relevant to the findings presented in the thesis. This leads into chapter 2 which is a more formal systematic literature review of ophthalmology training in sub-Saharan Africa (in submission to Eye).

Chapter 3 presents the research aims and objectives, and chapter 4 continues to detail the methodology used.

Chapter 5 outlines trainees' perspectives of training in sub-Saharan Africa (published paper).<sup>1</sup>

Chapters 6 and 7 cover the validation studies of the surgical competency assessment rubrics (both published papers),<sup>2 3</sup> ahead of chapter 8 which details the development of the simulation Surgery Training Centre. Chapters 9 and 10 present the main findings of the OLIMPICS (published in JAMA Ophthalmology)<sup>4</sup> and GLASS trials separately (in submission to the British Journal of Ophthalmology).

The final chapter summarises the findings overall, and highlights them in the context of what was known before, and what this research body has contributed. Recommendations and potential future directions for work are discussed. This is followed by references and appendices.

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## Glossary of Abbreviations

AC	Anterior chamber
ACGME	Accreditation Council for Graduate Medical Education
BCPB	British Council for the Prevention of Blindness
CBM	Christian Blind Mission
CEH	Community Eye Health
CEHI	Community Eye Health Institute
CONSORT	Consolidated standards of reporting trials
COECSA	College of Ophthalmology of Eastern Central & Southern Africa
COSECSA	College of Surgery of Eastern Central and Southern Africa
CPD	Continuing professional development
CSR	Cataract surgical rate
EACO	East Africa College of Ophthalmologists
ECCE	Extra-capsular cataract extraction
ESSAT	Eye surgical skills assessment test
FRCOphth	Fellow of the Royal College of Ophthalmologists (UK)
GCP	Good Clinical Practice
GLASS	Glaucoma Simulated Surgery
GOSTN	Global ophthalmology surgical training network
GMC	General Medical Council
GSR	Glaucoma Surgical Rate
HPCSA	Health Professions Council of South Africa
HReH	Human resources for eye health
IAPB	International Agency for the Prevention of Blindness
ICEH	International Centre for Eye Health
ICO	International Council of Ophthalmology
IOL	Intra-ocular lens
IQR	Inter-quartile range
ITT	Intention-to-treat
KCMC	Kilimanjaro Christian Medical Centre
LAN	Local area network
LMIC	Low & middle income country
LogMAR	Logarithm of the minimum angle of resolution
LSHTM	London School of Hygiene & Tropical Medicine
MCQ	Multiple choice question examination
MD	Mean Deviation
MD	Doctor of Medicine
MEd	Masters in Education
MIGS	Minimally invasive glaucoma surgery
MMed	Masters in Medicine
MSVI	Moderate & severe vision impairment
MURHEC	Mbarara University & Referral Hospital Eye Centre
NGO	Non-government organisation
NPCS	Non-physician cataract surgeon
NPMCN	National Postgraduate Medical College of Nigeria
OASIS	Objective assessment of skills in intra-ocular surgery
OCO	Ophthalmic Clinical Officer

OLIMPICS	Ophthalmic Learning & Improvement Initiative in Cataract Surgery
OPC	Organisation for the Prevention of Blindness
OphSET	Ophthalmology Surgical Education and Training
OSACSS	Objective structured assessment of cataract surgical skill
OSEA	Ophthalmology Society of Eastern Africa
OSEC	Ophthalmic Surgical Education Consortium
OSCAR	Ophthalmology Surgical Competency Assessment Rubric
OVD	Ophthalmic viscosurgical device
OWL	Ophthalmology wet laboratory
PCR	Posterior capsule rupture
PI	Principal investigator
RCOphth	The Royal College of Ophthalmologists, UK
RCT	Randomised controlled trial
SD	Standard deviation
SDP	Sustained deliberate practice
SICS	Small-incision cataract surgery
Sim-OSSCAR	Ophthalmic Simulated Surgical Competency Assessment Rubric
SLT	Selective laser trabeculoplasty
SOP	Standard operating procedure
SOS	Simulated ocular surgery
SSA	Sub-Saharan Africa
SSTU	Simulation Surgery Training Unit
SVI	Severe vision impairment
UCT	University of Cape Town
UK	United Kingdom
URE	Uncorrected refractive error
USA	United States of America
VA	Visual acuity
VL	Vitreous loss
WACS	West Africa College of Surgeons
WHO	World Health Organisation
ZPD	Zone of proximal development

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## 1. Introduction



Cataract surgery has been performed for over 4,000 years, first referenced in the Code of Hammurabi in Babylonia-Assyria in 2250 BC.<sup>5 6</sup> It is among the most cost-effective of all healthcare interventions.<sup>7</sup> A short operation can effectively restore vision, which in turn can contribute to poverty alleviation, especially among the most vulnerable members of society.<sup>8</sup> There are more than 230,000 ophthalmologists globally, and less than half perform cataract surgery.<sup>9</sup> Despite great efforts over the past two decades, spearheaded by the VISION 2020 initiative, cataract remains the number one cause of blindness worldwide.<sup>10</sup>



Mr Luka is blind. He knows the names of his seven grandchildren in the village, he recognises their voices. However, he has never seen them, not since the first was born eight years ago. He hails from a small remote village surrounded by maize fields next to a rocky escarpment in the Great Rift valley near the south of Lake Malawi.



Dr Dean was trying to teach cataract surgery to a young new eye surgeon. The operating theatre was a busy place. After the morning staff meetings and outpatient clinics around 30 patients were lining up for cataract surgery and other procedures. It was hot, it was noisy, it was busy, it was stressful. Stressful for Dr Dean as he tried to calmly explain the steps of the cataract operation again, blood pressure and cortisol levels increasing. Stressful for the new young trainee who was simultaneously attempting to listen, comprehend, and perform while verging on blind panic and increasing levels of receptive aphasia. Stressful for the patient who had never been to a hospital before, was terrified by the experience, and just wanted their cataract washed away.

Dr Dean took over and completed the procedure when the trainee faltered. Mr Luka was next on the list, and Dr Dean performed the entire cataract surgery, showing the trainee yet again how it should be done.

Doctors in remote rural areas are often in part administrators, managers, directors, financial planners, researchers, teachers and trainers; as well as clinicians and surgeons. Of the numerous tasks I was called on to perform during my years in a mission hospital in rural Malawi, there were none even remotely as stressful as teaching eye surgery. The only method at our disposal, aside from a few videos, lectures and books was step-wise live surgical training. This was very much the Halstedian apprentice model of training.<sup>11 12</sup> See one, do one, teach one. It was how I was trained. It simply was how one trained. It was very stressful.

When I saw Mr Luka in the clinic later in the week, I was grateful that both eyes were sparkling with joy. The outcomes of his cataract operations were good, and he was on his way home. He could not contain his happiness and shared it with us in song and dance. Eye surgeons are incredibly privileged to have the skills, vocation, and profession: the Ikagai to restore sight. It is exceptionally rewarding. However, in this moment of pure elation I was distressed by a thought. What if Mr Luka had been operated on by an untrained terrified new trainee, and if surgical complications and a poor visual outcome had ensued. Rather than return to his family and community with newfound vision and joy, he would have had to continue recognising his grandchildren by their voices alone.

*“Education is the most powerful weapon which you can use to change the world”*

- Nelson Mandela -

We absolutely need to train more eye surgeons. And this is true for surgical education of new eye surgeons, and the world of the patients they serve. Can we find a way to train more eye surgeons, more efficiently and safely, with fewer complications, to ensure that thousands more people like Mr Luka can see their grandchildren again?





## The burden of cataract and glaucoma in sub-Saharan Africa

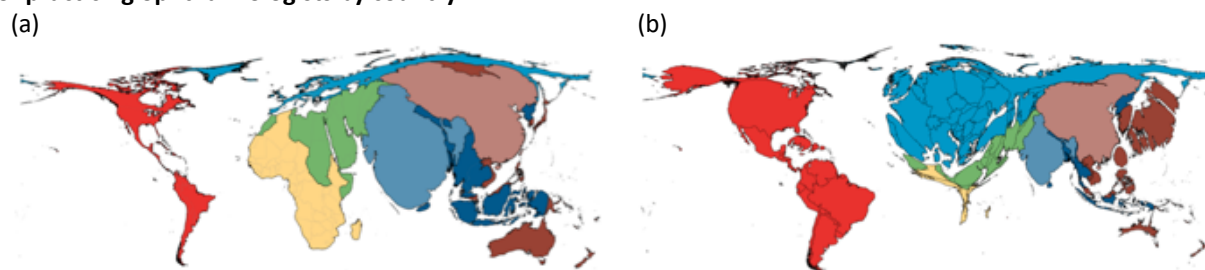
Globally there are 36 million people who are blind and a further 219 million with moderate or severe vision impairment (MSVI).<sup>10</sup> Approximately 80% of blindness is preventable or treatable, and 90% of the burden is in low and middle income countries (LMIC). Sub-Saharan Africa (SSA) has the highest prevalence of blindness of any region at 9% in the population >50 years.

Together, cataract and glaucoma account for half of blindness in the world,<sup>10</sup> and while surgery is the only management option for cataracts, advanced glaucoma will in many situations also require surgery. Cataract is a gradual opacification of the crystalline lens, typically presenting with a gradual onset over a few years of reduced vision, glare, and difficulty with bright or dim light in people aged over 60 or 70 years. One or both eyes may be affected. After a relatively simple diagnosis, referral to an eye department is needed for surgical management which is invariably a single episode day case procedure. Follow-up may be in the community or in a hospital clinic after a few weeks. Glaucoma is an ophthalmic disease which involves damage to the optic nerve. It results in typical optic nerve pathological changes (optic disc cupping), characteristic visual field loss; and is classically (but not always) associated with high intra-ocular pressure (IOP). However, the early stages of chronic glaucoma and ocular hypertension are asymptomatic. Screening is very challenging in resource poor and rural settings where there is no routine eye examination for people aged over 40 years, even if primary healthcare workers are trained.<sup>13</sup> Furthermore, measurement of IOP aside, there is no simple screening test with appropriately high sensitivity and specificity. Early accurate diagnosis is often complex, requiring clinical and visual field examination, and further assessments including measurement of corneal thickness, and optic disc optical coherence tomography. Damage to the optic nerve and resultant vision loss is irreversible in glaucoma, however many patients present late in the natural history of the disease with advanced visual field and acuity loss. Public health measures require an integrated multi-disciplinary team approach.

SSA is the region with the lowest number of ophthalmologists per capita, with about 2.5 per million, compared to 16.7 per million in Europe and the North America.<sup>9 14</sup> There is a striking mismatch between the burden of blinding disease and the availability of skilled staff to

address it within SSA (Figure 1). The region urgently needs an increased number of proficient eye surgeons to counter avoidable blindness from cataract and glaucoma.<sup>15</sup>

**Figure 1: Density equalised cartograms showing: (a) prevalence of blindness by WHO region, and (b) number of practicing ophthalmologists by country.<sup>16</sup>**



For example, 1.9 million people are blind and 7.5 million have MSVI from cataract in SSA. To tackle the current cataract backlog of 9.4 million people in SSA, each ophthalmologist would need to perform 7,000 operations. The cataract surgical rate (CSR) needed to eliminate vision impairment at the level of 6/18 can be estimated to be approximately 1,200 to 4,500 cataract operations per million population, per year.

Relatively few ophthalmologists perform trabeculectomy. There are around 500 people per ophthalmologist already blind from glaucoma, and the number with advanced glaucomatous disease who potentially warrant surgery, is considerably more. A glaucoma surgical rate of 500 per million population per year has been recommended.<sup>17</sup>

Small incision cataract surgery (SICS) is a widely accepted, appropriate and affordable procedure with high quality visual outcomes.<sup>18-21</sup> Glaucoma is the third leading cause of blindness (8%) and fourth leading cause of MSVI globally (2%),<sup>10</sup> and surgical trabeculectomy is often the primary treatment, partly due to the challenges of sustaining medical therapy.<sup>17</sup><sup>22-24</sup> These two surgical techniques were therefore chosen in the two trials described in this thesis.

### **Surgical Ophthalmology in Sub-Saharan Africa**

There are more than two hundred and thirty thousand ophthalmologists in the world, however a low proportion are trained and work in SSA.<sup>25</sup> In SSA, 2.5 ophthalmologists per

million serve a population of a billion, and this shortage is well documented.<sup>9 26</sup> It leads to several challenges, including the amount of time that is available for training. There is a need to develop innovative, efficient, evidenced-based, and cost-effective strategies for ophthalmic training in the region, and globally.

A recent review by the International Agency for the Prevention of Blindness (IAPB) resulted in the publication of the IAPB Training Institutions Database. This identified ten ophthalmology training institutions in nine Francophone SSA countries, two in two Lusophone countries, and thirty-nine ophthalmology training programmes in ten different Anglophone African countries.<sup>27</sup> The total capacity for trainees within the ophthalmology training programmes in the College of Ophthalmology East Central and Southern Africa (COECSA) region was 64 (in total, for all years). However, this capacity does not necessarily equate to or reflect the numbers currently being trained, and the IAPB concludes that “more needs to be done to assess and address the strength of individual training institutions as well as understand why some institutions are regularly over-subscribed”.<sup>27</sup> Since publication of the review in 2015, more training institutions have begun training ophthalmologists, and these have been included in the systematic review of ophthalmology training in SSA (chapter 2).

Within the COECSA region, the duration of training programmes varies from three years (in Kenya, and Uganda), to four years (in Ethiopia, Malawi, Tanzania, Zambia, and Zimbabwe). Training has been well established over the past four decades. Ophthalmology training programmes in COECSA follow a competency-based curriculum.<sup>28</sup> Training in cataract surgery generally starts in the second year of training, and training in glaucoma surgery (which is more complex) begins towards the end of the third year, if at all. The challenges of glaucoma surgery training are not isolated to SSA, but are global.<sup>29 30</sup> Aside from the overall need in Africa to train greater numbers of proficient ophthalmologists, there are a limited number of consultant ophthalmologist surgeon trainers within training institutions, with only limited time available for provision of training. With ever increasing demands on ophthalmology training programmes, most have reached capacity. There is a current pressing need to develop and validate new innovative approaches to deliver more effective, efficient and safer surgical ophthalmology training.

Because of this shortage of trained ophthalmologists in SSA, a specific paramedical cadre has developed. 'Cataract surgeons' were originally described in 1987,<sup>31</sup> and over the past three decades training institutions and programmes have been established for ophthalmic clinical officers (OCO), or non-physician cataract surgeons (NPCS), in Malawi, Kenya and Tanzania. Currently seventeen countries in SSA employ NPCSs, including Kenya, Tanzania and Uganda. However, two thirds of all the NPCS in SSA work in only three countries: Ethiopia, Kenya and Tanzania.<sup>32</sup> This current study did not include the cadre of OCO/NPCS, simply for the reason of standardisation; however this model of surgical training and the data from this study may provide benefit to NPCS surgical training in the future.

This thesis includes a systematic review of ophthalmology training in SSA, chapter 2. Data were also collected and analysed in a focussed trainee survey of ophthalmic surgical training, chapter 5.

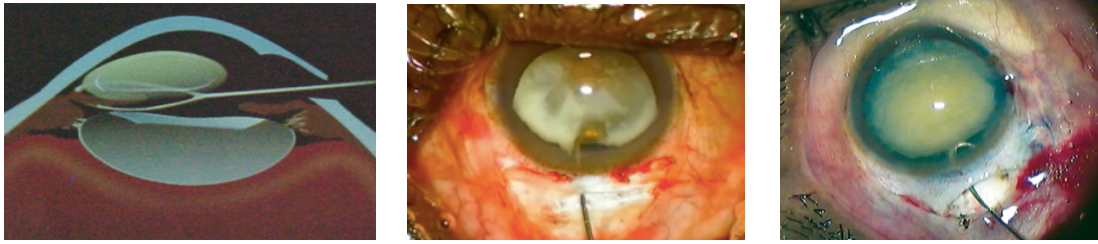
## Cataract Surgery

The procedure of sutureless scleral-tunnel small-incision cataract surgery (SICS) is the most commonly performed cataract surgery procedure in SSA, and is the main standard of care.<sup>33</sup> <sup>34</sup> The technique uses a smaller wound compared to the older technique of sutured extra-capsular cataract extraction (ECCE).<sup>35</sup> There is less post-operative astigmatism, and fewer suture-related problems for SICS versus ECCE. The clinical outcomes of phacoemulsification cataract surgery and SICS are comparable.<sup>19 20 36 37</sup> SICS is an appropriate, safe, and affordable technique for blindness prevention. While the technique of SICS was chosen for the OLIMPICS trial (chapter 9), it is recognised that there is an increasing demand for modern, more expensive phacoemulsification cataract surgery in SSA, and that study in South Africa showed less astigmatism and improved visual outcomes in the medium term following phacoemulsification.<sup>38</sup>

The International Council of Ophthalmology (ICO) have uploaded the live surgical procedure of SICS and this can be viewed on YouTube:

<https://www.youtube.com/watch?v=LszyZqqR5v4>

**Figure 2. The cataract nucleus removal in SICS.**



The primary outcome of cataract surgery is an improvement in visual acuity (VA). This can be measured without refractive correction (unaided), or with spectacle correction (best-corrected). It can be measured for distance (usually 6 metres) or near (usually 30cm). A secondary outcome of cataract surgery is often a moderate reduction in IOP. It is often very difficult, unrealistic, and expensive to measure post-operative visual acuity a few weeks after cataract surgery in rural LMIC settings due to the logistics of bringing the patient back to the hospital. Furthermore, there is evidence that day-one post-operative VA is a very good predictor of final VA.<sup>39</sup> It is critical for surgeons to collect and analyse their own cataract surgical outcomes, as there is clear evidence that such monitoring and personal reflection improves surgical quality and outcomes.<sup>40</sup> Tools for monitoring the outcomes of cataract surgery have been developed, and measurements included are: VA and complications.<sup>41</sup>

Complication rates vary for cataract surgery, depending on co-morbidity, the experience of the surgeon, the maturity of the cataract, and the technique used. Rates of complications for experienced surgeons for posterior capsule rupture (PCR) or vitreous loss (VL) vary from 1.92% to 6%.<sup>36 37 42</sup> The WHO recommends aiming for a complication rate (PCR rate) of less than 5%. Complication rates have been shown to be greater for trainee ophthalmologists.<sup>43</sup> PCR is the most commonly reported peri-operative complication of cataract surgery, and is widely used as benchmark for reporting surgical outcomes. Other post-operative complications were considered, including corneal oedema/decompensation and endophthalmitis. However, while superior corneal oedema can occur following poor sclero-corneal tunnel construction and Descemet's membrane stripping, it is difficult to grade and confidently assign cause. Endophthalmitis is a serious infective complication, however is thankfully relatively rare (less than 1 in a 1,000 cases), and is multifactorial in aetiology, not simply due to poor surgical technique.

## Glaucoma Surgery

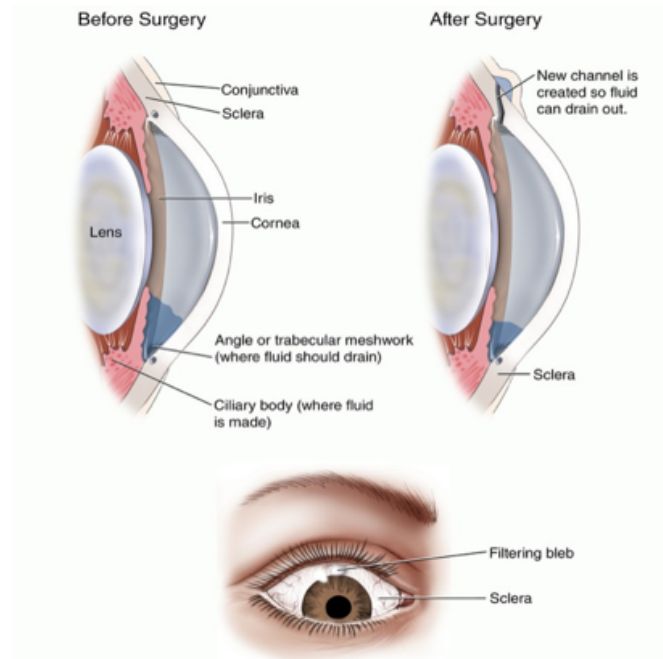
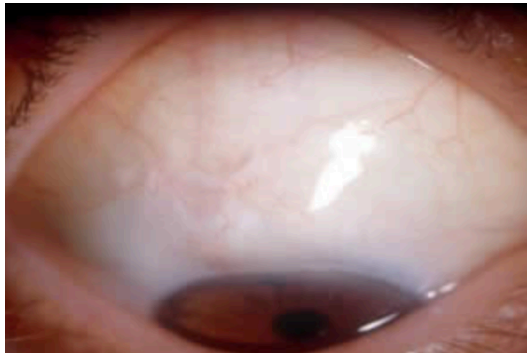
For glaucoma, all current widely-available treatments – whether medical, laser, or surgical – aim to reduce the IOP. In many cases, surgical trabeculectomy can be considered as a first-line treatment.<sup>44</sup> Surgical trabeculectomy remains the global gold-standard for glaucoma that is refractory to medical or laser management.

The overall aim of trabeculectomy glaucoma surgery is to reduce the IOP. A range of surgical outcome measures are monitored post-operatively in hospital clinics, and are also included in research studies.<sup>45</sup> These indicators may include IOP change, complications or return to theatre rates, and need for subsequent medical anti-IOP topical treatments.

Further commonly-used outcome measures include visual field mean deviation (MD) changes, and visual standards for driving. These outcome measures are considered outside of the remit of this study.

All and any complications were considered for reporting in the GLASS trial. The majority of these would occur in the first few post-operative weeks, and may include over-drainage or under-drainage. Over-drainage may be due to a conjunctival leak, or due to a loose scleral flap suture; and may be graded according to degree of anterior chamber shallowing. Under-drainage may be due to tight scleral sutures, and managed by bleb massage and pulling of the releasable scleral suture(s). Further intervention of bleb or flap needling may be required. Participants in the GLASS trial were invited to present a self-reported summary of these after the one-year follow-up period.

**Figure 3. Surgical Trabeculectomy**



The specific technique for surgical trabeculectomy taught in the training interventions in the GLASS Trial (chapters 8 and 10) presented in this thesis was the one refined by Professor Sir Peng Khaw of Moorfields Hospital, London, UK; and is considered an international gold-standard.<sup>46</sup>

## Surgical Education

Dr William Stewart Halsted not only introduced surgical rubber gloves to the operating theatre, and the concept of 'safe surgery', but also and most famously introduced a system to train young surgeons.<sup>11 12</sup> This 'apprentice model' of surgical education encompassed a pyramid of hierarchy and 'graduated responsibility'. Trainees had to be available 24 hours a day, seven days a week. Interestingly there was no prescribed length of training. Halsted would decide on promotion; and based on his assessment of capabilities, skill and talent would decide when a trainee was ready for practice. The traditional apprentice model of 'see one, do one, teach one' appears to also be the first formal pure competency-based surgical training. However, not all were guaranteed promotion and as trainees had to be constantly available, they lived in the hospital, were unmarried, and only men were allowed.

Since the early 1900s, surgical education has evolved. National and regional surgical training curricula have been developed and refined for implementing standardised surgical residency training. In many parts of the world surgical education is regulated by affiliated universities, national Colleges, or medical and dental councils. Competency-based training and assessment have been adopted by many training institutions, and minimum standards and duration of training set.<sup>47</sup> Broad-based surgical training programmes are still most commonplace, with specialisation and sub-specialisation following. Certification varies considerably around the world.

There is increasing complexity of surgical interventions and technologies, and a constantly expanding range of management options for surgically treatable conditions. Time available for surgical education, and surgical training opportunities are limited, and are not increasing.<sup>48</sup> Recent efforts have focussed on the efficiency of surgical education and the learning process. This includes practicing of basic surgical and micro-surgical skills away from the operating theatre, deconstructing surgical procedures and subsequent step-wise learning, and the role of simulation in surgical education.<sup>49</sup>



## Surgical Education and Simulation

It would appear to be of implicit benefit to patients, trainees and trainers that simulation in surgical education would offer and enable an accessible, safe, and reproducible method of learning surgical skills and procedures outside of the stress of the operating theatre. However, despite these explicit and implicit benefits, and the great enthusiasm surrounding simulation in surgical and certainly ophthalmic surgical training, questions remain.

- What is the evidence that this is the case?
- What aspects of education are the most impactful?
- Is there a best time for an intense simulation surgical education intervention during a three or four-year training programme?
- Are the skills obtained transferable to theatre? Simply put, does practicing eye surgery on a simulator only make a trainee better at operating on a simulator, or does it make the trainee better in the live-surgical setting too? This 'predictive validity', being the transfer of skills learnt in a simulation environment to live surgery, is challenging to measure.
- How does simulation-based surgical education impact surgical competence and confidence?
- And finally, perhaps most importantly, does intense simulation-based surgical training in the two main surgically treatable causes of global blindness (cataract and glaucoma) impact patient safety?

A systematic review of sixteen randomized controlled trials of simulation of techniques used in laparoscopic procedures concluded that there was a 'positive impact of simulation on operative time and predefined performance scores, however these alone are insufficient to demonstrate transferability of skills from the laboratory to the operating room'.<sup>50</sup>

A critical review of simulation-based medical education suggested twelve areas of best practices and features,<sup>51</sup> many of which have also been identified by other educational theorists. These twelve features and best practices included feedback, deliberate practice, curriculum integration, outcome measurement, simulation fidelity, skill acquisition and maintenance, mastery learning, transfer to practice, team training, high-stakes testing,

instructor training, and educational and professional context. These twelve educational features were built into the OLIMPICS and GLASS trials (chapters 8 to 10).

Much of the initial literature of the utility of simulation in surgical training is in the medical domain of abdominal laparoscopic surgery.<sup>52 53</sup> The methodology used in these studies provides an excellent foundation for current and future ophthalmology simulation-based surgical education research.

There are several challenges in surgical training. As Professor Roger Kneebone explains, “demands for patient throughput are increasing, while reductions in work hours mean that trainees’ opportunities for hands-on experience have been curtailed”.<sup>54</sup> These challenges are global, and in sub-Saharan Africa the demand for patient throughput is enormous for all healthcare professionals: trainees and trainers alike. Kneebone continues to argue that if “adequate experience can no longer be gained wholly through operating, effective adjuncts must be found. Simulation offers an environment in which learners can train until they reach specified levels of competency”. This statement lies squarely at the heart of this thesis. We absolutely need to, in SSA and beyond, explore and research ways to not only maximise the short time that trainers and trainees have, but enable trainees to attain benchmarked levels of surgical competency rapidly and effectively.

In a review paper on the features of medical simulators, it was illustrated that high-fidelity medical simulators facilitate learning in the right conditions. These include repetitive practice, providing feedback, curriculum integration, having a range of difficulty level, and having multiple learning strategies. The importance of individualized learning; where trainees have reproducible, standardized educational experiences and are active participants and not merely passive bystanders, was also highlighted.<sup>55</sup>

Intensive simulation-based surgical education has been shown to rapidly increase surgical skills, decrease complication rates, provide a safe and relaxed environment to learn in, and enable sustained deliberate practice,<sup>55</sup> however this has not yet been comprehensively proven for ophthalmic surgical training.<sup>56</sup>

## Simulation in Ophthalmic Surgical Training

### Simulation Curricula

Well-designed ophthalmic microsurgical skills courses have become mandatory in the UK, and must be completed by novice trainees before they are allowed to perform any intra-ocular surgery. Simulation is being integrated into ophthalmology training curricula.

The Royal College of Ophthalmologists' Education Committee have a Simulation Group. The College has mandated simulation as part of the curriculum, and expects trainees to undertake simulation on a regular basis.<sup>57</sup> They have published a parallel simulation curriculum.

In the USA, the Accreditation Council for Graduate Medical Education (ACGME) lays out what residency programmes are required to provide. They state that trainee residents must have surgical skills instruction using surgical skills development resources, including at minimum training in a hands-on surgical skills laboratory, and a structured hands-on simulation surgical skills curriculum that includes assessment [section IV.C.12].<sup>58</sup>

The Royal Australia and New Zealand College of Ophthalmology (RANZCO) have published a Basics of Ophthalmic Surgery Curriculum Standard. Within it there is a specific learning outcome to perform surgical skills in a wetlab, and specific performance criteria including a commitment to practice surgical skills in safe conditions prior to surgery on live patients.<sup>59</sup>

The College of Ophthalmologists of Eastern Central and Southern Africa (COECSA) has adopted a competency-based curriculum for ophthalmic trainees in the region. There are several learning domains, one of which is surgical skills. Of the seventeen separate surgical skills to be learnt, the very first is for 'Simulation and Wetlab'.<sup>60</sup> This illustrates the importance placed within COECSA on the use of simulation in surgical training.

It has been acknowledged however that the curriculum integration of simulation is only beginning, and as with many ophthalmology training programmes around the world is still at an advocacy-seeking level. There is no current universal, sustainable, standardised and educationally-underpinned regional training employment of ophthalmic simulation-based

surgical education. Furthermore, there is no current robust evidence or significant data testing the efficacy of simulation-based surgical education in cataract and glaucoma surgery, outside of computerised Eyesi simulators (VRMagic Holding AG, Mannheim, Germany).<sup>61-63</sup>

In a major systematic review, a team from Denmark screened over a thousand papers, and studied one hundred and eighteen trials involving simulation-based training or assessment of ophthalmic surgical skills among health professionals.<sup>56</sup> They correctly state that “using simulation models without knowledge of reliability, validity and efficacy may compromise patient safety, especially if the trained skills do not correlate with the skills needed for real-life performance”. They found the overall evidence for the use of simulation-based training or assessment in ophthalmology to be poor. Only two of the trials investigated transfer of skills into the operating theatre, and only four evaluated the effect of simulation-based training on patient-related outcomes. A lot more, and more rigorous, educational research investigating the validity, reliability and efficacy of simulation-based ophthalmic surgical training is needed.

The structured use of simulation is a relatively recent addition to surgical education. As with other medical specialities, in ophthalmology there is a focus on, and fascination with, attractive and highly-sophisticated technology models of simulation training.<sup>64</sup> This is for good reason, as current models are very well developed and used. There is however an argument to be made that high-tech does not always imply high-fidelity simulation. Certain aspects of a procedure are almost impossible to simulate using computer simulation models. This includes the surgical incisions made during cataract surgery, which are not included in the Eyesi. Low-tech models of ophthalmic simulated surgical training have been used for decades, and recent developments include the use of artificial eyes. Different models of simulation-based surgical education have their strengths and weaknesses; and all potentially have their place within an educational-theory underpinned training curriculum.

A difficult and yet crucial aspect of simulation in surgical education is predictive validity: the transfer of simulated skill to clinical practice in the operating theatre. In other words, does experience with a simulator lead to being a better surgeon. It has been shown that skills acquired on simulators do transfer to the operating room, and proficiency-based training maximises this benefit.<sup>65</sup> Although there is some evidence, and it is implicitly accepted, more

and robust educational research is needed to explicitly prove the predictive validity of simulation in ophthalmic surgical education. The OLIMPICS trial involves live surgical competency assessment at the 12-month evaluation, as well as an annual summarised report of cataract surgical experience.

Various animal eyes as well as human cadaver eyes have been used in ophthalmic surgical education. Most of these are reported in descriptive articles, as have the use of artificial model eyes. These are discussed below, followed by an illustration of ophthalmic computer simulators used in training.

### Animal and human cadaver eyes

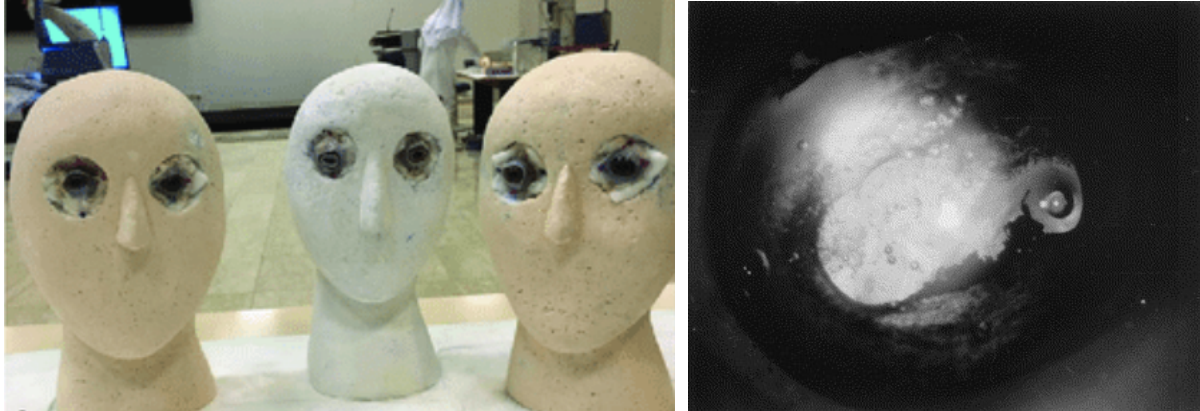
Porcine eyes are commonly used to simulate cataracts (Figure 4), however there are significant cultural limitations, and they are not available in the Middle East.<sup>66</sup> Chestnuts of differing hardness have been used to simulated cataracts when placed in porcine eyes.<sup>67</sup> Preliminary testing was performed on a hybrid training model using porcine eyes and a novel force and torque sensor to measure and record surgical instrument/tissue interaction.<sup>68</sup>

**Figure 4.** Porcine eyes mounted in basic wetlab for a porcine trabeculectomy<sup>69</sup> and mounted on a tactile sensor.<sup>68</sup>



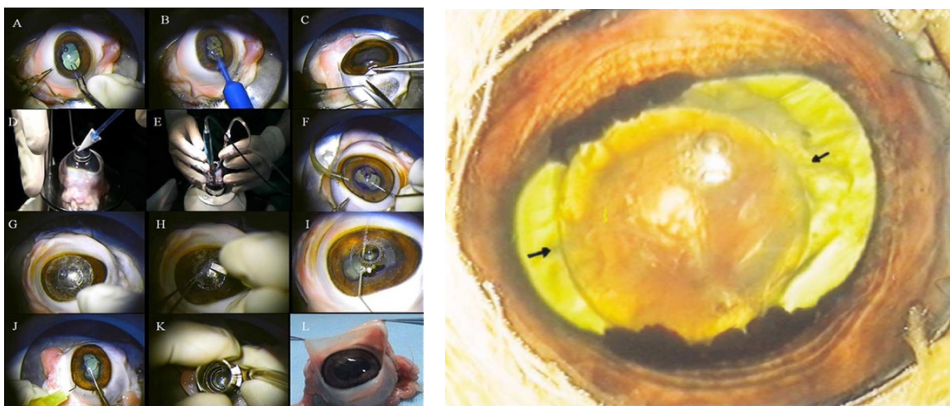
Enucleated caprine (goat) eyes have been used for cataract surgery training (Figure 5).<sup>70</sup>

**Figure 5. Goat eyes mounted on polystyrene heads<sup>71</sup> and Formalin-induced mature caprine cataract<sup>72</sup>**



Ovine (sheep) eyes are also an alternative where pigs are not available, and have been used in practice of cataract and glaucoma surgery.<sup>73</sup> However, the anterior chamber (AC) appears unstable during surgery and the lens is so thick that complete extraction is not possible. A human mature cataract nucleus has been implanted into an ovine lens for simulation cataract surgery (Figure 6).<sup>74</sup>

**Figure 6. Anterior segment surgery in ovine eyes. Human nucleus in ovine lens**



A similar idea has been used implanting a human cataract with its capsule into a rabbit eye.<sup>75</sup>

Human cadaver eyes have been used in cataract and glaucoma surgery training<sup>76-79</sup> Like animal models, there are limitations. The major challenges being reduction of the surgical view due to corneal oedema.

## **Artificial Eyes**

Artificial eyes made from plastic and other synthetic materials have been used and developed over the past decade for ophthalmic simulated training.

Eye devices developed for cataract surgery practice and using an artificial lens include Marty the Surgical Simulator (Iatrotech, Del Mar, CA, USA), Phaco-I (Phaco Practice Eye) (Madhu Instruments, Gurugram, Haryana, India) and the Phake-i Surgical Training System (Eye Care and Cure, Tucson, AZ, USA). The SimulEYE (Gulden Ophthalmics, Elkins Park, PA, USA) ophthalmic surgical training models have been developed for capsulorrhexis, pupil manipulations, intra-ocular lens (IOL) implantation, laser procedures (including selective laser trabeculoplasty (SLT)), and minimally invasive glaucoma surgery (MIGS).

The Eye4 Cataract series (Eyecre.at, Ötztal Bahnhof, Germany) was formerly known as 'the synthetic cataract eye for phaco training'. There are no published cohort studies, RCTs, or meta-analyses evaluating the efficacy or predictive validity of any of these devices for ophthalmic simulation surgical education. Furthermore, there is no robust evidence or evaluation of the fidelity of these models. There are no construct validity studies evaluating surgical performance tested on these artificial simulation eyes.

They are attractive devices, however there is no robust educational evaluation of their teaching and learning potential (Figures 7 – 9).



Figure 7a) Marty



7b) Phaco-i



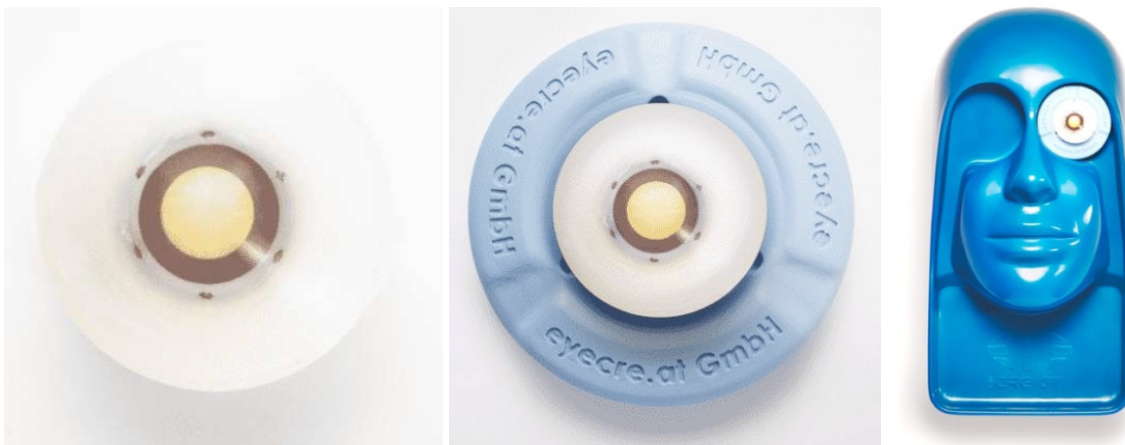
Figure 7c). Phake-i Surgical Training System



Figure 7d). SimulEYE



Figure 7e). Eye4 Cataract





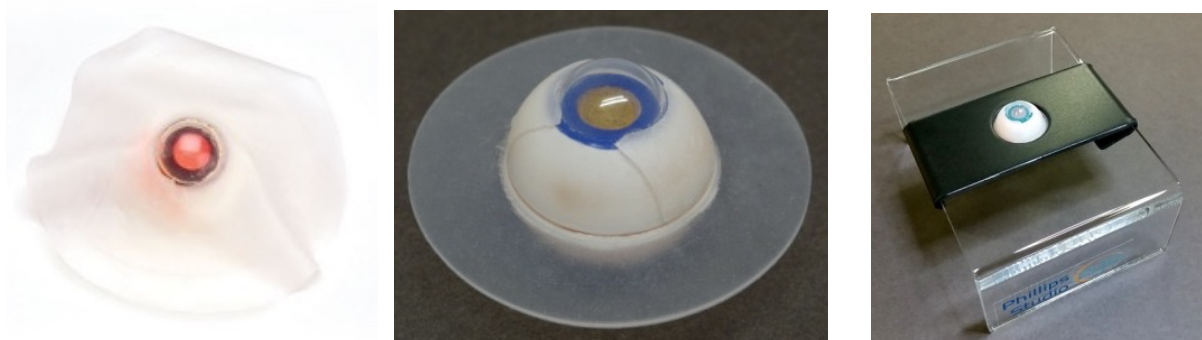
‘Kitaro DryLab’ is a tool to teach and learn some steps of cataract surgery, including the capsulorrhexis and sclero-corneal tunnel construction of SICS (Figure 8). It is mobile, and can be used on a desktop, and without the use of an operating microscope (Frontier Vision Co. Ltd., Hyogo, Japan).

**Figure 8. Kitaro Dry Lab Kit**



In the UK, Phillips Studio in Bristol have developed artificial eyes for use in training in a number of ophthalmic surgical procedures, including SICS and trabeculectomy.<sup>80</sup> (Figure 9)

**Figure 9: Phillips Studio artificial eyes for trabeculectomy and SICS**



The Principal Investigator (PI) worked in close partnership with Phillips studio to develop the SICS eye during pilot studies in Malawi and Uganda in 2015; and in the subsequent two years prior to the SOS trials. Five initial iterations were progressively developed before the final version 6.0 (Figure 9).

### Computerised simulators or virtual-reality models.

The use of computerized simulation models have been validated for cataract<sup>63 81 82</sup> and retinal surgery.<sup>83</sup> Three computerised simulators have been used for phacoemulsification cataract surgical training (Figure 10). These are the Eyesi simulator, the MicroVisTouch (ImmersiveTouch, Chicago, USA), and PhacoVision (Melerit Medical, Linkoping, Sweden).<sup>84</sup>

A simulation-based performance test and certification for cataract surgery has been established for use with the Eyesi simulator. The test showed evidence of validity, and appeared to be a useful and reliable assessment tool, both for cataract procedure-specific as well as general micro-surgical skills.<sup>85</sup> Other assessment tools used in ophthalmic surgical education will be discussed in the next section.

**Figure 10. Eyesi and MicroVisTouch Cataract Simulators**



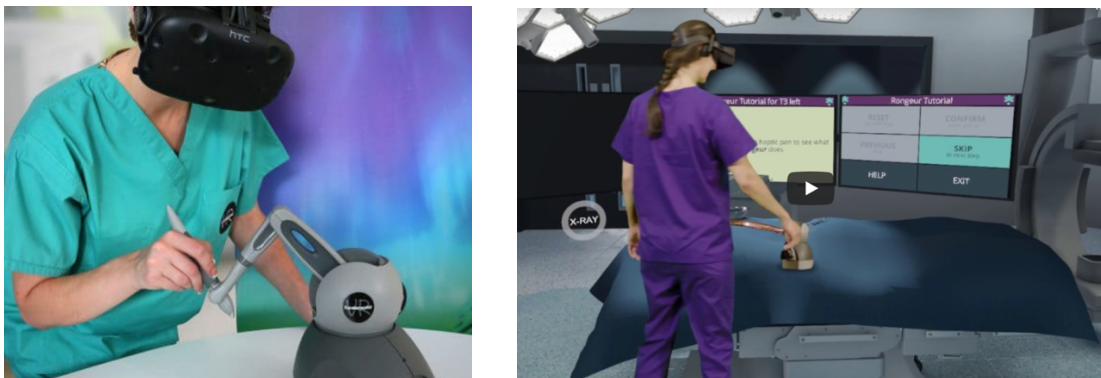
HelpMeSee (New York, USA) are in the final stages of developing a full-immersion surgical training simulator for the use within high capacity surgical education programmes for small-incision cataract surgery (Figure 11).<sup>86</sup>

**Figure 11. HelpMeSee SICS Simulator**



VR Fundamentals (London, UK), in partnership with Orbis International, have recently developed a computerised simulator for SICS (Figure 12). I have been the lead ophthalmic consultant for this project. This was finally submitted to Orbis for marketing and use in February 2020.

**Figure 12. VRFundamentals Virtual Reality Surgical Training**



Both the OLIMPICS and GLASS Trials focus on the utility of low-cost, high-fidelity simulation within a bespoke educational package of curriculum, assessment, practice, and feedback.

## Assessment tools in ophthalmic surgical training.

The right choice of assessment tool to evaluate the fidelity, reliability and validity of a training approach is an important component in surgical education. As graduate surgical education has changed over the past decade to a competency-based model, surgical training programmes have been directed by the Royal Colleges and General Medical Council (GMC) in the UK, Surgical Colleges in sub-Saharan Africa, and the ACGME in the US, to provide evidence of the attainment of competence by trainees.

For this, training institutions and programmes need valid competency assessment tools. Several such tools have been developed for surgical training in the field of ophthalmology. Validation of the use of artificial eyes and associated training assessment tools or rubrics are important, to determine their use as an objective and reliable training and assessment of surgical competence in ophthalmic surgical training.

Ophthalmic surgery competency assessment tools include the OSACSS (objective structured assessment of cataract surgical skill), developed as an objective performance-rating tool for phacoemulsification cataract surgery.<sup>87</sup> The ESSAT (eye surgical skills assessment test) is a three-station wet laboratory surgical skills assessment course was developed for ophthalmic trainees in the USA.<sup>88 89</sup> The OASIS (objective assessment of skills in intra-ocular surgery) was developed in Harvard, Boston in 2005.<sup>90</sup> The aim was to develop an objective ophthalmic surgical evaluation protocol to assess surgical competency and improve outcomes – developed specifically for phacoemulsification cataract. The main purpose of OASIS is the direct observation of live surgery, and surgical assessment.

The ophthalmology surgical competency assessment rubric (OSCAR) is an assessment matrix for live surgery, and different iterations for various surgical procedures have been developed and validated by the International Council of Ophthalmology (ICO).<sup>91 92</sup> It is based on a modified Dreyfus scale (novice, beginner, advanced beginner and competent),<sup>93</sup> as trainees were not expected to become proficient or expert during training. ICO-OSCARs for SICS and trabeculectomy have been validated and published.<sup>92 94</sup>

For the purpose of surgical competence assessment in the OLIMPICS and GLASS trials, this template was selected and re-designed as the ophthalmic simulated surgical competency assessment rubrics (Sim-OSSCAR) for the SICS and glaucoma surgical techniques on artificial eyes (chapters 6 and 7; Appendices 3a and 3 b).<sup>2,3</sup>

Both the OLIMPICS and GLASS trials use ophthalmic simulation surgical competency rubrics (Sim-OSSCARs) as the assessment tools for the masked double grading of surgical competency for the primary outcome measures. These Sim-OSSCARs have been validated as assessment tools, and are presented in chapters 6 and 7 of this thesis. They are also fundamentally important to the intervention training in both trials as they were used as learning tools during the training intervention course, with the digital classroom. Trainees video recorded their simulation performance of a surgical procedure, and then engaged in reflective learning by reviewing the recording and marking themselves against the Sim-OSSCAR.

.....

Nearly half of all blindness in the world is due to two surgically treatable conditions, and there is a need to train more ophthalmic surgeons. There is a need to train surgeons effectively, efficiently, and safely with often limited resources. The implicit potential benefits of simulation-based surgical education are not currently supported by robust and comprehensive evidence. The following chapter 2 explores more systematically the landscape of current ophthalmology training in SSA. The final chapter 11 picks up on questions raised, with further discussion and recommendations.

## 2. Systematic Literature Review of Ophthalmology Training in sub-Saharan Africa

### RESEARCH PAPER COVER SHEET

#### **SECTION A – Student Details**

Student	William Dean
Principal Supervisor	Matthew Burton
Thesis Title	The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East and Southern Africa.

#### **SECTION B – Paper already published**

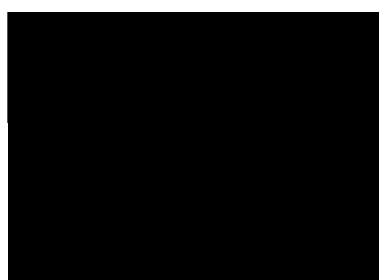
Where was the work published?	Eye (Lond)
When was the work published?	15 December 2020
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	
Have you retained the copyright for the work?*	Was the work subject to academic peer review?

Pages 41 to 58

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#### **SECTION D – Multi-authored work** – See following page

Student Signature:



Date: 12 March 2020

Supervisor Signature:

Date: 16 March 2020

Chapter 2 is a detailed systematic review of published and publicly-available literature on ophthalmology training in sub-Saharan Africa. The work was conducted together with a co-author, Iris Gordon, from the Cochrane Collaboration who supervised the literature search strategy.

I conducted the entire systematic literature review and screened all 366 abstracts and 49 selected papers. I constructed tables of regional societies, colleges, national training institutions and non-government organisations, and searched through available websites for content relating to ophthalmology training in SSA. Following data collection. I arranged the review paper in its current format.

John Buchan independently screened the abstracts for content, and Andrew Samuel independently reviewed and translated online resources. The entire paper was reviewed for content and final editing by all co-authors. Special focus was given for East Africa by Dr Stephen Gichuhi, Dr Ibrahim Matende and Dr Michael Burdon; West Africa by Professors Hannah Faal and Caleb Mpyet, Francophone Africa by Serge Resnikoff, and Southern Africa by Dr Linda Visser. Professor Matthew Burton supervised the design of the paper and final editing.





## Ophthalmology training in sub-Saharan Africa: a scoping review

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### Abstract

Sub-Saharan Africa is home to 12% of the global population, and 4.3 million are blind and over 15 million are visually impaired. There are only 2.5 ophthalmologists per million people in SSA. Training of ophthalmologists is critical. We designed a systematic literature review protocol, searched MEDLINE Ovid and Embase OVID on 1 August 2019 and limited these searches to the year 2000 onwards. We also searched Google Scholar and websites of ophthalmic institutions for additional information. We include a total of 49 references in this review and used a narrative approach to synthesise the results. There are 56 training institutions for ophthalmologists in eleven Anglophone, eleven Francophone, and two Lusophone SSA countries. The median duration of ophthalmology training programmes was 4 years. Most curricula have been regionally standardised. National, regional and international collaborations are a key feature to ophthalmology training in more than half of ophthalmology training programmes. There is a drive, although perhaps not always evidence-based, for sub-specialisation in the region. Available published scientific data on ophthalmic medical and surgical training in SSA is sparse, especially for Francophone and Lusophone countries. However, through a broad scoping review strategy it has been possible to obtain a valuable and detailed view of ophthalmology training in SSA. Training of ophthalmologists is a complex and multi-faceted task. There are challenges in appropriate selection, capacity, and funding of available training institutions. Numerous learning outcomes demand curriculum, time, faculty, support, and appropriate assessment. There are opportunities provided by modern training approaches. Partnership is key.

### Introduction

The 49 countries of sub-Saharan Africa (SSA) are home to 12% of the global population, one billion people [1]. Over 4 million of the population are blind (presenting visual acuity <3/60) [2, 3]. The age-standardised prevalence of blindness is 0.97%, and 41% of blindness is due to cataract [4]. Other leading causes of blindness include: uncorrected refractive error 12.5%, glaucoma 12.5%,

macular degeneration 4.5%, trachoma 4.3%, and diabetic retinopathy 0.5% [5].

Of the more than 230,000 ophthalmologists worldwide, there are only 2.5 ophthalmologists per million population in SSA, against a global mean of 31.7 [6]. Training of all cadres of eye health workers, including ophthalmologists, is crucial if the goals of VISION 2020 are to be attained, and universal eye care achieved [7]. We need to look beyond 2020 with an aim to achieving Sustainable

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Development Goal 3: Good Health and Well-being. In a sample of 21 countries in SSA in 2011, only five (Botswana, The Gambia, Kenya, Senegal and Sudan) met the VISION 2020 target ratio of eye surgeons per million population. VISION 2020 recommended a target of four ophthalmologists per million population, however most (80%) of the sample SSA countries had fewer than this. Of these, nearly 70% work in their respective capital city [8, 9].

There are 56 training institutions for ophthalmologists in 11 Anglophone, 11 Francophone, two Lusophone countries (Table 1) [10]. Setting up training institutions is challenging in situations with huge needs for clinical service provision; they are limited by available teaching faculty, time, financial and other resource constraints. Furthermore, the demand for services is often far less than the population need, with relatively low numbers of patients affording and seeking care. At the advent of VISION 2020 in 1999, initial priority actions within SSA included the 'development of collaborative regional training programmes for ophthalmologists to improve the quality of education and to increase the number of trainees' [11].

We therefore conducted a scoping literature review looking at peer-reviewed published papers and open-access resources from associated training colleges, governmental and non-governmental organisations.

## Methods

We searched MEDLINE Ovid and Embase OVID on 1 August 2019 and limited these searches to the year 2000 onwards. Searches were created using terms for ophthalmic staff and training. We used a search filter developed by the library services at the London School of Hygiene and Tropical Medicine to limit the results to reports pertaining to SSA. We did not impose any language limits on the search. The search strategies are available as an online appendix to this article. We checked the reference lists for potentially relevant studies and identified a further 17 references that met our inclusion criteria. Two authors independently reviewed full text articles and extracted the data independently.

We made a concerted effort to access as much grey literature as possible to ensure that relevant information not included in published literature could be included in this review. We undertook searches of Google Scholar and various eye related websites to identify entities who may have information on the provision of ophthalmology training. French terms included 'formation en ophtalmologie'; and Portuguese 'treinamento em oftalmologia'.

Data were specifically searched and collected under broad categories:

- Strategy, oversight and regulation.
- Selection, entry requirements and demographics.
- Ophthalmology training programme: duration, curricula, assessments, resources and support, funding, faculty, surgical education, and continuing medical education (CME).
- Fellowship or sub-speciality ophthalmology training.
- Exit examinations, qualifications, certification (local, national, regional and international).
- External input from Links, Non-Government Organisations, and visiting faculty.
- Broader training as part of the eye care team, research, and leadership.

## Results

The search yielded a total of 548 references. After 182 duplicate records were removed, we screened the remaining 366 references and identified 32 references which met the inclusion criteria. After checking the reference lists of these articles, we identified a further 17 articles which were eligible for inclusion in the review. In total, we included 49 referenced articles in this review (Table 2).

In total, we identified 56 training institutions (Table 1), six ophthalmology colleges in SSA (Table 3), 32 ophthalmological societies (Table 4), and 25 NGOs (Table 5). International agencies and organisations who are involved with ophthalmology training and education in Africa were also included in the search (Table 6). A total of 61 websites and publicly available reports were included in the grey literature review. Figure 1 summarises the search methodology and results. Most evidence was at the level of expert opinion and surveys (which accounted for 90% of papers). There were no meta-analyses or systematic reviews.

## Strategy and targets, oversight, regulation and accreditation

At a national and sub-national level, targets for human resources for eye health (HReH) are useful for planning, monitoring, and resource mobilisation, but they need to be updated and informed by evidence of effectiveness and efficiency [7].

Surgical training programmes in much of the West Africa sub-region are accredited through periodic audits of manpower, facilities, clinical services and academic programmes [12]. Ophthalmology training in Nigeria is further regulated and accredited by the National Postgraduate Medical College of Nigeria and the Medical and Dental Council of Nigeria, and in Ghana by the Ghana College of Physicians and Surgeons. The College of Ophthalmology within the Colleges of Medicine South Africa has oversight

**Table 1** Ophthalmology Training Institutions SSA [10].

Country	Institution	Duration (years)	Degree	Number of faculty	Yearly capacity
Angola	IONA Eye Institute, Luanda	4	Ophthalmology specialist	4	4
Benin	University of Abomey, Calavi		Diplôme d'Etudes Spécialisées (DES) <sup>a</sup>		8
Burkina Faso	National University Hospital Yalgado Ouédraogo, Ouagadougou		DES		3
Cameroon	Magrabi ICO Cameroon Eye Institute		Fellowship		
Cameroon	Faculty of Medicine and Biomedical Sciences, University of Yaoundé		DES		8
Cote d'Ivoire	University of Cocody		DES		6
Congo, DR	University of Kinshasa		DES		5
Congo, DR	University of Lubumbashi		DES		5
Ghana	Korle Bu Teaching Hospital, Accra	4	Fellowship		5
Ghana	Komfo Anokye Teaching Hospital, Kumasi, Ashanti	3	Membership		3
Guinea	Donka University Teaching Hospital, Conakry		Diploma		10
Ethiopia	Addis Ababa University, Medical Faculty, Dept. of Ophthalmology	4	Speciality certificate	11	7
Ethiopia	Jimma University	4	Speciality certificate	6	6
Ethiopia	University of Gondar	4	Speciality certificate	7	6
Kenya	University of Nairobi (UON), College of Health Sciences, School of Medicine	3	MMed (Ophth)	20 <sup>c</sup>	12
Madagascar <sup>b</sup>	Faculty of Medicine, Antananarivo	4	DES	4	10
Malawi	College of Medicine, University of Malawi, Blantyre	4	MMed	4	2
Mali	IOTA, Bamako		DES		10
Mozambique	Maputo Central Hospital	4	Ophthalmology specialist	5	4
Niger	Niamey National Hospital		DES		5
Nigeria	University College Hospital, Ibadan	5	Fellowship	14	6
Nigeria	Ahmadu Bello University Teaching Hospital, Shika, Zaria, Kaduna State	5	Fellowship	7	5
Nigeria	Lagos University Teaching Hospital, Idi- Araba	5	Fellowship	7	5
Nigeria	Lagos State University Teaching Hospital, Ike	5	Fellowship	6	5
Nigeria	Eye Foundation Hospital, Ikeja	5	Fellowship	13	6
Nigeria	Olabisi Onabanjo University Teaching Hospital, Sagamu	5	Fellowship	4	2
Nigeria	Obafemi Awolowo University Teaching Hospital	5	Fellowship	6	5
Nigeria	University of Benin Teaching Hospital, Benin City	5	Fellowship	14	5
Nigeria	University of Calabar Teaching Hospital, Calabar	5	Fellowship	5	4
Nigeria	University of Port-Harcourt Teaching Hospital, Port-Harcourt	5	Fellowship	9	3
Nigeria	Guinness Eye Centre, Nnamdi Azikiwe University, Onitsha	5	Fellowship	8	4
Nigeria	University of Nigeria Teaching Hospital, Enugu	5	Fellowship	16	8
Nigeria	University of Ilorin Teaching Hospital, Ilorin	5	Fellowship	8	5
Nigeria	Jos University Teaching Hospital, Jos	5	Fellowship	6	4
Nigeria	National Eye Centre, Kaduna	5	Fellowship	14	6
Nigeria	Aminu Kano University Teaching Hospital, Kano	5	Fellowship	10	4
Nigeria	St.Mary Catholic Eye Hospital/Eleta Eye Institute/Atapa Eye Care Iseyin	5	Fellowship	6	4
Senegal	University Cheikh Anta Diop, Dakar		DES		4
Rwanda	Rwanda International Institute of Ophthalmology, Kigali	4	MMed (Ophth)	3	4
South Africa	Stellenbosch University	4	MMed and FCOphth	6	2
South Africa	University of the Free State, Bloemfontein	4.5	MMed and FCOphth	2	8
South Africa	University of Cape Town	4	MMed and FCOphth	17	3
South Africa	University of KwaZulu-Natal, Durban	4	MMed and FCOphth	13	3
South Africa	Sefako Makgatho Health Sciences University	4	MMed and FCOphth	5	2
South Africa	University of Pretoria	4	MMed and FCOphth	5	2
South Africa	Walter Sisulu University Umtata	4	MMed and FCOphth	4	6
South Africa	Wits University Johannesburg	4	MMed and FCOphth	16	4
Tanzania	Kilimanjaro Christian Medical University College, Arusha	4	MMed (Ophth)	9	10
Tanzania	Muhimbili University of Health and Allied Sciences, Dar es Salaam	4	MMed (Ophth)	6	5
Togo	Faculty of Medicine and Pharmacy, University of Lome		DES		5
Uganda	Makerere University, College of Health Sciences, Kampala	3	MMed (Ophth)	4	8
Uganda	Mbarara University of Science and Technology	3	MMed (Ophth)	6	8
Zambia	University of Zambia School of Medicine Lusaka	4	MMed (Ophth)	4	4
Zimbabwe	University of Zimbabwe, Dept. of Ophthalmology, Harare	4	Masters in Medicine	5	6
Zimbabwe	United Bulawayo Hospitals	4	MMed and FCOphth	2	3

<sup>a</sup>Many Francophone countries deliver Diplôme d'Etudes Spécialisées (DES), which allows graduates to practice ophthalmology as a specialised MD. This could be translated as degree or diploma.

<sup>b</sup>Madagascar also provides 2-year training in 'essential ocular surgery' to MDs who then are allowed to practice cataract surgery. This training is additional and different from the 4 years training leading to a DES.

<sup>c</sup>Academic faculty are 12 and the rest are KNH teaching hospital consultants who also augment the UON—an example of partnership.

**Table 2** Papers included in systematic literature review.

Author and short title	Country/sub-region	Year	Study type	Level of evidence	Keywords/topic	Ref.
Babalola—the peculiar challenges of blindness prevention in Nigeria	Nigeria	2011	Review	5	Blindness prevention	[78]
Ayanniyi—trainee ophthalmologists' opinions on ways to improve cataract surgical rate	Nigeria	2009	Survey	3	Cataract	[39]
Bekibele—outcome of cataract surgery	Nigeria	2004	Retrospective case review	4	Cataract	[34]
Buchan—improving cataract surgical outcomes	East Africa	2018	Delphi survey	4	Cataract	[35]
Ezegwui—cataract surgery teaching hospital	Nigeria	2009	Retrospective case review	4	Cataract	[19]
Ezegwui—evaluation of complications of extracapsular cataract extraction performed by trainees	Nigeria	2014	Review	5	Cataract	[38]
Habibamu—cataract surgery southern Ethiopia	Ethiopia	2013	Review	5	Cataract	[41]
Dnyanmote—phacosurgery	Nigeria, Sudan	2015	Individual perspective	5	Cataract	[27]
Leucona—South Africa's cataract surgical rates	South Africa	2011	Survey	4	Cataract	[90]
Achigbu—rural eye care practice	Nigeria	2018	Survey	5	CEH	[92]
Ayanniyi—community eye health module in West Africa	West Africa	2009	Review	5	CEH	[65]
Agarwal—child eye health tertiary	SSA	2010	Survey	3	Child eye health	[31]
Bronsard—cataract in children	SSA	2018	Expert review	5	Child eye health	[28]
Courtright—childhood cataract in sub-Saharan Africa	SSA	2012	Review	4	Child eye health	[29]
Mvogo—surgical management of primary exotropia	Cameroon, Ethiopia, Kenya	2007	Case series	2c	Child eye health	[30]
Poore 2015 services for diabetic retinopathy	SSA	2015	Review	5	Diabetic retinopathy	[57]
Adegbehingbe—trabeculectomies Nigerian teaching hospital	Nigeria	2007	Retrospective case review	4	Glaucoma	[49]
Adekoya—surgical output and clinic burden of glaucoma in Lagos	Nigeria	2014	Multi-centre hospital-based	4	Glaucoma	[50]
Adekoya—challenges of management glaucoma	Nigeria	2015	Qualitative	5	Glaucoma	[51]
Egbert	West Africa	2002	Review	5	Glaucoma	
Kyari—ophthalmologists' practice patterns in achieving optimal management for glaucoma in Nigeria	Nigeria	2016	Survey	3	Glaucoma	[43]
Kyari—improving services for glaucoma Nigeria	Nigeria	2017	Review	5	Glaucoma	[52]
Onwubiko Glaucoma care in Nigeria	Nigeria	2019	Cross-sectional survey	3	Glaucoma	[46]
Quigley 2000 Long term results glaucoma surgery African	East Africa	2000	Retrospective case review	4	Glaucoma	[48]
Razai—eye care services glaucoma Botswana	Botswana	2015	Review	4	Glaucoma	[47]
Standerfer—glaucoma management developing countries	International	2009	Review	5	Glaucoma	[42]
Adeboye—the choice of ophthalmology	Nigeria	2006	Survey	3	HReH	[14]
Courtright—setting targets for human resources for eye health in sub-Saharan Africa—what evidence should be used?	SSA	2016	Review	5	HReH	[7]
Hale—task shifting	International	2013	Review	5	HReH	[89]
Mathenge	ECSA	2013	Editorial	5	HReH	[80]

Table 2 (continued)

Author and short title	Country/sub-region	Year	Study type	Level of evidence	Keywords/topic	Ref.
Mwangi	ECSCA	2017	Explorative qualitative case study	5	HReH	[20]
Nentwich 2014 reasons African ophthalmologists staying	Cameroon, Ethiopia, Kenya	2014	Survey	5	HReH	[82]
Palmer 2014 mapping human resources eye health	SSA	2014		4	HReH	[9]
Palmer 2014-trends and implications	SSA	2014		4	HReH	[8]
Zondervan—VISION 2020 LINKS programme	SSA	2013	Review	4	HReH	[79]
Mahmoud—Nigerian ophthalmic research	Nigeria	2012	Survey	5	Research	[87]
El-Maghraby—Cameroon Eye Institute	Cameroon	2019	Perspective report	5	Sub-specialisation	[24]
Kariuki	East Africa	2014	Cross-sectional	5	Sub-specialisation	[66]
Kariuki	East Africa	2015	Cross-sectional	5	Sub-specialisation	[67]
Kassam—The Sandwich Fellowship	Kenya	2009	Individual perspective	5	Sub-specialisation	[71]
Alemayehu—trichiasis by ophthalmologists	Ethiopia	2004	RCT	1b	Trachoma	[33]
Ayanmivi—ophthalmology training in Nigeria	Nigeria	2007	Semi-structured questionnaire	3	Training	[13]
Bode	West Africa	2012	Descriptive review	4	Training	[12]
Corbett—training the trainers	East Africa	2017	Descriptive	5	Training	[21]
Knoll—emigration an option	Tanzania, Ethiopia	2019	Interview questionnaire	3	Training	[91]
Masanganise—competency based ophthalmology training curriculum	Zimbabwe	2015	Review	5	Training	[15]
Yorston 2002 retinal detachment East Africa	East Africa	2002	Review	5	Vitreo-retinal	[60]
Schonfeld 2008 training programme for vitreoretinal surgery in Nairobi	Kenya	2008	Individual perspective	5	Vitreo-retinal	[58]
Schonfeld 2010 vitreo-retinal training East Africa	Kenya	2010	Individual perspective	5	Vitreo-retinal	[59]



**Table 3** The six regional ophthalmology colleges in SSA.

College of Medicine South Africa—College of Ophthalmology	<a href="https://www.cmsa.co.za/view_college.aspx?collegeid=13">https://www.cmsa.co.za/view_college.aspx?collegeid=13</a>
College of Ophthalmologists of Eastern, Central and Southern Africa	<a href="http://www.coecsa.org">http://www.coecsa.org</a>
Faculty of Ophthalmology, Ghana College of Physicians and Surgeons	<a href="https://gcps.edu.gh/?page_id=2385">https://gcps.edu.gh/?page_id=2385</a>
Faculty of Ophthalmology, National Postgraduate Medical College of Nigeria	<a href="http://nmpmcn.edu.ng/faculties/faculty-of-ophthalmology/">http://nmpmcn.edu.ng/faculties/faculty-of-ophthalmology/</a>
Mozambique College of Ophthalmology	<a href="http://ordendosmedicos.org.mz">http://ordendosmedicos.org.mz</a>
West African College of Surgeons—Faculty of Ophthalmology	<a href="http://www.wacscoc.org/index.php/faculties/ophthalmology">http://www.wacscoc.org/index.php/faculties/ophthalmology</a>

CAMES (Conseil Africain et Malgache pour l'Enseignement Supérieur) is not a college, but plays the leading role in coordinating post graduate national trainings and delivering professorships [<https://www.lecames.org/>].

**Table 4** Ophthalmological societies in SSA.

African Ophthalmology Council <sup>a</sup>	<a href="http://www.aofsite.org">http://www.aofsite.org</a>
Société Africaine Francophone d'Ophthalmologie <sup>b</sup>	<a href="http://soao-info.org">http://soao-info.org</a>
Benin Society of Ophthalmology	No website
Burkina Faso Society Ophthalmology	No website
Burundi Ophthalmological Society	No website
Cameroonian Society Ophthalmology	No website
Central African Society Ophthalmology	No website
Congolese Society Ophthalmology	No website
Gabon Society Ophthalmology	No website
Ivory Coast Society of Ophthalmology	No website
Malawi Ophthalmological Society	No website
Mali Society Ophthalmology	No website
Madagascar Society Ophthalmology	Website unavailable
Ophthalmological Association of South Sudan	Website unavailable
Ophthalmological Society of Ethiopia	<a href="http://www.ose.org.et">http://www.ose.org.et</a>
Ophthalmological Society of Ghana	<a href="http://osg-ghana.org">http://osg-ghana.org</a>
Ophthalmological Society of Nigeria	<a href="http://osnig.org">http://osnig.org</a>
Ophthalmological Society of South Africa	<a href="http://www.ossa.co.za">http://www.ossa.co.za</a>
Ophthalmological Society of Zimbabwe	No website
Ophthalmology Society of Kenya	No website
Rwanda International Institute of Ophthalmology	<a href="http://riio.rw">http://riio.rw</a>
Senegalese Society of Ophthalmology	Website unavailable
Société Guinéenne d'Ophthalmologie	No website
Société Mauritanienne d'Ophthalmologie	No website
Société Nigérienne D'Ophthalmologie (Niger)	<a href="http://www.sno.ne">http://www.sno.ne</a>
Somalia Ophthalmological Society	Website unavailable. Facebook page.
Sudanese Ophthalmological Society	Website unavailable
Tanzania Ophthalmology Society	No website
The Gambian Ophthalmological Society	No website
Togo Society of Ophthalmology	No website
Uganda Ophthalmological Society	No website
Zambia Ophthalmology Society	<a href="http://directpluszambia.wixsite.com/zos-site">http://directpluszambia.wixsite.com/zos-site</a>

<sup>a</sup>The AOC is a supra-national ophthalmology organisation, representing interests of national and sub-regional ophthalmological societies across SSA.

<sup>b</sup>SAFO is a supranational professional society (federation of national societies also accepting individual membership, especially for ophthalmologists from Francophone countries where there is no national society).

**Table 5** Non-government organisations.

Brien Holden Vision Institute	<a href="http://www.brienholdenvision.org/">www.brienholdenvision.org/</a>
CBM	<a href="http://www.cbmi.org/">www.cbmi.org/</a>
Commonwealth Eye Health Consortium	<a href="http://cehc.lshtm.ac.uk">http://cehc.lshtm.ac.uk</a>
Cure Blindness	<a href="http://www.cureblindness.org">http://www.cureblindness.org</a>
Fred Hollows	<a href="http://www.hollows.org/">www.hollows.org/</a>
Fondation Sanofi-Espoir	<a href="http://fondation-sanofi-espoir.com/en/">http://fondation-sanofi-espoir.com/en/</a>
Helen Keller Foundation	<a href="http://www.helenkellerfoundation.org">www.helenkellerfoundation.org</a>
IAPB	<a href="http://www.vision2020.org">www.vision2020.org</a>
International Eye Foundation	<a href="http://www.iefusa.org/">www.iefusa.org/</a>
KCCO	<a href="http://www.kcco.net/">www.kcco.net/</a>
Light for the World	<a href="http://www.light-for-the-world.org">www.light-for-the-world.org</a>
Lighthouse	<a href="http://www.lighthouse.org/">www.lighthouse.org/</a>
Lions Clubs	<a href="http://www.lionsclubs.org">www.lionsclubs.org</a>
Ophthalmic Sans Frontières	<a href="http://www.opht-sans-frontieres.org">www.opht-sans-frontieres.org</a>
ORBIS	<a href="http://www.orbis.org/">www.orbis.org/</a>
Organisation for the Prevention of Blindness	<a href="http://www.opc.asso.fr/">www.opc.asso.fr/</a>
Rothschild Foundation	<a href="http://www.fo-rothschild.fr">www.fo-rothschild.fr</a>
SEE	<a href="http://www.seeintl.org/">www.seeintl.org/</a>
Seva Foundation	<a href="http://www.seva.org/">www.seva.org/</a>
Sight for All	<a href="http://sightforall.org/">sightforall.org/</a>
SightLife	<a href="http://www.sightlife.org">www.sightlife.org</a>
SightSavers	<a href="http://www.sightsavers.org">www.sightsavers.org</a>
Thea Foundation	<a href="http://www.laboratoires-thea.com/en/fondation">www.laboratoires-thea.com/en/fondation</a>
Unite for Sight	<a href="http://www.uniteforsight.org">www.uniteforsight.org</a>
Vision Mundi	<a href="http://www.visionmundi.org">http://www.visionmundi.org</a>

Inclusion criteria were non-government or charity organisation, working in one or more countries in SSA, working in eye care or blindness prevention. The list was updated with input from co-authors, and when extracting data from referenced articles and websites searched. Websites were searched for terms 'education', 'training', 'surgery', 'curriculum', 'ophthalmology'.

**Table 6** International agencies and organisations.

French Academy of Ophthalmology (AFO)	
French College of Ophthalmology (COUF)	
French Society of Ophthalmology (SFO)	<a href="https://www.sfo.asso.fr">https://www.sfo.asso.fr</a>
International Agency for the Prevention of Blindness—Africa	<a href="http://www.iapb.org">www.iapb.org</a>
International Centre for Eye Health	<a href="http://iceh.lshtm.ac.uk">http://iceh.lshtm.ac.uk</a>
International Council of Ophthalmology	<a href="http://www.icoph.org">www.icoph.org</a>

for training ophthalmologists and examination standard setting (Table 2).

### Selection, entry requirements and demographics

Senegal required trainees to be a state medical doctor hospital intern. The two training programmes in Ghana, one in Zimbabwe, and four in South Africa stipulated registration with the National Medical & Dental Council, or Health Professional Council as entry requirement. One university in South Africa required applicants to have passed the first part of

the College of Ophthalmologists exam. Other training programmes (41/51; 80.4%) required only a medical degree (MD, MBBS, or MBChB) [10]. There is variation of the age range of trainees. A survey in Nigeria reported trainees' age range of 29–51 with a mean of 34.7 years [13].

In Nigeria, 6.6% of medical interns reported they would chose ophthalmology as a first choice for career [14]. There is a reported lack of formal ophthalmology training curricula for medical graduates, with associated ad hoc training of undergraduates in ophthalmology, and inconsistent assessment [15].

### Ophthalmology training programme: duration, curricula, assessments, resources and support, funding, faculty, surgical education, and continuing medical education (CME)

For the 56 training institutions for ophthalmologists in eleven Anglophone, eleven Francophone, and two Lusophone SSA countries (Table 1), there was a total combined annual training intake capacity of 287 [10]. The median duration of ophthalmology training programmes was 4 years (mean 4.2 years) with a range from 3 years (most programmes in East Africa) to 5 years (all of the 18 training programmes in Nigeria). Sixteen (31.4%) trainees in a Nigerian survey had stayed between 6 and 10 years in the programme [13].

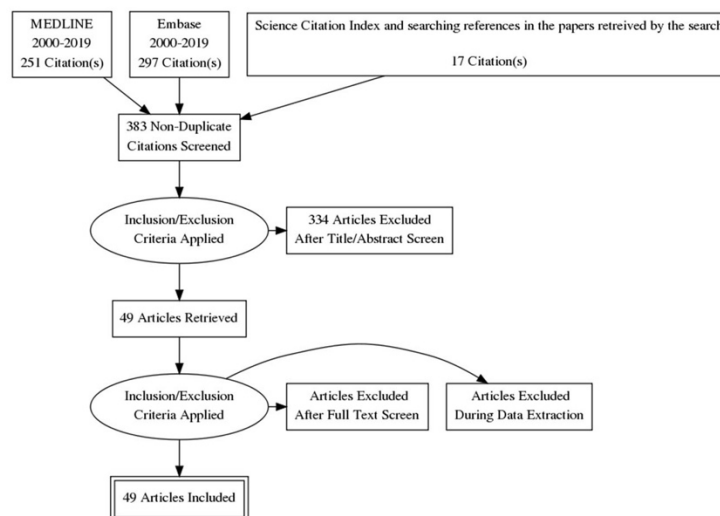
In general, residency training is funded by individuals, national Ministries of Health, and non-government organisation (NGO) [16]. Tables 4, 7 illustrate NGOs with specific reference to those supporting ophthalmology training.

The International Agency for the Prevention of Blindness (IAPB) and the African Ophthalmology Council (AOC), together with presidents of the six colleges of ophthalmology in SSA and the Société Africaine Francophone d'Ophtalmologie (SAFO) met in Ghana in early 2016. The aim of this historic meeting was to explore harmonising a curriculum for ophthalmology training across SSA. The plan is to achieve this by 2020 [17].

The West African College of Surgeons (WACS) have developed their resident training and examination structure. Following 3-years of residency, trainees will be expected to have achieved qualification as Members of the College (MWACS), able to provide general ophthalmology services. Depending on the requirements of the country or region in which Members anticipate working, they may apply to undertake a further 2 years' sub-specialist training to achieve Fellowship of the College (FWACS) [18].

District and mission hospitals are often used and accredited as training centres for post-graduate ophthalmology training [19]. These provide the volume of patients and the rural exposure to residents.

**Fig. 1** Flow diagram of literature search. PRISMA flow diagram of literature search and selection process.



**Table 7** NGO support of ophthalmology training in SSA.

NGO	Countries supported	Website
CBM [106, 107]	Angola, Democratic Republic of Congo, Ethiopia, Kenya, Rwanda, Malawi, South Africa, Swaziland, Tanzania, Uganda, Zambia, Zimbabwe	<a href="http://www.cbm.org/">www.cbm.org/</a>
Cure Blindness [108]	Ghana, Ethiopia, Rwanda	<a href="http://www.cureblindness.org">www.cureblindness.org</a>
Fred Hollows Foundation	Rwanda	
Fundacion Vision Mundi	Tanzania, Kenya, Burkina Faso	<a href="http://www.visionmundi.org">www.visionmundi.org</a>
Light for the World [109]	Mozambique, Uganda, Democratic Republic of Congo, Burkina Faso, Tanzania	<a href="http://www.light-for-the-world.org">www.light-for-the-world.org</a>
Lions International	Throughout SSA	<a href="http://www.lionsclubs.org/EN/how-we-serve/health/sight/">www.lionsclubs.org/EN/how-we-serve/health/sight/</a>
Ophthamo Sans Frontieres [110]	Cameroon	<a href="http://www.opht-sans-frontieres.org">www.opht-sans-frontieres.org</a>
Orbis [111]	Cameroon, Ethiopia, Ghana, Kenya, Malawi, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Zambia	<a href="http://www.orbis.org/">www.orbis.org/</a>
Organisation for the Prevention of Blindness (OPC) [112]	Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Guinea, Mali, Niger, Senegal	<a href="http://www.opc.asso.fr/">www.opc.asso.fr/</a>
Seva Foundation [76]	Tanzania	<a href="http://www.seva.org/">www.seva.org/</a>
Sightsavers [74, 113]	Guinea, Kenya, Mali, Tanzania, Uganda	<a href="http://www.sightsavers.org">www.sightsavers.org</a>
Tropical Health and Education Trust (THET)		
World Sight Foundation [114]	South Africa	<a href="http://www.worldsightfoundation.com">www.worldsightfoundation.com</a>

Continuing medical education (CME) or continuous professional development (CPD) is provided by all Ophthalmology Colleges in SSA (Table 2). Colleges may jointly offer CME or CPD.

### Training the trainers

The Royal College of Ophthalmologists and COECSA have been successful partners in a VISION 2020 LINK

since 2008. The LINK has focused on the development of harmonised curricula for trainee ophthalmologists, training-the-trainers (TTT), fellowship examinations for graduating trainee ophthalmologists, online CME, research capacity building and a mentoring programme for young ophthalmologists [20]. The TTT programme has successfully developed a pyramid of trainers equipped to cascade knowledge, skills and teaching in training across COECSA [21].



**Table 8** Total minimum prescribed surgical numbers over training.

	COECSA [100]	Ghana [101]	Malawi [102]	Tanzania [103]	South Africa [104]	WACS [105]
Cataract extraction	50–350	50	200	150	300	100
Glaucoma surgery			30	10	10	10
Lid surgery			25	18	40	40
Strabismus			20	3	20	3
Laser		40	50	53	60	10
Retinal detachment buckling			10		(20)	
Conjunctival neoplasia excision			25	5		
Enucleation/evisceration		5	50	8	1	10
Exenteration				4		

COECSA College of Ophthalmologists of Eastern Central and Southern Africa, WACS West Africa College of Surgeons.

The ICO have developed ‘milestones’ and a teaching the teachers curriculum and initiative. Fondation Théa supports the ICO ‘teaching the teachers’ programme to improve training in ophthalmology in Francophone and Lusophone Africa [22, 23]. The ICO Programme Directors Course has been hosted at the Magrabi ICO Cameroon Eye Institute [24]. The Moorfields Eye Hospital partnership with WACS conducts a TTT course at the annual WACS meeting.

### Surgical education

Surgical training in Francophone countries varies with the training programme, ranging from non-existent to full; while all Anglophone ophthalmology training programmes in SSA include surgical education [7].

### Specific prescribed/expected numbers

Table 8 illustrates the total surgical numbers that trainees are expected to perform, by the completion of training (where published data is available).

### Simulation/dry-lab/wet-lab

A full immersion computerised simulator for training in manual small incision cataract surgery is in development [25]. HelpMeSee support cataract surgery through surgical partners in Madagascar, Togo, The Gambia and Sierra Leone. The simulator and high-volume SICS training model is not currently being used in SSA [26].

One article highlighted that in Sudan, being a majority Islamic nation, pigs are not slaughtered there and hence no pig eyes are available. Goat eyes differ significantly from human eyes and hence have little value in wet lab teaching [27].

Ophthalmologists in Francophone countries will benefit from simulation surgical training at CHRU Clermont-Ferrand Gabriel-Montpied hospital in France [23].

### Sub-speciality residency training

#### Paediatric ophthalmology and strabismus

Accessing training opportunities for paediatric ophthalmology and childhood cataract management is challenging, especially in Francophone Africa, and there continues to be a shortage of paediatric ophthalmologists and other staff members needed to staff child eye health tertiary facilities [28]. Paediatric ophthalmology resources are available in Francophone countries, and most are in the private sector. Surgical management of childhood cataract has become more specialised, and a team based approach has been adopted in the fellowship training of many paediatric ophthalmologists [29]. This includes improved anaesthetic services, and optometrist low-vision care. There has been a plea for the training of more ophthalmologists, and the equipping of more hospitals for strabismus surgery following an outcomes study in Cameroon [30]. Of a sample of 27 child eye health tertiary facilities across Africa, all ophthalmologists reported having undergone fellowship training in paediatric ophthalmology [31]. Two centres offer a paediatric ophthalmology fellowship which also provided training in paediatric ophthalmology for residents.

#### Eye lids/oculoplastics/orbit

Most surgical interventions for trachoma trichiasis are performed by non-physician technicians [32]. The surgical outcomes of these integrated eye care workers are the same as ophthalmologists [33]. Orbit and oculoplastics training



in Aravind has been supported by Foundation Théa for ophthalmologists from Benin [23].

### Cornea/anterior segment

Surgical training, as well as service provision in terms of corneal grafts is a challenge as very few units in SSA have access to donated corneas for graft surgery.

### Cataract

Not all ophthalmologist in SSA can necessarily be assumed to have been trained in cataract surgery [8]. All 54 training institutions teach cataract surgery to trainees. Surgical training opportunities in teaching and non-teaching hospitals are a challenge for many trainees where several compete for the few cataract cases booked for surgery. The use of mobile ‘cataract’ camps, cottage hospitals, and outreach clinics from bigger city hospitals has been advantageous in providing larger numbers of cataract cases for trainee ophthalmologists [34]. Improved training of surgeons was the top-ranked factor rated in a Delphi exercise for improving cataract surgical outcomes in Africa [35]. Some visiting faculty may teach cataract surgery, especially phacoemulsification, however many training institutions do not routinely offer phacoemulsification training [36, 37].

Intra-operative complications of posterior capsule rupture have been reported at 6.2% for trainees in Nigeria [38]. Structured training and regular review of training curricula to reflect the need of the community was perceived by 92.6% of trainees to be an action that can increase CSR [39]. Trainees visit teaching institutions abroad. One Nigerian trainee reported on an 8-week cataract training course in Aravind Eye Hospitals, Madurai, India; having observed 1527 and performed (supervised) 75 extra-capsular cataract extractions [40]. Univariate analysis in a study in southern Ethiopia showed that higher cataract surgery productivity was associated with a higher number of surgeries during training [41].

### Glaucoma

Glaucoma is very challenging to manage in SSA. There is an urgent need to address the widespread knowledge gap that currently exists among all levels of eye-care workers, including ophthalmologists, in secondary and tertiary healthcare institutions [42]. In a nationwide survey of 250 ophthalmologists in Nigeria, 79% felt their training in glaucoma was excellent or good. However, 46% felt they needed more training in glaucoma diagnosis and surgery [43]. In West Africa, the training of ophthalmologists has historically stressed cataract surgery, and put little emphasis on glaucoma [44]. Improved training in glaucoma as part of

the eye care team is an important strategic component for improving glaucoma care services [45]. Advocacy, public awareness and training of glaucoma specialists were the three main recommendations for improving glaucoma care in Nigeria [46]. In Botswana, neither of the two general ophthalmologists had a sub-speciality interest in glaucoma [47].

Glaucoma surgical training is very challenging. Trabeculectomy is an intricate and long procedure to perform, patients’ vision is slightly worse after surgery, in some areas <50% of patients accept surgery, and in many areas of SSA the majority of ophthalmologists are reluctant to perform trabeculectomies [44, 48]. Surgical trabeculectomy is not commonly done in a teaching hospital [49, 50]. Trainees have complained that they ‘are really not doing any glaucoma surgery’ [51].

It is recognised that to improve patient access to treatment for glaucoma, institutions need to be strengthened with training in surgical and laser skills, equipment, and the establishment of glaucoma care teams [52]. Glaucoma fellowship training is offered over 1 or 2 years at Aravind Eye Hospitals in India [53]. Glaucoma sub-speciality training for ophthalmologists from Ethiopia and Ghana has been provided by the Himalaya Cataract Project in Tilganga, Nepal [54]. Glaucoma sub-speciality training is offered in Cameroon [24].

### Retina

There is good evidence of the need for training in the screening, diagnosis, and laser treatment of diabetic retinopathy in SSA [55]. A recent survey in Tanzania showed that only 9.5% of ophthalmologists had undergone specialist medical retina training [56]. Planning and developing diabetic retinopathy screening and management programmes requires a health systems approach, with multi-disciplinary teams led by ophthalmologists [57]. However, in SSA the number of ophthalmologists with specialist training in retinal diseases is low, hence there might be concern that self-identifying leaders will not emerge. The curriculum of the eye care workforce should reflect the demands of the diabetes epidemic [57].

During a long-term training collaboration between German and Kenyan teaching institutions and VR specialists, operations performed by local Kenyan ophthalmologists independently, without intervention of visiting German specialists, increased from 29.4% (in 2000) to 78.6% (in 2006) [58]. During the same period, the percentage of vitreo-retinal operations performed by resident surgeons alone increased from 55.6% (in 2000) to 85.9% (in 2007) [59].

A review of the surgical outcomes of 254 eyes in a training institution in East Africa showed good success rates of 73.2%, and recommended that greater emphasis should

be given to the recognition and treatment of retinal detachment in regional training programmes for ophthalmologists [60].

The establishment of fellowship training in, and facilities for pars plana vitrectomy in SSA, has been highlighted for not only retinal disease and vitreous opacities, but also the complications of cataract surgery [61]. The establishment of services increases the number of medical and surgical retinal cases for trainees to learn from [62].

### Neuro-ophthalmology

There is only one published report of neuro-ophthalmology training in SSA, detailing a course that was developed for ophthalmologists in Malawi [63]. A survey in Nigeria showed that 47.7% of ophthalmologists had no formal training in neuro-ophthalmology during residency [64]. Sponsored sub-speciality training opportunities would serve to increase enrolment in neuro-ophthalmology.

### Community eye health

In a cross-sectional survey of trainee ophthalmologists attending a community eye health (CEH) course in Nigeria, 85% believed that the CEH programme was very relevant to Ophthalmology. However, 74% wanted the module duration reduced [65].

### Sub-speciality fellowship training

Over two-thirds (69%) of trainees in East Africa preferred to sub-specialise, favouring training institutions offering hands-on-training and proven experience in the sub-specialisation [66]. However, only a third (32%) of practicing ophthalmologists had actually sub-specialised [67].

The Commonwealth Eye Health Consortium (CEHC), which includes COECSA and WACS as well as multiple institutions outside the region, has offered over one hundred clinical fellowship attachments to ophthalmologists from low and middle-income (LMIC) Commonwealth countries, most of which have come from SSA. The aim has been the enhancement of ophthalmology sub-specialty knowledge and skills, and the delivery of high-quality eye care, and subsequent return of Fellows to more effectively relieve the burden of blindness in their own countries [68].

The International Council of Ophthalmology (ICO) offers 3–12-month fellowship training opportunities to ophthalmology trainees from developing countries, including those in Africa [69]. These are funded in partnerships with Fred Hollows, the ICO Foundation and other sources.

COECSA and WACS have met to develop sub-specialist fellowship training in both sub-regions [70].

A five-layered ‘Sandwich Fellowship’ model has been developed in partnership between training institutions in Kenya and Canada [71]. The most widely used ‘sandwich fellowship’ in ophthalmology has been developed by the ICO. The ICO Sandwich Fellowships Programme is an addition to the ICO 3 months Fellowships Programme in which hosts visit the fellow’s home clinic 1–2 years after completion of the fellow’s first training stay. The aim of this visit is to find out where the fellow may need additional support. ICO fellows then return to the host hospital or clinic for a further 3 months’ training to meet these individual needs. Another year later the Hosts visit again the fellow’s institution to enhance ongoing cooperation [72].

The West African ophthalmic sub-speciality training centre has been established in Accra, Ghana. Part of the vision is to establish a programme of accredited sub-specialist ophthalmology training within West Africa, and a faculty of West African trainers to teach [73].

Sightsavers, through the ‘Promoting Quality Ophthalmology in East Africa’ project have supported twelve ophthalmologists in sub-speciality training. Specialities included paediatric ophthalmology, glaucoma, oculoplastics, orbit, ocular oncology, phaco cataract surgery, community eye health, and epidemiology and biostatistics [74].

The Centre de Formation Ophtalmologique d’Afrique Centrale (CFOAC) provides sub-specialist training through a link with the University of Rostock [75]. Orbis has recently been a key partner in growing the Magrabi ICO Cameroon Eye Institute into a sub-speciality eye health training centre for Francophone Africa. The Seva Foundation supports sub-speciality training in corneal transplantation and retina [76].

### Exit examinations, qualifications, certification (local, national, regional and international)

South African graduates of ophthalmology training programmes are required to pass the three-part Fellowship exams of the College of Ophthalmologists (which is within the Colleges of Medicine of South Africa) [77]. The COECSA Fellowship Exam is available to trainees who have completed their MMed Ophthalmology training and exams. Fellowship of WACS is an exit-level examination available to members. Figure 2 illustrates the different training infrastructures in terms of exit qualifications.

### External input from links, non-government organisations, and visiting faculty

Ophthalmologists are supported in their training by many NGOs. Table 7 illustrates the numerous international





**Fig. 2 Map of Africa illustrating training qualifications.** A pictorial summary representation of the most common graduate ophthalmology training qualifications.

NGOs, and the countries in which they directly support (with either financial support of individual trainees, training institutions, or faculty) ophthalmology training.

A review article in Nigeria concluded that there is ‘an abdication of responsibility for both training and service on the part of the government to the International NGOs. Teaching hospitals no longer generate enough patient surgical load to support training’ [78].

Many ophthalmology training institutions have links with overseas institutions, in either Europe, the USA or elsewhere [79]. In many instances, these bilateral links and partnerships involve ophthalmology training. COECSA has linked with the Royal College of Ophthalmologists in the UK [20].

## Networks and collaboration

Regional ophthalmology training initiatives and collaboration have been promoted in East Africa. The goal being to stimulate exchanges between training institutions, pooling educational resources, having joint teaching appointments, and promoting trainee mobility. It is recognised that there is a critical shortage of ophthalmologists in SSA, and this translates to an even greater shortage of ophthalmic trainers. Having a regional network of training institutions which are each supported to excel in their speciality areas of strength, would avoid the proliferation of poorly resourced ‘comprehensive ophthalmology’ training institutions in each country [80].

The Himalayan Cataract Project has partnered with Orbis International and the Moran Eye Centre (USA) to provide training opportunities for ophthalmologists in Ghana [81].

The 'Afro-German-Eye-Net' (AGENT) was established in 2006 and sub-speciality continuing medical education and Summer schools have been conducted in East and Central Africa [82].

The Diabetic Retinopathy Network was established in 2014. International participating ophthalmology institutions from nine countries in SSA are paired with UK VISION 2020 LINK ophthalmology departments are involved. The focus in East Africa has been on training centres and building up tertiary centres with an intended outcome of shared learning for the management of diabetic retinopathy [83].

The SAFO provides an important collaboration platform between ophthalmologists and national ophthalmology societies of Francophone countries in SSA. A main objective is to hold an annual congress, which in 2020 will be in Yaoundé, Cameroon with a focus on 'Training in Ophthalmology' ('Formation en ophtalmologie') [84].

### Attitudes, ethics and responsibilities

A qualitative study in South Africa illustrated that the conventional practice in hospitals is for trainees to perform cataract surgery under supervision of consultants, and evaluation of the progress in ophthalmic surgical training was essentially an apprenticeship model [85]. Trainee ophthalmologists are required by their college to maintain a surgical logbook of procedures performed. This logbook contains some procedure details including complication rates, however no systematised quantitative evaluation of the logbook is conducted by trainees or the training institutions. In terms of improving cataract surgical outcomes in Africa, a Delphi exercise ranked 'improved training of surgeons' as the top priority [35].

### Audit

Prospective monitoring has been shown to improve outcomes of cataract surgery, however it is unclear whether this is taught and re-enforced in ophthalmology training programmes [86].

The transfer of the desirable character, attitude, ethics and responsibilities, and indeed its assessment is a challenging aspect of training. There are no published examples where this has been addressed and documented.

### Broader training as part of the eye care team, research, and leadership

COECSA has established the Young Ophthalmologists Forum for young and newly qualified ophthalmologists.

The networking forum helps participants to develop leadership and networking skills, as well as promote research [74].

The acquisition of surgical and managerial skills, as well as availability of qualitative ophthalmic resource material were judged to be adequate by 35 (68.7%), 40 (81.6%) and 38 (74.5%) of trainees respectively in Nigeria [13].

A larger survey of Nigerian trainees showed that research was rated fourth in importance, after clinical service, teaching, and community service. Of the respondents, 91.8% rated securing funding as either the 'higher' or the 'highest' among factors that negatively impacted conducting research [87]. More recently numerous SSA countries, including Kenya, Nigeria, and South Africa are making having a Ph.D. a prerequisite for senior career advancement in the university environment. There have been efforts to develop this capacity through the CEHC Ph.D. fellowship programme.

The Kilimanjaro Centre for Community Ophthalmology works to strengthen academic training of ophthalmology trainees through teaching and supervision of community-based field work [88].

### Workforce

Non-physician cataract surgeons (NPCS) are a valuable cadre in some countries in SSA. Successful eye care programmes using NPCS are characterised by having strong support, often by an ophthalmologist [89]. Medical officer cataract surgeons have high reported cataract surgical outputs, and more training for medical officer surgeons in South Africa has been recommended [90]. Training for Technicien Supérieur en Ophtalmologie is provided at the CFOAC in the Democratic Republic of Congo [75].

Reasons reported by African ophthalmologists for staying in their current region/country included good working conditions, commitment to help, the possibility of further training, family ties, and a general feeling of satisfaction [82]. Further reasons given by ophthalmology trainees in Ethiopia and Tanzania have similarly been wanting to support/serve community, family, and high demand of specialists [91]. The majority (75%) of trainee ophthalmologists in Nigeria are unwilling to practice in rural areas, citing absence of infrastructure and facilities [92].

### Discussion

Available published scientific data and evidence for ophthalmology training in SSA is sparse. The authors accept limitations within this review, including a rapidly changing landscape of information. It is also accepted that 'ophthalmology training' is a generic term, and that there are groups



of professionals practicing ophthalmology, including NPCS and other allied healthcare professionals for whom training was not fully reported in this review. Ophthalmology training is one aspect of training in SSA, and a large experience is published relating to both medical and surgical training in other specialities from which many examples may be used to highlight potential avenues and approaches. This literature is absent from and outside of the scope of this review.

VISION 2020 recommended a target of 1 ophthalmologist per 250,000 population. Currently there are an estimated 2.5 ophthalmologists per million population in SSA, and an estimated 250–350 newly trained ophthalmologists per year. To attain the VISION 2020 recommended target of 4 ophthalmologists per million population, an increase of at least 1300 ophthalmologists would be needed in SSA. This solution, to train more ophthalmologists may seem obvious, however the situation is complex. Can current workforces absorb newly trained staff, not only in terms of work capacity; but also additional supervision, management and standard equipment? Are there policies and provisions for the deployment, remuneration, and retention of newly trained eye care professionals? [93]. As recognised by the IAPB and other key stakeholders, the training of new ophthalmologists is only the start. It is critical to be able to offer employment, equip them to be able to work, and ongoing support and continuing training opportunities.

Sub-speciality surgical education is challenging in SSA. There is a lack of corneal graft donor tissue. Vitreo-retinal surgery is highly dependent on expensive equipment. Surgical management of glaucoma has been recommended as the first-line treatment, however there is evidence that ophthalmologists in SSA do not perform enough glaucoma surgery [44, 94, 95]. A study in Nigeria showed that the number of glaucoma surgeries performed per ophthalmologist per month was 0.5 and 1.1 for tertiary and secondary hospitals respectively [50]. Reasons suggested for reluctance to offer glaucoma surgery included late presentation, lack of patient satisfaction, complications of surgery, and negative publicity [51]. This low number of surgical procedures for glaucoma impacts on training and surgical opportunities for ophthalmology trainees in SSA. Major strides have been recently made in harmonisation of sub-speciality training and curricula in SSA.

A survey of ophthalmologists at CME courses in East Africa illustrated that the main reasons for staying in their current region/country were good working conditions, commitment to help, possibility of further training, familial ties and general feeling of satisfaction. Professional development elsewhere and better income abroad were named as the main reasons for considering migration [82].

A comparative study of OST in Malawi and Germany highlighted that overall goal of training in Germany is

mainly a medical ophthalmologist, whereas in Malawi it is an ophthalmic surgeon [96].

Networks and partnerships are ubiquitous for training in ophthalmology in SSA. National or university ophthalmology training institutions partner with other eye units to provide training opportunities in-country. Six main colleges of ophthalmology encompass the West Africa and COECSA sub-regions, and Southern Africa; representing a total of 49 countries. Further international links exist with the IAPB, ICEH, ICO, the Royal College of Ophthalmologists, and other colleges and societies. National, sub-regional and international partnerships exist between numerous universities, Ministries of Health, NGOs, eye care institutions and individuals. These networks, collaborations and partnerships appear fundamental to the sustainable training of ophthalmologists to the highest standards maximising often limited resources.

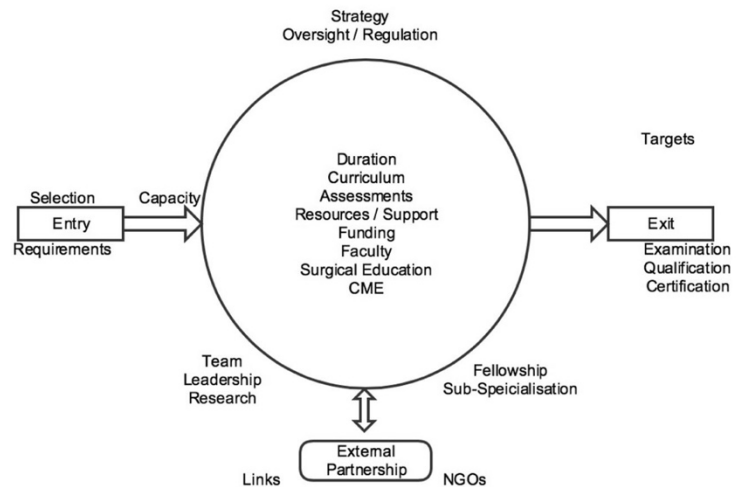
## Conclusions

Appropriately qualified ophthalmologists and allied eye health care professionals should be available and skilled, well-supported and productive if the goals of VISION 2020 are to be reached. Targets for HReH are useful for planning, monitoring, and resource mobilisation; however, they need to be updated and informed by evidence of effectiveness and efficiency [7].

Training of ophthalmologists is a complex and multifaceted task (Fig. 3). There are challenges in appropriate selection, capacity, and funding of available training institutions. Numerous learning outcomes demand curriculum, time, faculty, support, and appropriate assessment. Aside from the remaining backlog of cataract blindness and visual impairment, there is a drive, although perhaps not always evidence-based, for further sub-specialisation in the region [97–99]. In most SSA countries, tertiary level institutions are more developed than secondary level facilities. Strengthening these secondary-level facilities would increase access to eye care beyond capital cities. While subspecialists are key for training and education in tertiary level institutions, secondary level facilities require ophthalmologists skilled in comprehensive ophthalmology, including cataract and glaucoma surgery as well as laser procedures.

Ultimately there is a huge burden of eye disease in SSA. There are limited resources in the region: not only in terms of eye-care service provision, but in the number of training institutions for ophthalmologists (and indeed all eye healthcare workers), the number of available trainer faculty, and trainers' time. What is evident is the successful and innovative approach in the SSA region to deal with this challenge. The national, regional and international

**Fig. 3 Ophthalmology training.** Interaction overview diagram illustrating the complexity and multi-faceted nature of training in ophthalmology.



collaborations; sharing of expert resources; and standardisation of training curricula are lessons that many parts of the world could benefit from.

New, innovative and collaborative methods of teaching and learning are needed in response to what the demands on the doctor will be in the future, due to the many and rapid technological changes. Training needs to be in alignment with the demands on tomorrow's doctor in terms of sustainability, the environment, profit and people.

## Summary

- Training in ophthalmology is complex and multi-faceted.
- Standardised and competency-based ophthalmology curricula have developed.
- There is a regional drive for sub-specialisation within ophthalmology.
- Networks, collaborations and partnerships are important to the sustainable training of ophthalmologists to the highest standards, maximising often limited resources.

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## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

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### **3. Summary of Research Aims and Objectives**

Building on the background of the burden of avoidable blindness, the need for innovative approaches to surgical education, and the need for robust educational research, we designed the simulated ocular surgery (SOS) trials. The trials would include assessment of surgical competency, and as such assessment rubrics needed to be developed and validated. These are discussed in chapters 6 and 7 ahead of a detailed discussion in chapter 8 of how the Surgery Training Unit was established. Chapters 3 and 4 detail the research aims, objectives and methodology; and this is followed by a study of the trainees' perspective of ophthalmology training in SSA in chapter 5.

## Objectives

### Overall Objective

The hypothesis this study will tested was that intense simulation-based ophthalmic surgical education together with conventional training, is superior to standard conventional training alone, for the acquisition of competence.

The overall purpose of this research is to develop the evidence base to guide enhanced, high-quality skills development in ophthalmic surgical training in SSA which could then be scaled-up to include other regions. The evidence-base could subsequently be used to inform the planning and implementations of ophthalmology surgical training programmes globally. The main question for both trials is whether adding simulation-based surgical training to conventional training results in improved acquisition of high-quality skills. The outcomes will include measures of surgical competence, surgical quality, and confidence.

### Specific Objectives

1. To conduct a systematic literature review on 'ophthalmology training in sub-Saharan Africa' (Chapter 2).
2. Conduct a trainee survey of current curricula and training practice for ophthalmic surgery in COECSA & neighbouring countries (Chapter 5).
3. Conduct two validation studies of the SICS and trabeculectomy Sim-OSSCARs: exploring face, content and construct validity, and reliability (Chapters 6 and 7).
4. To establish a purpose-designed simulation Surgery Training Unit at the Community Eye Health institute (CEHI), Groote Schuur Hospital, University of Cape Town (UCT), South Africa.
5. To conduct the OLIMPICS Trial: a randomised controlled trial for SICS; whether simulation-based surgical incubator training leads to improved acquisition of high-quality surgical skills, with objectively assessed competence, confidence, knowledge, and surgery-specific outcomes and surgical numbers (Chapter 9).
6. To conduct the GLASS Trial: a randomised controlled trial for trabeculectomy; whether

simulation-based surgical incubator training leads to improved acquisition of high-quality surgical skills, with objectively assessed competence, confidence, knowledge, and patient-specific outcomes and surgical numbers (Chapter 10).

### **Geographic location of OLIMPICS and GLASS Trials, and Surgery Training Unit.**

Chapter 4 describes the study setting, inclusion and exclusion criteria for both trials, and refers to the detailed research protocol. The protocol, and methods sections of chapters 9 and 10 describe the sample size calculations for each trial. We estimated a minimum sample size of 23 in each arm of both trials, adding a further 2 for possible drop-outs. This meant we would need to recruit a total of 100 trainee ophthalmologists, and approach even more than 100 to assess for eligibility. The survey of ophthalmology training in SSA in chapter 5 illustrates the yearly intake capacity for ophthalmology training institutions in the region. The 3 centres in Ethiopia have a total annual intake of 19, the 2 universities in Uganda a total of 16, 2 in Tanzania total 15, and the single university training institution in Kenya 12. It was apparent early on in the planning of the SOS trials, that there would be no one single training institution or even country that could provide all the trainees. South Africa could have been considered if the cataract surgery procedure of choice was phacoemulsification rather than SICS, as is the case for Egypt. Nigeria has an impressive 17 ophthalmology training institutions with a total annual capacity of 81 trainees (table 1, chapter 2). At the time of design of the SOS trial, there was unrest in regions of Nigeria, and the West Africa College of Surgeons (WACS) was in the process of reconfiguring its training curricula.

The decision to take a perhaps more arduous multi-country approach to participant recruitment, and basing the Surgery Training Unit in South Africa was borne not only out of the sample size calculations, but more out of personal professional relationships and the longer term drive for sustainability of the overall purpose of this project. If the alternative hypothesis of the SOS trials was true, we wanted to ensure engagement from the beginning. Therefore for sustainability of the educational approach, and for more rapid and effective development of ophthalmic simulation surgery training units (pending results of the trials and further funding) in the SSA sub-region we were planning from the very start for advocacy and curriculum integration. We wanted to engage with, partner with, and work with training

institutions not only for recruitment into the trials, but also for long-term development of ophthalmic simulation-based surgical education, should the approach prove to have had a demonstrable and significant effect. The ultimate goal was to work collaboratively to improve surgical education in order to improve the quality of patient care and reduce avoidable blindness. As the African proverb: “If you want to go fast, go alone; if you want to go far, go together”.

## 4. Research Methodology

### General Information

#### Project Title

The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East and Southern Africa.

#### Identifying numbers

LSHTM Application Reference Number: **11795**

UCT Departmental Research Committee Reference: **2016/191**

UCT HREC (Human research ethics committee): **259/2017**

Kenyatta National Hospital - University of Nairobi Ethics Research Committee: **P473/08/2017**

Makerere University SOMREC (School of Medicine Research Ethics Committee): **00002062**

Mbarara University REC: **13/06-17**

Uganda National Council for Science & Technology: **HS2302**

KCMC RERC: **2027/1070**

National Institute for Medical Research (Tanzania): **NIMR/HQ/R.8a/Vol.IX/2765**

University of Zimbabwe Joint Research Ethics Committee: **259/17**

Pan-African Clinical Trial Registry: **PACTR201803002159198** (date of registration:30/3/2017)

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#### Coordinating Research Institution:

London School of Hygiene & Tropical Medicine

#### Collaborating Training Institutions

- Department of Ophthalmology, University of Nairobi, Kenyatta National Hospital, PO Box 19676, Nairobi – 00202, Kenya.
- Department of Ophthalmology, School of Medicine, PO Box 7062, Makerere University, Kampala, Uganda.
- Mbarara University & Referral Hospital Eye Centre (MURHEC), Mbarara University of Science and Technology, PO BOX 1410, Mbarara, Uganda.
- Kilimanjaro Christian Medical Centre (KCMC), Moshi, Tanzania.
- Department of Ophthalmology, University of Zimbabwe, Churchill Avenue, Mount Pleasant, Harare, Zimbabwe.
- Division of Ophthalmology, Groote Schuur Hospital and Red Cross Children's Hospital, University of Cape Town (UCT), South Africa.

### Study Sponsor

London School of Hygiene & Tropical Medicine is the main research sponsor for the study. For further information regarding the sponsorship conditions, please contact the Research Governance and Integrity Office:

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Study Funders are mentioned in appendix 2 on page 229, and include:

- British Council for the Prevention of Blindness (London, UK)
- Ulverscroft Foundation (Leicester, UK)
- CBM (Greenville, SC, USA)
- Queen Elisabeth Diamond Jubilee Trust (London., UK)
- Orbis International (New York, USA)
- L'Occitane Foundation (Paris, France)
- Lavelle Fund for the Blind (New York, USA)
- Lions Knysna (South Africa)

## Study Summary

<b>Title</b>	The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East and Southern Africa.
<b>Design</b>	<p>Prospective, single-masked randomised controlled education-intervention trials of intense simulation-based surgical education versus current standard conventional training alone, of ophthalmologists-in-training in five East and Southern African countries.</p> <p>Two separate trials: (1) OLIMPICS*: cataract surgery simulation training vs conventional alone; and (2) GLASS**: glaucoma surgery simulation training vs conventional training alone. *<i>Ophthalmic learning &amp; improvement initiative in cataract surgery.</i> ** <i>Glaucoma simulated surgery</i></p>
<b>Aims</b>	To investigate whether intense simulation-based surgical education improves competence, surgical outcomes, and confidence; compared to conventional training alone.
<b>Intervention</b>	All participants, by the end of the study, received the educational intervention of 5-days intense simulation-based training' at the Surgical Training Unit, University of Cape Town. The intervention groups received this training at week one; and the matched controls after a period of one year. The 'intervention training' specifically was a 5-day intense course of lectures, small-group teaching, practical surgical simulation training, videos, and assessments. <b><i>This training was in addition to, and an enhancement of the trainees' normal current standard conventional training, and not designed to replace it.</i></b>
<b>Control Training</b>	Control, or standard/conventional, training was variable between countries, training institutions, and individuals. Typically, training involved a weekly timetable of clinics (general or specialist), theatre sessions (cataract, or specialist), research, and teaching.
<b>Outcome measures</b>	<p>Assessments and follow-up time points were at baseline (month 0, and week 1 (end-of-training course), 3 months, 12 months and 15 months.</p> <p><b><i>Primary outcome measure:</i></b> mean global competency assessment score at 3-months post-training intervention:</p>

### OLIMPICS Trial

The primary outcome was the procedure-specific repeated measures analysis of Sim-OSSCAR score of three simulation SICS surgical procedures performed at 3-months.



## **GLASS Trial**

The primary outcome measure was the procedure-specific repeated measures analysis of Sim-OSSCAR score of three simulation trabeculectomies performed at 3-months.

### ***Secondary outcome measures:***

- Sim-OSSCAR assessments at end of training intervention, 12-months and 15-months for the GLASS and OLIMPICS Trials; mean value of three replicates, performed in the same manner as per the primary outcome measure.
- Live surgery ICO-OSCAR assessment at 12-months for the OLIMPICS Trial; mean value of three replicates, performed in the same manner as per the primary outcome measure.
- The number of surgical procedures (either SICS or trabeculectomy as appropriate) was recorded for fifteen months between 0-months and 12-months.
- OLIMPICS Trial (SICS) – for a period of 12 months (for all SICS surgical procedures performed):
  - Day 1 Visual Acuity (VA) – LogMAR (equivalent)
  - Peri-operative Complications (posterior capsule rupture (PCR))
- GLASS Trial (Trabeculectomy): Supervised ‘live’ glaucoma surgery (supervised by Consultant) were to be recorded during the twelve-months, only if the trainee was deemed able by a local Consultant Ophthalmologist. These were to be scored in the same masked manner, using the Trabeculectomy ICO-OSCAR (Appendix 4d).

### ***Further Exploratory Analysis:***

- Surgeon confidence rating scores (Assessed at baseline, three and twelve months)

## **Population**

The simulation surgical training was conducted in Cape Town, South Africa. Trainees had follow-up assessments in their home training institutions in the University of Nairobi, Kenya; Makerere University, Kampala, Uganda; MURHEC, Mbarara, Uganda; KCMC, Moshi, Tanzania; and University of Zimbabwe, Harare.

Patient cataract surgical outcome data was collected by participants as per normal good clinical practice. This data was summarised over 12 months, and a summary report sent to the PI with no personal patient identifiable information.

## **Eligibility**

OLIMPICS (SICS training) RCT Inclusion criteria for trainee:

1. Trainee ophthalmologist in year one or two of MMed course of collaborating Institution
2. Agreed to be randomly allocated to training ‘Intervention’ or ‘Control’ groups

3. Agreed to, and sign agreement to not discuss, or share in any way, any of the details of the educational intervention for the first three months
4. Having performed zero complete SICS procedures
5. Having performed part of (or assisted in) <10 SICS procedures
6. Agreed to baseline assessment, assessment at three, twelve and fifteen months; Agreed to monitor, anonymise, and report all surgical outcomes of all patients operated during the one year period (month 1 to 12)

OLIMPICS Trial (SICS training) RCT Exclusion criteria:

1. Performed one or more complete SICS procedures, or parts of ten or more separate procedures
- .....

GLASS Trial (Glaucoma surgery training) RCT Inclusion criteria for trainee:

1. Trainee ophthalmologist in year two, three or four of MMed course of collaborating Institution
2. Agreed to be randomly allocated to 'Intervention' or 'Control' training groups
3. Agreed to not discuss, or share in any way, any of the details of the educational intervention for the first three months
4. Have performed zero complete surgical trabeculectomy
5. Have performed parts of, or assisted in <5 surgical trabeculectomies
6. Agreed to baseline assessment, assessment at three, twelve and fifteen months; Agree to report surgical numbers for all patients operated during the one year period (month 0 to 12)

GLASS (Glaucoma surgery training) RCT Exclusion criteria for trainee:

1. Performed one or more complete surgical trabeculectomies, or parts of five or more trabeculectomy procedures

**Duration**

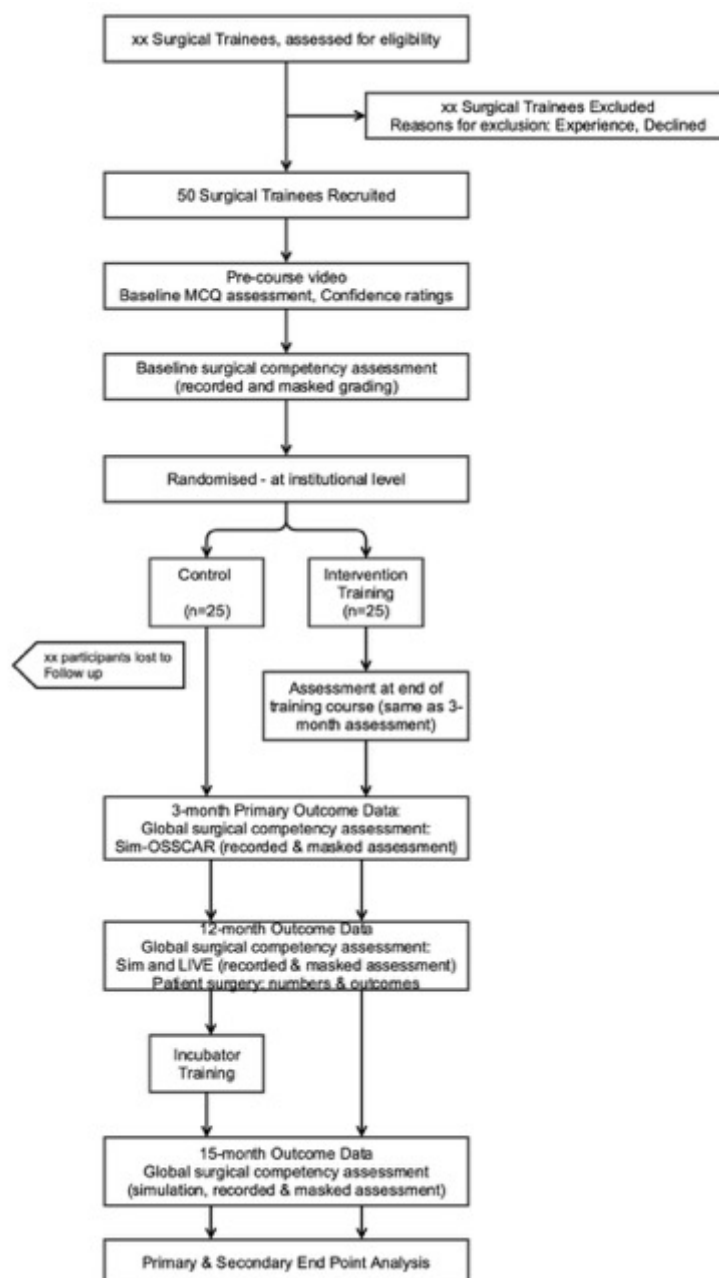
The overall project duration was three years. The fieldwork took one and a half years.

**Protocol**

The full protocol of the Simulated Ocular Surgery Trials is available via the LSHTM Research Online repository:

<https://researchonline.lshtm.ac.uk/id/eprint/4654987>

Figure 13. Study Outline Reference Diagram



The two trials had the same study plan: (1) cataract simulation training vs standard training; and (2) glaucoma simulation training vs. standard training. The only difference was the 12-month assessment: this was with simulation and *supervised* live surgery (patients) for the OLIMPICS Trial (SICS training groups); The assessments for the GLASS Trial (trabeculectomy) training groups were only using artificial (simulation) eyes.

## Study Design

The main research programme involved **two separate** randomised controlled single-masked, parallel-group, educational-intervention trials. These were the OLIMPICS Trial and the GLASS Trial.

The two trials had very similar methodologies and therefore are described together in this research methodology chapter. Each trial had two arms: (a) 'simulation-based educational in addition to conventional training' intervention and (b) 'standard conventional training alone' control arm. Surgical trainees were recruited to only one of the two trials, dependent on their eligibility according to inclusion and exclusion criteria. They were randomised to one of the two arms. Surgical competency was assessed at baseline, on the final day of the intervention training course, at 3-months, 12-months and 15-months. The primary outcome was the 3-month score.

## Study Setting

This was a multi-centre and multi-country study. We enrolled trainee ophthalmologists (doctors currently undergoing post-graduate Masters in Medicine (MMed) specialist training) from six ophthalmology training programme institutions in East and Southern Africa: Nairobi, Kenya; Moshi, Tanzania; and Kampala and Mbarara, Uganda; Cape Town, South Africa, and Harare, Zimbabwe. The simulation-based 'intervention' training was conducted at the purpose-built Surgery Training Unit, Community Eye Health Institute (CEHI), University of Cape Town (UCT), South Africa.

## Study Duration

The training was conducted during 2017, 2018, and 2019. Follow-up of the participants' surgical outcomes and output was completed by October 2019.

## Study Participants

Current trainees (between October of 2017 and June 2018) in all six training institutions were selected according to the inclusion and exclusion criteria, and randomised.

## **Inclusion / Exclusion Criteria**

### **OLIMPICS Trial (SICS):**

#### **Inclusion Criteria**

- Zero complete SICS procedure performed as primary surgeon.
- Parts of less than ten separate SICS procedures performed or assisted.
- Trainee ophthalmologist in year one or two of MMed course of collaborating Institution.
- Agreed to be randomly allocated to 'Intervention' or 'Control' training groups.
- Agreed to, and sign agreement not discuss, or share in any way, any of the details of the educational intervention for 12 months.
- Agreed to baseline assessment, assessment at three, twelve and fifteen months; Agree to monitor, anonymise, and report all surgical outcomes of all patients operated during the 12-month period.

#### **Exclusion Criteria**

- One or more complete SICS procedures performed as primary surgeon.
- Performed parts of ten or more separate SICS procedures or assisted.

### **GLASS Trial (Trabeculectomy):**

#### **Inclusion Criteria**

- Zero complete surgical trabeculectomy procedure performed as primary surgeon.
- Parts of less than five surgical trabeculectomy procedures performed or assisted.
- Trainee ophthalmologist in year 2, 3 or 4 of MMed course of collaborating Institution.
- Agreed to be randomly allocated to 'Intervention' or 'Control' training groups.
- Agreed, and signed agreement to not discuss, or share in any way, any of the details of the educational intervention for 12 months.
- Agreed to baseline assessment, assessment at three, twelve and fifteen months; Agree to monitor, anonymise, and report all surgical outcomes of all patients operated during the 12-month period.

#### **Exclusion Criteria**

- One or more trabeculectomy procedures performed as primary surgeon.
- Performed parts of, or assisted in five or more separate trabeculectomy procedures.

## Informed Consent

Potential participant trainees were informed of the training opportunity and the study. Heads of Department were involved in the process and are co-authors to the OLIMPICS and GLASS trial papers.

Trainee participants were informed in detail about the nature of the education-intervention study; that the training offered no official qualification and would not be recorded in their national training evaluation; that trainees in the 'control' arm would be offered the same simulation-based education opportunity in Cape Town, after the initial study period of one year. All surgeons participating were free to leave the study at any time. Appendices 1a to 1d detail participant information and consent.

Permission was sought from the Head of Department for trainees to be enrolled, and take time away from work duties to be involved in the training.

## Withdrawal Criteria

Trainee participants, in either the 'intervention' or 'control' groups were free to leave the study at any time. If this is the case for any participant, no effort was made to recover any costs incurred or equipment provided. Data collected up to the point of withdrawal of consent will have been anonymised and securely stored, and will still be held and included in intention-to-treat analysis.

## Pre-randomisation baseline assessment

This included evaluation of previous surgical experience, as per inclusion/exclusion criteria. Following informed and written consent, participant trainees are invited to perform a standardised quiz/test. This 30 multiple choice question (MCQ) test was on basic sciences, and the basic diagnosis and surgical management of either glaucoma or cataract. It formed baseline data for participants. All participants independently performed three simulation procedures. These were recorded, anonymised, and remotely assessed using the Sim-OSSCAR.<sup>2 3</sup> (Appendices 3a and 3b). This provided the baseline score for all participants: intervention and control.

## Randomisation

### Sequence generation

The randomisation sequences were computer generated and administered centrally by a statistician based at the LSHTM who was independent of all other aspects of the trial. We used block randomisation (block size 2 or 4), with a separate sequence for each recruitment site, to ensure balance. The statistician generated the code / sequence (as a block of 2 or 4).

### Allocation Concealment

The statistician did not have access to information about subsequent allocation, and the individual potential participants. The PI, co-investigators, and participants had no prior access to the random sequence.

### Randomisation Implementation

Trainees within the same training institution, who met the appropriate inclusion and exclusion criteria for either OLIMPICS or GLASS Trials (as detailed above), were eligible for randomisation to the 'intervention' or 'control' arm.

For example: A block of four potential participants are identified in Makerere (MK) Uganda for the OLIMPICS trial. Cards with the allocation or a block of four (two intervention and two control) were printed and placed in sealed opaque envelopes (Figure 14). Physically, in Uganda, a block of four identical envelopes (e.g. block number 11) was selected. Participants were invited by the Head of Department to pick one of the four envelopes. In this example, Makerere OLIMPICS trial randomisation block 11 allocation might be:

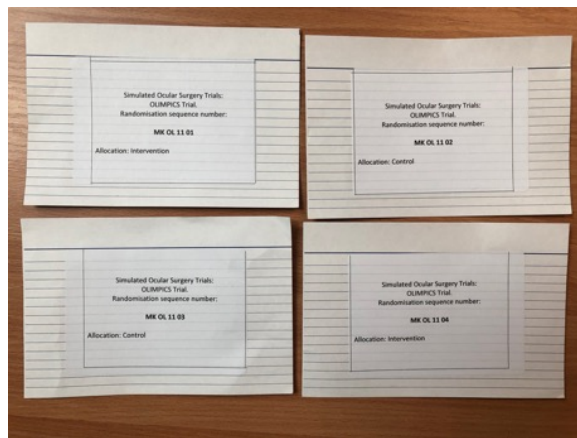
MKOL1101	Intervention
MKOL1102	Control
MKOL1103	Control
MKOL1104	Intervention



**Figure 14a) Block of 4 sealed opaque envelopes**



**14b) Insert cards with allocation**



## The Intervention

We aimed to provide a safe, focused, appropriate, educationally-validated and already piloted intense 5-day residential training programme based at the Surgical Training Unit (STU) at UCT. The STU and intervention training courses are discussed in detail in chapter 8, as well as appendices 7 and 8.

## Outcomes

In the OLIMPICS Trial, participants were assessed on four occasions after recruitment (in addition to baseline): final day of the intervention course, 3-months, 12-months, and 15-months (3 months after the control group receive the intense simulator training). On the baseline and follow-up assessments, simulation SICS procedures were recorded (with masked assessment using the Sim-OSSCAR).<sup>2</sup> At 12-months supervised live surgical SICS procedures were recorded if possible, and marked (remote and masked assessment using the ICO-OSCAR).<sup>94</sup>

In the GLASS Trial, participants were also assessed on four occasions after recruitment (in addition to baseline): end of intervention course, 3-months, 12-months and 15-months. Three simulation surgery procedures will be recorded on each occasion, and remotely double marked in a masked fashion against the Sim-OSSCAR for trabeculectomy.<sup>3</sup> A provision was made for **supervised** live surgical trabeculectomy procedures to be recorded and assessed around the 12-month mark, entirely dependent on a local Consultant Ophthalmologist's subjective appraisal of the participant's surgical ability. As per standard practice in the teaching of a surgical procedure, it was expected that the consultant would take over the supervised surgery if she/he deemed necessary. No instructions were given to local supervising consultants regarding the threshold of taking over surgery.

### Primary Outcome – OLIMPICS Trial

***The primary outcome measure of the OLIMPICS Trial was the procedure specific repeated measures analysis of Sim-OSSCAR score performed three times at 3-months.*** The analysis of the primary outcome measure was based on the differences in the Sim-OSSCAR scores by arm. Each item in the matrix is graded on a modified Dreyfus score (novice, advanced beginner, and competent). The total possible score is 40 points.

The simulation assessments were recorded using a standard microscope and recording device (Zeiss Stemi 305 EDU microscope (Carl Zeiss Microscopy GmbH, Jena Germany)), with all participants wearing similar blue latex-free surgical gloves (Figure 15). Recordings were given a randomly-generated and anonymous 7-digit number to give no indication as to in which arm the surgeon is, which training centre they are from, their identify, or the timing of the

assessment. Grading of the surgical video was conducted separately by two masked observers, independently watching the recorded surgery performed by the trainee at a separate time and place. Both observers are experienced cataract surgeons, with expertise in SICS, and had undergone familiarisation training in the use of the Sim-OSSCAR. Intra- and Inter-observer reliability studies were conducted, and kappa correlation calculated.

**Figure 15. Participant assessment in collaborating training institution**



#### Primary Outcome – GLASS Trial

***The primary outcome measure of the GLASS Trial was the procedure specific repeated measures analysis of Sim-OSSCAR score performed three times at 3-months.*** The analysis of the primary outcome measure was based on the differences in the repeated measures analysed Sim-OSSCAR scores between baseline and 3-months, by arm. Each item in the

matrix was graded on a modified Dreyfus score (novice, advanced beginner, and competent). The total possible score is 40 points.

Recordings were given an anonymous number to give no indication as to which arm the surgeon is in. Assessments of the surgical video were conducted separately by two masked observers, watching the recorded surgery performed by the trainee at a separate time and place. Both observers are experienced glaucoma surgeons and consultants, and surgical trainers. Intra- and Inter-observer reliability studies were conducted, as for the OLIMPICS trial.

#### Secondary Outcomes:

1. Sim-OSSCAR assessments at end-intervention, 12-months and 15-months for the GLASS and OLIMPICS Trials; mean value of three replicates, performed in the same manner as per the primary outcome measure.
2. Live ICO-OSCAR<sup>94</sup> assessment at 12-months for the OLIMPICS Trial; mean value of three replicates, performed in the same manner as per the primary outcome measure.
3. The number of surgical procedures (either SICS or trabeculectomy as appropriate) will be recorded for fifteen months between 0-months and 15-months.
4. OLIMPICS Trial (SICS) – for a period of 12 months (for all SICS surgical procedures performed):
  - Day 1 Visual Acuity (un-corrected & best corrected) – LogMAR (equivalent)
  - Peri-operative complications (posterior capsule rupture)
5. GLASS Trial (Trabeculectomy): Supervised ‘live’ glaucoma surgery (supervised by Consultant) will be recorded during the twelve-months, only if the trainee is deemed able by a local Consultant Ophthalmologist. These will be filmed (using a Zeiss OPMI operating microscope) and scored in the same masked manner using the Trabeculectomy OSCAR (Appendix 4d).<sup>92</sup>

Gathering and recording of surgical outcome data is part of normal good clinical practice. No patient identifiable information was made available through this study. Anonymised surgical audit outcome data on all patients operated on by trainee ophthalmologists (as part of their normal supervised and regulated ophthalmology training) in both the ‘intervention’ and

‘control/standard training’ groups of both trials were collected from their log-books for the period of fifteen months, between 0 months and 15 months (post-educational intervention). This data was sent as a summary audit report to the PI.

#### Qualitative Outcomes / Additional Exploratory Analysis:

6. Surgeon confidence scores: recorded at baseline, three and twelve months (Appendix 5b)
7. Semi-structured individual interviews conducted in the second week of the training course to primarily learn about surgical training experience and perspectives (see Appendix 5a). These interviews were recorded, transcribed, thematised and analysed. All information will be kept confidential and anonymous.

## Analysis

The analysis plan is detailed in appendix 4 on page 225. This was developed in collaboration with the trial advisory committee, predominantly statistician experts at the London School of Hygiene & Tropical Medicine.

## Prevention of Bias

It is accepted that there will be variability in individual participants' inherent or natural surgical aptitude.

All efforts were made to standardise the training offered to the 'intervention' participants. The intense simulation course was held in the same standardised surgical training unit at the University of Cape Town. The training was all conducted by the PI. All recordings of simulation procedures were performed using the same microscope (Zeiss Stemi 305), and all intervention and control participants wore the same colour blue surgical gloves. All recordings of live surgical procedures were recorded using the same iPhone 5s camera where possible, with all participants using the same blue surgical gloves, and note being taken of if/when the supervising Consultant Ophthalmologist takes over.

Video recordings of procedures were allocated a random 7-digit number, and subsequently stored onto an encrypted computer, and a separate encrypted hard drive. This random number was the only identifiable information available when the simulation/surgical procedure was assessed. This ensured the masking of the assessor to the participant's intervention/control arm, the training institution, and the timing of the assessment.

Every effort was made to reduce 'contamination' bias. It was agreed with Heads of Departments that while access to local simulation or wet-lab training would continue, there would be no comparable or equivalent simulation-based training courses for SICS or trabeculectomy for the duration of the study. No comprehensive cataract or glaucoma simulation training courses had been planned for the duration of the trials. All trainee participants had access to a wet-lab (Figure 17, page 116). Trainees in Makerere University in

Kampala had to travel to Mbarara in western Uganda to access the shared wet-lab. There was no difference in the analysis of both trials.

Participants furthermore signed an informed consent form detailing that they will in no way share any of the details of the course or educational intervention between either 'intervention' and/or 'control' groups; for a minimum of three months following the primary intervention in Cape Town. In effect this implied the entire year of initial follow-up, until the control group participants had attended their training course intervention in Cape Town.

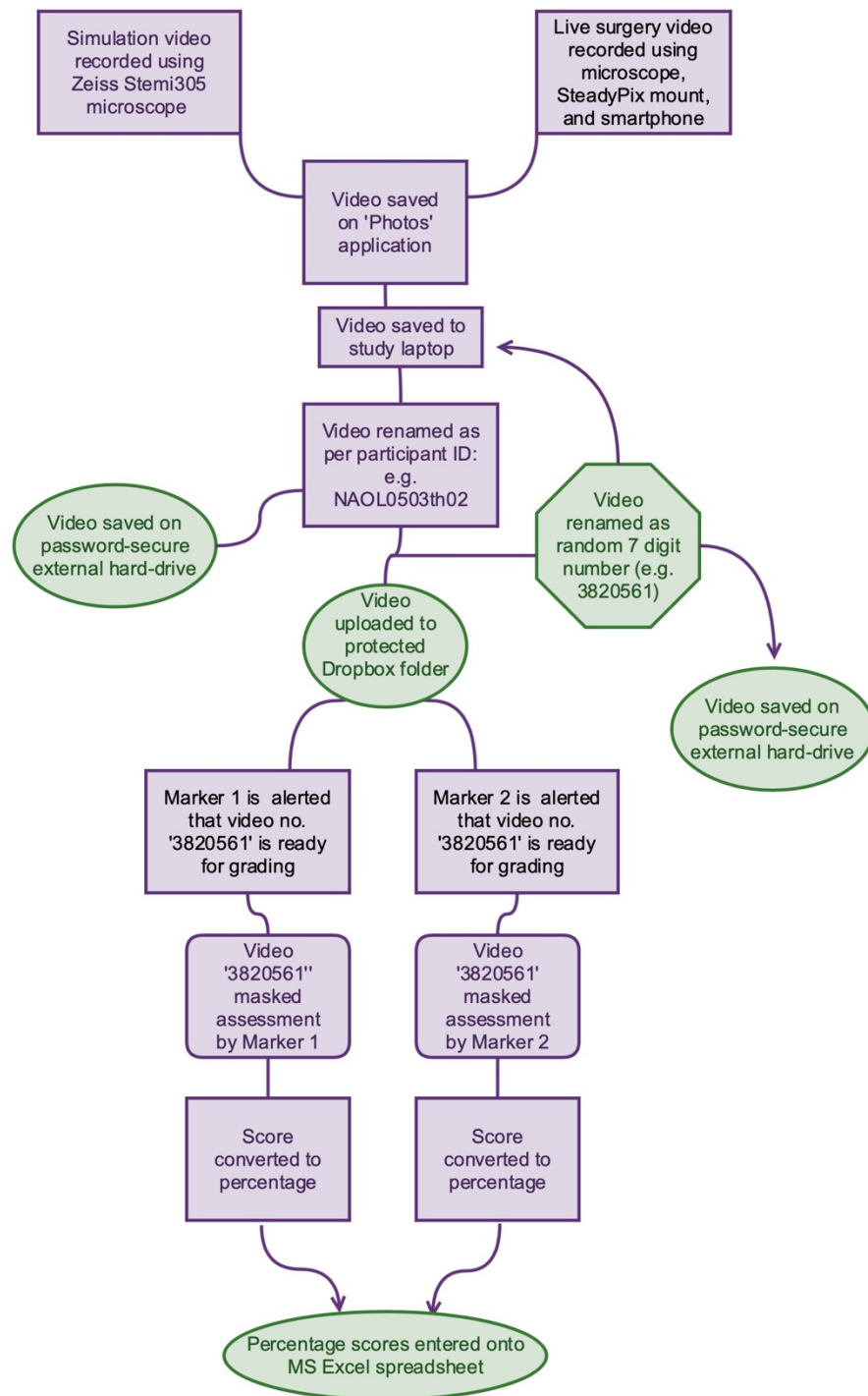
### Observer Bias

Recordings were converted to an MP4 format, and coded. The coding identified the pre-random number of the participant and which trial (e.g. Nairobi [NA] participant 03 in randomisation block 5 of the OLIMPICS trial [NAOL0503]; with subsequent indication of the month of assessment (e.g. month 3 [TH]); and finally the order of recording of that group of assessment (e.g. second recoding of three [02]). This with the above example, the second recording of the three-month assessment for the third participant in randomisation block three for Nairobi in the OLIMPICS trial would be enumerated: NAOL0503TH02. This recording was then saved on a password-protected external hard drive, and uploaded to a password-protected DropBox folder.

The recordings were renamed as a randomly generated seven-digit number (e.g. 6253815). The code sheet was generated by a LSHTM statistician (Min Kim) and was not available to the assessors. Once assessors were notified that the video was ready for marking, the random number was the only identifiable information available when the simulation/surgical procedure was assessed, thus completely masking the assessor to the participant's intervention/control arm and personal identity. Figure 16 details the flow of video recording, masked marking, and recording of scores.



Figure 16. Video recording and marking flow diagram



A number of standard risk-of-bias criteria are suggested for RCTs (or studies with a separate control group). The following were addressed during the SOS Trials as appropriate.

**Table 1: Risk of bias criteria assessment**

Criteria	Risk	Comments
Allocation sequence randomly generated (selection bias)	Low	Process described
Allocation sequence concealed (selection bias)	Low	Centralised randomisation scheme (LSHTM)
Similarity of baseline outcome measurements	Low	Performance measured prior to intervention (Baseline MCQ and OSSCAR)
Baseline characteristics similar	Low	Intervention & Control participants block randomised within same training institution
Blinding of participants & personnel (performance bias)	Unknown / Low	Participants & PI will know which arm they are in. Objective assessments will be masked.
Incomplete outcome data addressed (attrition bias)	Unknown	Missing outcome measures may bias the results. ITT (intention-to-treat) analysis possible
Study adequately protected against contamination	Unclear	Contamination between 'Intervention' and 'Control' groups is possible, but all effort has been made to reduce this.
Study free from selective outcome reporting (reporting bias)	Low	All outcomes will be included in analysis and reported
Intervention independent of other changes	Low	Other events/variables within surgical training will be identified and noted, for both arms
Intervention likely to affect data collection	Unclear / Low	Collection of patient-specific surgical outcome data is part of GCP, however, the intervention itself may increase reporting.

## Data Management

All recordings of surgeries (either simulated or real) were anonymised. Recordings are kept on an encrypted computer hard drive, and a separate back-up encrypted hard-drive in a safe in a locked office by the PI, and numerically randomised. Any identifiable information (of the performing surgeon) is kept separately on an encrypted spreadsheet. No patient identifiable information was recorded at any time. Recordings were transported on an encrypted hard-drive.

All participant information was randomised, anonymised and encrypted. All patient-related surgical outcomes data was anonymised and numerated as per local policy. No patient identifiable information was made available outside of the hospital or training institution, or be made available in any form to the PI.

## Expected Outcomes of the Study

The outcome of the SOS trials is to test the Null Hypothesis that there is no association or relationship between the educational intervention of 'intense simulation-based surgical education' versus 'standard surgical training' in Sub-Saharan Africa for glaucoma and separately for cataract surgical competency.

If the analysed data from this study does indeed statistically prove the alternate hypothesis, then there is the potential that the results can be used for future planning of ophthalmic surgical training, not only in sub-Saharan Africa, but globally.

## Quality Assurance

### Good Clinical Practice

Institutional, National, and Regional Good Clinical Practice (GCP) guidelines was followed and monitored in terms of training, performance of supervised surgery as part of training, patient care, patient confidentiality, and monitoring of outcomes of surgery.

## Study Management

Overall study management responsibility lies with the Principal Investigator. Three monthly Project Update Reports will be circulated to co-investigators. Six monthly reports will be sent to the three major funders. Weekly Project Reports will be sent to the Principal Investigator (LSHTM).

## Ethical Considerations

### Ethical Approval

Ethics approval was obtained from 10 separate ethics and research committees:

LSHTM Application Reference Number: **11795**

UCT Departmental Research Committee Reference: **2016/191**

UCT HREC (Human research ethics committee): **259/2017**

Kenyatta National Hospital - University of Nairobi Ethics Research Committee: **P473/08/2017**

Makerere University SOMREC (School of Medicine Research Ethics Committee): **00002062**

Mbarara University REC: **13/06-17**

Uganda National Council for Science & Technology: **HS2302**

KCMC RERC: **2027/1070**

National Institute for Medical Research (Tanzania): **NIMR/HQ/R.8a/Vol.IX/2765**

University of Zimbabwe Joint Research Ethics Committee: **259/17**

Pan-African Clinical Trial Registry: **PACTR201803002159198** (date of registration:30/3/2017)

Educational ethics are important to consider separately for this study.

### Patient Informed Consent

Patient participants were informed that the outcomes of their surgery will be recorded as per normal good clinical practice and standard training. At the year one mark, three patients per 'intervention' participant and three patients per 'control' participant were asked for informed consent to video record their surgery. The surgery was anonymised, and no patient identifiable information was kept. Patients had the right to refuse consent for video recording, and this in no way would affect their treatment or surgery plan. Photographs or videos of patients are often a part of clinical practice, teaching, telemedicine, or research. A standard consent form (Appendix 6), similar to local consent forms for clinical photography for research purposes only, was read by or to patients in their local language; and they were invited to sign.

## Participant / Trainee Informed Consent

Each trainee eye surgeon attending the training and involved in qualitative research was invited to read and sign a consent form (Appendices 1a and 2a). It was emphasised that there was no fee for the course and all educational materials were given free of charge.

Participant trainees should understand that the course is for their personal educational benefit, and they gave permission for anonymised data from the study to be published in peer-reviewed literature as part of broader research into surgical training techniques.

No personal identifiable information would be included at any stage.

Interviews, opinions, video recordings of assessments, and surgical outcome data of the education and training were to be used only for academic purposes.

No assessment or report would be given to any of the participant trainees' colleagues, or surgical or educational supervisors. In other words, the training intervention in both the OLIMPICS and GLASS trials was as a boost to 'standard training', and not a replacement: none of the results of this study of training would form a part of the participants' training record.

None of the data collected or reported would be made available to participants' work or training institutions, or be used for any future job selection. A 'certificate of attendance' would be provided to all participants who complete the training (in both the 'intervention' and 'control' groups) in Cape Town and subsequent three-month assessment upon request. However, it was to be made clear that this certificate and all/any of the training carried no accreditation, nor official continuous professional development (CPD) points.

Trainee participants were free to leave the study at any time. If this was the case for any participant, no effort would be made to recover any costs incurred or equipment provided.

It was important to clarify that trainee participants in the 'control' arm were to be offered the same training as the 'intervention' arm, only after a period of one year.

Patients with cataract and glaucoma were indirectly involved in this study. However, it is important to emphasise that supervised surgery conducted in this study, by trainee participants (in both the intervention and control arms), was part of standard and regulated training; and supervised by qualified and registered senior eye surgeons as per normal practice.

Patient outcome data was anonymised, and no personal patient identifiable information was made public, and no personal patient identifiable information was made available to any of the Investigators outside of the country. Patients operated in both the 'intervention' and 'control' arms were during normal standard training, and thus regulated by the Medical Councils and Educational Training Committees of Kenya, South Africa, Tanzania, Uganda and Zimbabwe.

The methodology of both the OLIMPICS and GLASS trials is further described in the main trial papers, chapter 9 and 10. Before commencing the trials, we sought to refine and validate the critical surgical competency assessment rubrics, the Sim-OSSCARs. This is described in chapters 6 and 7.

We also sought to take a snapshot of ophthalmology training in SSA, from the important perspective of the trainees. We designed and conducted a comprehensive survey, which is described next in chapter 5.



## 5. Survey of Ophthalmologists in Training

### RESEARCH PAPER COVER SHEET

#### **SECTION A – Student Details**

Student	William Dean
Principal Supervisor	Matthew Burton
Thesis Title	The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East and Southern Africa.

#### **SECTION B – Paper already published**

Where was the work published?	Wellcome Open Research		
When was the work published?	November 2019		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	Yes	Was the work subject to academic peer review?	Yes

Pages 88 to 98

\*Creative commons licence – CC-AT

#### **SECTION C – Prepared for publication, but not yet published**

Where is the work intended to be published?	
Please list the papers authors in the intended authorship order:	
Stage of publication	

#### **SECTION D – Multi-authored work** – See following page

Student Signature:

Date: 12 December 2019

Supervisor Signature:

Date: 16 January 2020

Chapter 5 describes the results of a survey of ophthalmologists-in-training in the East, Central, and Southern Africa region. The work was conducted in the format of an online survey.

I designed the concept and themes of the survey and the majority of questions. Further refinement and editing of questions was done by Dr Stephen Gichuhi, Dr John Buchan, Dr Ibrahim Matende, Ronnie Graham, Dr Simon Arunga, Dr William Makupa and Dr Linda Visser. Ronnie Graham, Dr Stephen Gichuhi and Dr Linda Visser worked to ensure complete lists and data of training institutions in the region. Min Kim assisted with the statistical analysis. Professors Colin Cook and Matthew Burton supervised the methodology and final edits. I consulted previous trainee surveys performed and published in the past 10 years to attain some level of standardisation.

I performed all data collection and management, as well as preliminary analyses. I was responsible for the organisation of the discussion and final edit of the manuscript.



## RESEARCH ARTICLE

# Survey of ophthalmologists-in-training in Eastern, Central and Southern Africa: A regional focus on ophthalmic surgical education [version 1; peer review: 2 approved]

William Dean <sup>1,2</sup>, Stephen Gichuhi <sup>3</sup>, John Buchan <sup>1</sup>, Ibrahim Matende<sup>4</sup>, Ronnie Graham<sup>5</sup>, Min Kim<sup>6</sup>, Simon Arunga<sup>1</sup>, William Makupa<sup>7</sup>, Colin Cook<sup>2</sup>, Linda Visser <sup>8</sup>, Matthew Burton <sup>1,9</sup>

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<sup>9</sup>Moorfields Eye Hospital NHS Foundation Trust, London, UK

**v1** First published: 27 Nov 2019, 4:187 (<https://doi.org/10.12688/wellcomeopenres.15580.1>)

Latest published: 27 Nov 2019, 4:187 (<https://doi.org/10.12688/wellcomeopenres.15580.1>)

## Abstract

**Background:** There are 2.7 ophthalmologists per million population in sub-Saharan Africa, and a need to train more. We sought to analyse current surgical training practice and experience of ophthalmologists to inform planning of training in Eastern, Central and Southern Africa.

**Methods:** This was a cross-sectional survey. Potential participants included all current trainee and recent graduate ophthalmologists in the Eastern, Central and Southern African region. A link to a web-based questionnaire was sent to all heads of eye departments and training programme directors of ophthalmology training institutions in Eastern, Central and Southern Africa, who forwarded to all their trainees and recent graduates. Main outcome measures were quantitative and qualitative survey responses.

**Results:** Responses were obtained from 124 (52%) trainees in the region. Overall level of satisfaction with ophthalmology training programmes was rated as 'somewhat satisfied' or 'very satisfied' by 72%. Most frequent intended career choice was general ophthalmology, with >75% planning to work in their home country post-graduation. A quarter stated a desire to mainly work in private practice. Only 28% of junior (first and second year) trainees felt surgically confident in manual small incision cataract surgery (SICS); this increased to 84% among senior trainees and recent graduates. The median number of cataract surgeries performed by junior trainees was zero. 57% of senior trainees were confident in performing an anterior

## Open Peer Review

Reviewer Status

	Invited Reviewers	
	1	2
version 1 published 27 Nov 2019	report	report

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vitrectomy. Only 29% of senior trainees and 64% of recent graduates were confident in trabeculectomy. The mean number of cataract procedures performed by senior trainees was 84 SICS (median 58) and 101 phacoemulsification (median 0).

**Conclusion:** Satisfaction with post-graduate ophthalmology training in the region was fair. Most junior trainees experience limited cataract surgical training in the first two years. Focused efforts on certain aspects of surgical education should be made to ensure adequate opportunities are offered earlier on in ophthalmology training.

### Keywords

Ophthalmology, Training, Africa

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## Introduction

The 49 countries of sub-Saharan Africa (SSA) are home to 12% of the global population, and 23% of the global burden of disease<sup>1</sup>. The age-standardized prevalence of blindness (presenting visual acuity <3/60) is 1.3%, and 35% of blindness is due to cataract<sup>2</sup>. Uncorrected refractive error (URE) accounts for 13.2% of blindness, macular degeneration 6.3%, trachoma 5.2%, glaucoma 4.4%, and diabetic retinopathy 2.8%<sup>3</sup>. URE is the most common identified cause of moderate/severe vision impairment (MSVI) (45.0%) followed by cataract (17.7%)<sup>3</sup>.

Of the more than 200,000 ophthalmologists worldwide, there are only 2,700 in SSA; a ratio of 2.7 ophthalmologists per million population<sup>4</sup>. This compares to 27,000 ophthalmologists for the 323 million people of the United States, a ratio of 83 per million<sup>4,5</sup>.

In absolute numbers, 1.7 million people in SSA are blind from cataract, and a further 3.1 million have MSVI. The cataract surgery rate needed to eliminate cataract visual impairment at the level of 6/18 has been estimated from mathematical modelling to range from 1,200 to 4,500 surgeries/year/million population in different communities within SSA<sup>6</sup>. Thus, with an average of 2.7 ophthalmologists per million population in SSA, each ophthalmologist would have to perform a mean of 444–1667 cataract operations annually. To deal with the backlog of 4.8 million people with cataract blindness and MSVI, each individual ophthalmologist would have to perform over 3,500 cataract operations, in addition to the numbers required to tackle incident cataract.

A number of ophthalmology trainee surveys have been conducted over the past ten years, including Nigeria<sup>7</sup>, the USA<sup>8,9</sup>, Canada<sup>10</sup>, Jordan<sup>11</sup>, India<sup>12</sup>, and China<sup>13</sup>, but no international survey of the training programs in Eastern, Central, and Southern Africa has been published to understand the current training provision and experience as a whole.

Within Eastern, Central, and Southern Africa there are 24 training institutions (Table 1). In total, 21 are Anglophone, two are Lusophone, and one is Francophone. In South Africa, the College of Ophthalmology provides a national standard curriculum. In 2013, OSEA (Ophthalmology Society of Eastern Africa) and EACO (Eastern Africa College of Ophthalmologists) merged to form COECSA (College of Ophthalmologists of Eastern, Central and Southern Africa). Many training institutions within COECSA have started using a collaboratively developed, standardised curriculum<sup>14</sup>.

There is substantial variability in ophthalmology training between countries in terms of numbers of trainees enrolled relative to the population size, available faculty, facilities, infrastructure, curricula, funding, clinical case volume, materials and equipment. Moreover, anecdotally there seems to be substantial variation in the exposure to surgical training.

In view of recent efforts towards sub-regional harmonization of curricula, increases in enrolment numbers, and adoption of newer

educational methods (including competency-based medical education (CBME) and simulation-based surgical education), we conducted a mixed qualitative and quantitative study to survey the objective and subjective perspectives of current and recent ophthalmology trainees in SSA.

## Methods

### Ethics

This study was approved by the research ethics committees of the London School of Hygiene & Tropical Medicine (11795) and the University of Cape Town (259/2017). Participants were provided with information about the nature of the survey prior to participation. As the survey was anonymous, individual written consent was not required prior to voluntary participation, and this was approved by ethics committees. Anonymity was assured by password protection of the survey account, and no personal information being exported into data sheets.

### Study design

A mixed methods research approach was used. Although quantitative-dominant, qualitative data was important in the study of complex interactions underlying ophthalmic surgical training.

A standardized questionnaire was designed by a panel of experienced trainer ophthalmologists in Kenya, South Africa and the UK. The questions and possible responses underwent an iterative process of refinement, through the participation of additional ophthalmology trainers in SSA. The web-based SurveyMonkey (San Mateo, CA, USA) platform was used for the questionnaire. The main groups of questions included current ophthalmology training; ophthalmology surgical training including simulation, perceptions of surgical training, surgical confidence, total numbers of surgeries performed and future career aspirations. The survey is available as *Extended data*.

### Participants and data collection

Eligible individuals for inclusion were all current ophthalmology trainees and recently qualified ophthalmologists ( $\leq 3$  years since training completed), at any of the ophthalmology training institutions within the Eastern, Central and Southern Africa sub-regions (Table 1). These doctors have synonymous titles in different sub-regions: trainee, registrar, or resident. For this study, the term 'trainee' is used.

A link to the web-based questionnaire was sent to all heads of eye departments and training programme directors of ophthalmology training institutions in the Eastern, Central and Southern Africa region, who forwarded to their trainees and recent graduates in September 2017. Three reminders were sent over a six-month period to those that had not completed the survey. The survey was also publicized via the International Agency for the Prevention of Blindness (IAPB) quarterly Africa Newsletter<sup>15</sup>.

For closed questions, possible responses were on a five-point ordinal Likert scale: very satisfied, somewhat satisfied, neutral,



**Table 1. Ophthalmology training institutions in Eastern, Central and Southern Africa region<sup>16</sup>.**

Country	Institution	Duration (years)	Degree	Number of faculty	Yearly capacity	No. of responses
Angola	IONA Eye Institute, Luanda	4	Ophthalmology specialist	4	4	0
Ethiopia	Addis Ababa University, Medical Faculty, Dept. of Ophthalmology	4	Specialty certificate	11	7	0
Ethiopia	Jimma University	4	Specialty certificate	6	6	0
Ethiopia	University of Gondar	4	Specialty certificate	7	6	10
Kenya	University of Nairobi, College of Health Sciences, School of Medicine	3	MMed (Ophth)	20	12	34
Madagascar	Faculty of Medicine, Antananarivo	4	Degree	4	10	0
Malawi	College of Medicine, University of Malawi, Blantyre	4	MMed	4	2	1
Mozambique	Maputo Central Hospital	4	Ophthalmology specialist	5	4	0
Rwanda	Rwanda Institute of Ophthalmology, Kigali	4	MMed (Ophth)	3	4	0
South Africa	Stellenbosch University	4	MMed & FCOphth	6	2	6
South Africa	University of the Free State, Bloemfontein	4.5	MMed & FCOphth	2	2	1
South Africa	University of Cape Town	4	MMed & FCOphth	17	3	7
South Africa	University of KwaZulu- Natal, Durban	4	MMed & FCOphth	13	3	4
South Africa	Sefako Makgatho Health Sciences University	4	MMed & FCOphth	5	2	0
South Africa	University of Pretoria	4	MMed & FCOphth	5	2	0
South Africa	Walter Sisulu University Umtata	4	MMed & FCOphth	4	2	1
South Africa	Wits University Johannesburg	4	MMed & FCOphth	16	4	6
Tanzania	Kilimanjaro Christian Medical University College, Arusha	4	MMed (Ophth)	9	10	10
Tanzania	Muhimbili University of Health and Allied Sciences, Dar es Salaam	4	MMed (Ophth)	6	5	0
Uganda	Makerere University, College of Health Sciences, Kampala	3	MMed (Ophth)	4	8	16
Uganda	Mbarara University of Science and Technology	3	MMed (Ophth)	6	8	9
Zambia	University of Zambia School of Medicine Lusaka	4	MMed (Ophth)	4	4	3
Zimbabwe	University of Zimbabwe, Dept. of Ophthalmology, Harare	4	Mastersin Medicine	5	6	14
Zimbabwe	United Bulawayo Hospitals	4	MMed & FRCOphth	2	3	0

somewhat dissatisfied, and very dissatisfied (see *Extended data*). Discrete numerical data was used for further quantitative questions. Free text responses were allowed for open questions. These were collated, and manual coding used before manual thematic analysis.

The total number of current ophthalmology trainees and ophthalmologists who completed training within the last three years was estimated at 240. To encourage attainment of

responses, incentive strategies were employed. Participants were invited to enter a lottery for an iPad. Offering non-monetary incentives has been shown to increase survey responses by one half<sup>17</sup>.

#### Data analysis

Data were exported from SurveyMonkey into Excel (Version 15.31) for data management and analysis. For the quantitative data, we present descriptive statistics. Linear regression



analysis was used for surgical experience and satisfaction with the training programme. For qualitative analysis, responses were collated from open question responses, and analysed thematically using manual coding. Verbatim quotations were used for common themes, and for comparison between different respondents.

## Results

### Respondent characteristics

Questionnaires were sent to 240 potential participants (140 current trainees and 100 recent graduates) and 124/240 (51.7%) responded. Assuming a population sample proportion of 50% (0.5), with a confidence level of 95%, the response rate of 52% (124/240) would mean a margin of error of 6.1% around the point proportion estimates, which we deemed acceptable.

The mean age of respondents was 30.8 years (range 26 – 46) and 58/124 (46.8%) were female. Respondents represented the full range of training years: 1<sup>st</sup> Year, 28 (22.6%); 2<sup>nd</sup> Year, 23 (18.5%); 3<sup>rd</sup> Year, 17 (13.7%); 4<sup>th</sup> Year, 13 (10.5%); and recent graduates, 43 (34.7%). Responses were received from all countries with training institutions, except Angola, Madagascar and Mozambique (Table 1).

In response to the question: 'What is/was your overall level of satisfaction with your ophthalmology training programme?', 89 (71.8%) were satisfied (combining very satisfied and somewhat satisfied), and 12 (9.7%) were dissatisfied (combining somewhat dissatisfied, and very dissatisfied) (Figure 1).

### Surgical training

Participants were asked about live surgical training experience. Overall, satisfaction levels with surgical training experience were moderate: 67 (54.0%) were satisfied with the quality of base hospital operating theatre training, and 50 (40.7%) were satisfied with surgical outreach training. In total, 60 (48.4%) were satisfied with the cataract case volume during training. However, only 50 (40.7%) and 53 (43.1%) were satisfied with their non-cataract case volume and complexity, respectively (Figure 1). A total of 92 (86.0%) stated that during training they use biometry on all cataract patients operated, however 4 respondents reported that this was not always available.

The numbers of procedures performed (during training) were reported (Table 2). Of note, during the first two years of training, median cataract procedures performed was zero. For the 23 (60.5%) first and second year trainees who had performed



Figure 1. Horizontal bar diagram illustrating proportions of response on a five-point Likert scale.

**Table 2.** Total number of procedures performed by trainees (during training).

Procedure	Year 1/2 residents			Year 3/4 residents, Fellows			Graduates (past 3 years) During training		
	Mean	Median	Range	Mean	Median	Range	Mean	Median	Range
SICS	37	0	0-500	84	58	0-300	166	125	0-570
ECCE	28	0	0-300	64	10	0-400	51	2	0-300
Phaco	25	0	0-300	101	0	0-604	63	0	0-550
Paediatric cataract	1	0	0-15	3	0	0-20	8	2	0-100
Lid surgery	14	5	0-76	36	20	0-200	58	50	0-100
Lid surgery (trichiasis)	1	0	0-10	13	3	0-150	26	5	0-100
Evisceration	14	5	0-100	29	20	0-100	29	20	3-100
Exenteration	1	0	0-15	3	0	0-20	4	2	0-20
Corneal graft	0	0	0-0	2	0	0-23	1	0	0-5
Trabeculectomy	2	0	0-20	4	1	0-30	9	5	0-50
Strabismus (recti)	3	0	0-30	12	0	0-78	6	0	0-80
Retinal laser	30	0	0-300	144	15	0-900	85	28	0-422
Glaucoma laser	4	0	0-100	17	0	0-100	19	3	0-150

ECCE: Extra-capsular cataract extraction; SICS: Small-incision cataract surgery

no cataract surgeries, 10 (43.4%) were satisfied overall with the ophthalmology training programme, and 3 (13.0%) were dissatisfied. When specifically asked about cataract surgery case volume, 2 (8.7%) were satisfied, and 7 (30.4%) were dissatisfied. Conversely, for junior trainees who had performed over 10 cataract surgeries, 9 (69.2%) were satisfied overall with the training programme, and 7 (53.8%) were satisfied with cataract case volume. Linear regression analysis found a significant positive relationship between the numbers of cataract surgeries performed and overall satisfaction with the training programme ( $p=0.043$ ).

Participants were asked the question “At the present time, are you confident performing the following types of procedure independently?”, and offered a response on a five-point Likert scale. The degree of self-reported confidence increased steadily with increasing years of training (Figure 2). Out of 28 senior trainees (year 3 or 4), the number agreeing or strongly agreeing that they felt confident in independently performing SICS was 22 (78.6%), extra-capsular cataract extraction 14 (50.5%), phacoemulsification 8 (28.6%), retinal laser 16 (57.1%), trabeculectomy 8 (28.6%) and lid surgery 15 (53.6%).

Thematic analysis of the qualitative responses regarding the ‘best surgical trainer’ found that the most commonly perceived positive attribute was patience (reported by 41 [41.4%]). This was followed by time afforded by the trainer (15 [15.2%]), skill/competence of the trainer (13 [13.1%]) and being calm (9 [9.1%]). One respondent described their best trainer as “patient, calm, and doesn’t take over too quickly”.

When asked about their ‘least good’ trainer, a similar theme arose: with ‘impatience’ being the most commonly reported negative attribute (reported by 24 [25.8%]). One trainee stated that the trainer was “not available, was in a hurry, was impatient. Did not even look at what I was doing”; and another that a

trainer had “no time to supervise”. Trainee surgeons did not appreciate anger, with one describing “screaming and shouting”; and another how “shouting in theatre made the patient and I anxious”. When asked about areas for improvement, respondents mentioned supervision, development of wet-labs, increased surgical and clinical exposure.

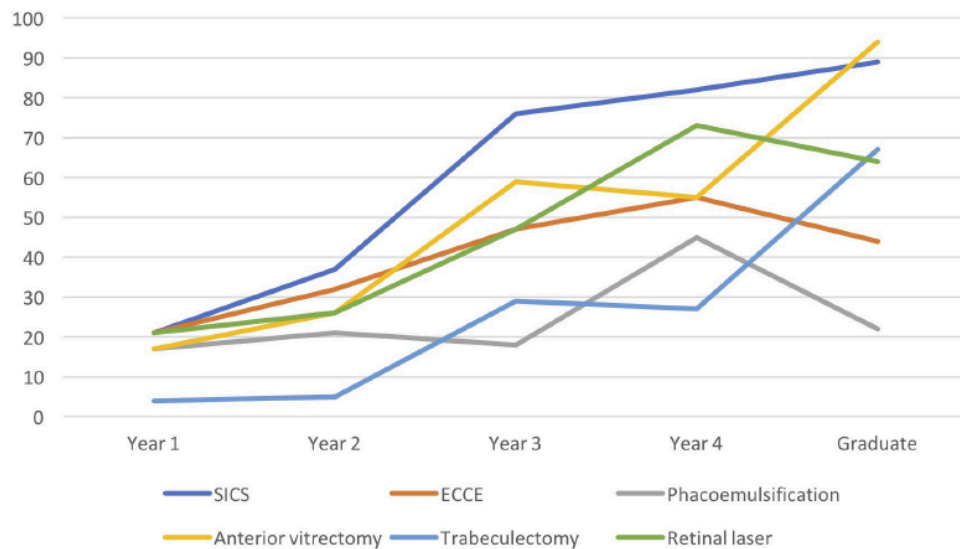
Participants were asked “What is/was the part of your surgical training that you most feel needs improving?”. The most common areas identified were cataract (21 [22.6%]) and glaucoma (18 [19.4%]) surgery training. In total, 17 trainees (18.2%) highlighted the need for improved supervision, and 9 (9.7%) the need for better wet-labs/surgical skills centres. One trainee noted “I also wish we would be allowed to start surgery early enough based on our surgical skills and not on our year of study.”

### Simulation surgery training centres

Different terminology, such as surgical wet-lab, dry-lab and skills centre, is used to describe surgical training outside of the live operating theatre. For this study, the term ‘simulation surgery training centre’ (SSTC) encompasses all of these.

An SSTC was available for 92 (76.7%) trainees; however only 35 (29.2%) stated that there was a specific SSTC curriculum. One third (39 [33.6%]) had almost never spent time in SSTC during training, and only 24 (20.7%) had spent >2 hours per week. The median time spent in simulation training was 0–1 hours per week. Most (79 [71.2%]) stated they were ‘almost never’ supervised by a consultant in SSTC, and 5 (4.5%) stated they were supervised >50% of the time. Regarding supervision in SSTC by a fellow/senior trainee: half (59 [53.1%]) stated they were almost never supervised by a senior trainee, and 16 (14.4%) stated they were supervised >50% of the time.

Less than half (52 [46.4%]) stated there were adequate consumables, 50 (44.6%) adequate instruments; only 25 (22.5%)



**Figure 2. Surgical confidence percentages by year of training.** Self-reported surgical confidence was assessed in response to the question "At the present time are you confident in performing the following types of procedure independently?". The options were: 'strongly agree', 'slightly agree', 'neutral', 'slightly disagree', or 'strongly disagree'. The graph plots the proportion responding 'strongly agree' or 'slightly agree' per procedure per year.

had access to educational materials (books, videos, curricula). Regarding simulation eye materials available to residents, the most common were porcine (58 [52.7%]) and goat eyes (44 [40.0%]). Artificial eyes had been used for surgical training by 27 (24.5%), cow eyes by 26 (23.6%) and human cadaver eyes by four (3.6%). Only one trainee had experience with computerized/virtual reality simulation

#### Cataract surgery outcome monitoring

Cataract surgical outcomes were routinely monitored by 88 (83.8%) trainees; this was mostly recording day one post-operative visual acuity. The most common reason for monitoring surgical outcomes was to ensure a successful outcome (26 [34.2%]), improve surgical skills (14 [18.4%]), learn from mistakes or complications (12 [15.8%]), for personal assessment (11 [14.5%]) and to build confidence (4 [5.3%]). Two surgeons mentioned 'benchmarking' against WHO standards. Four surgeons stated it was a requirement within the hospital.

For the challenges of monitoring outcomes, the most common issue was around follow-up difficulties and time constraints. One resident stated, "most cataract surgeries are done during community outreach and you hardly ever review the patients subsequently since we go back to our training centres".

#### Career aspirations and motivation

Participants were asked about their career intentions by sub-specialty. Although 41 (34.2%) expressed interest in general ophthalmology, the large majority (91 [74.0%]) also expressed interest in one or more sub-specialty areas (Table 3). A total of 22 (18.3%) indicated an interest in academia or research.

Over one-third of respondents (41 [34.2%]) stated a future work-place preference for a 'Government Hospital'. The second most common was University Teaching Hospital (34 [28.3%]) (Table 3). Although private practice (27 [22.5%]) was third; many did identify a balance, with two residents stating, "private practice is more profitable than working in government, but the latter is more satisfying" and "mixed public and private because public is difficult to organize but important for poor people".

We asked about the country they intended to practice in long-term: 93 (86.9%) plan to work in their home country, while only one in eight (14 [13.1%]) stated a desire to work abroad. Totally, 58 (77.3%) specifically stated they would want to work in either the capital city or other urban environment, whereas only 15 (20.0%) stated they would plan to work in a rural area. When asked their reasons for their choice of where to work, 39 (32.2%) stated that this was where the need was. Family also plays a large part in the decision, for 21 (17.4%) family was the main reason, with one respondent explaining: "whereas to work in a rural area is serving the most in need population, the minimum social life is not adequate for my family. Any urban area is an option since I can still reach out [to] many needy people and get a favourable environment for my family". Further thematic analysis of the reasons given for this work location choice included quality of life, pay and private practice.

#### Discussion

This is the first regional survey of ophthalmologists in training in Eastern, Central, and Southern Africa. We did not directly



**Table 3. Future career preferences.**

<b>Ophthalmology career intentions: "At this time, what is your career choice?" (select one, or more which apply)</b>		
<b>Specialty/Clinical area</b>	<b>n/120</b>	<b>%</b>
General Ophthalmology	41	34.2
Cataract	28	23.3
Vitreo-retinal	27	22.5
Oculoplastics	21	17.5
Community Eye Health	20	16.7
Glaucoma	20	16.7
Cornea	19	15.8
Paediatric and Strabismus	19	15.8
Medical Retina	11	9.2
<b>Future work environment preferences: "What kind of eye unit do you plan to mostly work in (more than 50% of time)?"</b>		
<b>Type of health facility</b>	<b>n/120</b>	<b>%</b>
Government hospital	41	34.2
University Teaching Hospital	34	28.3
Private Practice	27	22.5
Mission Hospital	10	8.3
Community / Public Health	7	5.8
Academia (non-clinical)	1	0.8
<b>Geographic working preference: "Geographically, where would you plan to work (select all that apply)?"</b>		
<b>Future work geography</b>	<b>n/121</b>	<b>%</b>
Home country	93	76.9
Abroad	14	11.6
Capital city	27	22.3
Other urban/city	31	25.6
Rural area	14	11.6

Footnote: Some of the respondents did not answer all questions; the denominator is provided for each.

compare training institutions, but rather provide institutions as a current benchmark for the region. If a repeat survey is undertaken using the same methodology in a few years this will provide a reference point for comparison.

Emphasis has been given in this current study to trainee experience, satisfaction and confidence. Competence is challenging to measure in surgical training. This is in part due to the lack of validated assessment tools and benchmarks, but also variability in training programme format. Contemporary approaches to training and traditional Halstedian apprentice-style surgical training is being replaced by more outcome-defined, demonstrable, learner-centred, assessable curricula of competencies<sup>18</sup>. Competency-based ophthalmology curricula and tools have been developed. These include the ophthalmology milestones project<sup>19</sup>, and workplace-based assessments<sup>20</sup>, however CBME curricula and assessment tools are not yet uniformly used throughout SSA<sup>21,22</sup>.

The overall level of satisfaction with ophthalmology training programs was fair, with seven out of ten satisfied, and less than

one in ten dissatisfied. This is encouraging, as much has been achieved in the past years despite the challenge of enrolment numbers increasing. Great efforts have been made to develop regional standards of ophthalmic training, develop standardized curricula and post-graduate fellowship or board level-exams. This is less than a recent survey of residents in the USA which reported a 94% 'highly satisfied' rating<sup>8</sup>.

However, when focusing on surgical education, only 57% were satisfied with their cataract case volume in training; and this reduced to 20% for first and second year trainees. The median number of cataract surgeries performed by first and second year trainees was zero. This is a cause for concern, considering that some training programs are only three years in duration. For all cataract surgeries combined, the total median and mean numbers performed by senior trainees were 96 and 222, respectively. This reflects the large range (3 to 1,100) and the variation in the cataract surgical procedures taught in SSA. A large survey in the USA showed the median and mean number of cataract procedures completed by trainees by the end of training was 100 and 113, respectively<sup>23</sup>. A more recent survey of US

program directors showed that third-year trainees had completed a mean of 155 phaco cataract surgeries as primary surgeon<sup>24</sup>. These figures are more almost double the 83 minimum average number of cataract operations that a training program must provide to gain accreditation<sup>25</sup>.

Senior (final) year trainees are under great pressure to reach these surgical numbers and have their surgical logbooks completed. This often leads to a hierarchical approach to surgical training and opportunity. Final year trainees often have complete priority over junior trainees for cataract surgical training cases. For senior trainees and recent graduates in this survey, cataract experience is reasonable with nearly half having completed >100 procedures during training. This may not be a high enough number ahead of being sent out to independently run a service in a remote setting.

The amount of retinal laser experience was good, and this is encouraging considering recent increases in the incidence of diabetic retinopathy across the continent. Paediatric cataract and corneal graft surgery can certainly be within the domain of sub-specialist fellowship-level training, and therefore surgical experience in this survey may be acceptable. However, glaucoma is the third most common cause of blindness globally<sup>26</sup>, and it is of concern that mean and median trabeculectomies performed by senior trainees and recent graduates is less than ten. Non-glaucoma-specialist ophthalmologists often shy away from performing a surgical trabeculectomy, as patient satisfaction is low: vision will often be worse post-operatively, never better<sup>27,28</sup>. Surgical management of advanced glaucoma is often the first line of treatment and should be within the remit of a general ophthalmologist.

The surgical experience of trainees in visceration/enucleation is high. The mean and median number of procedures performed by senior trainees and graduates (during training) was twenty or more. This can be explained by the prevalence of severe infections, trauma, and tumours.

It is often a challenge within ophthalmology training institutions, sometimes oversubscribed, for surgical trainees to have enough time and appropriate cases to teach surgery effectively. Exploration of innovative and effective ways to train efficiently and safely. To this end, some training institutions have established working relationships with other eye units as satellite surgical training centres.

Although SSTCs were available for over two-thirds of residents, less than one-third were satisfied with the quality of teaching provided, and 40% had almost never spent time in an SSTC. This is in line with trainee ophthalmologists' perspectives in Nigeria where only 33.3% had supervised SSTC sessions<sup>29</sup>. Ophthalmic simulation-based surgical education is underutilized and unstructured. Yet it offers the potential to substantially enhance the quality, speed and safety of surgical skills acquisition<sup>30</sup>. For simulation-based surgical education to work, instruction, supervision, feedback, a curriculum, and outcome (surgical competency) measurement are required<sup>31</sup>.

The culture of the training environment is also critical. Trainees' appreciation of patience, and not anger or impatience, is in line with surgical education throughout the world<sup>32,33</sup>, but may be more so in Africa. As Thomas Fasokun, Professor of Adult Education at Ile-Ife (Nigeria) concludes: "anxiety is one issue that dominates the participation of African adults in learning. For learning to take place, the level of anxiety in the learner must be minimized. Adults are quick to react unfavourably to unnecessary pressure on them"<sup>34</sup>. Adult-orientated teaching methods need to be employed in ophthalmic surgical education.

Recently 'training-of-trainers' initiatives have been successfully implemented in the COECSA region in partnership with the International Council of Ophthalmology (ICO) and The Royal College of Ophthalmologists, UK. This training in teaching and assessment skills has had a positive impact on training<sup>35,36</sup>.

The high pressure and stressful environment of the operating theatre, the huge burden of disease, and the need for a calm environment to learn and practice surgery naturally lean towards a simulation surgical skills centre as a potentially valuable solution. Furthermore, we could use educational theory underpinned simulation-based surgical education to provide calm and high-impact training. Trainees could be 'competent' in cataract or glaucoma surgery using simulation, to then be afforded opportunities for supervised surgical training sooner in their training program.

SSA has an age-standardized prevalence of blindness of 1.3%, 35% of which is due to cataract; and 2.7 ophthalmologists per million population. Taking a cataract surgical rate of 500 as typical for SSA, this means the average ophthalmologist in SSA currently does just 185 cataracts per year (500/2.7). The share of these cases used for training is not high as government training institutions are not typically high-volume. Funding for ophthalmology training, including surgical education, is a challenge not only in many countries in SSA, but worldwide. Some of the money brought in for training needs to be spent on increasing cataract surgical case numbers so the substrate for training exists. Some training institutions are now looking towards developing stronger referral systems rather than an expansion of outreach, to improve patient flow.

Career preferences for surgical sub-specialities (cataract, vitreo-retinal, cornea and oculo-plastics) is in line with other surveys around the world. It is encouraging that the most common career aspiration was 'general ophthalmology' (34%). This is consistent with a recent small cross-sectional study of ophthalmology masters students in Eastern Africa, where 69% of respondents wanted to sub-specialise<sup>37</sup>. With 2,700 ophthalmologists for one billion population in SSA, most ophthalmologists do indeed need to be generalists. Sub-specialty career preferences do not necessarily align with training opportunities and service needs. There is ongoing collaborative discussion in the region as to how sub-specialists would be trained, and on what needs basis. Universal eye health will only be achieved if difficult and challenging sub-specialized

needs are met as well as cataract and URE. There is a need for collaborative work-force planning upon which to base the need for sub-specialist ophthalmology training. However, such efforts should be cognizant of the ongoing need to tackle the burden of blindness and vision impairment due to cataract and URE.

Most (77%) respondents plan to work in their home country. However, only one in ten stated they would plan to work in a rural area. A recent study of human resources for eye health in 21 countries in SSA found that 67.2% of ophthalmologists work in the national capital cities<sup>38</sup>. The ophthalmologist plays an important part in the eye care team. There are currently too few ophthalmologists to meet the current need, however the situation should gradually improve over the next decade. The emphasis should not necessarily be on placing ophthalmologists in rural areas with low population density. With ophthalmologists predominantly in larger towns and national capital cities, there is a greater need for task-shifting; better integration of primary, secondary and tertiary health care; and strengthening of referral systems.

The third most common workplace preference was private practice (22.5%). With a quarter of ophthalmologists stating a desire to serve and help the community in need, and nearly a quarter planning for private practice; it is interesting that these were not mutually exclusive. As one participant illustrated “I want to serve the underserved communities in the rural areas and at the same time run a private practice in the city”. Another participant further added “There is a better fiscal opportunity, but also it is easier to get donor funds for research or outreach”. Dual practice is common among health professionals worldwide, however further research is necessary to ascertain the impact on the achievement of universal health coverage<sup>39</sup>.

## Conclusion

This survey illustrates that although the mean number of cataract surgeries performed (during training) by senior trainees or recent graduates is adequate, the vast majority of these are performed in the final years of training. More than half of junior trainees’ cataract experience is zero. Is this the best approach to producing proficient ophthalmic surgeons: to cram surgical numbers in the final year, rather than facilitate gradual and sustained building of competence and confidence?

This survey allows us to collectively raise research questions regarding training. These may include exploring qualitatively why some trainees get so few surgical cases, and quantitatively to investigate the link between low surgical numbers in training and complication rates in the first two years of consultant work.

The results will inform us as we continue discussions about minimum standards.

Ophthalmic surgical education and opportunity is complex. It would perhaps make sense to train trainee eye surgeons to a level of competence rapidly and safely using simulation; then immediately follow-up with live supervised surgical training. This approach would accelerate training, improve trainee competence, confidence and satisfaction in training; and ultimately improve outcomes and services for patients.

## Ethics approval and consent to participate

This study was approved by the research ethics committees of the London School of Hygiene & Tropical Medicine (11795) and the University of Cape Town (259/2017). Participants were provided with information about the nature of the survey prior to participation. Participation was entirely voluntary. As the survey was anonymous, individual written consent was not required prior to voluntary participation.

## Data availability

### Underlying data

LSHTM Data Compass: Survey of Ophthalmologists-in-Training in Eastern, Central and Southern Africa - Survey data and questionnaire, <https://doi.org/10.17037/DATA.00001464><sup>40</sup>.

This project contains the following underlying data:

- Trainee\_Survey\_SSA\_-\_Complete\_Responses\_Anonymised

This data is under restricted access due to the assurance given to participants that responses would be kept completely confidential. Specifically, some training institutions and even countries may only have one or two trainees who could therefore easily be identified by default. The data set can be accessed by completing the Request Form, which requires that the intended use for the data is specified. Data available under the LSHTM Data Compass Data Sharing Agreement.

### Extended data

LSHTM Data Compass: Survey of Ophthalmologists-in-Training in Eastern, Central and Southern Africa - Survey data and questionnaire, <https://doi.org/10.17037/DATA.00001464><sup>40</sup>.

This project contains the following extended data:

- Questionnaire
- Data codebook

Data available under the LSHTM Data Compass Data Sharing Agreement.

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## 6. Validation of the Ophthalmic Simulated Surgical Competency Assessment Rubric for Manual Small-Incision Cataract Surgery (Sim-OSSCAR)

### RESEARCH PAPER COVER SHEET

#### **SECTION A – Student Details**

Student	William Dean
Principal Supervisor	Matthew Burton
Thesis Title	The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East and Southern Africa.

#### **SECTION B – Paper already published**

Where was the work published?	Journal of Cataract & Refractive Surgery		
When was the work published?	9 September 2019		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	Yes	Was the work subject to academic peer review?	Yes

Pages 101 to 106

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#### **SECTION C – Prepared for publication, but not yet published**

Where is the work intended to be published?	
Please list the papers authors in the intended authorship order:	
Stage of publication	

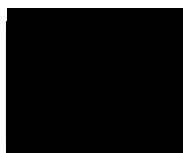
#### **SECTION D – Multi-authored work** – See following page

Student Signature:



Date: 12 December 2019

Supervisor Signature:



Date: 16 January 2020

Chapter 6 describes the design and validation of the ophthalmic simulation surgical competency assessment rubric (Sim-OSSCAR) for SICS. The concept was based on the International Council of Ophthalmology's OSCAR (ophthalmology surgical competency assessment rubric). The idea of modifying the live surgery ICO-OSCAR for use in simulation was my own. I removed certain aspects of live surgery that could not be taught or assessed easily in a simulation environment (for example haemostasis), and simplified the rubric.

I designed the face and content validity study, and the reliability aspect of the study. Dr Neil Murray and Dr John Buchan and I performed the video assessments for the construct validity and reliability, and Dr Karl Golnik gave advice on the methodology. Min Kim assisted with the statistical analysis, and Professor Matthew Burton supervised the final editing.

# Ophthalmic Simulated Surgical Competency Assessment Rubric for manual small-incision cataract surgery



William H. Dean, FRCOphth, Neil L. Murray, MD, John C. Buchan, FRCOphth, Karl Golnik, MD, Min J. Kim, MSc, Matthew J. Burton, PhD

**Purpose:** To develop and test the validity of a surgical competency assessment tool for simulated small-incision cataract surgery (SICS).

**Setting:** Participating ophthalmologists contributed from 8 countries.

**Design:** Qualitative and quantitative development and evaluation of face and content validity of an assessment rubric, and evaluation of construct validity and reliability.

**Methods:** The SICS Ophthalmic Simulated Surgical Competency Assessment Rubric (Sim-OSSCAR) was developed and assessed for face and content validity by an international group of experienced ophthalmologists. Groups of novice and competent surgeons from 4 countries were recorded performing surgery, and masked assessments were performed by 4 expert surgeons, to determine construct validity and reliability.

**Results:** The Sim-OSSCAR for SICS was assessed by a panel of 12 international experts from 8 countries. In response to the

question, "Do you think the OSSCAR represents the surgical techniques and skills upon which trainees should be assessed?", all respondents either agreed or strongly agreed. Face validity was rated as 4.60 (out of 5.0). The content was iteratively agreed to by the panel of experts; final content validity was rated as 4.5. Interobserver reliability was assessed, and 17 of 20 items in the assessment matrix had a Krippendorff  $\alpha$  correlation of more than 0.6. A Wilcoxon rank-sum test showed that competent surgeons perform better than novices ( $P = .02$ ).

**Conclusions:** This newly developed and validated assessment tool for simulation SICS, based on the International Council of Ophthalmology's Ophthalmology Surgical Competency Assessment Rubric, has good face and content validity. It can play a role in ophthalmic surgical education.

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Cataract is the most common cause of blindness, accounting for 12.6 million of the 36-million blind people worldwide, along with 52.6-million people with moderate or severe vision impairment.<sup>1</sup> Small-incision cataract surgery (SICS) is a widely accepted, appropriate, and affordable procedure that can deliver high-quality visual outcomes.<sup>2–5</sup>

SICS is one of the most commonly performed surgical procedures worldwide.<sup>6,7</sup> Therefore, training ophthalmologists to perform the operation safely and efficiently

is of major ophthalmic public health significance. Despite this need, concerns remain in several regions over the safety, quality, and efficiency of surgical training for cataract surgery.<sup>6,8</sup> The use of simulation-based surgical education, before and during the initial period of "live" surgery training, potentially has much to contribute. There is, however, a paucity of data on efficacy of simulation-based surgical education for the SICS technique. Therefore, as a first step to address this evidence gap, we have designed a surgical-skill

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From the International Centre for Eye Health (Dean, Buchan, Burton), London School of Hygiene and Tropical Medicine, the Imperial College London (Dean), the Tropical Epidemiology Group (Kim), Faculty of Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine, and the Moorfields Eye Hospital (Burton), London, England; the Royal Australian and New Zealand College of Ophthalmologists (Murray), Sydney, Australia; the International Council of Ophthalmology (Golnik), San Francisco, California, USA.

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assessment tool for use during simulation-based training, based on the International Council of Ophthalmology's Ophthalmology Surgical Competency Assessment Rubric (ICO-OSSCAR).<sup>9</sup>

Surgical education is a journey characterized by gradually increasing knowledge and skill. Surgeons begin their training as "novices," and with time spent observing and learning, they progress to being an "advanced beginner." Someone who is "competent" can perform a task independently to a standard that is acceptable, though it might lack refinement.<sup>10</sup> Surgeons who are "proficient" have developed a deep understanding and are able to see actions and situations more holistically. "Expert" surgeons can cope with and adapt to complex and new situations. This is the Dreyfus model of skills acquisition and expertise.

The Ophthalmic Simulated Surgical Competency Assessment Rubric (Sim-OSSCAR) was developed to aim toward the stage of "competence." Using the Sim-OSSCAR as a learning and formative assessment tool, with a simulation eye, the novice SICS trainee would become competent. It is envisaged that a trainee should proceed to supervised surgery training on patients in the operating theater only after having attained the competence stage.

In the domain of medical and surgical education, validity refers to the degree to which an instrument measures what it sets out to measure. Content validity is whether the test measures a specific skill, and not other aspects such as anatomical knowledge. Face validity describes whether the chosen tasks resemble those that are performed during a surgical procedure in a real-life situation. Inter-rater reliability is the degree of agreement amongst different graders, and it will provide a measure of consensus.

The aim of the current study was to develop and validate a tool for use within training programs to assess trainee surgeons performing SICS. The ICO-OSSCAR template was selected as the starting point and redesigned for assessing a simulated SICS surgical technique on an artificial eye. This Sim-OSSCAR was then deployed in conjunction with the use of an artificial eye specifically developed for SICS.<sup>A</sup>

## MATERIALS AND METHODS

### Sim-OSSCAR Content Revision and Development

The ICO OSCAR for SICS was developed by experts at the ICO using a modified Dreyfus scale (novice, beginner, advanced beginner, and competent).<sup>11,B</sup> The "proficient" and "expert" steps of the scale were excluded. In this study, the original ICO-OSSCAR was modified to develop an assessment and training tool for simulated ophthalmic surgical education in SICS surgery. The ICO-OSSCAR was initially edited to remove content not appropriate for simulation-based surgical training. The OSCAR was further adapted to a modified three-stage Dreyfus scale (novice, advanced beginner, competent). The draft of the Sim-OSSCAR was sent to a panel of 8 international content experts for further amendments to the content and structure of the Sim-OSSCAR. These people were selected for their experience and expertise in performing and teaching SICS. Responses were collated and synthesized into a final version of the rubric, which was distributed for further review.

### Face and Content Validity Assessment

Face and content validity were assessed using a standardized closed question evaluation on a 5-point Likert scale. This was done by a group of 12 international expert SICS cataract surgeons remotely via email, half of whom had been involved in the initial revision process. These SICS surgeons were selected based on their expertise and to ensure international representation. They teach and perform SICS surgery in Angola, Argentina, Ghana, Haiti, India, Malawi, Nepal, New Zealand, United Kingdom, and the United States. Surgeons were asked, "Do you think the Sim-OSSCAR represents the surgical techniques and skills upon which trainees should be assessed?" and "Would you change any of the cells/content? (If so, please include specific details)." Surgeons were also asked, "Do you think the Sim-OSSCAR (used with the artificial eye) is an appropriate way to assess trainees' surgical skill?" Responses on the 5-point Likert scale were given a numerical value and entered onto an Excel spreadsheet (Microsoft Corp.) before calculating the means  $\pm$  SD. After the initial face and content validation round, three further minor amendments were made to the Sim-OSSCAR, and this validation process was repeated.

### Interobserver Reliability Assessment

To assess interobserver Sim-OSSCAR grading reliability, 8 simulated SICS procedures, which were performed by 8 separate cataract surgeons, were recorded. Four of the surgeons were novice trainee surgeons and 4 were experienced ophthalmologists (who had performed more than 100 SICS procedures). The procedures were performed on the SICS-specific artificial eye, made by Philips Studio, and recorded using a Stemi 305 microscope with AxioCam ERc5s camera and Labscope digital classroom (all Carl Zeiss Meditec AG). The videos were anonymized so that the people doing the scoring were masked to the level of the trainee. The recordings were independently graded by 4 expert SICS surgeons who currently or had previously worked in high-volume training ophthalmology units in Ethiopia, India, Malawi, the Western Pacific region, and Sierra Leone. Each surgeon independently scored the videos of 8 simulation SICS procedures using the Sim-OSSCAR.

### Analysis

Data were managed in Excel and analyzed with Stata software (version 15.1, StataCorp, LLC). Krippendorff  $\alpha$  was selected as the inter-rater agreement coefficient because there were multiple raters providing nonbinary ordinal scores. This was calculated separately for each of the 20 steps of the Sim-OSSCAR on a three-point ordinal point scale (0, 1, or 2). A value of 0.60 was deemed acceptable for a newly developed rubric.<sup>12,13</sup> A Wilcoxon rank-sum test was performed using the ranks for mean scores for novice and competent surgeons.

The validation study was approved by the Medicine Education Ethics Committee, Faculty Education Office (Medicine), Imperial College, London (MEEC1415-12), and the London School of Hygiene & Tropical Medicine ethics committee (11795).

## RESULTS

### Sim-OSSCAR Content Revision and Development

An international reference group of 8 surgeons from 6 countries contributed to the initial development of the SICS Sim-OSSCAR. Table 1 shows the changes that arose from the editing of the ICO-OSSCAR. The steps of draping, cauterization, irrigation/aspiration, and iris protection were removed. This group provided feedback on the content of the SICS Sim-OSSCAR. The discussion focused on anesthesia; preparation of the ocular surface; sterilizing the surgical field with povidone-iodine; conjunctival incision with

**Table 1. Initial editing of ICO-OSSCAR for small-incision cataract surgery to develop the Sim-OSSCAR.**

ICO-OSSCAR Item Label	Action/Change	Sim-OSSCAR Item Label
Draping	Removed	
Scleral access and cauterization	Removed cauterization and edited	Scleral incision
Irrigation/aspiration technique with adequate removal of cortex	Removed	
Wound closure (including suturing, hydration, and checking security as required)	Edited – suturing and hydration of wound removed	Procedure finish
Conjunctival and corneal tissue handling	Edited – reference to conjunctival tissue removed	Scleral and corneal tissue handling
Iris protection	Removed	
Overall speed and fluidity of procedure	Edited – Fluidity included as separate item, times adjusted	Overall speed of procedure

ICO-OSSCAR = International Council of Ophthalmology's Ophthalmology Surgical Competency Assessment Rubric; Sim-OSSCAR = Ophthalmic Simulated Surgical Competency Assessment Rubric

flap, cautery, or hemostasis; decreasing pupil size; iris prolapse; and irrigation/aspiration clearance of cortical lens material. Comments regarding the global indices content also included adequacy of anesthesia and preparation. Consensus was reached that these content suggestions (Table 1) could be excluded from the Sim-OSSCAR because they largely related to live surgery and could not be simulated either by the artificial eyes or animal eye models. The initial Sim-OSSCAR was approved by the panel.

#### Face and Content Validity

The face and content validity were independently assessed by a group of 12 surgeons (6 of whom were in the initial reference group of 8). In response to the Face Validity question, "Do you think the Sim-OSSCAR (used with the artificial eye) is an appropriate way to assess trainees' surgical skill?," all 12 of the respondents either agreed or strongly

agreed. Overall, face validity was rated as  $4.60 \pm 0.52$  out of 5 as a mean summation of 12 separate scores.

In response to the Content Validity question, "Do you think the Sim-OSSCAR represents the surgical techniques and skills upon which trainees should be assessed?," all 12 respondents either agreed or strongly agreed. The content was finally agreed upon by the panel of experts, and the content validity was rated as 4.5 (out of 5).

#### Interobserver Reliability

Interobserver reliability was assessed by an international panel of 4 experts in SICS. Eight separate masked video recordings of simulation SICS were sent to each expert surgeon for scoring using the Sim-OSSCAR. The recorded procedures represented a range of surgeon skills from complete novice to competent. The mean score for "novices"

**Table 2. Inter-rater Krippendorff  $\alpha$  correlation for 20 facets of the Sim-OSSCAR.**

Facet	Item	Krippendorff $\alpha$	Percent Agreement
Specific step			
1	Scleral fixation	0.660	0.792
2	Paracentesis	0.663	0.792
3	OVD insertion	0.773	0.854
4	Scleral incision	0.869	0.917
5	Scleral tunnel	0.900	0.938
6	Sclerocorneal tunnel	0.896	0.938
7	Corneal entry	0.617	0.750
8	Capsulotomy/capsulorhexis start	0.414	0.604
9	Capsulotomy/capsulorhexis completion	0.767	0.854
10	Hydrodissection	0.782	0.875
11	OVD insertion	0.685	0.813
12	Prolapse of nucleus partially into AC	0.677	0.792
13	Nucleus extraction	0.894	0.938
14	IOL insertion	0.673	0.792
Global indices			
15	Corneal distortion	0.894	0.938
16	Eye positioned centrally within microscope view	0.394	0.583
17	Scleral and corneal tissue handling	0.880	0.938
18	Intraocular spatial awareness	0.796	0.875
19	Overall fluidity of procedure	0.518	0.708
20	Overall speed of procedure	1.000	1.000

AC = anterior chamber; IOL = intraocular lens; OVD = ophthalmic viscosurgical device; Sim-OSSCAR = Ophthalmic Simulated Surgical Competency Assessment Rubric



Table 3. Total score correlation.

Video	Grader Score: n/40				Mean $\pm$ SD
	A	B	C	D	
1	5	1	2	5	3.25 $\pm$ 2.06
2	2	2	1	2	1.75 $\pm$ 0.50
3	2	2	1	0	1.25 $\pm$ 0.96
4	0	0	1	1	0.50 $\pm$ 0.58
5	39	37	33	37	36.5 $\pm$ 2.52
6	25	24	15	22	21.5 $\pm$ 4.51
7	36	35	29	34	33.5 $\pm$ 3.11
8	33	33	32	32	32.5 $\pm$ 0.58

was  $1.7 \pm 1.0$ , and the mean score for “competent” SICS surgeons was  $31.0 \pm 2.7$ , out of a maximum score of 40.

To assess the interobserver agreement on the specific items in the Sim-OSSCAR, Krippendorff  $\alpha$  coefficients were calculated. Table 2 shows the results for all 20 items in the Sim-OSSCAR, of which 17 exhibited an inter-rater agreement coefficient of Krippendorff  $\alpha$  greater than 0.60. Three items had a lower Krippendorff  $\alpha$  coefficient: “capsulotomy/capsulorhexis start,” “eye positioned centrally,” and “overall fluidity of the procedure.”

#### Construct Validity

Construct validity is an assessment of the “sharpness” of a tool: can it discriminate between two distinct groups? For this study, these groups are the novice and competent surgeons. Table 3 shows the total score for each separate grader for all 8 videos. Novice surgeons were graded with a mean score range of 0.50 to 3.25 (out of 40), with standard deviations varying between graders’ scores of 0.50 to 2.06. Competent surgeons were graded with a mean score range of 21.5 to 36.5 (with standard deviations varying from 0.58 to 4.51). A Wilcoxon rank-sum test showed that competent surgeons perform better than novices ( $P = .02$ ).

#### DISCUSSION

Globally, 65.2-million people are blind or moderate/severely vision impaired because of cataract.<sup>1</sup> Twenty-eight percent of countries have less than 4 ophthalmologists per one-million people.<sup>14</sup> By subregion, the lowest mean ratio is 2.7 ophthalmologists per one million in Sub-Saharan Africa. There is a disproportionately high prevalence rate of cataract blindness in regions with the fewest ophthalmologists and cataract surgeons. There is a huge need for an increased number of well-trained ophthalmic surgeons, both ophthalmologist and nonphysician cataract surgeons to tackle this burden. There is a growing appreciation of the role of simulation in surgical education, especially in the initial acquisition of competence.

The SICS Sim-OSSCAR (Figure 1) was developed to provide a formative assessment tool for initial cataract surgical training. The Sim-OSSCAR for SICS has good face and content validity as well as interobserver reliability and construct validity. It is important to note that face and content validity were quantified using closed-ended questions.

Although open-ended comments were invited, we accept that this is a potential source of response bias.

Fidelity is important in simulation-based surgical education. Animal eyes have been used for training; however, the tissue feel in terms of rigidity or elasticity is different than human eyes. Animal eyes have a small window of fidelity before they disintegrate, cannot be used as a “standardized” training model, and often need preparation with formalin (aqueous solution of formaldehyde).<sup>15,16</sup> Artificial eyes offer standardization, and overall fidelity was rated as “high” or “very high” by 79% of the trainees on SICS courses (manuscript in preparation). Fidelity of scleral tunnel formation and capsulorhexis steps of SICS were rated “high” or “very high” by 100% of the trainees.

The OSACSS (Objective Structured Assessment of Cataract Surgical Skill) was developed as an objective performance-rating tool.<sup>17</sup> The grading system contained global as well as phacoemulsification cataract surgery task-specific elements. Significant improvements in live surgical procedures have been shown after virtual reality cataract surgery training, as assessed by OSACSS.<sup>18</sup> The OASIS (Objective Assessment of Skills in Intraocular Surgery) was also developed for phacoemulsification cataract surgery as an objective ophthalmic surgical evaluation protocol to assess surgical competency.<sup>19</sup> The SPESA (Subjective Phacoemulsification Skills Assessment) assesses trainee performance in cataract surgery by combining a global approach, assessing detailed stage-specific criteria of critical components of cataract surgery.<sup>20</sup>

The ICO-OSCARs were originally based on the OSACSS; however, they were expanded upon by creating a set of behaviorally anchored scoring matrices that explicitly and precisely define what is expected for each step. The rubric was based on a modified Dreyfus model<sup>10</sup>; however, the final “expert” category was omitted because trainees were not expected to become experts during training. The ICO-OSCAR, as well as all other valuation tools described above, are aimed at assessment of surgical competence in the live operating theater setting. This currently validated Sim-OSSCAR is for use with SICS rather than phacoemulsification surgery, and it is aimed for use in a simulation surgical skill’s center before live surgical training has commenced. It can be used during initial instruction, whereby the trainee SICS surgeon uses it as a clear list of the steps of the procedure. It can be used as a guide of what exactly is expected for each step to be deemed “competent.”

Although models have been available for modern phacoemulsification cataract surgery for over a decade, no artificial eyes had been previously developed for SICS. A full-immersion computerized SICS simulator is in the final stages of development; however, it is not yet widely available.<sup>21</sup>

The primary aim of the SICS Sim-OSSCAR is to provide a formative assessment tool. It could be used as a summative assessment tool upon which to progress the successful trainee to live supervised surgical training in SICS. It may be left to the trainer or training institution to benchmark appropriately, depending on the setting and educational goals. An example might be to require a mean of 75% score

Trainee: \_\_\_\_\_ Evaluator: \_\_\_\_\_ Date: \_\_\_\_\_

Ophthalmic Simulated Surgical Competency Assessment Rubric – Manual Small Incision Cataract Surgery (Sim-OSSCAR:SICS)					
		Novice (score = 0)	Advanced Beginner (score = 1)	Competent (score = 2)	Score (Not done score = 0)
1	<b>Scleral fixation</b>	No scleral fixation; inappropriate place; tissue trauma	Appropriate position of scleral fixation, but needs to re-grip. Mild tissue trauma	Good position of fixation, no need to re-grip, no trauma. Firm and stable scleral fixation throughout scleral tunnel formation.	
2	<b>Scleral incision</b>	Inappropriate location, shape and size; hesitant incision.	Either one of the incision location, shape or size is incorrect.	Good incision location (superior), shape (frown) and size (>8mm).	
3	<b>Paracentesis</b>	Inappropriate width, length and location. Trauma to iris or anterior capsule on entry.	Inappropriate location, width, length, or timing. Anterior chamber mostly stable.	Wound of adequate length, width (1-2mm), and correct location (near limbus, lower).	
4	<b>Viscoelastic insertion</b>	Does not insert viscoelastic, or has difficulty accessing anterior chamber through paracentesis.	Administers viscoelastic, but one of: appropriate time, amount, or cannula position are incorrect.	Viscoelastic administered in appropriate amount, at appropriate time, with cannula tip clear of lens capsule and endothelium.	
5	<b>Scleral tunnel</b>	Inappropriate tunnel depth, hesitant dissection. Button-hole and/or premature entry.	Able to dissect forward, and understands that tunnel depth is incorrect but unable to correct.	Tunnel constructed at correct plane. If inappropriate plane, able to rectify.	
6	<b>Sclero-corneal tunnel</b>	Does not extend into clear cornea. Button-hole and/or premature entry.	Does not extend >1mm into clear cornea. Internal tunnel not wider than external.	Extends tunnel into clear cornea >1mm, wider limbal corneal tunnel than at scleral incision.	
7	<b>Corneal entry</b>	Hesitant keratome entry into AC. Uses instrument other than keratome for entry. Require wound extension or suturing.	Entry at mostly right plane. Able to extend but with repeated use of viscoelastic. Internal valve irregular. Require wound extension or suturing.	Fluently enters in right plane. Wound length adequate with no further need for extension. Retains viscoelastic during extension.	
8	<b>Capsulotomy / Capsulorhexis start</b>	Tentative; size and position are inadequate for nucleus density, incorrect capsulotomy position.	Mostly in control, slow initial start. Capsulotomy in correct position (superior linear, central CCC).	Correct and smooth start to capsulotomy / capsulorhexis. Delicate approach and confident control of cystotome.	
9	<b>Capsulotomy / Capsulorhexis completion</b>	Tentative; size and position are inadequate for nucleus density, incorrect capsulotomy position. Radial tear	Mostly in control, few awkward or repositioning movements. Capsulotomy in correct position. Radial tear corrected.	Adequate size and position for nucleus, no tears. AC depth throughout the capsulorhexis. Appropriate final capsulotomy for IOL size, visual axis clear.	
10	<b>Hydro-dissection:</b>	Hydrodissection fluid not injected.	Fluid injected, but inappropriate location (not inferior and under anterior capsule).	Fluid injected with ease under anterior capsule and inferiorly.	
11	<b>Injection of viscoelastic</b>	Doesn't inject viscoelastic into eye	Injects insufficient viscoelastic. Injects only into PC or AC	Injects adequate viscoelastic into capsule bag behind nucleus, and AC	
12	<b>Prolapse of nucleus partially into AC</b>	Unable to dial upper equator of nucleus into AC. Hooks anterior nuclear surface. Iris and corneal touch.	Multiple attempts required to prolapse upper equator of nucleus into AC with more than minimal resistance. No corneal touch.	Prolapse of upper equator with minimal resistance. No damage to pupil and iris.	
13	<b>Nucleus extraction</b>	Damages endothelium, iris or capsule, unable to hold and extract nucleus, movements not coordinated. Pierces posterior capsule.	Removes nucleus after repeated attempts, more than one piece, might need wound extension prior to extraction.	Extracts nucleus with one or two attempts; proper wound size in relation to nuclear density.	
14	<b>IOL insertion</b>	Grips IOL incorrectly, inserts IOL incorrectly, multiple attempts. No IOL.	Hesitant insertion of IOL, more than one attempt to insert. Correct IOL orientation.	Inserts IOL into capsular bag efficiently, correctly, and in first attempt	
<b>GLOBAL INDICES</b>					
15	<b>Wound Neutrality and Corneal Distortion</b>	Frequent wound, scleral and corneal distortion.	Mild and infrequent (<3) corneal distortion folds occur.	No distortion folds are produced. The length and location of incisions prevents distortion of the cornea.	
16	<b>Positioned Centrally Within Microscope View</b>	Constantly requires repositioning. Surgical operating field frequently in periphery or out of view.	Mild fluctuation in surgical field position / centration.	The surgical is kept centered during the surgery.	
17	<b>Scleral and Corneal Tissue Handling</b>	Tissue handling is rough and damage occurs.	Tissue handling decent but potential for damage exists.	Tissue is not damaged nor at risk by handling.	
18	<b>Intraocular Spatial Awareness</b>	Instruments often in contact with capsule, iris, corneal endothelium; blunt second instrument not kept in appropriate position.	Rare contact with capsule, iris, endothelium. Often has blunt second hand instrument in appropriate position.	No accidental contact with capsule, iris, corneal endothelium. Blunt, second hand instrument is kept in appropriate position.	
19	<b>Overall Fluidity of Procedure</b>	Hesitant, frequent starts and stops, not at all fluid.	Occasional inefficient and/or unnecessary manipulations occur	Inefficient and/or unnecessary manipulations are avoided	
20	<b>Overall Speed of Procedure</b>	Case duration more than 30 minutes, or not completed.	Case duration 20-30 minutes.	Case duration less than 20 minutes.	
<b>TOTAL</b>					

Good Points: \_\_\_\_\_

Suggestions for development: \_\_\_\_\_

Based on the International Council of Ophthalmology (ICO)-Ophthalmology Surgical Competency Assessment Rubric-SICS (ICO-OSSCAR: SICS)

Figure 1. The Ophthalmic Simulated Surgical Competency Assessment Rubric for manual small-incision cataract surgery (Sim-OSSCAR:SICS).

(30/40) over three cases, and no “zero” scores in any of the 20 steps.

Kappa measures (such as Krippendorff  $\alpha$ ) correct for chance agreement as the coefficients tend to punish variables with strongly skewed distributions. This explains the higher percentage agreements in Table 2. Three steps of

the SICS Sim-OSSCAR had a lower interobserver reliability, with a Krippendorff  $\alpha$  less than 0.60. These three steps were the starting of the capsulotomy, centration, and fluidity.

First, separate techniques for starting a capsulotomy or capsulorhexis exist in conventional cataract surgery: a continuous curvilinear capsulorhexis, linear (or envelope)



capsulotomy, and a can-opener technique. Different cataract surgeons will themselves have subtle variations within these. Second, a limitation of the Stemi 305 microscope and Labscope App is the high zoom when recording, relative to what the surgeon sees through the binocular eyepieces. Finally, “fluidity” is by definition a subjective term and description.

We hope that the use of the newly developed Sim-OSSCAR will assist eye surgeon trainees in gaining competence and confidence within simulation-based surgical education, before then progressing to supervised live surgery.

We present a newly validated learning and assessment tool for simulation-based surgical education in cataract surgery. Its aim is ultimately to guide and assess initial simulation surgical training in SICs, to then give trainees the green lights to progress to live supervised surgery.

#### WHAT WAS KNOWN

- Ophthalmology surgical competency assessment tools exist for live cataract surgical evaluation.

#### WHAT THIS PAPER ADDS

- Surgical competency can be reliably measured for simulated cataract surgery.

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## 7. Validation of the Ophthalmic Simulated Surgical Competency Assessment Rubric (Sim-OSSCAR) for Trabeculectomy

### RESEARCH PAPER COVER SHEET

#### **SECTION A – Student Details**

Student	William Dean
Principal Supervisor	Matthew Burton
Thesis Title	The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East and Southern Africa.

#### **SECTION B – Paper already published**

Where was the work published?	BMJ Open Ophthalmology		
When was the work published?	August 2019		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	Yes	Was the work subject to academic peer review?	Yes

Pages 109 to 115

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#### **SECTION C – Prepared for publication, but not yet published**

Where is the work intended to be published?	
Please list the papers authors in the intended authorship order:	
Stage of publication	

#### **SECTION D – Multi-authored work** – See following page

Student Signature:



Date: 12 December 2019

Supervisor Signature:



Date: 16 January 2020

Chapter 7 describes the design and validation of the ophthalmic simulation surgical competency assessment rubric (Sim-OSSCAR) for glaucoma trabeculectomy surgery. The concept was based on the International Council of Ophthalmology's OSCAR (ophthalmology surgical competency assessment rubric). The idea of modifying the live surgery ICO-OSCAR for use in simulation was my own, as with the Sim-OSSCAR for SICS. I removed certain aspects of live surgery that could not be taught or assessed easily in a simulation environment (for example cautery and haemostasis), and simplified the rubric to a 3-point modified Dreyfus scale.

I designed the face and content validity study, and the reliability aspect of the study. Dr John Buchan, Dr Fisseha Admassu Professor Andrew McNaught and I performed the video assessments for the construct validity and reliability, and Dr Karl Golnik gave advice on the methodology. Min Kim assisted with the statistical analysis, and Professor Matthew Burton supervised the final editing.

# Ophthalmic simulated surgical competency assessment rubric (Sim-OSSCAR) for trabeculectomy

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## ABSTRACT

**Background/aims** To develop, test and determine whether a surgical-competency assessment tool for simulated glaucoma surgery is valid.

**Methods** The trabeculectomy ophthalmic simulated surgical competency assessment rubric (Sim-OSSCAR) was assessed for face and content validity with a large international group of expert eye surgeons. Cohorts of novice and competent surgeons were invited to perform anonymised simulation trabeculectomy surgery, which was marked using the Sim-OSSCAR in a masked fashion by a panel of four expert surgeons. Construct validity was assessed using a Wilcoxon rank-sum test. Krippendorff's alpha was calculated for interobserver reliability.

**Results** For the Sim-OSSCAR for trabeculectomy, 58 of 67 surgeons (86.6%) either agreed or strongly agreed that the Sim-OSSCAR is an appropriate way to assess trainees' surgical skill. Face validity was rated as 4.04 (out of 5.00). Fifty-seven of 71 surgeons (80.3%) either agreed or strongly agreed that the Sim-OSSCAR contents represented the surgical technique of surgical trabeculectomy. Content validity was rated as 4.00. Wilcoxon rank-sum test showed that competent surgeons perform better than novices ( $p=0.02$ ). Interobserver reliability was rated  $>0.60$  (Krippendorff's alpha) in 19 of 20 steps of the Sim-OSSCAR.

**Conclusion** The Sim-OSSCAR for trabeculectomy, a newly developed and validated assessment tool for simulation glaucoma surgery, has validity and reliability. It has the potential to play a useful role in ophthalmic surgical education.

## INTRODUCTION

Glaucoma is the third most common cause of blindness globally after cataract and uncorrected refractive error.<sup>1</sup> Surgical treatment for glaucoma is considered when medical and laser treatment options are exhausted, inappropriate, or unavailable. In many instances, surgical trabeculectomy is considered as a first-line treatment for moderate to advanced glaucoma. Early surgery can provide lower intraocular pressure (IOP) than medical therapy.<sup>2,3</sup> A prospective multicentre randomised controlled trial is currently underway to compare the effectiveness of primary medical and primary surgical management for people presenting

## Key messages

### What is already known about this subject?

- ▶ A surgical competency assessment tool has already been developed and validated for live glaucoma surgery.

### What are the new findings?

- ▶ A new surgical competency assessment tool has been developed and validated for use in initial simulation-based surgical training in glaucoma surgery.

### How might these results change the focus of research or clinical practice?

- ▶ Ophthalmology training institutions might focus on the use of simulation-based acquisition of surgical competence before live surgical training.

with advanced glaucoma, the Treatment of Advanced Glaucoma Study.<sup>4</sup>

Surgical education for glaucoma is challenging. Opportunities for trainees are often sparse. In the USA, the mean number of trabeculectomies performed by trainees is four.<sup>5</sup> Similarly, in sub-Saharan Africa the mean number performed by senior trainees was also four (article under review). This may be due to reluctance of surgeons to perform and patients to accept surgery, driven at least in part by the lack of expectation of improvement in vision and visual field loss. Vision never improves, and often is slightly worse following surgery: a recent meta-analysis showed that visual function (mean deviation and best-corrected visual acuity) drops after surgery, however, the gains from reduced rate of progression balance after 18 months, leaving patients better off.<sup>6</sup> Moreover, the operated eye may be an only eye, often with good visual acuity. There is recent evidence that visual field loss can improve after surgery reduces the IOP.<sup>7</sup>

A structured curriculum, involving extensive simulation-based training, can assist in introducing trainees to glaucoma surgery.<sup>5</sup> However, there is a paucity of data on the efficacy of simulation-based surgical education in



glaucoma surgery techniques, including trabeculectomy. Therefore, to begin to address this gap, we designed a surgical competency assessment tool for simulated trabeculectomy surgery, based on the International Council of Ophthalmology (ICO) ophthalmology surgical competency assessment rubric (OSCAR) for trabeculectomy.<sup>8</sup>

Surgeons begin their training in a specific technique as 'novices', having incomplete knowledge and understanding, approaching a task relatively mechanistically. After time observing, learning and practicing under supervision a novice may progress to being an 'advanced beginner', demonstrating situational awareness and a working understanding of what is before them. They tend to see actions as a series of separated steps, and can complete some simpler surgical steps without supervision. A surgeon who is 'competent' in a technique has a good working and background understanding, and sees actions in relation to goals, at least partly in context. They may complete work independently to a standard that is acceptable, though it may lack refinement. They are capable of deliberate planning and can formulate surgical routines.<sup>9</sup> Proficiency and full expertise are considered outside of the scope of this context of simulation-based surgical education in trabeculectomy. Even after an ophthalmology trainee has completed training, there is still a great amount of continued training and experience to be gained in order

to become a glaucoma 'specialist' and attain a level to be considered and gain recognition as an 'expert'.<sup>10</sup>

It is towards the stage of 'competent' through structured ophthalmic surgical training that this development and use of the ophthalmic simulated surgical competency assessment rubric for trabeculectomy (Sim-OSSCAR) is designed to support. The Sim-OSSCAR is aimed at evaluating the progress made by a trainee towards a basic level of competence, in a simulation environment. Specifically, it addresses the binary question: has the trainee invested sufficient sustained deliberate practice on artificial materials for the trainer to decide it is reasonable to progress to supervised live surgical training?

In medical and surgical education, validity refers to the degree to which an instrument measures what it sets out to measure. Face validity describes whether the simulated tasks resemble those that are performed during a surgical procedure in a real-life situation. Content validity is whether the test resembles a specific skill, not other aspects such as anatomical knowledge. Intergrader reliability is the degree of agreement among different graders, and will provide a measure of consensus.

It is accepted that a unified approach of demonstrating evidence to either support or refute the overall validity of an instrument should be used.<sup>11</sup> Studies of the assessment of surgical education, training and curricula should

Trainee: \_\_\_\_\_

Evaluator: \_\_\_\_\_

Date: \_\_\_\_\_

Ophthalmic Simulated Surgical Competency Assessment Rubric - Trabeculectomy (Advanced eye) (Sim-OSSCAR:Trab)

		Novice (score = 0)	Advanced Beginner (score = 1)	Competent (score = 2)	Score (Not done score = 0)
1	Globe stabilization	Unable to perform clear corneal traction suture placement. Suture not placed in central cornea. Penetration.	Is able to place a corneal traction suture with hesitation or multiple attempts, and is able to secure suture to ensure correct globe positioning	Is able to perform a corneal traction suture placement with ease at one attempt, and is able to secure suture to ensure correct globe positioning.	
2	Conjunctival peritomy	Peritomy in inappropriate place. Jagged edges or tears in conjunctiva (>2). Too small (<2 clock hours) or too large (>6 clock hours).	Peritomy of reasonable size. One or two small tears or jagged edges [radial relieving incisions are OK].	Peritomy of good size (3-5 clock hours at limbus) and position. No tears / uneven jagged edges [radial relieving incisions OK]	
3	Scleral incision	Hesitant/multiple attempts required to make scleral partial thickness incision. Inaccurate placement/inadequate depth and length.	Scleral partial thickness incision performed, though hesitant, in correct position. Inaccurate/inadequate depth or length.	Scleral partial thickness incision in correct position. Correct depth (half thickness) and length (4mm).	
4	Corneal groove to allow buried releasable suture	Corneal grooves inaccurately placed/too deep; or not performed at all.	Corneal grooves accurately placed. Slightly too deep or too shallow.	Corneal grooves accurately placed, correct depth.	
5	Paracentesis	Hesitant/multiple (or no) attempts to make paracentesis. Damage to iris/lens from paracentesis incision.	Paracentesis performed, though hesitant. In correct position, without inadvertent injury to iris/lens.	Paracentesis efficiently performed, in correct position, without inadvertent injury to iris/lens.	
6	Formation of scleral flap	Unable to form a scleral flap safely without unintended changes in thickness of flap / risk of overly thin flap / risk of entering anterior chamber (AC) too posteriorly.	Able to form a scleral flap safely without unintended changes in thickness of flap/risk of overly thin flap / risk of entering AC too posteriorly; but hesitant, and not efficiently	Able to form a scleral flap safely without unintended changes in thickness of flap/risk of overly thin flap / risk of entering AC too posteriorly, efficiently. [OK if crosses conj insertion]	
7	Placement one releasable scleral flap suture	Is unable to place and tie scleral flap releasable suture.	Is able to eventually place and tie releasable flap suture, but inefficient/multiple attempts. Corneal loop of releasable suture not buried in cornea.	Is able to efficiently place and tie scleral flap releasable suture. Corneal loop of releasable sutures fully buried in cornea via corneal groove.	
8	Placement of one fixed (or releasable) scleral flap suture	Is unable to place and tie scleral flap fixed suture (or second releasable).	Is able to eventually place and/or tie second flap suture, but inefficient/multiple attempts.	Is able to efficiently place and tie scleral flap suture. Checks IOP before locking suture.	
9	Full thickness corneal incision into AC	Unable to efficiently enter AC. Entry too large (>75% flap width).	Able to perform a full-thickness corneal incision, though hesitant. Size or position incorrect.	Able to make full-thickness corneal incision into AC. Correct size and position.	

Based on the International Council of Ophthalmology (ICO)-Ophthalmology Surgical Competency Assessment Rubric

**Figure 1** Ophthalmic simulated surgical competency assessment rubric: trabeculectomy (Sim-OSSCAR: Trab). IOP, intraocular pressure.

have discrete benchmarks as guides: described as face, content, construct, concurrent, discriminative and predictive validity.<sup>12</sup> There is an even greater need for this in high-stakes assessments such as Board or Surgical College certification examinations. The ICO OSCAR for trabeculectomy has been validated for live surgical performance assessment.<sup>8</sup> This current study is not aimed at validation of a curriculum nor a high-stakes live surgical assessment.

In this study, we aimed to modify the ICO OSCAR, using it as a starting point for developing a formative and summative assessment tool for simulated ophthalmic surgical training in trabeculectomy surgery.

## METHODS

### Trabeculectomy Sim-OSSCAR content revision and development

The ICO OSCAR for trabeculectomy was previously developed by experts at the ICO using a modified Dreyfus scale (novice, beginner, advanced beginner and competent).<sup>8,9</sup> In this study, we have modified the original ICO OSCAR to develop an assessment and training tool for simulated ophthalmic surgical education in trabeculectomy surgery.

The ICO OSCAR was initially edited to remove content not appropriate for simulation-based surgical training. The OSCAR was further adapted to a modified

three-stage Dreyfus scale (novice, advanced beginner, competent). The 'proficient' and 'expert' steps of the scale were excluded. The draft of the trabeculectomy Sim-OSSCAR was sent electronically to a panel of four international content experts for further amendments to the content and structure of the Sim-OSSCAR. These people were selected for their experience and expertise in performing and teaching trabeculectomy surgery. Responses were collated electronically and synthesised into a final version of the rubric, which was distributed for further review. Amendments suggested by only one of the four experts, and disagreements were discussed until a majority consensus was reached.

The Sim-OSSCAR was designed to be used in conjunction with artificial eyes specifically developed for trabeculectomy by Phillips Studios (Bristol, UK),<sup>13</sup> which has been in used in training programmes for the past 6 years. It could be used in conjunction with surgical training using animal eyes.

### Face and content validity assessment

The Sim-OSSCAR together with the artificial eye for glaucoma surgery, were presented to delegates at the International Glaucoma Society meeting in Germany. Delegates included expert glaucoma surgeons from around the world, and all were consultant or fellow

10	<b>Formation of sclerostomy with punch/blade.</b>	Unable to insert Kelly's punch to perform sclerostomy / to complete sclerostomy with blade. No sclerostomy made.	Able to use punch/blade to form sclerostomy, though hesitant. Sclerostomy too small/large.	Able to use punch/blade to form a full thickness sclerostomy. Correct size and anterior position.	
11	<b>Peripheral iridectomy</b>	Unable to retract iris and perform iridectomy.	Able to retract iris, but unable to complete iridectomy, or iridectomy too anterior.	Able to retract iris, perform iridectomy.	
12	<b>Reformation of AC using BSS via paracentesis, titration of IOP</b>	Failure to reform AC with BSS. Failure to adjust tightness of releasable / fixed sutures adequately.	AC successfully reformed with BSS, but failure to check IOP too high (via digital IOP estimation), and need to release IOP via paracentesis.	AC efficiently reformed BSS, scleral flap confirmed to be watertight efficiently, IOP not excessive (efficient estimation of IOP via digital pressure), but if so, IOP reduced via efficient release of aqueous via paracentesis / adjustment of sutures.	
13	<b>Conjunctival suturing</b>	Unable to place and tie conjunctival sutures, or places only one suture.	Is able to eventually place and tie conjunctival sutures, but inefficient / multiple attempts. Places only two sutures.	Is able to efficiently place and tie conjunctival sutures. Places three or more sutures.	
14	<b>Conjunctival suture – burying of knots</b>	No attempt made to bury conjunctival suture knots.	Attempts made to bury conjunctival knots, but inefficient, suture snaps, or unable to bury more than one knot.	Fluent attempt made to bury conjunctival knots along correct line of suture. Able to rotate and bury two or more knots.	
<b>GLOBAL INDICES</b>					
15	<b>Tissue handling</b>	Tissue handling is often unsafe with inadvertent damage, or excessively aggressive or timid.	Tissue handling is safe but sometimes requires multiple attempts to achieve desired manipulation of tissue.	Tissue handling is efficient, fluid and almost always achieves desired tissue manipulation on first attempt.	
16	<b>Surgical Field Positioned Centrally Within Microscope View</b>	Very limited or delayed repositioning. Surgical operating field often at periphery of microscope view.	Surgical operating field occasionally at periphery of microscope view.	Surgical operating field occasionally at periphery of microscope view. Adjusts microscope as needed without delay.	
17	<b>Technique of holding suture needle in needle holder</b>	Loads needle in proper direction for fore-hand pass but sometimes loads incorrectly for backhand pass. Loads too close or too far from the swaged end of needle.	Loads needle properly for forehand and backhand needle pass but is inefficient and often requires multiple attempts.	Loads needle properly and efficiently for forehand and backhand needle passes.	
18	<b>Technique of surgical knot tying</b>	Require multiple extra hand maneuvers to make first throw lay flat, and/or loosens first throw while attempting second throw.	Is able to tie a flat surgeon's knot first throw but second and third throws are inefficient. Does not inadvertently loosen first throw.	Is able to efficiently tie a flat, square surgeon's knot.	
19	<b>Overall fluidity of procedure</b>	Hesitant, frequent starts and stops. Not at all fluid.	Occasional inefficient and/or unnecessary movements or manipulations occur.	Inefficient and/or unnecessary manipulations are avoided.	
20	<b>Overall speed of the procedure</b>	Case duration more than 45 minutes; or case not completed.	Case duration between 30 and 45 minutes.	Case duration less than 30 minutes	

Good Points: \_\_\_\_\_ TOTAL:  

Suggestions for development: \_\_\_\_\_

Based on the International Council of Ophthalmology (ICO)-Ophthalmology Surgical Competency Assessment Rubric

**Figure 2** Ophthalmic simulated surgical competency assessment rubric: trabeculectomy (Sim-OSSCAR: Trab). IOP, intraocular pressure; BSS, balanced salt solution .





ophthalmologists with a subspecialty interest in glaucoma. Questions were asked about the trabeculectomy Sim-OSSCAR regarding face and content validity. On a five-point Likert scale, surgeons were asked “Do you think the OSSCAR represents the surgical techniques and skills upon which trainees should be assessed?”. Surgeons were also asked: “Do you think the Sim-OSSCAR (used with the artificial eye) is an appropriate way to assess trainees’ surgical skill?”. Responses on the five-point Likert scale were given a numerical value, entered onto a Microsoft Excel spreadsheet, prior to calculating the mean.

#### Interobserver reliability assessment

To assess interobserver Sim-OSSCAR grading reliability we recorded eight simulated trabeculectomy procedures, which were performed by eight separate trainee ophthalmologists. Four were novice trainee surgeons (assisted in less than five trabeculectomies) and four were experienced ophthalmologists (performed more than 100 trabeculectomies). The procedures were performed on the trabeculectomy-specific artificial eye. The simulated surgery was recorded using an Axiocam ErC5reV2 camera mounted to a Stemi 305 desktop microscope (Zeiss, Oberkochen, Germany). The videos were anonymised so that the people doing the scoring were masked to the level of the trainee. The recordings were independently graded using the trabeculectomy Sim-OSSCAR by four ophthalmologists who are highly experienced in trabeculectomy surgery. Expert assessors were masked to the training status of the trainee. Krippendorff’s alpha was calculated for interobserver agreement correlation of the trabeculectomy Sim-OSSCAR ordinal marking scale for each of the 20 sections (figures 1 and 2). Low inter-rater reliability was considered for values of  $\alpha_k < 0.60$ .<sup>14 15</sup>

Wilcoxon rank-sum test was performed using the rank sum of the mean scores for novice and competent surgeons. All analysis was performed using Stata V.15.1.

## RESULTS

### Trabeculectomy Sim-OSSCAR content revision and development

The changes arising from the editing of the ICO-OSCAR are shown in table 1. The steps of draping, traction suture, tenons dissection, haemostasis, application of antimetabolite, knowledge of instruments and communication with team were removed. The first stage of ‘globe stabilisation’ included only a clear-corneal traction suture, and not a superior-rectus suture. The expert review group provided feedback on the content of the trabeculectomy Sim-OSSCAR.

### Face and content validity

Seventy-one surgeons from 22 countries responded to the first question regarding the content of the Sim-OSSCAR, of these 57 (80.3%) either agreed or strongly agreed that the Sim-OSSCAR contents represented the surgical technique of surgical trabeculectomy. The mean content validity was rated as 4.00 (out of 5.00).

Sixty-seven surgeons responded to the second question regarding the face validity of the assessment tool, of 58 (86.6%) either agreed or strongly agreed that the Sim-OSSCAR is an appropriate way to assess trainees’ surgical skill. The mean face validity was 4.04.

### Interobserver reliability

Interobserver reliability was assessed by four expert trabeculectomy surgeons. Eight separate masked video

**Table 1** Initial editing of ICO OSCAR for trabeculectomy

Stage of procedure	Action	New Sim-OSSCAR	Comment
Draping	Deleted		
Corneal or superior rectus traction suture	Deleted and edited	Globe stabilisation	
Conjunctival incision and Tenon’s dissection	Deleted and edited	Conjunctival peritomy	Tenon’s dissection deleted
Maintaining haemostasis	Deleted		
Application of antimetabolite	Deleted		
Full thickness incision into anterior chamber (AC)	Added		
Scleral flap suturing/AC reformation	Split into separate sections, edited	Releasable, interrupted sutures	Further AC reformation
Conjunctival closure	Edited	Conjunctival suturing, burying	
Knowledge of instruments	Deleted		
Communication with surgical team	Deleted		
Overall speed and fluidity of procedure	Edited	Fluidity separate	Times changes

ICO, International Council of Ophthalmology; OSCAR, ophthalmology surgical competency assessment rubric; Sim-OSSCAR, ophthalmic simulated surgical competency assessment rubric.

**Table 2** Inter-rater Krippendorff's alpha correlation for 20 facets of the Sim-OSSCAR

	Item	Krippendorff's alpha	Per cent agreement
1	Globe stabilisation	0.902	0.934
2	Conjunctival peritomy	0.666	0.792
3	Scleral incision	0.895	0.938
4	Corneal groove(s)	0.782	0.875
5	Paracentesis	0.880	0.934
6	Formation of scleral flap	0.782	0.875
7	Releasable suture	0.755	0.854
8	Fixed/releasable suture	0.635	0.750
9	Corneal incision into AC	0.665	0.771
10	Sclerostomy	0.796	0.875
11	Peripheral iridectomy	0.782	0.875
12	Reformation of AC	1.000	1.000
13	Conjunctival suturing	0.696	0.792
14	Suture burying	0.673	0.792
<b>Global indices</b>			
15	Tissue handling	0.787	0.854
16	Surgical field positioned centrally within microscope view	0.512	0.667
17	Needle holding	0.665	0.771
18	Knot tying	0.639	0.771
19	Overall fluidity of procedure	0.743	0.854
20	Overall speed of procedure	1.000	1.000

AC, anterior chamber; Sim-OSSCAR, ophthalmic simulated surgical competency assessment rubric.

recordings of simulation trabeculectomy were sent to each expert surgeon for scoring using the Sim-OSSCAR. The mean score for 'novices' was 4.2 (SD 0.9) and mean for 'competent' trabeculectomy surgeons was 33.4 (SD 1.8), out of a maximum score of 40.

To assess the interobserver agreement on the specific items in the Sim-OSSCAR, we calculated Krippendorff's alpha. A value of 0.60 was deemed acceptable for newly developed rubric.<sup>14 15</sup> Table 2 illustrates the results for all 20 items in the Sim-OSSCAR, of which 19 exhibited an inter-rater agreement coefficient of  $\alpha_k > 0.60$ . Only the positioning of the microscope view had a  $\alpha_k < 0.60$ .

### Construct validity

Construct validity is an assessment of the 'sharpness' of a tool: can it discriminate between two distinct groups. For this study these groups are the novice and competent surgeons. Table 3 illustrates the total score for each separate grader for all eight videos.

Novice surgeons were graded with a mean score range of 0.50–13.5 (out of 40), with SD varying between graders' scores of 0.58–1.5. Competent surgeons were graded with a mean score range of 29.75–37.25 (SD varying from 1.50 to 2.52). A Wilcoxon rank-sum test showed that competent surgeons perform better than novices ( $p=0.02$ ).

### DISCUSSION

Glaucoma remains a major cause of vision impairment and blindness globally. Four million people have moderate or severe vision impairment, and 2.9 million are blind from glaucoma.<sup>1</sup> Despite this major burden of disease, trainee eye surgeons perform few glaucoma surgeries during training. There are many challenges in surgical education, with increasing demands for patient

**Table 3** Total score correlation

Video	Grader score: n/40				Mean	SD
	A	B	C	D		
1	2	0	1	3	1.50	1.29
2	0	1	0	1	0.50	0.58
3	14	12	14	14	13.50	1.00
4	0	2	0	3	1.25	1.50
5	34	32	32	28	31.5	2.52
6	38	36	36	39	37.25	1.50
7	29	29	32	29	29.75	1.50
8	37	35	36	33	35.25	1.71

Videos 1–4 were performed by novice surgeons, 5–8 by competent surgeons. Scores were out of a possible total of 40. Four expert surgeons (A, B, C and D) graded all eight videos independently.

throughput, and reducing opportunities for trainees' hands-on experience.<sup>16</sup> These challenges are global. If adequate experience cannot be gained through operating, effective adjuncts should be found.

There has been an increase in the use of simulators in ophthalmic surgical training in the past years.<sup>17–19</sup> This offers an environment in which learners can train until they reach specified levels of competency.<sup>16</sup> Through simulation-based surgical education, permission to fail can be built into the learning process without risking patient safety. This is especially important in intricate and challenging microsurgical procedures such as trabeculectomy. Furthermore, patients may present with advanced glaucoma, having already lost the vision in one eye. Many glaucoma surgeries are performed on a patient's only eye.

A trainee should proceed to supervised surgery training on patients in theatre only after having attained a level of competence in the simulated setting. Therefore, a structured training programme needs to include the formal assessment of the performance of simulated surgery, using a validated tool such as the trabeculectomy Sim-OSSCAR. The specific aim of this training and assessment rubric is to help train an eye surgeon who is a novice in trabeculectomy, to a competent level, such that they can commence supervised live surgical training.

The trabeculectomy Sim-OSSCAR has good interobserver reliability. The one step of the rubric to be rated less than 0.6 was 'surgical field positioned centrally within microscope view'. This is likely due to the limitation of the Zeiss Stemi305 microscope which has a higher zoom when recording, relative to the surgeon's binocular view. Therefore, the recorded image does not fully reflect the surgeon's experience.

There are limitations with the use of the Sim-OSSCAR. Its use should be flexible depending on the simulation environment. For artificial eyes, certain amendments or allowances could be made. These may include adding additional text:

- ▶ Toothed forceps for peripheral iridectomy (PI) (rather than micro-notched or suture tying forceps).
- ▶ Use of larger sutures (8-0) for scleral and conjunctival suturing, and allowances for slipping.
- ▶ Larger sclerostomy (than the 0.5 mm or 1 mm in live surgery).
- ▶ Flap should be measured from the limbus, and not the conjunctival insertion (which is usually 1–2 mm from the limbus due to a small band of glue which secures the silk mesh used to simulate conjunctiva). Furthermore, the conjunctival sutures would therefore traverse the middle of the scleral flap.
- ▶ Conjunctival suture 'burying' includes starting the suture from underneath the conjunctiva.

The Sim-OSSCAR should aid initial acquisition of competence for the novice glaucoma surgeon. The goal should be to use it as a formative assessment tool within a simulation-based surgical training programme for trabeculectomy, to take a novice surgeon to the stage of

competent. It could then be used as a summative assessment tool to give the green light to proceed to supervised live surgical training. It would be up to individual ophthalmic surgeon trainers or training institutions to benchmark appropriately. A guide could be a mean total score of 80% over three simulated cases, and none of the 20 individual steps scoring a 'zero'.

We anticipate that this newly developed and validated competency assessment tool will help trainees and trainers in overcoming the challenges of training in glaucoma surgery. Further rigorous validation studies should be conducted for the educational curricula for glaucoma surgical education as a whole.

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**Competing interests** None declared.

**Patient consent for publication** This is an ophthalmic surgical competency assessment rubric validation paper, and as such no patients or public were involved in the design or conduct of this study.

**Ethics approval** The validation study was approved by the Medicine Education Ethics Committee (MEEC), Faculty Education Office (Medicine), Imperial College, London (MEEC1415-12); and London School of Hygiene & Tropical Medicine ethics committee (11 795).

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## 8. Establishing a Simulation Surgery Training Unit

Simulation-based surgical education is an emerging domain. It has the potential to facilitate the instruction and learning of skills in a calm and safe environment. It affords the sustained deliberate practice necessary for the acquisition and maintenance of surgical skills. It allows trainees to have permission to fail, and upon appropriate feedback and reflection, remediation without risk to patient safety.

‘Wet-lab’ or ‘dry-lab’ or ‘skills centre’ are terms commonly used to describe a simulation surgical training unit. For ophthalmology, they range from the very high-tech labs to rudimentary microscopes in dark rooms. They are not uncommon in the Eastern and Southern Africa region, and some are illustrated in figure 17. They may consist of a microscope, range of used instruments, variable consumables and low-fidelity animal eyes if available.

**Figure 17.** Wet-labs in Kenya, Tanzania, Uganda, and Zimbabwe



Educationally, there is a sign-in sheet detailing time spent practicing alone or engaged in near-peer instruction and surgical education. Instruction, feedback, outcome assessment and reflective learning, and curricula are lacking. As stated by one head of department in East Africa, “In the wet lab the supervisor only sees the end-product and not the process (instrument handling skill, difficulties encountered are not evaluated).”.

The OLIMPICS and GLASS trials demanded an educational-theory underpinned curriculum, outcome measurements of surgical competency, and a digital classroom to facilitate this and reflective learning. The simulation surgical skills centre, the Surgery Training Unit (STU) was developed from a blank canvas and empty room. Every aspect of the physical design of the STU was developed to facilitate learning. This included a classroom to facilitate small group and buzz group discussions, multi-media teaching facilities, and a white-board for interactive analyses of surgical technique. The classroom intentionally included mints and plentiful cold and hot refreshments to create a relaxed, friendly and calm environment; and thus encourage participants to engage in discussions and be relaxed when learning. Zeiss Stemi 305 desktop microscopes were connected to a router and local area network (LAN). iPads with the Zeiss Labscope App could connect to all the microscopes at once, enabling the PI to observe surgery being performed by all participants and provide timely feedback. Each microscope could link to an individual iPad allowing participants to record their surgical procedures, and engage in reflective learning when watching them and marking against the Sim-OSSCAR.

Other physical aspects included a comprehensive supply of microsurgical instruments, surgical blades, artificial eyes, and other consumables. Consumables included apples and tomatoes for deliberate practice of specific surgical steps, foam and sutures, ultrasound gel to simulate ophthalmic viscosurgical devices (OVDs), and intra-ocular lenses (IOLs). Out-of-date surgical consumables were used wherever possible to contain costs.

The intervention courses aimed to improve the surgical competence of participants. While the focus was on skills, the courses broadly addressed the three domains of learning: knowledge and understanding, skills, and attitudes related to either cataract or glaucoma. A core syllabus was selected following discussion with expert colleagues and course pilot testing. Each module of the course was developed as a standard operating procedure (SOP) with intended learning outcomes (educational objectives). These are all detailed in the online

repository. Educational theory was used to inform each module, and the framework of 12 features and best practices of simulation-based medical education described by McGaghie was used.<sup>51</sup>

This chapter describes the establishment of the physical simulation Surgery Training Unit at the University of Cape Town, and the development of the surgical education courses.

## Facilities

The Surgery Training Unit was designed to accommodate four, five, or six trainees during any one course. A central round table classroom, with a large flat-screen monitor and whiteboard is seen in figure 18.

**Figure 18.** The Surgery Training Unit, University of Cape Town



Six individual desks were situated around the edge of the room with adjustable draftsman chairs. These desks were each equipped with a Stemi 305 microscope, instrument tray, and sharps bin.

## Equipment

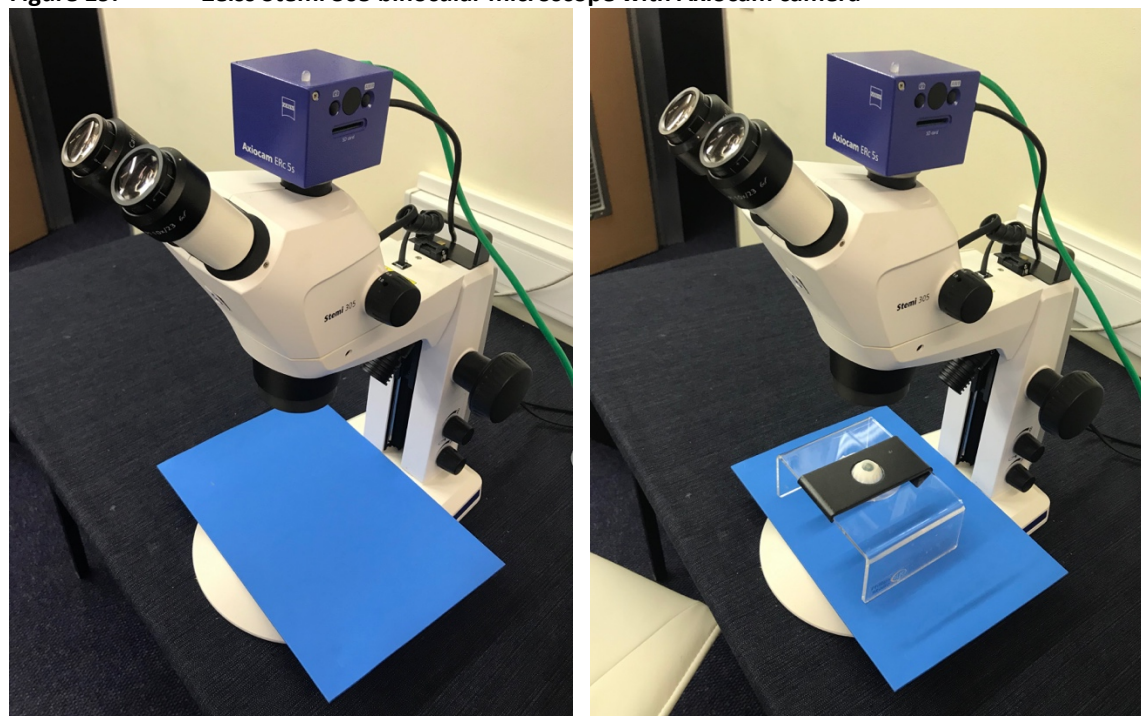
Intra-ocular microsurgery for cataract and glaucoma requires an operating microscope. Second hand simple binocular operating microscopes are commonly used in wet labs (Figure 17), however these invariably do not have a co-observer tube, and do not have any recording capabilities. Zeiss Stemi 305 microscopes (Figure 19) are compact desktop binocular microscopes originally designed for 'biological education, labs, and industrial production environments' (<https://www.zeiss.com/microscopy/int/products/stereo-zoom-microscopes/stemi-305.html>). When paired with the Zeiss Axiocam digital camera, it is possible to connect the microscopes to a local area network (LAN). This is achieved via Ethernet cables between the cameras and a network switch, and subsequently a wireless router. Tablets, for example Apple iPads, can connect to this wireless router. The Zeiss Labscope App, when downloaded onto the tablet, is then used to connect the tablet to any individual, or indeed all networked microscopes. This creates a digital classroom for a surgeon trainer to observe trainees, and provide feedback; for trainees to record their surgery and review it thus engaging in reflective learning; and for investigators to record and save surgical videos for the main outcomes of the OLIMPICS and GLASS trials.



**Table 2. Equipment used in the simulation Surgery Training Unit (6 stations)**

Equipment	Quantity	Reference / Description
Zeiss Stemi 305 microscope	6	With EDU stand and Axiocam ERc 5s <a href="https://www.youtube.com/watch?v=9cuHmNcRri8">https://www.youtube.com/watch?v=9cuHmNcRri8</a>
Network switch	1	<a href="https://www.tp-link.com/us/home-networking/8-port-switch/l1008g">https://www.tp-link.com/us/home-networking/8-port-switch/l1008g</a>
Wireless router	1	<a href="https://www.netgear.com/home/products/networking/wifi-routers/">https://www.netgear.com/home/products/networking/wifi-routers/</a>
iPad Air 2	6	With IOS v12.4.1 and Labscope v2.8.1
Flat screen LED TV	1	With HDMI to Apple lightening cable, HDMI to laptop cable
Basic mount for artificial eyes	6	Phillips Studio: <a href="http://www.phillipsstudio.co.uk">http://www.phillipsstudio.co.uk</a> Basic mount: PS-020b Recently developed for use with Stemi 305 microscopes eith EDU stand: Eye Holder – Stemi: PS-020s Newer version: PS-040 SRT (simulation rotational training) -Head

**Figure 19. Zeiss Stemi 305 binocular microscope with Axiocam camera**



## Instruments

A range of microsurgical instruments were procured for the Surgery Training Unit. Figures 20 and 21 illustrate the instrument and consumable sets used in SICS and trabeculectomy surgery respectively.

**Figure 20. Instrument and consumable set for SICS**



Figure 20 from left to right [bottom row]: Hoskins fixation forceps, 15° blade, 2mL syringe with ultrasound gel (for use as ophthalmic viscosurgical device (OVD)), crescent blade (2.5mm, angled, bevel-up), keratome blade (3mm), 1mL insulin needle bent in to cystotome, 10mL syringe with water and canula, 2mL syringe fish-hook (bent 30G needle), 5mL syringe with irrigating Vectis cannula and water, curved tying forceps (for IOL implantation), IOL dialler, straight Vannas scissors, capsule forceps; [top right] IOL, needle holder.

**Figure 21. Instrument and consumable set for trabeculectomy.**

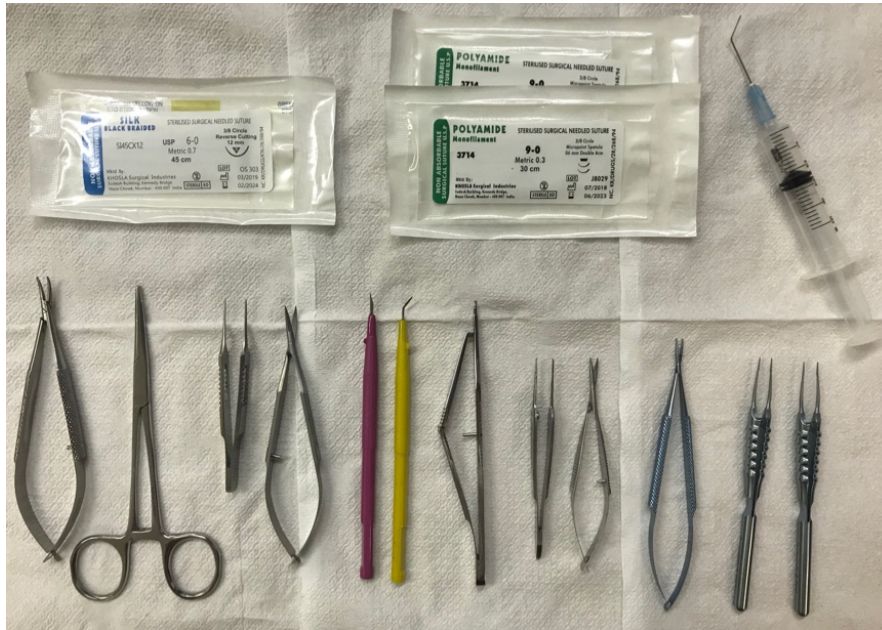


Figure 21 from left to right [bottom row]: Curved needle holders, artery forceps, micro-notched forceps, Westcotts scissors, 15° blade, crescent blade, Kelly's punch, Hoskins toothed forceps, Vannas scissors, fine needle holder, straight suture tying forceps; [top] 6/0 silk clear-corneal-traction suture, 9/0 nylon suture for scleral flap and conjunctiva, 5mL syringe with water and cannula.

## Consumables

A range of consumables was required for practice of basic microsurgical skills, deliberate practice of specific steps of the surgical procedures, and performance of simulated cataract and glaucoma surgeries.

For all stations and both the OLIMPICS and GLASS trial intervention courses, these included:

Sharps bins

- Gloves – latex-free blue non-sterile examination gloves were used at all times. Ophthalmic microsurgery is never performed without surgical gloves, and the use of them in a simulation setting added to fidelity.
- Syringes – these included 2ml syringes for simulated ophthalmic viscosurgical devices (OVD), and 5ml syringes for use with simulated balanced salt solution (BSS), tap water.
- Needles – these were 30G needles for use as cystotomes and fishhooks.
- Cannula – 23G or 25G cannula were used with syringes
- Foam – A4 foam sheets were used for deliberate practice of suture techniques.
- Apples – Used for deliberate practice of cataract scleral tunnels, and trabeculectomy scleral flaps.<sup>95</sup>

For the cataract surgery training course of the OLIMPICS trial, further consumables were used:

- Ultrasound gel – Standard medical ultrasound gel was mixed with 50% water to simulate OVDs. Once mixed and shaken, the mixture of gel and water was rested for 5 days to allow the numerous small bubbles to rise.
- Tomatoes – Large tomatoes were placed in a microwave for 90 seconds to loosen the skin. The exocarp or skin of a tomato ranges from 50 to 200µm in thickness, greater than the 14-20µm of the human lens capsule. However, this low-cost medium-fidelity model was adequate for the deliberate practice of the capsulotomy stage of the SICS procedure.

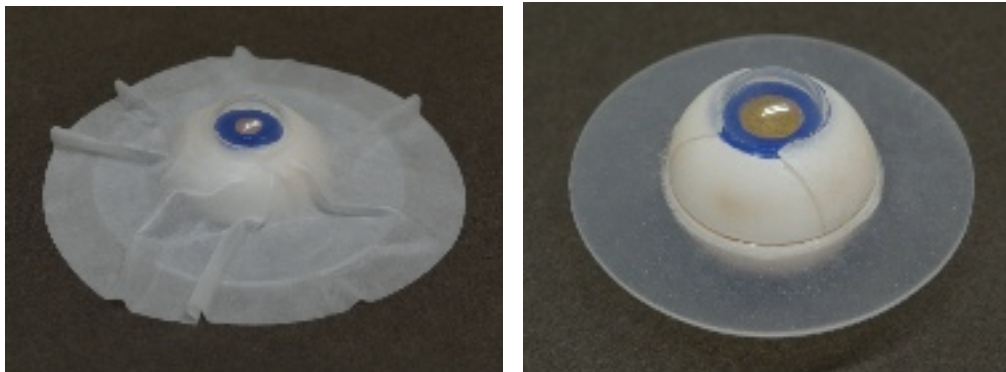
## Artificial eyes

Model artificial eyes were used in both trials during assessment and training. These were developed by Phillips Studio in Bristol, UK. The manufacturers had no input into the design, conduct and analysis of both the OLIMPICS and GLASS trials. The principal and co-investigators, co-authors, collaborator, and trial advisory committee have no financial interest or conflicts of interest to declare.

The 'Advanced TrabEye' (PS-023) had been developed independently at Phillips Studio, Bristol, UK.<sup>96</sup> I had no role in its development or refinement.

The 'SICS Eye' (PS-027) was developed during pilot studies in 2015 and 2016 in collaboration with myself and the engineers at Phillips Studio (Figure 22). Initial iterations had either a complete artificial scleral surround or three separate scleral patches. These were refined to two opposite patches for ideal width and fixation. Initial lens nuclei were either too soft or too large, both in horizontal and vertical diameter. A flatter harder lens with a smaller diameter had a greater fidelity for nucleus extraction. Initially, a plastic mesh was glued onto the posterior lens surface for increased grip, however this would over time slip off and was not needed with the harder lens compound.

**Figure 22.** The simulation Advanaced TrabEye and SICS Eye.





**Figure 23. Training underway in the Surgery Training Unit**



## Educational Content

The overall goal of the intense simulation-based surgical education intervention courses in both the OLIMPICS and GLASS trials was to provide core training in the three domains of learning: knowledge and understanding, skills, and attitudes. Major and important aspects of basic and clinical sciences relating to either cataract or glaucoma and their management were covered. The majority of the time was spent on skills learning and sustained deliberate practice. Attitudes towards practice, patients, the team and surgical outcome audit were discussed. Great efforts were made to avoid a didactic lecture-based teaching style. Rather, interactive teaching and engagement, small group and buzz group discussions were used. This approach leaned towards the principles of andragogy, where the PI adopted a role of facilitator and resource, and instruction for trainees focussed more on process and critical decision-making as a surgeon rather than content. Motivation and readiness to learn was encouraged, and much of the skills practice was self-directed. In all discussions on patient selection, surgical techniques, management of complications, and post-operative care efforts were made to focus on the higher levels of Bloom's taxonomy of learning.

The courses are summarised in chapters 9 and 10, and in appendices 7 and 8. Each of the separate modules and classes were developed with specific intended learning outcomes, and are described in individual standard operating procedures (SOP) which are illustrated as hyperlinks in tables 3 and 5 (pages 127 and 130).

**Table 3. Core modules of the OLIMPICS Intervention**

Topic	Teaching Type	Educational Theory	Duration (minutes)	Links
Pre-course video	Online		30	<a href="https://www.youtube.com/watch?v=LszyZqgR5v4">https://www.youtube.com/watch?v=LszyZqgR5v4</a>
Introductions	Small group	Learning intention / Intended learning outcomes		
Burden of Disease	SG, Exercise		30	<a href="https://www.dropbox.com/s/6lpu1zxw35nhbku/1-1 Burden of Disease.pptx?dl=0">https://www.dropbox.com/s/6lpu1zxw35nhbku/1-1 Burden of Disease.pptx?dl=0</a>
Suturing	SG Video Instruction Practical	Peyton's 4-stage skill Feedback	90	<a href="https://www.dropbox.com/s/0d1qcuewk8tgy8h/1-2 Basic Suturing.pptx?dl=0">https://www.dropbox.com/s/0d1qcuewk8tgy8h/1-2 Basic Suturing.pptx?dl=0</a> <a href="https://www.dropbox.com/s/hs4n6bzc7qv4cp/1-2 Suturing ESHC4.mov?dl=0">https://www.dropbox.com/s/hs4n6bzc7qv4cp/1-2 Suturing ESHC4.mov?dl=0</a> <a href="https://www.dropbox.com/s/ko60vf70k7r5rd8/1-2 Suturing Richard Caesar Surgery.mp4?dl=0">https://www.dropbox.com/s/ko60vf70k7r5rd8/1-2 Suturing Richard Caesar Surgery.mp4?dl=0</a>
SICS Technique			60	<a href="https://www.dropbox.com/s/q76a3yfsqymbd81/1-3 Sutureless ECCE technique 29 June 2015.ppt?dl=0">https://www.dropbox.com/s/q76a3yfsqymbd81/1-3 Sutureless ECCE technique 29 June 2015.ppt?dl=0</a>
Learning Theory & Expertise			30	<a href="https://www.dropbox.com/s/ru99eqfy4gr9dgz/1-4 Learning %26 Expertise.pptx?dl=0">https://www.dropbox.com/s/ru99eqfy4gr9dgz/1-4 Learning %26 Expertise.pptx?dl=0</a>
Introduction to Sim-OSSCAR			30	Appendix 3a
SICS Video	Self-directed		30	<a href="https://www.youtube.com/watch?v=LszyZqgR5v4">https://www.youtube.com/watch?v=LszyZqgR5v4</a>
Scleral Tunnel		Peyton's 4-stage skill Feedback Sustained deliberate practice	90	<a href="https://www.dropbox.com/s/v0xf3ucztbcjuy/1-1%20Scleral%20Tunnel.pptx?dl=0">https://www.dropbox.com/s/v0xf3ucztbcjuy/1-1%20Scleral%20Tunnel.pptx?dl=0</a> <a href="https://www.dropbox.com/s/4decytut9uh53y5/2-1%20Tunneling.mov?dl=0">https://www.dropbox.com/s/4decytut9uh53y5/2-1%20Tunneling.mov?dl=0</a> <a href="https://www.dropbox.com/s/2yb1ak0u7aqsvvl/2-1%20Apple%20Tunnel%20.mov?dl=0">https://www.dropbox.com/s/2yb1ak0u7aqsvvl/2-1%20Apple%20Tunnel%20.mov?dl=0</a>
Capsulotomy		Peyton's 4-stage approach (skill) Feedback Sustained deliberate practice	120	<a href="https://www.dropbox.com/s/7zf03tqtomladot/2-5%20capsulorrhexis%2008-ARR.ppt?dl=0">https://www.dropbox.com/s/7zf03tqtomladot/2-5%20capsulorrhexis%2008-ARR.ppt?dl=0</a> <a href="https://www.dropbox.com/s/ayzevw6u6j25i1p/2-2%20Tomato%20CCC.mp4?dl=0">https://www.dropbox.com/s/ayzevw6u6j25i1p/2-2%20Tomato%20CCC.mp4?dl=0</a>
Demonstration of simulation SICS			30	<a href="https://www.dropbox.com/s/o3ms1xgw3jtziq4/2-3%20SICS%20min%20simulation%20video.mp4?dl=0">https://www.dropbox.com/s/o3ms1xgw3jtziq4/2-3%20SICS%20min%20simulation%20video.mp4?dl=0</a>
Pre-operative assessment			30	
Complications & Management			60	<a href="https://www.dropbox.com/s/638wrg60mqfmr3e/2-6%20Complications%20of%20Cataract%20Surgery.ppt?dl=0">https://www.dropbox.com/s/638wrg60mqfmr3e/2-6%20Complications%20of%20Cataract%20Surgery.ppt?dl=0</a>

Post-operative care & audit			60	<a href="https://www.dropbox.com/s/htjt78cjhq96vza/3-1%20Post-operative%20Complications%20%26%20Cataract%20Surgery%20Audit.ppt?dl=0">https://www.dropbox.com/s/htjt78cjhq96vza/3-1%20Post-operative%20Complications%20%26%20Cataract%20Surgery%20Audit.ppt?dl=0</a>
Lens extraction & IOL implantation		Peyton's 4-stage skill Feedback Sustained deliberate practice	60	<a href="https://www.youtube.com/watch?v=LszyZqqR5v4">https://www.youtube.com/watch?v=LszyZqqR5v4</a> <a href="https://www.dropbox.com/s/8rq59xd4ug4owm6/3%20Fish%20hook%20bending%20Steve.mpeg?dl=0">https://www.dropbox.com/s/8rq59xd4ug4owm6/3%20Fish%20hook%20bending%20Steve.mpeg?dl=0</a>
Introduction to SICS SOS		Mental rehearsal	30	
SICS SOS		Feedback Sustained deliberate practice Reflective learning Outcome measurement	>300	

The outline of the week timetable for the OLIMPICS trial intervention is illustrated in table 4.

**Table 4. Timetable for OLIMPICS intervention training course**

<b>Day</b>	<b>Morning 8:00 – 10:30</b>	<b>Midday 11:00 – 1:00</b>	<b>Afternoon 2:00 – 5:00</b>	<b>Evening (Homework)</b>
<b>Sunday</b>	<i>Candidates arrive in Cape Town</i>			Free
<b>Monday</b>	Introductions. Burden of disease. Suturing / basic microsurgical skills.	SICS Video. Learning theory & expertise. Sim-OSSCAR.	Suturing. Review.	<i>SICS Video. Suturing.</i>
<b>Tuesday</b>	Review. Scleral Tunnel. Sim-OSSCAR. Demonstration of SICS SOS.	Pre-operative assessment. Capsulotomy SOS.	Review. Complications.	<i>Tunnel. Capsulotomy.</i>
<b>Wednesday</b>	Review. Post-operative care/Audit (outcome monitoring). Endophthalmitis: protocol & group.	OSSCAR. Demonstration of SOS. SICS SOS practical: nucleus extraction & IOL placement.	SICS SOS. Review.	<i>SICS Video. What to cover again.</i>
<b>Thursday</b>	Review. SICS SOS. What to cover again.	In-depth interviews. SICS SOS.	Suturing. Scleral Tunnel. Capsulotomy.	<i>SICS SOS.</i>
<b>Friday</b>	Review. Sim-OSSCAR / ICO-OSCAR.	SICS SOS.	Planning forward: SDP and Individual Training Plans.	Free
<b>Saturday</b>	<i>Candidates depart Cape Town</i>			



**Table 5. GLASS Course Modules**

Topic	Teaching Type	Educational Theory	Duration (minutes)	Links
Pre-course video	Online		30	<a href="https://www.dropbox.com/s/n2wj9yl7rvv4a83/Trabeculectomy%2030%20min%20QT.mov?dl=0">https://www.dropbox.com/s/n2wj9yl7rvv4a83/Trabeculectomy%2030%20min%20QT.mov?dl=0</a>
Introductions	Small group	Learning intention / Intended learning outcomes		
Burden of Disease	SG, Exercise		30	<a href="https://www.dropbox.com/s/6lpu1zxw35nhbku/1-1%20Burden%20of%20Disease.pptx?dl=0">https://www.dropbox.com/s/6lpu1zxw35nhbku/1-1%20Burden%20of%20Disease.pptx?dl=0</a>
Suturing	SG Video Instruction Practical	Peyton's 4-stage skill Feedback Sustained deliberate practice	90	<a href="https://www.dropbox.com/s/0d1qcuawk8tgy8h/1-2%20Basic%20Suturing.pptx?dl=0">https://www.dropbox.com/s/0d1qcuawk8tgy8h/1-2%20Basic%20Suturing.pptx?dl=0</a> <a href="https://www.dropbox.com/s/hs4n6bzc7qv4cp/1-2%20Suturing%20ESHC4.mov?dl=0">https://www.dropbox.com/s/hs4n6bzc7qv4cp/1-2%20Suturing%20ESHC4.mov?dl=0</a> <a href="https://www.dropbox.com/s/ko60vf70k7r5rd8/1-2%20Suturing%20Richard%20Caesar%20Surgery.mp4?dl=0">https://www.dropbox.com/s/ko60vf70k7r5rd8/1-2%20Suturing%20Richard%20Caesar%20Surgery.mp4?dl=0</a>
Modern Trabeculectomy			60	<a href="https://www.dropbox.com/s/qdyk9e4je2wper3/1-3%20Modern%20Trabeculectomy%202017%20DM.pdf?dl=0">https://www.dropbox.com/s/qdyk9e4je2wper3/1-3%20Modern%20Trabeculectomy%202017%20DM.pdf?dl=0</a>
Learning Theory & Expertise			30	<a href="https://www.dropbox.com/s/ru99eqfy4gr9dgz/1-4%20Learning%20%26%20Expertise.pptx?dl=0">https://www.dropbox.com/s/ru99eqfy4gr9dgz/1-4%20Learning%20%26%20Expertise.pptx?dl=0</a>
Introduction to Sim-OSSCAR			30	<u>Appendix and 3b</u>
Advanced suturing		Peyton's 4-stage skill Feedback Sustained deliberate practice	120	<a href="https://www.dropbox.com/s/on6p4uwuncekl5/2-6%20Releasable%20%26%20Conj%20Suturing.pptx?dl=0">https://www.dropbox.com/s/on6p4uwuncekl5/2-6%20Releasable%20%26%20Conj%20Suturing.pptx?dl=0</a>
Trab Video	Self-directed		30	<a href="https://www.dropbox.com/s/n2wj9yl7rvv4a83/Trabeculectomy%2030%20min%20QT.mov?dl=0">https://www.dropbox.com/s/n2wj9yl7rvv4a83/Trabeculectomy%2030%20min%20QT.mov?dl=0</a>
Scleral Flap		Peyton's 4-stage skill Feedback Sustained deliberate practice	90	
Demonstration of simulation trabeculectomy			30	
Pre-operative assessment			30	
Complications & Management			60	<a href="https://www.dropbox.com/s/7qw2witaehr1/3-1%20Complications%20of%20%20Glaucoma%20Surgery%20.pptx?dl=0">https://www.dropbox.com/s/7qw2witaehr1/3-1%20Complications%20of%20%20Glaucoma%20Surgery%20.pptx?dl=0</a>

Post-operative care & audit			60	<a href="https://www.dropbox.com/s/b3c9znh7fc4mtdg/3-2%20Post-operative%20Care%20following%20Trabeculectomy.pptx?dl=0">https://www.dropbox.com/s/b3c9znh7fc4mtdg/3-2%20Post-operative%20Care%20following%20Trabeculectomy.pptx?dl=0</a>
AC entry, sclerostomy, and PI		Peyton's 4-stage skill Feedback Sustained deliberate practice	60	
Introduction to trab SOS		Mental rehearsal	30	<a href="https://www.dropbox.com/s/n9bok66kepo61q1/2-3%20Trabeculectomy.mp4?dl=0">https://www.dropbox.com/s/n9bok66kepo61q1/2-3%20Trabeculectomy.mp4?dl=0</a>
Trab SOS		Feedback Sustained deliberate practice Reflective learning Outcome measurement Zone of proximal development	>300	

The outline of the week timetable for the GLASS trial intervention is illustrated in table 6.

**Table 6. Timetable for GLASS intervention training course**

<b>Day</b>	<b>Morning 8:00 – 10:30</b>	<b>Midday 11:00 – 1:00</b>	<b>Afternoon 2:00 – 5:00</b>	<b>Evening (Homework)</b>
<b>Sunday</b>	<i>Candidates arrive in Cape Town</i>			Free
<b>Monday</b>	Introductions Burden of disease. Suturing.	Trab Video. Learning theory & expertise. Sim-OSSCAR.	Suturing. Traction suture. Review.	<i>Trab Video. Suturing.</i>
<b>Tuesday</b>	Review. Scleral Tunnel/Flap SOS. Sim-OSSCAR. Demonstration of trab SOS.	Pre-operative assessment. Scleral tunnel/flap SOS.	Releasable sutures. Conjunctival sutures. Review.	<i>Tunnel/Flap. Releasable sutures.</i>
<b>Wednesday</b>	Review. Complications. Management of complications.	Sim-OSSCAR. Post-operative care/Audit. Iridectomy. Trab SOS practical.	Trab SOS. Review.	<i>Trab Video. What to cover again.</i>
<b>Thursday</b>	Review. Trab SOS. What to cover again.	In-depth interviews. Trab SOS.	Suturing. Scleral tunnel/flap formation. Releasable sutures.	<i>Trab SOS.</i>
<b>Friday</b>	Review. Sim-OSSCAR / ICO-OSCAR.	Trab SOS	Planning forward: SDP and Individual Training Plans.	Free
<b>Saturday</b>	<i>Candidates depart Cape Town</i>			

It is important to emphasise that the SOS trials did not aim to assess the utility of the mere availability of a simulator. Rather an intense simulation-based surgical education course underpinned by educational theory had been developed, and this was provided in a purpose-built simulation Surgery Training Unit.

## **Educational Frameworks for SOS trial topics**

Chapter 11 discusses the educational facets of ophthalmic simulation-based surgical education, and describes these in the chronological order of the intervention training courses of the SOS trials. The educational framework of the topics in this research were evaluated and selected over a 3-year period leading up to the start of the trials.

Constructivism theory is an approach to learning that recognises prior experiences of the learner, and continuous building and amending of structures or schemata in the mind that hold knowledge. As Heather Fry explains “as new understandings, experiences, actions and information are assimilated and accommodated the schemata change”.<sup>97</sup> “Learning (whether in cognitive, affective, interpersonal or psychomotor domains) is said to involve a process of individual transformation. Thus people actively construct their knowledge”.<sup>97 98</sup> This constructivist approach was taken to the design and conduct of the educational intervention in the GLASS and OLIMPICS trials. Although participants were novice to cataract or glaucoma surgery in the psychomotor domain by definition of the inclusion criteria, they were not ‘blank slates’ or novice ophthalmic surgeons. Constructivism holds that we learn by accommodating new knowledge and understanding into and with, extending and supplanting old knowledge and understanding.

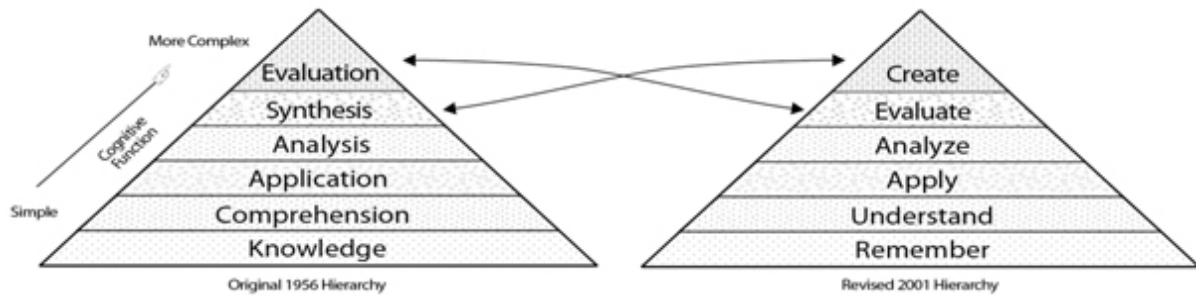
Andragogy, or adult learning, is defined as the art and science of helping adults learn. The five main principles include self-direction, accumulation of experiences, experience of a need to know something, being more problem-centred than topic-centred, and recognition that the most powerful motivators are internal. There is debate whether adult theory truly does differ wholly from pedagogy, however elements of the principles were incorporated within this study. ‘Types’ of learning derived from adult learning theory are student autonomy, self-directed learning, and experiential learning. David Kolb developed the constructivist

perspective of 'experiential learning' as a cycle of active experimentation, concrete experience, reflective observation and abstract conceptualisation.<sup>99</sup> Reflection (or reflective observation) is a key aspect of experiential learning, and as will be shown was a critical part of the active learning process for participants during the intervention courses described in this chapter. The Kolb Learning Cycle has been criticised for being over-simplified and ignoring non-experiential ways of learning. Furthermore the learning cycle provides little emphasis on goals, intention, and decision-making.<sup>100</sup> Goals and motivation were important in trainee participants experience in the SOS trials, they were constantly encouraged to 'want to become a better surgeon'.

Bloom's taxonomy of knowledge from 1956 was revised in 2001, and was constructed to categorise the goals of a curriculum in terms of implicit and explicit cognitive skills and abilities.<sup>101-103</sup> While this taxonomy was a useful framework for designing the OLIMPICS and GLASS trial curricula and intended learning outcomes, it was also useful to explain to participants that the intervention courses were not designed merely to impart knowledge and understanding, but that I would be asking them to analyse and evaluate key aspects of cataract or glaucoma surgery. The strength of Bloom's taxonomy lies in its usable structure. However weaknesses include variability in the definitions used: what exactly does evaluate or create mean? A further criticism may be its contempt for proficiency level, where it "fails to acknowledge that learners may perform at varying levels of proficiency within each type of higher order thinking skill".<sup>104</sup> A participant in the OLIMPICS trial may be perfectly capable of analysis, evaluation and synthesis; however would not be expected to perform to an expert level of evaluation of the different cataract surgical techniques. A further criticism may be the pyramid hierarchical structure itself, with the placement of knowledge and understanding at the bottom implying that they are least important. They are not unimportant, and there are some critical facts and concepts that an eye surgeon needs to remember and understand. I would not want to be operated on by a surgeon who did not know that the lens is supported by more delicate zonules in pseudoexfoliation, or understand that the corneal endothelium does not regenerate as the epithelium.



**Figure 24. Bloom's Taxonomy of Learning: Original and Revised** <sup>104</sup>



Future and perhaps more comprehensive iterations of the courses presented in this chapter, including the hybrid approach discussed in chapter 11, could build on Marzano and Kendall's New Taxonomy, rather than Bloom's revised taxonomy.<sup>105</sup> This two-dimensional framework depicts three systems of thought self-system, metacognitive, and cognitive system (comprising four sub-components of knowledge utilisation, analysis, comprehension and retrieval); aside three different domains of learning (information, mental procedures, and psychomotor procedures). If the SOS courses were to be redesigned or re-tasked, educational objectives or intended learning outcomes could be easily classified within the two dimensions (the first dimension representing the six categories of mental processes, the second being the three domains of knowledge).

The Dreyfus model of skills acquisition originally presented for the United States Airforce proposed that a learner passes through five distinct stages. These were originally identified as novice, competence, proficiency, expertise and master.<sup>93</sup> This was revised later to novice, advanced beginner, competence, proficiency and expertise.<sup>106</sup> This forms a valuable model for surgical education, and is central to this thesis. For the OLIMPICS and GLASS trials, the role of simulation-based surgical education was framed as the stages of novice to competent; with the accepted limitation that proficiency and expertise should be stages attained during live and more complex surgical training. A criticism of this model is that there is no empirical evidence for the presence of stages in the development of expertise. A further critique is that although intuition is a feature of proficiency and expertise, it does not define intuition as holistic or analytic, and does not does not describe how experts capture the entirety of a situation.<sup>107</sup> Although this is perhaps outside of the remit of this thesis, Dr Patricia Benner's 'novice to expert' theory adapted the Dreyfus model to account for clinical context. Adapting

the educational approach from this thesis to interprofessional team training should perhaps adopt Benner's stages of nursing proficiency.<sup>108</sup>

Ericsson highlighted the role of 'deliberate practice' being distinct from work or play, and that for expertise to be attained, this practice should be deliberate, sustained over years, and characterised by the desire to improve.<sup>109 110</sup> Ericsson's research showed that even the most talented of performers needed years, a minimum of ten years and 10,000 hours of intense training to win international competitions.<sup>111</sup> The obvious analogy for surgical education is the expert surgeon who has been operating 16 hours a week for over 12 years. Obviously, the SOS trials' educational intervention of 5 days, or around 20 hours of deliberate practice would come nowhere close to attainment of expertise. In fact Ericsson's central thesis that expert performance has little connection with hereditary gifts or talents (in other words experts are made, not born), and perhaps simplistically misinterpreted assumption that one single factor, practice, may explain the attainment of expertise; does appear to be at odds with the complexity of human development.<sup>112</sup> For the purpose of this thesis, Ericsson's key theme of sustained deliberate practice was used for the crucial development of procedure-specific competence. Practicing scleral tunnel or flap formation on apples in a deliberate way, sustained over hours, and reinforced by the desire to improve paid dividends.

Before the deliberate practice of particular steps of a procedure, Peyton's 4-stage approach was used as a template to teach the practical skill.<sup>113</sup> The approach consists of four stages:

**Demonstration:** The trainer performs the skill in real time without commentary.

**Deconstruction:** The trainer performs each step slowly with an added commentary and explanation.

**Comprehension:** The trainer performs each step while the student describes every step of the skill.

**Execution:** The trainee performs the skill step by step while simultaneously providing commentary.

Studies have been conducted using only steps 2 and 4, or "see one, do one"; and a modified 3-step approach (omitting step 3). These were unable to show superiority of the 4-step approach.<sup>114</sup> Peyton's 4-step approach has also been combined with Gagné's instructional model for teaching ophthalmic slit-lamp examination.<sup>115</sup> Gagné suggested 9 events of instruction that enhance student learning: gain attention, inform student of objectives,

stimulate recall of prior learning, present stimulus, provide guidance for the student, elicit performance, provide feedback, assess performance, and enhance retention and transfer.<sup>116</sup> A weakness of Peyton's 4-stage approach is that it does not integrate theory with practice. Although helpful as a 4-stage or modified 3- or 2-stage demonstration of and initial learning of a skill, it does not take into account the evidence or reasoning behind the practice. In reality, a combined approach was used in the SOS trials educational interventions whereby a modified 3-step approach was used (commonly omitting step 3) combined with prior statement of objectives and clinical reasoning, and immediate feedback.

.....

The OLIMPICS and GLASS trials ran parallel during a near two-year period. However, they were completely separate trials, with trainees recruited into only one trial according to strict inclusion criteria. A total of 11 separate one-week courses were conducted for the OLIMPICS trial, and 11 separate one-week courses were conducted for the GLASS trial.

## 9. The OLIMPICS Trial

### RESEARCH PAPER COVER SHEET

#### **SECTION A – Student Details**

Student	William Dean
Principal Supervisor	Matthew Burton
Thesis Title	The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East and Southern Africa.

#### **SECTION B – Paper already published**

Where was the work published?			
When was the work published?			
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	<table><tr><td>Was the work subject to academic peer review?</td><td></td></tr></table>	Was the work subject to academic peer review?	
Was the work subject to academic peer review?			

Pages 148 to 166

\*Creative commons licence – CC-BY

#### **SECTION C – Prepared for publication, but not yet published**

Where is the work intended to be published?	Lancet
Please list the papers authors in the intended authorship order:	See below
Stage of publication	In submission

#### **SECTION D – Multi-authored work** – See following page

Student Signature:



Date: 12 March 2020

Supervisor Signature:



Date: 18 March 2020

Chapter 9 describes the ophthalmic learning and improvement initiative in cataract surgery (OLIMPICS) trial. This prospective educational-intervention RCT compares the effect of intense simulation-based surgical education for small incision cataract surgery (SICS) compared to conventional training alone. I developed ideas around the need for innovative approaches to surgical education in sub-Saharan Africa in discussions with Professor Colin Cook in 2014 and 2015. The concept of performing an RCT to answer critical questions was developed in discussions with Professor Matthew Burton in 2015 and 2016.

I designed, fundraised, developed and completed the establishment of a purpose-built simulation Surgery Training Unit at the Community Eye Health Institute, University of Cape Town (UCT). This was detailed in chapter 8, as well as appendices 7 and 8. I was responsible for the design of the training intervention course, ensuring appropriate educational theory to underpin all aspects of the training. I created the bulk of the educational materials. Cybersight and Dr John Sandford-Smith, Dr Richard Caesar contributed some teaching materials.

The RCT was conducted with 50 trainee ophthalmologists in Kenya, Tanzania, Uganda, and Zimbabwe. All training interventions were conducted at UCT by myself during 11 separate one-week courses in late 2017, 2018 and early 2019.

I was the principal investigator for the OLIMPICS trial. I led the study design, developed the protocol and standard operating procedures with guidance from Professor Matthew Burton. I consulted with lead ophthalmology consultants in collaborating institutions, Dr Stephen Gichuhi, Dr William Makupa, Dr Agrippa Mukome, Dr Juliet Otiti, and Dr Simon Arunga.

Dr Subhashis Mukherjee and Dr Lloyd Harrison-Williams independently performed the masked grading of over 700 surgical videos. I was responsible for reliability study of the grading. Min Kim assisted with data analysis and David McLeod gave advice on statistical analysis methodology.

I prepared the first draft of the entire manuscript, and all co-authors made comments on successive drafts and approved the final version before journal submission. I acted as guarantor of the final published version of the paper.



# Intense Simulation-Based Surgical Education for Manual Small-Incision Cataract Surgery

## The Ophthalmic Learning and Improvement Initiative in Cataract Surgery Randomized Clinical Trial in Kenya, Tanzania, Uganda, and Zimbabwe

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**IMPORTANCE** Cataracts account for 40% of cases of blindness globally, with surgery the only treatment.

**OBJECTIVE** To determine whether adding simulation-based cataract surgical training to conventional training results in improved acquisition of surgical skills among trainees.

**DESIGN, SETTING, AND PARTICIPANTS** A multicenter, investigator-masked, parallel-group, randomized clinical educational-intervention trial was conducted at 5 university hospital training institutions in Kenya, Tanzania, Uganda, and Zimbabwe from October 1, 2017, to September 30, 2019, with a follow-up of 15 months. Fifty-two trainee ophthalmologists were assessed for eligibility (required no prior cataract surgery as primary surgeon); 50 were recruited and randomized. Those assessing outcomes of surgical competency were masked to group assignment. Analysis was performed on an intention-to-treat basis.

**INTERVENTIONS** The intervention group received a 5-day simulation-based cataract surgical training course, in addition to standard surgical training. The control group received standard training only, without a placebo intervention; however, those in the control group received the intervention training after the initial 12-month follow-up period.

**MAIN OUTCOMES AND MEASURES** The primary outcome measure was overall surgical competency at 3 months, which was assessed with a validated competency assessment rubric. Secondary outcomes included surgical competence at 1 year and quantity and outcomes (including visual acuity and posterior capsule rupture) of cataract surgical procedures performed during a 1-year period.

**RESULTS** Among the 50 participants (26 women [52.0%]; mean [SD] age, 32.3 [4.6] years), 25 were randomized to the intervention group, and 25 were randomized to the control group, with 1 dropout. Forty-nine participants were included in the final intention-to-treat analysis. Baseline characteristics were balanced. The participants in the intervention group had higher scores at 3 months compared with the participants in the control group, after adjusting for baseline assessment rubric score. The participants in the intervention group were estimated to have scores 16.6 points (out of 40) higher (95% CI, 14.4-18.7;  $P < .001$ ) at 3 months than the participants in the control group. The participants in the intervention group performed a mean of 21.5 cataract surgical procedures in the year after the training, while the participants in the control group performed a mean of 8.5 cataract surgical procedures (mean difference, 13.0; 95% CI, 3.9-22.2;  $P < .001$ ). Posterior capsule rupture rates (an important complication) were 7.8% (42 of 537) for the intervention group and 26.6% (54 of 203) for the control group (difference, 18.8%; 95% CI, 12.3%-25.3%;  $P < .001$ ).

**CONCLUSIONS AND RELEVANCE** This randomized clinical trial provides evidence that intense simulation-based cataract surgical education facilitates the rapid acquisition of surgical competence and maximizes patient safety.

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[Invited Commentary](#)

[Supplemental content](#)

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Of the 36 million people globally who are blind, more than one-third have blindness due to cataracts.<sup>1</sup> Surgery remains the only treatment option for cataracts. An estimated 14 million cataract operations are performed globally annually.<sup>2,3</sup> Cataract surgery can effectively restore vision, is one of the safest and most cost-effective of all health care interventions, and confers a large financial return on investment.<sup>4,5</sup> However, in many regions, the rate of cataract surgery is insufficient to address the burden of avoidable blindness.

Of the more than 230 000 ophthalmologists worldwide, the lowest mean number of ophthalmologists per million population is found in sub-Saharan Africa, at 2.5.<sup>6</sup> The global estimated mean number of ophthalmologists per million population is 31.7; however, less than half perform cataract surgery (mean number, 14.1 ophthalmologists per million population).<sup>6</sup> There is an urgent need to train and equip more ophthalmic surgeons to address the burden of surgically treatable blindness.

In sub-Saharan Africa, the median number of cataract surgical procedures performed by trainee ophthalmologists in the first 2 years of training was zero.<sup>7</sup> In mainland China, the median number of cataract surgical procedures performed by senior trainees by the end of 3 years of training was zero.<sup>8</sup> Traditional surgical education is resource intensive. Slowly building surgical competence through trial and error by practicing solely on patients is unethical, and maximizing patient safety and reducing surgical errors must be priorities. Simulation-based education can help address this training need, especially in low-income settings where the disease magnitude is greatest.<sup>9</sup>

Intensive simulation-based surgical education has been shown to increase surgical skills and decrease complication rates.<sup>10</sup> During the past 10 years, randomized clinical trials (RCTs) have been conducted for surgical education, predominantly in laparoscopic surgery.<sup>11</sup> The literature on simulation-based surgical education in eye care, however, is inadequate, despite widespread adoption and large expenditure.<sup>12</sup>

Many animal, cadaver, artificial, and virtual reality models have been used in ophthalmic surgical education, including for cataracts.<sup>12-15</sup> Retrospective studies have shown a reduction in complication rates with access to, and mandatory training using, a virtual reality simulator for cataract surgery training.<sup>16,17</sup> Recent systematic reviews of trials involving simulation-based training or assessment of ophthalmic surgical skills concluded that studies are heterogeneous and that methodological rigor is inadequate.<sup>12,18</sup>

We therefore designed and conducted the Ophthalmic Learning and Improvement Initiative in Cataract Surgery (OLIMPICS) Trial. The aim of the trial was to evaluate the effect of intense simulation-based surgical education in cataract surgery on surgical competence, as well as subsequent live surgery outputs and outcomes compared with conventional training alone.

## Methods

### Study Design

We designed a multicenter, multicountry, investigator-masked, parallel-group RCT conducted from October 1, 2017,

### Key Points

**Question** Does the addition of simulation-based surgical education to conventional training improve cataract surgical competence among trainees?

**Findings** In this randomized clinical trial, a simulation-based training intervention resulted in an almost 3-fold increase in objectively assessed surgical competence of trainees.

**Meaning** These results support pursuing simulation-based surgical training units, which may lead to safer, more effective, and more efficient surgical skills before trainees progress to conventional live surgical training.

to September 30, 2019. Competency was assessed at baseline and in follow-up assessments over the course of 15 months. Trainee ophthalmologists from 5 ophthalmology training program institutions in Nairobi, Kenya; Moshi, Tanzania; Kampala and Mbarara, Uganda; and Harare, Zimbabwe were assessed for eligibility. Written informed consent was obtained from all participants. Participants were given no incentives or compensation. No changes to methods were made after trial commencement (trial protocol in [Supplement 1](#)). Ethical approval was attained from 10 separate research ethics committees. Full details are in [Supplement 1](#).

### Participants and Prerandomization Baseline Assessment

Inclusion criteria included having performed zero complete manual small-incision cataract surgery (SICS) procedures as primary surgeon and having performed parts of (or assisted in) fewer than 10 separate SICS procedures. After consent, participant trainees were evaluated in country. Baseline assessment included recorded performance of 3 surgical simulation procedures each. These assessments were anonymized and remotely graded in a masked fashion using the Ophthalmic Simulation Surgical Competency Assessment Rubric (Sim-OSSCAR).<sup>19</sup> A standardized knowledge assessment was also administered, providing further baseline data. Participants were assured of confidentiality and anonymity of individual outcome assessments.

### Randomization

The randomization sequences were computer generated centrally by a statistician (M.J.K.) based at the London School of Hygiene & Tropical Medicine who was independent of all other aspects of the trial. We randomly allocated candidates at the site level into batches of 2 or 4 trainees, with equal numbers of intervention and control allocations in each batch. Pre-printed allocation cards that specified the center, batch group, unique identifier, and allocation (intervention or control) were concealed inside opaque sealed envelopes. This ensured that the principal investigator, coinvestigator, and participants had no prior knowledge of the allocation until the envelopes were opened. All the envelopes in the batch had an identical external appearance and batch label code. All trainees in the batch were each invited to simultaneously select and open one of the envelopes and to reveal their allocation card. If an odd number of participants were identified in a center, the final par-



participant was invited to select 1 of 2 identical envelopes in a batch of 2. This ensured randomization, as all candidates had an equal chance of being in either group.

### Intervention

The simulation-based training was conducted at the purpose-built Surgery Training Unit, University of Cape Town, South Africa. The SICS procedure was deconstructed and instruction on individual steps was achieved using the Peyton 4-stage approach to teaching a practical skill.<sup>20</sup> Feedback was given to participants while they engaged in sustained deliberate practice of a particular step.<sup>21</sup> Once all parts of the SICS procedure were covered, the full procedure was performed on high-fidelity synthetic simulation eyes,<sup>22</sup> after a round of mental rehearsal (the cognitive rehearsal of a task before practice).<sup>23</sup> Participants were able to record their surgical performance and engage in reflective learning by watching their performance on an iPad.<sup>24</sup> This was enhanced by formative assessment and outcome measurement as they graded their performance against the Sim-OSSCAR.<sup>19</sup> All training was conducted by one of us (W.H.D.). The study protocol and standard operating procedures, including a detailed description of the intervention, are available in [Supplement 1](#).

Control participants were offered the same training in Cape Town, South Africa, after 1 year. Both the intervention and control groups continued to undergo conventional postgraduate ophthalmology training.

### Outcomes

Participants were followed up at 3 months after the intervention and at 1 year. Assessments included 3 sequential simulation SICS procedures recorded in the same manner as the baseline assessment. There was no time limit on the surgical procedure recordings. Further assessments included a supervised live SICS procedure at 12 months and a summary report of cataract surgery numbers and outcomes over 1 year. No changes to study outcomes were made after trial commencement.

The primary outcome measure was the difference in Sim-OSSCAR<sup>19</sup> scores between groups at 3 months. Each of the 20 items in the matrix was graded on a modified Dreyfus score (novice, advanced beginner, and competent). The minimum score was 0 points and the total possible score was 40 for each procedure. Masked assessments were performed remotely by 2 independent expert SICS surgeons (S.M. and L.H.-W.).

Secondary outcome measures included assessment of surgical competence at 12 months (live and simulation), number of live SICS procedures performed, and surgery outcomes for a period of 12 months. Number and outcomes of live SICS procedures performed were self-reported retrospectively in a summary report after 12 months.

### Statistical Analysis

Based on data from a pilot study, we anticipated a difference in Sim-OSSCAR scores between groups of 9 of 40 points, and an estimated variability of 0.9 SD. We therefore calculated that a sample of 23 individuals in each group would have 80% power and 95% confidence to detect a significant difference in scores.

We aimed to recruit 25 individuals per group, to provide 2 extra participants per group for any loss to follow-up.

The distributions of baseline variables by treatment group were compared. The primary outcome measure was the mean score of 3 masked assessments at 3 months of simulation surgical performance using the Sim-OSSCAR.

Intention-to-treat analysis was used for all outcome measures. Primary analysis included a linear regression model with mean Sim-OSSCAR scores at 3 months as the outcome and trial group as the exposure, adjusting for baseline mean Sim-OSSCAR score taking training center as a random effect. A similar approach was used for secondary outcome measures of competence. Mean live SICS procedure ICO (International Council of Ophthalmology) Ophthalmology Surgical Competency Assessment Rubric (ICO-OSCAR)<sup>25</sup> score at 1 year was analyzed by a *t* test. The number of surgical procedures performed in 1 year was analyzed using a Poisson regression, with trial group as the exposure of interest, adjusting for training center. Patient-specific outcomes for all surgical procedures performed during the 12-month period included the number of patients with poor postoperative visual acuity per surgeon, analyzed using the Wilcoxon rank-sum test. Further assessment included percentage rates of operative complications of posterior capsule rupture (PCR), analyzed using linear regression.

An  $\alpha$  level of  $P < .05$  was considered statistically significant for the primary outcome. *P* values were 2-sided. A  $\kappa$  coefficient of 0.75 or more for interassessor agreement of video grading scores was considered to be excellent.<sup>26</sup>

Data were initially entered into Microsoft Excel, version 15.31 (Microsoft Corp). Statistical analysis was performed using Stata, version 15.1 (StataCorp). A data monitoring and trial advisory committee oversaw the study.

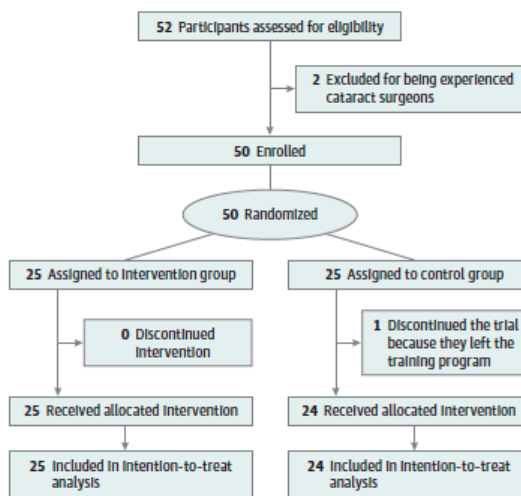
### Prevention of Bias

It is accepted that there will be variability in individual participants' inherent or natural surgical aptitude. All efforts were made to standardize the training offered to the intervention participants (as well as to the control participants after the 1-year period). The intense simulation course was held in the same standardized surgical training unit, and all training was conducted by one of us (W.H.D.). Recordings of live and simulation surgical procedures were anonymized. Every effort was made to reduce contamination bias. Numerous standard risk-of-bias criteria may be used to evaluate RCTs. These criteria are further illustrated in the trial protocol ([Supplement 1](#)).

## Results

A total of 52 potential participants were assessed for eligibility between October 1, 2017, and May 21, 2018. Fifty participants were recruited, and 49 participants were included in the final intention-to-treat analysis ([Figure 1](#)). Two potential participants were excluded before randomization owing to prior surgical experience. One trainee in the control group completed baseline assessments but suddenly left the training program, and was not contactable. All 5 ophthalmology training

Figure 1. Trial Flowchart



The control group received the allocated intervention after an initial follow-up period of 1 year.

Table 1. Baseline Characteristics of the Intention-to-Treat Population

Characteristic	Intervention group (n = 25)	Control group (n = 24)
Age, mean (SD), y	32.4 (5.0)	32.2 (4.3)
Sex, No. (%)		
Female	16 (64.0)	10 (41.7)
Male	9 (36.0)	14 (58.3)
Year of training, mean (median)	1.4 (1)	1.5 (1)
MCQ score, mean (SD), %	60.2 (4.7)	65.8 (3.3)
SICS procedures assisted or partially performed, mean (median)	0.6 (0)	0.6 (0)

Abbreviations: MCQ, multiple-choice question; SICS, small-incision cataract surgery.

programs contributed participants (4 from the Kilimanjaro Christian Medical Centre, 8 from Mbarara University, 10 from Makerere University, 17 from the University of Nairobi, and 10 from the University of Zimbabwe). There were no unintended effects in each group.

**Table 1** shows participants' baseline characteristics. There was good balance between groups. A total of 757 videos from across the different time points were independently graded in a masked fashion, each by 2 graders, of which 297 baseline and 3-month recordings contributed to the primary outcome measure. Interobserver reliability correlation showed a  $\kappa$  coefficient of 0.86 for total scores. Intraobserver agreement was 0.87.

The mean (SD) Sim-OSSCAR scores at 3 months were 33.7 (3.0) (84.3% of points) for the intervention group and 17.9 (5.9) (44.8% of points) for the control group ( $P < .001$ ) (**Table 2**). Linear regression analysis of Sim-OSSCAR scores at 3 months, taking into account center clustering, illustrated a large effect of the intervention. Those who received the training were estimated to have unadjusted scores 15.8 points higher (95% CI,

13.2-18.5) ( $P < .001$ ) than those who did not receive the training. The difference in Sim-OSSCAR scores was 16.6 points higher (95% CI, 14.4-18.7) with adjustment for baseline scores ( $P < .001$ ) (**Table 2** and **Figure 2**).

The mean (SD) Sim-OSSCAR scores at 1 year were 32.9 (3.6) (82.3%) for the intervention group and 24.2 (5.5) (61.1%) for the control group (**Table 2**). Scores at 1 year were 8.5 points (95% CI, 6.7-10.9;  $P < .001$ ) higher in the intervention group compared with the controls, adjusting for baseline scores, supporting a continued benefit from the training intervention.

Live surgical performance on patients was recorded anonymously at the 1-year mark for both groups, before the training course intervention began for the control participants. The mean surgical competency score using the ICO-OSCAR was 62.3 of 95 (65.6%) for the intervention group and 45.0 of 95 (47.4%) for the control group (difference, 17.3 points; 95% CI, 5.2-29.3;  $P = .006$ ).

The total number of live SICS procedures performed in 1 year (from 0 to 12 months) was recorded for each participant. Intervention group participants performed a mean of 21.5 surgical procedures as the primary surgeon and assisted in 24.6 cataract surgical procedures. Control group participants performed 8.5 surgical procedures as the primary surgeon and assisted in 10.9 cataract surgical procedures during the same period. The mean difference was 13.0 surgical procedures (95% CI, 3.9-22.2;  $P < .001$ ). Poisson regression analysis, with trial group as the exposure of interest, adjusting for training center, showed strong evidence that those who received the intervention training performed more live surgical procedures (as primary surgeon or assistant) than did those in the control group; those receiving the intervention performed 2.5 times (95% CI, 2.2-3.0) as many surgical procedures as those who did not.

The proportion of good outcomes (day 1 presenting visual acuity,  $\geq 6/18$ ) was 36.8% (138 of 375) and of poor outcomes (presenting visual acuity,  $< 6/60$ ) was 10.1% (38 of 375) for the intervention group; for the control participants, the proportion of good outcomes was 25.6% (30 of 117) and of poor outcomes was 12.8% (15/117). There was no significant difference in the proportion of good or poor outcomes between groups (Wilcoxon rank-sum  $P = .90$  for the intervention group and  $P = .95$  for the control group).

The mean PCR proportion during the 1 year after the training intervention was 70.7% lower at 7.8% (42 of 537) for intervention trainees, compared with 26.6% (54 of 203) for the control participants for the same 12-month period (difference, 18.8%; 95% CI, 12.3%-25.3%;  $P < .001$ ). **Figure 3** illustrates the regression plot of the number of cataract surgical procedures performed and number of PCRs by group. For those who had performed surgery, logistic regression (where the unit is surgery, outcome is PCR, and intervention is the only difference) illustrated a strong effect of the intervention. Intervention participants had a higher chance of having no PCR (odds ratio, 4.27; 95% CI, 2.74-6.65;  $P < .001$ ).

## Discussion

The OLIMPICS trial has demonstrated that an intense 5-day simulation-based cataract surgical education course success-



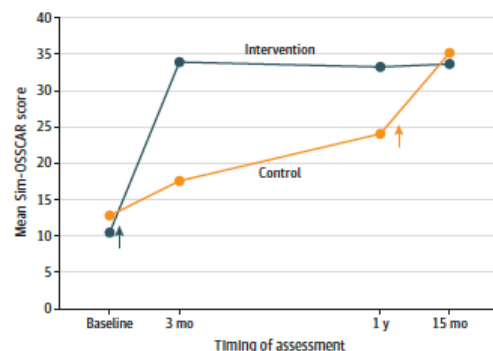
Table 2. Objective Evaluation of SICS Sim-OSSCAR Scores at Baseline and 3 Months

SICS simulation competency	Mean (SD) [%] <sup>a</sup>		Difference score, %	95% CI <sup>a</sup>	P value
	Intervention group score	Control group score			
Baseline	10.8 (6.7) [27.0]	12.8 (6.9) [32.0]	2.0 (5.0)	-1.9 to 5.8	.32
At 3 mo	33.7 (3.0) [84.3]	17.9 (5.9) [44.8]	15.8 (39.5)	13.2 to 18.5	<.001
At 12 mo	32.9 (3.6) [82.3]	24.4 (5.5) [61.0]	8.2 (15.5)	5.5 to 11.0	<.001
At 15 mo	33.5 (1.7) [83.8]	35.4 (2.2) [88.5]	1.9 (4.8)	-1.5 to 5.3	.26

Abbreviations: SICS, small-incision cataract surgery; Sim-OSSCAR, Ophthalmic Simulation Surgical Competency Assessment Rubric.

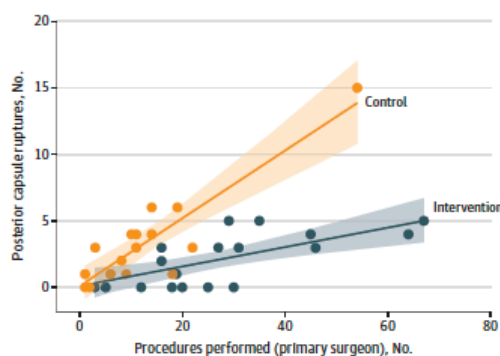
<sup>a</sup> Scores are out of a possible maximum score of 40.

Figure 2. Surgical Competency Scores by Group



Arrows indicate training intervention for intervention and control groups. Sample sizes for groups at baseline are intervention, 25 and control, 24; at 3 months are intervention, 25 and control, 24; at 1 year are intervention, 22 and control, 23; and at 15 months are intervention, 10 and control, 16. Scores are of a possible total of 40. Sim-OSSCAR indicates Ophthalmic Simulation Surgical Competency Assessment Rubric.

Figure 3. Linear Regression of Number of Posterior Capsule Ruptures and Number of Cataract Surgical Procedures by Group



Data from 21 intervention and 16 control trainees. Shaded areas indicate 95% CIs.

fully improved the main outcome of cataract surgical competence at 3 months, and that the benefits persist over 1 year. There is evidence from secondary outcomes that live surgical performance was improved and patient safety benefited from reduced surgical complication rates. This multicenter RCT supports the use of intense simulation training for cataract surgery.

Although the trainees in the intervention group performed and assisted in more live cataract surgical procedures in the year after the intervention training, it is unlikely that the better competency scores in the intervention group at 3 months are a result of having performed more SICS procedures. This is because most cataract surgery cases performed as primary surgeon were after the first 3 months of the study.

The implications for real-world training programs are compelling. Trainee eye surgeons should be afforded the opportunity to participate in focused, intense simulation training courses. We believe that supervised live surgical training on patients should begin only after engaging in adequate deliberate practice with feedback, reflective learning, and a competency outcome assessment benchmarked to appropriate standards. The International Council of Ophthalmology has developed a comprehensive residency curriculum and standards for graduates to have basic competence before performing cataract surgery.<sup>27</sup>

The implications for patient safety are ethically imperative. We illustrated a dramatic 70.7% reduction in surgical complication rates in the cases performed as primary surgeon in the first year of conventional training. Retrospective studies have shown that access to a virtual reality simulator for cataract surgery training (Eyesi; VR Magic) resulted in a 38.1% reduction in PCR rates for cataract surgical procedures performed by junior trainees in the UK, from 4.2% to 2.6%.<sup>16</sup> Mandatory simulator training for novice residents in the US showed a retrospective comparative reduction in PCR rates from 4.8% to 2.2%.<sup>17</sup> A retrospective study in India of wet-laboratory cataract surgery training using goat eyes showed PCR rates of 14.3% vs 6.9%.<sup>28</sup>

### Limitations and Strengths

This study has some limitations. A potential limitation of the OLIMPICS trial is the use of the Sim-OSSCAR<sup>19</sup> rather than live surgical competency assessment with the ICO-OSCAR<sup>25</sup> as the primary outcome measure. We argue, however, that this is a strength. The simulation environment and use of the validated Sim-OSSCAR affords participants the chance to complete as much of the cataract surgery procedure as they can without potential harm to patients, whereas live surgery is prone to greater variation that impairs its use for comparative purpose with small samples. All live surgery performed at the 12-month assessment was supervised by a local senior surgeon. At their professional discretion, they could take over surgery at any time, and for that part of the procedure the trainee would score zero on the live ICO-OSCAR rubric. The live surgical competency scores are therefore more complex to interpret. They are based on the variable takeover threshold of dif-



ferent senior surgeons; the comorbidity, risk-stratification, and complexity of a particular case; the confidence level of an individual trainee; and other factors. The use of the simulation artificial eye afforded a standardization that would not have otherwise been achievable in the live surgical setting. Furthermore, it would have been unsafe and unethical for untrained surgeons to be evaluated on surgical procedures performed on patients at a very early stage. Limitations of the study also include variability in training opportunities and training environments. To mitigate against this variability, the randomization was stratified by institution, resulting in equal numbers of intervention and control participants within an institution. This may, to a large extent, compensate for the inter-institutional variability, leading to balance between trial groups in factors such as cataract case mix (number and complexity). Another potential limitation, which is impossible to quantify, is the Hawthorne effect, whereby the behavior of participants of a study is altered owing to their awareness of being observed.<sup>29</sup>

This study also has some strengths. The strengths of the OLIMPICS trial are its RCT methodology, standardized intervention training for all participants, investigator masking, and double marking of all 757 surgical videos (each video was marked by 2 independent graders).

A critical review of simulation-based medical education suggested 12 areas or features of best practice,<sup>30</sup> many of which had been identified by other educational theorists. Of these,

skill acquisition and maintenance, feedback, sustained deliberate practice, curriculum integration, outcome measurement, and simulation fidelity are key.<sup>10</sup> These findings suggest that simulation-based surgical education should not be perceived as merely having access to a wet laboratory, dry laboratory, or computerized or full-immersion virtual reality simulator. For greatest impact, simulation-based surgical education should be seen and used as a comprehensive educational package. Part of this included the digital classroom, where procedures are recordable so that the trainee gets feedback on the whole process and can also review it themselves, engaging in critical reflective learning.

## Conclusions

The OLIMPICS trial illustrated a positive effect on patient safety. Not only are trainees and trainers afforded a safe, calm, and effective environment to teach and learn away from patients but the result appears to be a substantial reduction in the rates of surgical complications. With RCT-level evidence of the utility of intense simulation-based surgical education for cataract surgery, the opportunity is presented for us to protect the patients we and our trainees serve, to collectively and collaboratively work together to have this approach to surgical education implemented and mandated.

### ARTICLE INFORMATION

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for the integrity of the data and the accuracy of the data analysis.

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**Additional Contributions:** Nathan Congdon, MD, MPH, Queen's University Belfast, reviewed the

manuscript. He was not compensated for his contribution.

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## 10. The GLASS Trial

### RESEARCH PAPER COVER SHEET

#### **SECTION A – Student Details**

Student	William Dean
Principal Supervisor	Matthew Burton
Thesis Title	The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East and Southern Africa.

#### **SECTION B – Paper already published**

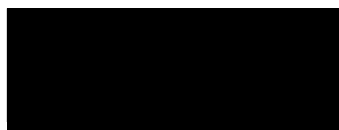
Where was the work published?	British Journal of Ophthalmology		
When was the work published?	January 2021		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*		Was the work subject to academic peer review?	

Pages 170 to 190

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#### **SECTION D – Multi-authored work** – See following page

Student Signature:



Date: 22 November 2020

Supervisor Signature:



Date: 22 November 2020

Chapter 10 describes the glaucoma simulated surgery (GLASS) trial. This prospective educational-intervention RCT compares the effect of intense simulation-based surgical education for glaucoma trabeculectomy surgery compared to conventional training alone. The original ideas around the need for innovative approaches to surgical education in sub-Saharan Africa were developed in discussions with Professor Colin Cook in 2014 and 2015. The concept of performing an RCT to answer critical questions was developed in discussions with Professor Matthew Burton in 2015 and 2016. Initially this was only for cataract surgery, however glaucoma was included as a separate trial.

I designed, fundraised, developed and completed the establishment of a purpose-built simulation Surgery Training Unit at the Community Eye Health Institute, University of Cape Town (UCT). This was detailed in chapter 8, as well as appendices 7 and 8. I was responsible for the design of the training intervention course, ensuring appropriate educational theory to underpin all aspects of the training. I created the bulk of the educational materials. Cybersight and Dr Demetri Manasses, Dr Richard Caesar, Professor Peng Khaw, Professor Pete Shah, and Dr John Sandford-Smith contributed some teaching materials.

The RCT was conducted with 51 trainee ophthalmologists in Kenya, South Africa, Tanzania, Uganda, and Zimbabwe. All training interventions were conducted at UCT by myself during 11 separate one-week courses in late 2017, 2018 and early 2019.

I was the principal investigator for the GLASS trial. I led the study design, developed the full protocol and standard operating procedures with guidance from Professor Matthew Burton. I consulted with lead ophthalmology consultants in collaborating institutions, Dr Stephen Gichuhi, Dr William Makupa, Dr Agrippa Mukome, Dr Juliet Otit, Dr Simon Arunga, Dr Heiko Phillipin, and Professors Colin Cook and Nagib du Toit.

Dr Fisseha Admassu and Dr Karinya Lewis independently performed the masked grading of over 700 surgical videos. I was responsible for reliability study of the grading. Min Kim assisted with data analysis and David McLeod gave advice on statistical analysis methodology.

I prepared the first draft of the entire manuscript, and all co-authors made comments on successive drafts and approved the final version before journal submission. I acted as guarantor of the final published version of the paper.





# Simulation-based surgical education for glaucoma versus conventional training alone: the GLaucoma Simulated Surgery (GLASS) trial. A multicentre, multicountry, randomised controlled, investigator-masked educational intervention efficacy trial in Kenya, South Africa, Tanzania, Uganda and Zimbabwe

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## ABSTRACT

**Background/Aim** Glaucoma accounts for 8% of global blindness and surgery remains an important treatment. We aimed to determine the impact of adding simulation-based surgical education for glaucoma.

**Methods** We designed a randomised controlled, parallel-group trial. Those assessing outcomes were masked to group assignment. Fifty-one trainee ophthalmologists from six university training institutions in sub-Saharan Africa were enrolled by inclusion criteria of having performed no surgical trabeculectomies and were randomised. Those randomised to the control group received no placebo intervention, but received the training intervention after the initial 12-month follow-up period. The intervention was an intense simulation-based surgical training course over 1 week. The primary outcome measure was overall simulation surgical competency at 3 months.

**Results** Twenty-five were assigned to the intervention group and 26 to the control group, with 2 dropouts from the intervention group. Forty-nine were included in the final intention-to-treat analysis. Surgical competency at baseline was comparable between the arms. This increased to 30.4 (76.1%) and 9.8 (24.4%) for the intervention and the control group, respectively, 3 months after the training intervention for the intervention group, a difference of 20.6 points (95% CI 18.3 to 22.9,  $p<0.001$ ). At 1 year, the mean surgical competency score of the intervention arm participants was 28.6 (71.5%), compared with 11.6 (29.0%) for the control (difference 17.0, 95% CI 14.8 to 19.4,  $p<0.001$ ).

**Conclusion** These results support the pursuit of financial, advocacy and research investments to establish simulation surgery training units and courses including instruction, feedback, deliberate practice and reflection with outcome measurement to enable trainee glaucoma surgeons to engage in intense simulation training for glaucoma surgery. The trial was registered at the Pan African Clinical Trials Registry in March 2017, (<https://pactr.samrc.ac.za/Search.aspx>) and is currently closed to recruitment.

**Trial registration number** PACTR201803002159198.

## INTRODUCTION

Globally, 36 million people are blind, and glaucoma is the third leading cause after cataract and uncorrected refractive error.<sup>1</sup> Trabeculectomy remains a gold standard and cost-effective surgical management for glaucoma.<sup>2–3</sup> Surgical treatment of glaucoma may be a first-line management strategy in moderate cases and is essential for treating advanced and severe glaucoma.<sup>4–5</sup> Despite the need, there is a reticence among many ophthalmologists to perform trabeculectomy, most easily attributable to lack of surgical training in glaucoma procedures and challenges in patient safety performing delicate surgery on what may be a patient's only seeing eye.<sup>6–8</sup> The number of trabeculectomies being performed is reducing and this has a further impact on training.<sup>9</sup> The use of glaucoma drainage devices has increased over the past three decades, and more recently minimally invasive glaucoma surgery (MIGS) has also played a role in the reduced number of trabeculectomies performed.<sup>10</sup>

An international survey of 38 countries showed a glaucoma surgical rate of 139 (range 3–500) surgeries performed per million population per year.<sup>11</sup> There is a need to perform more glaucoma surgeries in order to reduce the burden of avoidable blindness. Despite this need, only half of final year trainees in the UK are confident in performing surgical trabeculectomy.<sup>6</sup> The median number of glaucoma surgeries performed by senior trainee ophthalmologists (soon to become consultants) in sub-Saharan Africa was 1.<sup>7</sup> Less than half of consultant ophthalmologists in Scotland and West Africa perform any glaucoma surgery.<sup>12–13</sup> Hence, training of eye surgeons in glaucoma surgery, particularly trabeculectomy, needs to be increased while aiming for high-quality surgical education to ensure the best possible outcomes of a technically challenging operation.

Simulation offers an environment in which learners can train until they reach specified levels



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of competence.<sup>14</sup> Simulation-based surgical education can rapidly increase surgical skills, decrease complication rates, provide a safe and relaxed environment to learn in, and enable sustained deliberate practice.<sup>15</sup>

David Kolb<sup>16</sup> developed the constructivist perspective of 'experiential learning' as a cycle of active experimentation, concrete experience, reflective observation and abstract conceptualisation (figure 1A). Reflection (or reflective observation) is a key aspect of experiential learning and can be included in simulation training courses. Ericsson<sup>17, 18</sup> highlighted the role of 'deliberate practice' being distinct from work or play, and that for expertise to be attained this practice should be deliberate, sustained (over years) and characterised by the desire to improve. This sustained deliberate practice is also a key facet in a simulation training intervention, although aimed towards the stage of 'competence' rather than 'expertise' in the Dreyfus model of skills acquisition.<sup>19</sup>

Numerous simulation models have been used in ophthalmic surgical education, predominantly for cataract.<sup>20–23</sup> An apple peel and cellophane model has been used for trabeculectomy training with scleral flap construction.<sup>24</sup> Artificial model eyes are available for trabeculectomy, drainage devices and MIGS.<sup>25, 26</sup> However, the impact of intensive simulation-based surgical education has not yet been comprehensively proven for ophthalmic surgical training and certainly not for glaucoma surgical training.<sup>23</sup> We therefore designed and conducted the GLaucoma Simulated Surgery (GLASS) trial. The aim was to evaluate the effect of intense simulation-based surgical education in glaucoma surgery on surgical competence, confidence and live surgery outputs compared with conventional training alone.

## METHODS

### Study design

We designed a randomised controlled, parallel-group efficacy trial. Participants were randomised to one of two arms, with intended 1:1 allocation ratio. The predefined primary outcome

was the 3-month surgical competency score. There were no changes to the methods after trial commencement. The study protocol is available at <https://researchonline.lshtm.ac.uk/id/eprint/4654987>.

### Participants

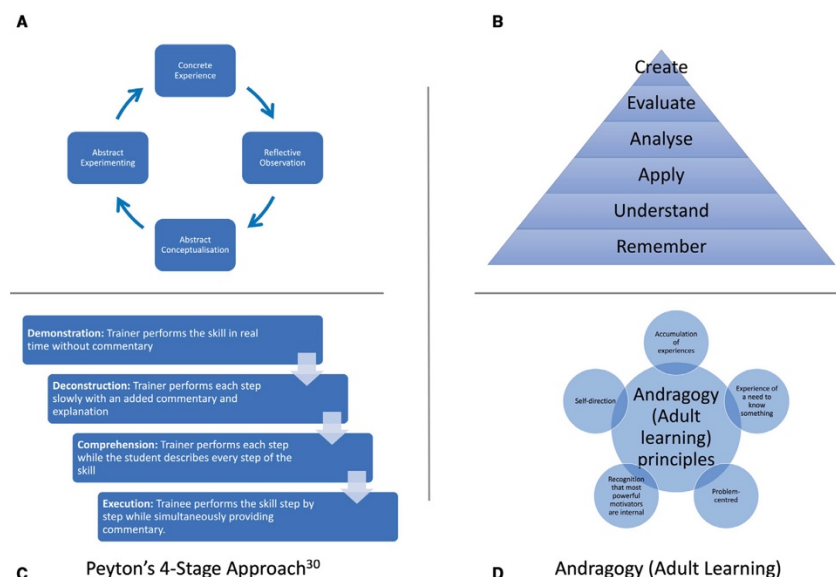
We enrolled trainee ophthalmologists from six university post-graduate training institutions in Kenya, Tanzania, Uganda, South Africa and Zimbabwe, selected according to inclusion criteria of having performed no trabeculectomy procedure as primary surgeon and part-performed or assisted in less than five. Trainees were in their second, third or fourth year of training. Training was similar in each centre in terms of duration (3–4 years) and glaucoma surgical experience. Informed written consent was obtained. Trainees in both arms continued with their regular training during the study period. Control arm participants were offered no placebo intervention, but were offered the same educational intervention in Cape Town after the initial 1-year follow-up period. Training, travel and accommodation expenses were funded; however, participants were given no further incentives or compensation.

### Prerandomisation baseline assessment

Following enrolment, participants were assessed for baseline surgical competence. This involved performing three simulation trabeculectomy procedures on artificial eyes or parts thereof as far as known by the participant. The video recordings were anonymised and remotely assessed using the Ophthalmic Simulated Surgical Competency Assessment Rubric (Sim-OSSCAR).<sup>27</sup> A knowledge test was administered comprising 30 multiple choice questions on glaucoma, further adding to baseline participant data.

### Randomisation

Each of the six university training centre recruitment sites had its own separate randomisation sequence. The randomisation



**Figure 1** Educational frameworks: (A) Kolb's learning cycle<sup>16</sup>; (B) Bloom's taxonomy of learning<sup>29</sup>; (C) Peyton's four-stage approach<sup>30</sup>; (D) andragogy (adult learning).



sequences were computer-generated centrally by a statistician based at the London School of Hygiene and Tropical Medicine, who was independent of all other aspects of the trial. We randomly allocated candidates at the site level into batches of two or four trainees, with equal numbers of intervention and control allocations in each batch. Preprinted allocation cards which specified the centre, batch group, unique identifier and allocation (intervention or control) were concealed inside opaque sealed envelopes. This ensured that the principal investigator, coinvestigator and participants had no prior knowledge of the allocation until the envelopes were opened. All the envelopes in the batch had an identical external appearance and batch label code. All trainees in the batch were each invited to simultaneously select and open one of the envelopes and to reveal their allocation card. If an odd number of participants were identified in a centre, the final one was invited to select one of two identical envelopes in a batch of two. This ensured randomisation as all candidates had an equal chance of being in either arm.

### Intervention

The intervention course was based on adult educational theory, aiming where possible towards the higher cognitive functions of Bloom's taxonomy of learning (figure 1B).<sup>28 29</sup> The trabeculectomy procedure was deconstructed in short steps, which were taught using Peyton's four-stage approach to teaching a practical skill.<sup>30</sup> A weakness of Peyton's four-stage approach is that it does not integrate theory with practice, and a modified three-step approach was used (commonly omitting step 3) combined with prior statement of objectives and clinical reasoning and immediate feedback (figure 1C). Feedback was given to participants while they engaged in sustained deliberate practice of a particular step.<sup>17</sup> We used both low-cost, moderate-fidelity materials, including foam for meticulous suturing practice and apple peels for scleral flap construction.<sup>24</sup> Once all parts of the surgical procedure were covered to a level of competence, the full procedure was performed on high-fidelity synthetic simulation surgery eyes (PS-OS-010, Phillips Studio, Bristol, UK),<sup>25</sup> following a round of mental rehearsal.<sup>31</sup> The procedures were performed using Zeiss Stemi 305 microscopes (Carl Zeiss Microscopy, Jena, Germany). The microscopes were equipped with cameras and linked to a central router and local area network. The Zeiss Labscope App (V.2.8.1) on iPads completed the digital classroom, allowing surgeons to record their performance. On completion of a simulated trabeculectomy, trainees engaged in reflective learning by watching the performance back on the iPad and grading against the Sim-OSSCAR.<sup>27 32</sup> Key andragogy principles, including problem-centred (rather than topic-centred) learning, internal motivation and self-direction, were incorporated (figure 1D). A more detailed description of the intervention is available in the online supplemental appendix.

### Outcomes

Participants were followed up at 3 months postintervention, at 1 year and at 15 months. Outcomes were assessed from video recordings of the simulation surgical procedures. Each video was independently graded by two masked graders who were experts in glaucoma surgery and had undergone familiarisation training using the Sim-OSSCAR. Video recordings of procedures were allocated a random seven-digit number, being the only identifiable information available for grading. Thus, assessors were masked to the participant's identity, allocation arm, training institution, as well as timing of surgical assessment.

The primary outcome measure was the mean score of three masked assessments of simulation surgical performance using the Sim-OSSCAR<sup>27</sup> at 3 months. The total possible score was 40 points per assessment. If data were missing from one assessment, then the mean of two or the result of one assessment was used. Live surgical training opportunities for trabeculectomy are sparse<sup>7</sup> and were not part of the intervention in the GLASS trial. We aimed to assess any effect of the intervention over a reasonable period of time, rather than merely the final day of an intense training course; hence, 3 months was chosen for the primary outcome measure.

Secondary outcome measures included surgical competence scores on the final day of the intervention training course, at 12 months and at 15 months (being 3 months after the control group had received their training intervention). Control group participants received exactly the same 1-week training intervention as the intervention group, after the 12-month assessment. The maintenance of surgical skills learnt in a simulation environment assessed over different time points has been reported as a valid methodology, predominantly in laparoscopic virtual reality and box trainer simulation surgical education research.<sup>33</sup> The number of surgical procedures (live trabeculectomy) performed as primary surgeon, as well as assisting surgeon, was reported for 12 months. These were self-reported retrospectively in a summary report after 12 months. Outcomes were recorded in terms of complications and surgical success (defined as intraocular pressure (IOP) <21 mm Hg at last assessment with no further treatment).

There were no changes to trial outcomes after the trial commenced. Additional exploratory analysis included surgeon confidence scores (on a 10-point Likert scale, anchored at 1='not confident at all' and 10='very confident') recorded at baseline and at 3, 12 and 15 months.

### Statistical analysis

Based on pilot data we calculated a sample of 23 individuals in each arm would have 80% power and 95% confidence to detect a significant difference. We aimed to recruit 25 per arm to provide 2 extra participants as modest loss to follow-up. The baseline characteristics of participants were tabulated and the distributions of these variables by treatment arm were compared to assess for imbalance.

The trial had a prespecified data analysis plan. Intention-to-treat (ITT) analysis was used for all outcome measures. The primary outcome was analysed by Wilcoxon rank-sum and a linear regression model for Sim-OSSCAR at 3 months, with trial arm as the exposure, adjusted for surgical training centre and baseline mean Sim-OSSCAR score. Secondary outcome measures were analysed by linear regression, as per the approach used for the primary outcome.

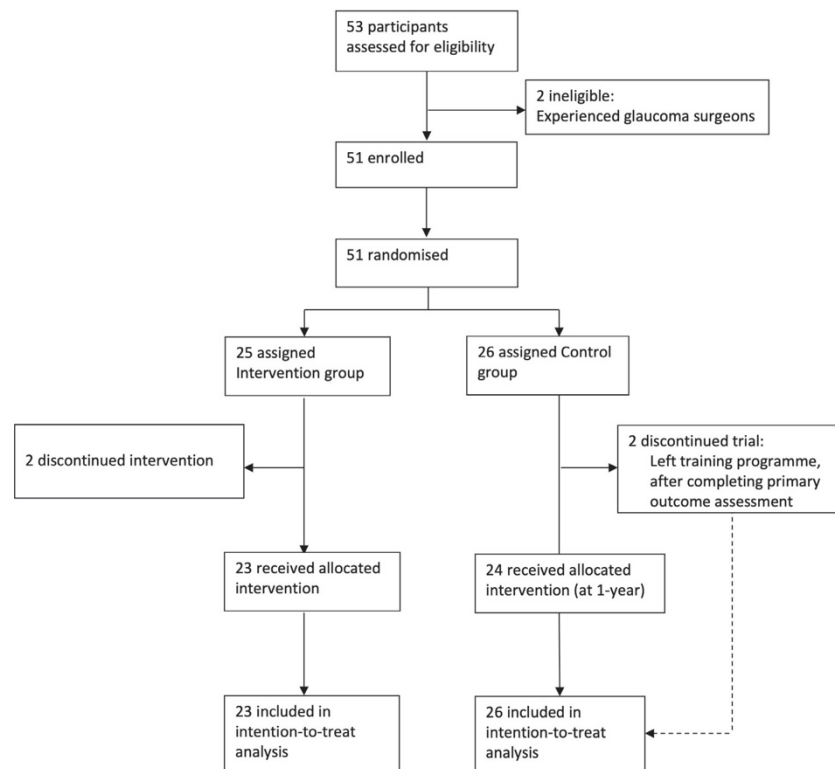
The number of surgeries performed over 1 year was analysed using Poisson regression, with trial arm as the exposure of interest, adjusting for training centre. Confidence rating scores (assessed at baseline and at 3, 12 and 15 months) were analysed using Wilcoxon rank-sum test.

An alpha level of  $p < 0.05$  was considered statistically significant for the primary outcome. A kappa coefficient of  $\geq 0.75$  for inter-rater agreement was considered excellent.<sup>34</sup>

Data were initially entered into Microsoft Excel (V.15.31). Statistical analysis was performed using Stata V.15.1. A data monitoring and trial advisory committee oversaw the study.

### Prevention of bias

It is accepted that there will be variability in individual participants' inherent or natural surgical aptitude. All efforts were



**Figure 2** GLASS trial profile. GLASS, Glaucoma Simulated Surgery.

made to standardise the training offered to the ‘intervention’ participants (as well as the ‘control’ participants after the 1-year period). The intense simulation course was held in the same standardised surgical training unit at the University of Cape Town. The training was conducted by WHD.

It is recognised that surgical education is complex and multifaceted. However, every effort was made to reduce ‘contamination’ bias. A number of standard risk-of-bias criteria are suggested for randomised controlled trials (RCTs) (or studies with a separate control group). These are summarised in the online supplemental appendix table.

## RESULTS

A total of 53 potential participants were assessed for eligibility. Fifty-one were recruited, with 25 allocated to the intervention group and 26 to the control group. Forty-nine were included in the final IIT analysis, with two dropouts from the

intervention group. [Figure 2](#) illustrates the trial profile. Two potential participants were excluded prerandomisation due to prior surgical experience. One intervention group participant failed to travel for the intervention training due to visa issues. Another participant completed only part of the intervention course and subsequently failed to respond to repeated invitations for follow-up.

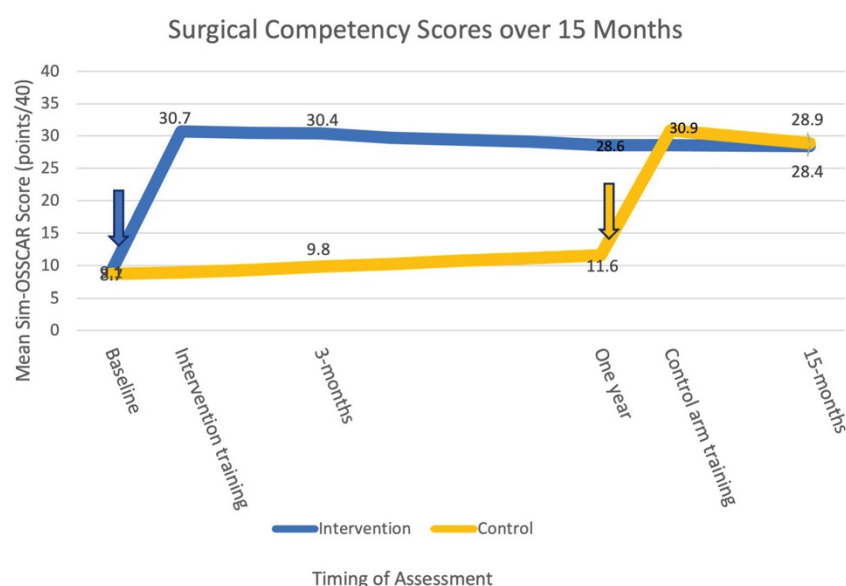
[Table 1](#) shows the demographic data of the participants. There was good balance between the two arms. All ophthalmology training programmes and countries contributed participants (Kenya 17, South Africa 2, Tanzania 12, Uganda 14 and Zimbabwe 4). There were no unintended effects in either arm.

A total of 604 videos were independently graded, of which 287 were directly included in the primary outcome measure analysis. Interobserver reliability correlation of outcome assessors showed a kappa correlation of video total scores of 0.83. The intraobserver agreement was 0.88.

**Table 1** Baseline demographic characteristics of GLASS trial participants

Characteristics	All (N=49)	Intervention (n=23)	Control (n=26)	P value
Age, mean±SD	33.2±4.0	33.1±3.7	33.2±4.3	0.82
Sex, n (%)				
Female	23 (46.9)	12 (52.2)	12 (46.2)	0.67
Male	26 (53.1)	11 (47.8)	14 (53.8)	
Year of training, median (mean)	2 (2.5)	2 (2.5)	2 (2.4)	
MCQ score (%), mean±SD	75.7±9.7	77.4±8.5	74.2±10.6	0.29
Trabeculectomy procedures assisted or part-performed, mean (median)	0 (0)	0 (0)	0 (0)	

GLASS, Glaucoma Simulated Surgery; MCQ, multiple choice question.



**Figure 3** Surgical competency (score out of 40) over 15 months by arm. The arrows indicate the training course intervention. Sim-OSSCAR, Ophthalmic Simulation Surgical Competency Assessment Rubric.

The mean Sim-OSSCAR score at 3 months was 30.4 (76.1%, SD 4.4) and 9.8 (24.4%, SD 3.6) for the intervention and the control group, respectively. Those who received the training were estimated to have unadjusted scores of 20.6 points higher (95%CI 18.3 to 22.9) ( $p<0.001$ ). The difference was 20.4 points higher (95%CI 18.7 to 22.2) with adjustment for baseline scores and training centre ( $p<0.001$ ).

Surgical competency at 12 months was maintained by the intervention group: a mean score of 28.6 points (SD 3.9). The mean competency score of the control group was 11.6 (SD 4.4) (mean difference 17.0, 95%CI 14.8 to 19.4,  $p<0.001$ ).

Surgical competency was assessed on the final day of the training course for each group (figure 3). This increased from a baseline of 9.1 out of 40 (22.8%) to 30.7 (76.9%) (SD 5.1) for the intervention group. Before the control group undertook the training intervention (at the 12-month assessment), their mean competency score was 11.6 (29.0%) and this increased to 30.9 out of 40 (77.6%) (SD 3.7) at the end of the training course ( $p<0.001$ ) (table 2, figure 3).

The baseline mean self-reported confidence in 'glaucoma surgical skills' was 3.0 out of 10 for intervention and 3.2 for control participants ( $p=0.72$ ). This increased to a mean of 6.4

and 3.7 at 3 months, respectively ( $p<0.001$ ) (figure 4A). Confidence 'as an eye surgeon' was rated on the same 10-point scale. There was no difference at baseline or 3 months between the arms ( $p=0.38$ ). At 12 months, the intervention group participants were more confident as eye surgeons: mean 7.86 vs 6.56 ( $p=0.022$ ) (figure 4B).

The total number of trabeculectomies performed over 1 year was recorded for each participant. The intervention group trainees performed a mean of 3.2 live trabeculectomies as primary surgeon (median 2, range 0–15, IQR 0–4) in the year following the intervention training. In the same year period, control participants performed a mean of 0.15 (median 0, IQR 0–0). Poisson regression analysis, with trial arm as the exposure of interest, adjusting for training centre showed a large effect ( $p<0.001$ ). Of the 26 control participants, 25 had performed zero trabeculectomy as primary surgeon, with only one having performed four supervised live surgeries. Of the 23 intervention participants, 14 (61%) had performed trabeculectomies ( $\chi^2$   $p<0.001$ ). The incident ratio for the 1-year period showed intervention participants were 20.3 times more likely to perform surgery ( $p<0.001$ ). The intervention trainees assisted in a mean of 4.8 trabeculectomies and the control group trainees assisted in a mean of 0.7 over the same 1-year period. Complications (including conjunctival

**Table 2** Objective evaluation of SICS Sim-OSSCAR scores: intervention versus control groups

Timing of simulation trabeculectomy competency assessment	Intervention Score*, mean (%) (SD)	Control Score*, mean (%) (SD)	Difference†	95% CI Score*	P value
Baseline	9.1 (22.6) (5.0)	8.7 (21.8) (3.7)	–0.3	–2.8 to 2.2	0.788
Final day of training course‡	30.7 (76.9) (5.1)		21.7	19.0 to 24.4	(0.117)‡
3-month (primary outcome)	30.4 (76.1) (4.4)	9.8 (24.4) (3.6)	20.6	18.3 to 22.9	<0.001
12-month	28.6 (71.5) (3.9)	11.6 (29.0) (4.4)	17.0	14.8 to 19.4	<0.001
Final day of training course‡		30.9 (77.6) (3.7)	19.2	17.3 to 21.0	(0.117)‡
15-month	28.4 (71.0) (2.1)	28.9 (72.3) (5.0)	–0.5	–7.1 to 6.0	0.873

\*Score out of 40 points.

†Adjusting for training centre as a fixed effect.

‡Training course intervention was after 12 months for control participants ( $p=0.177$  relates to intervention vs control on final day of training course). Sim-OSSCAR, Ophthalmic Simulation Surgical Competency Assessment Rubric.



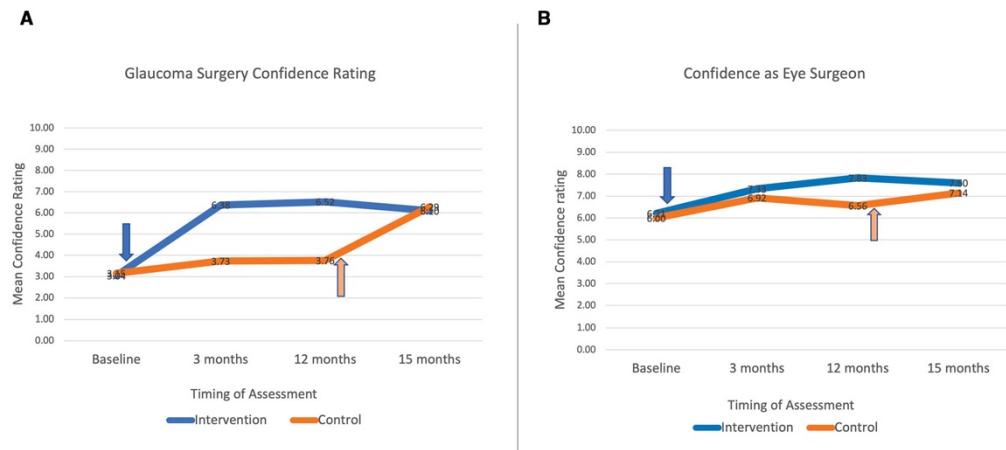


Figure 4 (A) Confidence rating in glaucoma surgery and (B) confidence rating as an eye surgeon.

leak and hypotony) were recorded for 12.2% (6 of 49) of the intervention group which performed surgeries. Surgical success (IOP <21mm Hg, no further glaucoma treatment) was observed in 83.4% (41 of 49) of eyes. The number of surgeries performed by the control group (4 in total for all 26 participants) was too low for any meaningful comparative analysis.

## DISCUSSION

The GLASS trial demonstrated that the intervention of an intense 5-day simulation-based training course successfully improved the main outcome of glaucoma surgical competence at 3 months. There is evidence from secondary outcomes that these benefits persisted over more than a year. There is further evidence that the quantity of live surgeries performed benefited from the intervention, as did self-reported confidence of participants in general and procedure-specific surgical ability.

It is likely that a combination of factors was related to the sustained increase in competence. After the training, participants were certainly more competent and confident in glaucoma surgery, but were also probably more motivated to perform supervised live surgery. Consultant ophthalmologists in collaborating training institutions would take notice of an increase in motivation and confidence and respond to a rapid and demonstrable increase in surgical competence of their trainees.

Ophthalmology training courses globally range from 3 to 7 years, and it is not possible from these data to determine the best timing of an intense simulation-based surgical educational intervention for glaucoma surgery. Competence, confidence and subsequent live surgical experience are linked, and therefore a recommendation for the best time of a GLASS training intervention could be the start of a glaucoma firm or rotation. Evidence from primary and secondary outcome measures of the GLASS trial indicates that the benefits of the training were very strong and equal for both the control and intervention group participants 1 year apart.

Limitations of the GLASS trial include the use of a simulation assessment of surgical competence. Both the Sim-OSSCAR for trabeculectomy and the live surgery ICO-OSCAR are validated competency assessment tools.<sup>27,35</sup> However, it is perhaps also a strength that the ICO-OSCAR was not used as an outcome measure, as only one of the control participants performed any glaucoma surgery in the initial 1-year follow-up period. A strength of the GLASS trial is its RCT methodology, which to the authors knowledge is the first time ever applied to glaucoma simulated surgical education. Further

strengths include standardised intervention training for all participants, and investigator masking and double assessment of all 604 simulation surgical videos.

Surgical education in glaucoma is challenging.<sup>8,9,13,36</sup> Fewer glaucoma surgical procedures are being performed overall, the microsurgical procedure is intricate and requires meticulous technique, and long-term follow-up is needed beyond when a trainee would have moved on.<sup>8,37</sup> Trainee ophthalmologists in Australia perform a mean of between 1.1 and 1.6 trabeculectomies per year,<sup>8,38</sup> and trainees in the UK have a mean annual trabeculectomy rate of 0.5.<sup>39</sup> Residents in the USA have completed a mean of 8.6 trabeculectomies by the end of their 3-year residency; however, two-thirds (67%) of residents begin operating as primary surgeon performing trabeculectomy only in their final year.<sup>40</sup> The impact of curtailed hands-on glaucoma training opportunities is mitigated by the availability of subspecialty training fellowships in Australia, UK and USA.

Challenges in glaucoma management in sub-Saharan Africa include late presentation at an advanced stage of disease progression; lack of access to, affordability of, and adherence to medical therapy; low follow-up rates; and healthcare workforce shortages.<sup>41</sup> It is imperative that general ophthalmologists be trained in glaucoma surgery and to a high standard considering the potential for surgical failure due to the propensity for scarring and the importance of good outcomes in a group of patients who may already be blind in the other eye. Many trainees will have finished their ophthalmology specialist training without having completed any glaucoma surgery and would then be less likely to perform many as a junior consultant. This would only act to keep the glaucoma surgical rate below the level needed to alleviate the burden of avoidable blindness due to advanced glaucoma.

Participants who received the training intervention in the GLASS trial went on to perform a greater number of live surgical trabeculectomy procedures in the year after the training intervention compared with control trainees. All participants benefited from a rapid and sustained increase in competence, thus making them more likely to maximise training opportunities when they arise.

Intense simulation training in glaucoma surgery affords a rapid and sustained increase in surgical competence and confidence as a surgeon, and impacts the number of live surgeries subsequently performed. It provides a calm environment in which to learn and practise the intricate and meticulous skills of surgical trabeculectomy. It provides a safe environment with no danger to patients.

Surgical outcomes for trabeculectomy performed by intervention group participants were comparable with previous reports of resident-performed glaucoma surgery.<sup>42</sup> However, rather than simply the availability of a simulator or artificial eyes as a simulation model, instruction, feedback, sustained deliberate practice and reflection with outcome measurement were all important aspects of the educational intervention. If used as a comprehensive educational package, simulation can play a pivotal role in training ophthalmic surgeons in advanced surgical techniques.

We now have the RCT-level evidence to suggest that it is an ethical, clinical and educational imperative for ophthalmology training institutions to pursue the use of intense simulation training in glaucoma to ensure trainees attain a benchmarked level of competence before operating on patients in a high-stakes, high-risk environment.

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AUTHOR PROOF



## 11. Discussion & Recommendations

### A Personal Journey

We all have moments in life that have a defining influence on the course we take. Working in a mission hospital in rural Malawi for many years was exceptionally rewarding, and exceptionally stressful in equal measure. The stress of teaching surgery was even greater than when saving the pet dog from a hyena in the middle of the night, crossing paths with an indifferent black mamba in the process. I enjoyed so much the rich and humbling work of restoring sight to blind and vision impaired villagers from throughout Central Malawi. It simply is not work you can ever tire of, even if performing 30 or 50 cataract surgeries a day, and over 5,000 in the years I live in that special place, Nkhoma. However, I simply could not stand the feelings of inadequacy and blind panic when talking a novice cataract surgeon through the steps of a procedure on a terrified, and either catatonic or hypermobile patient. I knew then that something had to be done to find a better way to teach eye surgeons, especially in an area and region which so urgently needs more of them.

My moment came two years after I had left. I had returned to visit, and was aboard a catamaran in the sunset off the shore of Cape Maclear, towards the south of Lake Malawi. Looking back at the shore and village and Billy Riordan Memorial Clinic, in that peaceful moment I imagined a bespoke surgical training facility for eye surgeons from throughout sub-Saharan Africa. It was a perfectly calm venue to learn and practice. Over a cup of tea with Professor Colin Cook at the University of Cape Town three days later, I explained my idea. Colin completely understood the need for more surgical training opportunities in the region, however politely pointed out that Cape Maclear was 4 hours' drive from the nearest airport, and malaria was endemic. However, how about Cape Town? This appeared a great idea, however the Health Professions Council of South Africa might object to dozens of trainee eye doctors coming to the University to practice surgery. Fortuitously, at that time I was studying for my Masters in Surgical Education at Imperial College London, and had recently completed the module on simulation in surgical education. The problem, possible solution, and means

to test the solution suddenly combined. It was later that year during a chance meeting with Professor Matthew Burton that the concrete ideas around the randomised controlled trials were developed.

Although the stress of teaching surgery in Malawi was an initial motivator to attempt to find a solution, it was not my main motivation for continuing the near decade-long journey. I instinctively knew that I may have found a potential solution to a very challenging problem, and wanted to ask the question: “Can simulation impact ophthalmic surgical training in sub-Saharan Africa”. The next step was learning how to answer that question. That, in essence, is what a PhD is: teaching you how to ask a question, and teaching you how to answer it. The term philosophy comes from the Greek ‘φιλοσοφία’, or philosophia meaning ‘love of wisdom’. Doctor, from the Latin ‘docere’, means ‘teacher’. A PhD thus implied a teacher of the love of wisdom, and is exactly what I aimed to achieve in not only the training of 100 eye surgeons in the SOS trials, but in diving deep into the question of surgical education in a resource-poor blindness prevention setting. I imagined teaching not only surgical skills, but imparting at least some of the understanding of becoming a good surgeon for trainees to continue. I imagined a world where the trainer, trainee and patient didn’t have to panic and stress quite so much. Where trainees were enabled in a demonstrably impactful way to learn, improve and maintain their surgical skills, knowledge and attitudes in a safe and calm manner. This was a very powerful positive motivator, and it rapidly crystallised into a powerful positive goal. Mohammed Ali, possibly the world’s greatest boxer, used a visualisation technique called ‘future history’ whereby he would picture himself having already won an upcoming fight, celebrating with hands in the air. It’s a powerful construct, imagining the positive feelings after having achieved a future goal; then simply working back to the present through everything that has to happen to get there.

Motivation has been studied by psychologists for decades, and originally referred to within behaviourist theory in terms of intensity and direction.<sup>117</sup> Psychologists Oettingen and Gollwitzer further explain that “motivation has been traditionally defined as energy, direction, and the determinants of motivation as need, expectation, and incentive value”.<sup>118</sup> The direction of impacting surgical training in SSA was clear. I had the energy, however would rely on key partners and stakeholders to maintain it. I understood the broader need, and this



is discussed in the next section. The expectation was a hopefully realistic five-year timetable and map; and the incentive value was the quality of surgical education to be achieved.

Before I had come to understand my motivation for the whole work presented in this thesis, the truth was I had spent many years battling self-doubt over examinations, up to the point where I would enter a catastrophic state of nervousness and terror at the start of exams, I would set myself up to fail, even if I did manage to calm down before the end of the assessment. Six-months of professional performance training, positive goal visualisation, and training to overcome self-doubt enabled me to better understand and harness motivation. Hard work was of course also required.

With my personal motivation in place, the project became a work of passion. Sustaining it over the years, and the long-term sustainability (as further described in the 'Delivering Surgical Education' later in this chapter) relied and relies on the kind, inspirational, and exceptional people I have been fortunate enough to meet and work with along the way.

## The Need

Of the more than 7 billion people in the world, 36 million are blind and a further 217 million have moderate or severe vision impairment.<sup>10 119</sup> There are 12.6 million people blind, and 52.6 million with MSVI due to cataract. A further 2.9 million are blind and 4 million have MSVI due to glaucoma. Apart from cataract and glaucoma: trachoma trichiasis, corneal opacity, vitreo-retinal conditions and paediatric cataract are also causes of blindness or visual impairment that could be surgically treated, or prevented by early surgery. There is a clear and present need to perform many surgeries for blindness prevention.

There are, however, 76 million with glaucoma, and this huge eye care need is encompassed within the 'iceberg' idea of healthcare needs.<sup>120</sup> This is not those who are already blind, but those with good vision in need of eye care. Although surgical trabeculectomy was the focus of the GLASS trial, surgery is not the main issue with glaucoma management. At least five separate classes of topical ophthalmic medications are available for the control of IOP. Numerous laser options exist, including selective laser trabeculoplasty (SLT), argon laser trabeculoplasty (ALT), nd-YAG laser iridotomy for angle closure glaucoma, and trans-scleral cyclodiode laser. Many of these are being explored in the context of glaucoma management in low and middle-income settings.<sup>121-123</sup>

Only around half of the 230,000 ophthalmologists in the world perform surgery, and regions with the greatest burden have the lowest ratios of ophthalmologists to population.<sup>9</sup> We urgently need to train future generations of eye surgeons and equip them to tackle the need. If all 65 million people with cataracts causing blindness or vision impairment were to have their 130 million eyes operated on by the 115,000 ophthalmic surgeons, then each surgeon would have to perform 1,130 operations to clear this burden of disease. This calculation is of course simplistic. We would have to facilitate and fund the surgery; barriers would have to be overcome; and patients would need to present and consent. Furthermore, these huge numbers are themselves simplistic. There may be over 12 million people blind from cataracts, but this blindness is experienced on a very personal level. There may be 115,000 ophthalmic surgeons in the world, however their surgical education and expertise is also experienced on a personal and individual level.



## Surgical Education in Ophthalmology

Historically, ophthalmic surgical education has been in the traditional apprentice Halstedian model.<sup>11 124 125</sup> Over the past decade more structured curricula and approaches have been used within a competency-based framework.<sup>126</sup> There is a need to maximise the time and efforts of ophthalmologists involved in surgical education, especially in resource-poor environments where the need is often greatest. There is wide variation in ophthalmic surgical education globally. In the UK, the median number of cataract surgeries performed (supervised or unsupervised) by the end of 7 years of ophthalmic specialist training is 592 (IQR: 472-738; mean: 631).<sup>127</sup> In the USA the median was 100 (mean 113) for final year residents.<sup>128</sup> In mainland China this was zero.<sup>129</sup>

Participants in the intervention group of the OLIMPICS trial performed 2.5 times more surgery than controls, a mean of 22 cataract surgeries performed as primary surgeon versus 9 respectively. There are multiple possible mechanisms for this. From the trainee perspective, confidence had doubled, competence had trebled, and motivation would have increased and become more focussed. Local consultant and senior trainee surgeon trainers would know that intervention participants had been to Cape Town for extra training, and may have been keen to afford trainees the opportunity to show their skills.

One consultant in Uganda commented *“I had a surgical camp in Kanungu and went with two of our residents, one in second year and one in first year then. Both of them had attended a one week simulation SICS training in Cape Town. To my surprise a first-year resident did a cataract case under my observation and finished it with little help from me and the VA next day was 6/12. This is enough to show that that training under Dr Will is extremely important. many thanks to you Dr Will and all the supporting team.”*

Although the increase in numbers of surgeries performed (and assisted) was higher for those that had received the intervention is complex and multi-faceted, the simplest reason is most likely. A consultant surgeon trainer seeing a confident trainee perform to a three-fold higher level of competence, with a 72% lower complication rate, would likely offer them more live surgical training opportunities.

Participants in the GLASS trial intervention arm performed 3 trabeculectomies, versus zero in the control arm, during the year following the training intervention. If the 5,000 ophthalmology trainees completing their training worldwide each year undertook similar surgical education, this would equate to a further 15,000 people with glaucoma having this potentially blindness-preventing surgical procedure performed. This is, however, a much too simplistic and broad conclusion. For the more senior trainees (compared to participants in the OLIMPICS trial), surgical competence in trabeculectomy increased 236% and confidence as a glaucoma surgeon doubled. It is perhaps this dramatic increase of confidence in surgical ability that is most important. There is a reticence and lack of confidence amongst around half of ophthalmologists and senior trainees to perform any glaucoma surgery.<sup>1 29 130-132</sup> If a GLASS approach could be implemented for all senior trainees and junior consultants worldwide, the potential increase in confidence and competence of surgeons and the numbers of glaucoma surgeries performed would greatly impact the burden of avoidable blindness due to glaucoma.

The challenge will be translating the results of the SOS trials into practice, adapting the education approach to local ownership and use, and maintaining educational standards. Any translational change will need to be managed with the inclusion of key educational theory and facets of simulation-based surgical education.



## Educational Facets of Ophthalmic Simulation-based Surgical Education

A strength of the OLIMPICS and GLASS trials was the robust RCT methodology. A further strength was the training intervention. The intervention of a one-week intense simulation training course was developed over two years, and pilot-tested in Uganda, Malawi and South Africa as a Masters in Surgical Education (MEd) degree thesis. Specific resources were developed, and international experts in cataract and glaucoma surgery kindly offered further resources. Orbis International hosted the courses online on their Cybersight platform. The design, content, and context of the training interventions have been described in the main trial papers, chapters 9 and 10, as well as chapter 8.

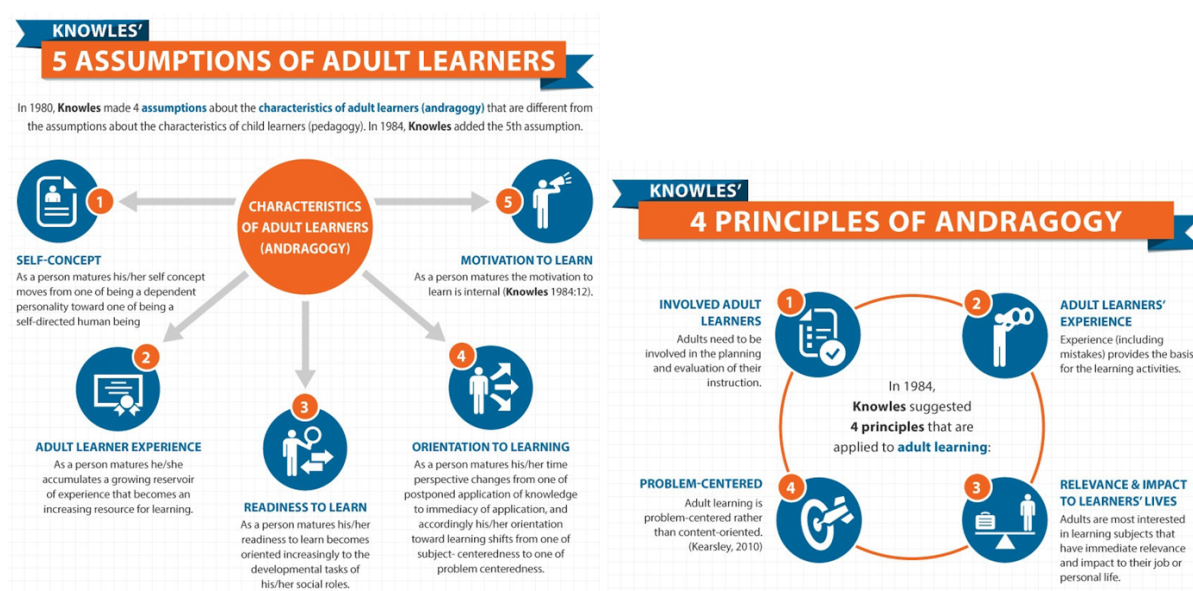
It was not merely the availability of a simulator or artificial eye or surgical skills facility per se, but the efficacy of simulation-based surgical education as a whole package that was evaluated. The following section describes what this educational package entailed, in chronological order of the intervention course (Tables 3, 4, 5, and 6 in Chapter 8).

Blended learning, involving online and face-to-face education and learning has become popular over the past two decades. It has been termed the 'new normal' in higher-education teaching.<sup>133</sup> A meta-analysis illustrated that while students studying online performed slightly better than face-to-face students, those in courses that blended online and face-to-face components performed significantly better than a purely online course (effect size +0.35,  $p < 0.001$ ).<sup>134</sup> The online component of the OLIMPICS and GLASS trial blended course is difficult to account for, as most participants had not accessed the Cybersight modules before attending the residential course in Cape Town. There were and are internet issues in many parts of the world, and this needs to be taken into account when designing online courses. Cybersight does have functionality with low bandwidth connectivity, however this still assumes internet, electricity, and laptop or smart device availability.

Motivation and intent are difficult to quantify. At the start of the course, a round of introductions included a reflective response from all participants to the question: "What do you want to get out of this week?". Responses ranged from learning skills, managing complications, being a better surgeon, and perform better. This simple reflection allowed participants to begin to explore and explicitly state their motivations and intent. A final

statement was made by the PI to the effect of “I will do everything for you to be competent by the end of the week, but the one thing I ask of you is that you have to want to be a better surgeon”. This statement clarified the need for self-motivation. Andragogy (the method and practice of teaching adult learners) differs from pedagogy, and it is important for adult teaching and learning for differing facets to be recognised (Figure 25). The American educationalist Malcolm Knowles popularised the term in the 1960s, and his theory involved assumptions related to the motivation of adult learning, including that of self-concept.<sup>135</sup> One of the key principles of adult learning is that adults must want to learn. Andragogy relies on self-motivation and self-determination, and although this principle may be implicit, it was made explicitly clear to all participants at the outset of the intervention course.

**Figure 25. Assumptions of Adult Learners and Principles of Andragogy<sup>135 136</sup>**



Introductions were followed by the module ‘Burden of disease’ in which participants were invited to work through the exercise of calculating how many cataract (and or glaucoma) surgeries need to be performed per ophthalmologist in their home region simply to clear the backlog or point prevalence of blindness and vision impairment, or prevent blindness from glaucoma. This naturally led to discussions of the broader need to perform more surgery, and therefore the need to learn. The lecture and small group teaching on ‘Learning Theory and Expertise’ illustrated the educational theory underpinning the intervention course.

The first practical session involved basic microsurgical skills. Foam sheets and a relatively large 5/0 or 6/0 suture was used to perform a simple interrupted surgical suture. The PI demonstrated this using Peyton's four-stage technique of learning a practical skill.<sup>137</sup> This involves:

1. Trainer performs the task.
2. Trainer performs the task and describes what is being done.
3. Trainer performs the task and the trainee describes what is being done.
4. Trainee performs the task and describes what is being done.

Participants in both the OLIMPICS and GLASS trials were novice cataract (SICS) or glaucoma (trabeculectomy) surgeons, having performed zero of the respective surgery as primary surgeon. Participants in the OLIMPICS trial were however more junior than those in the GLASS trial on average. Some were novice surgeons, and had not had any basic microsurgical skills instruction. This initial practical session was important in the instruction and/or correction of techniques of holding instruments, tying a simple surgical knot, as well as familiarisation with the microscopes.

Each procedure was deconstructed into important constituent parts. The timetables are illustrated in chapter 8, however this was very flexible. The teaching and learning of each step followed the same pattern:

- Instruction. This involved a powerpoint presentation and/or video clip, small group discussion about the details of a step, and then specific skill instruction.
- Initial performance by the participants, with feedback.
- Sustained deliberate practice. Participants were guided to perform a task to a precise and deliberate result, and to ensure each repetition was the same. As appropriate, skills were refined to increasing complexity and to closer replicate and mimic those aspects of the live procedure that were being taught. This was especially true of the intricate releasable and conjunctival sutures used in trabeculectomy. No time limits were set on this process. Feedback was constantly given to trainees as they engaged in deliberate practice, and practice was continued until a demonstrable and repeatable level of competence and confidence was reached by each participant. Two anecdotes were used to assist in the process. The first was a small group discussion around the difference between an amateur and a professional: 'An amateur practices

something enough, so they can get it right; a professional practices something so much, that they can't get it wrong'. The second anecdote was from the 1984 movie *The Karate Kid*. The clip of 'wax-on, wax-off' was shown to participants, with the discussion about the importance of repetitive sustained deliberate practice to perfect a specific part of a surgical procedure. In the *Karate Kid*, it was the defensive parrying or blocking technique of karate, practiced by waxing dozens of cars; in the surgery training unit it was the 20 scleral tunnels or flaps performed on each of five apples.

The performance of a full simulated surgical procedure involved mental rehearsal, deliberate practice, feedback, reflective learning, and outcome measurement.

All training was conducted in a specifically designed calm and facilitatory environment to enable learning. This created a collaborative, more informal, and relaxed environment in which to learn and practice microsurgery.

Dreyfus described a 5-stage model of the mental activities involved in directed skill acquisition.<sup>93</sup> (Figure 26). Participants in the OLIMPICS trial were novice cataract surgeons, and those in the GLASS trial were novice glaucoma surgeons.

The focus of the SOS trials was on initial introduction of novice surgeons to a technique, and the use of simulation-based education for attainment of competence. Proficiency can be described as having developed a deep understanding and being able to see actions and situations holistically. A proficient should be able to prioritize the importance of different aspects and achieve a high standard of performance routinely. This might be possible with the use of ophthalmic simulation-based surgical education.

Figure 26. Dreyfus Model of Skill Acquisition.<sup>93</sup>



Full expertise and the assessment of an expert surgeon is outside of the scope of this thesis. An expert has an authoritative and deep holistic understanding and deals with routine matters intuitively. They can go beyond existing interpretations and achieve excellence with ease. Experts should be able to transcend reliance on rules and guidelines, and have developed a more analytical approach to new situations and complications or problems that may arise.

Is it indeed possible to teach 'expertise', as it is possible to teach a professional musician, a professional rugby player how to handle stress, how to train in resilience, how to constantly aim for expertise?

The OLIMPICS and GLASS trials' intervention courses focussed on the key and core aspects on cataract and separately glaucoma, within the frame of the three domains of learning: knowledge and understanding, skills and attitudes. The attitudes taught and discussed in small group focussed on trainees' approach and motivation to learning, their approach to surgical outcomes and monitoring of results, or audit. The intended learning outcomes could



focus on the attainment of expertise, maintaining the very highest standards, and resilience training to cope under great pressure?

Lev Vygotsky described the zone of proximal development (ZPD) as the distance between the actual developmental level as determined by independent problem solving and the level of potential development as determined through problem-solving under adult guidance, or in collaboration with more capable peers".<sup>138</sup> When a trainee is in the ZPD for a particular skill, appropriate assistance can give them a boost to transition through and achieve the task. Educators can focus on three components in this process. The presence of someone more knowledgeable, social interaction with a skilful trainer that allows the trainee to observe and practice, and scaffolding or guided learning.

Could these and other educational principles underpinning the training interventions in the SOS trials be combined with resilience and pressure-related training? A systematic review has illustrated a host of approaches that could be adapted for ophthalmic education.<sup>139</sup> The 'pressure principle' is a multi-faceted approach developed by Dr Dave Alred to preparing for high pressure environments, integrating strands of anxiety, managing learning, implicit-explicit balance, behaviour, environment, sensory shutdown and thinking correctly under pressure.<sup>140</sup> These 7 strands are all woven around the common thread of language.

Ophthalmic microsurgical procedures may be complex and high-risk, demanding meticulous skill and expert management under high pressure. A hybrid high impact educational intervention could be designed incorporating advanced simulation-based surgical education, high-pressure training, all immediately linked to a robustly scaffolded live surgical mentorship. This could apply to corneal surgery (penetrating keratoplasty), glaucoma surgery (trabeculectomy, drainage devices), vitreo-retinal surgery (pars-plana vitrectomy), and even cataract surgery (phacoemulsification and paediatric cataract).

## Elements of Educational Intervention with Greatest Impact

While the intervention courses covered all three domains of learning, it was the psychomotor or skills domain which was dominant rather than the affective (or attitudes) and cognitive (knowledge and understanding). Didactic teaching was kept to a minimum, and while the knowledge and understanding gained from lectures and small group discussions may have impacted the final outcomes, it was the skills (psychomotor) and attitudes (affective) that were most impacted.

The intentionally created calm and collaborative environment enabled participants to feel comfortable and safe. A further important affective aspect was motivation. Self-motivation was emphasised from the very beginning of the courses during the initial introductions. The opening statement of the course was “For this to succeed, you have to want to be a better surgeon”. This motivation to constantly improve was re-emphasised throughout the week. Confidence is key for novice trainees, however over-confidence is counter-productive and may be unsafe. Positive feedback was given during initial practice, and during complete procedures. Assurance was given when surgical errors were made, and constructive feedback and reflection addressed these. As Kneebone illustrated, trainees were given permission to fail, in a safe and calm simulation environment. All these facets combined to develop trainees confidence in their surgical skills.

However, the most fundamental elements of the intervention that really made a difference to the final outcomes were within the psychomotor or skills domain of learning. Once trainees saw for themselves that their surgical skills were rapidly improving, their confidence grew, their attitude towards sustained deliberate practice benefitted, and they became more motivated to improve even further.

Initial patient instruction in basic microsurgical skills, and procedure specific techniques was beneficial; however once participants were advanced beginners, it was sustained deliberate practice which had the greatest impact on skill acquisition and maintenance. What was perhaps the most profound was the effect of reflective learning. The digital classroom afforded the ability to record a procedure and watch it immediately, self-assessing against the Sim-OSSCAR and providing reflexive commentary about what went well and what could

have been improved. Repeating this process drove competency scores on an ever upward trajectory, and strengthened confidence even more.

Constructivist learning theory involves a process of individual transformation. People actively construct their knowledge, while recognising prior experiences.<sup>97</sup> However, learning does not take place in isolation. At numerous occasions during the courses, a collaborative learning was adopted whereby two participants worked together to learn and practice. This near-peer teaching, increasingly becoming more recognised as a valuable teaching and learning method in medical education, was especially valuable when a participant was struggling with a particularly challenging step of the surgical procedure.

## Limitations

There are numerous limitations to this work, some of which have been discussed in chapters 9 and 10 (pages 136-146 and 147-157).

Both the OLIMPICS and GLASS trials aimed to evaluate the effect of intense simulation-based surgical education on competence, confidence, and patient-related outcomes. The primary outcome measure was surgical competence. The goal of a simulation-based surgical education intervention is to enable the participant to become a better surgeon. This predictive validity is key, describing whether the simulation intervention leads to improved performance in a live operating theatre. It would seem obvious and intuitive that the live surgical performance should be the primary outcome measure of the SOS trials.

Participants were followed up for one year, and a further 3 months following the control group training interventions. The timing of the primary outcome measure was defined by the central question of this thesis. Does intense simulation-based surgical education lead to a rapid increase in surgical competence, or a lasting increase in competence? To answer the question, surgical competence assessments were made at different time points: on the final day of the training course, at 3-months, 12-months and again 3-months following the control group training intervention. A main focus of this thesis is the efficiency of intense simulation-based surgical education. Training opportunities and resources are limited, especially in sub-Saharan Africa where there are only 2.5 ophthalmologists per million population, against a global average of 32 per million.<sup>9</sup> The primary outcome measure for the SOS trials was therefore the initial change in competence at 3-months, rather than the immediate (final day of the training course) or longer term (12-month) impact.

An initial potential limitation is the choice of primary outcome measure of both SOS trials. This was the mean global competency assessment score at 3-months, using the use of the Sim-OSSCAR<sup>2 3</sup> rather than live surgical competency assessment with the ICO-OSCAR<sup>91 92</sup> as the primary outcome measure. Although the predictive validity of simulation training (the live surgery one-year competency score for the SOS trials) might appear the obvious choice of primary outcome measure, I would argue however that the use of the Sim-OSSCAR score at 3-months is a strength. The simulation environment and use of the validated Sim-OSSCAR affords participants the chance to complete as much of the cataract surgery procedure that

they can without potential harm to patients, whereas live surgery is prone to greater variation that impairs its use for comparative purpose with small samples. All live surgery performed at the 12-month assessment was supervised by a local senior surgeon. At their professional discretion, they could take over surgery at any time, and for that part of the procedure the trainee would score zero on the live ICO-OSCAR rubric. The live surgical competency scores are therefore more complex to interpret. They are based on the variable take-over threshold of different senior surgeons; the co-morbidity, risk-stratification and complexity of a particular case; the confidence level of an individual trainee; and other factors. Appendices 3c and 3d (pages 267 to 270) illustrate the live surgery ICO-OSCARs. Each rubric uses a modified Dreyfus scale of expertise: novice, beginner, advanced beginner and competent, with points being given for each step of the procedure or global competency indices as 2, 3, 4 and 5 respectively. However, if a step is not performed by the trainee or performed by the preceptor, a score of zero is given. This is a critical limitation of the ICO-OSCAR for use as an assessment tool for the primary outcome measure. It has the potential to create an 'on-off' effect whereby if the senior surgeon takes over or any number of reasons, the trainee is simply marked zero for that step. To overcome this variability in scores, much larger numbers of live surgery assessments would need to be conducted. Sample size calculations indicated that a minimum of ten live SICS surgery procedures would need to be assessed, rather than three. The cost of funding ten live surgeries for 50 participants was a potential £20,000 to £30,000. This may have been surmountable, and even desirable to offer funding for, however it was not known before the OLIMPICS trial whether all 50 participants would be able to perform live cataract surgery in significant numbers. In SSA, the median number of cataract surgeries performed by trainee ophthalmologists in the first two years of training was zero.<sup>1</sup> Participants in the OLIMPICS trial were in their first two years of training. While live surgical performance was indeed a key outcome measure, there were concerns shared by the trial steering committee and research ethics review committees that there would be significant data missing due to challenges in providing live surgical assessment for more junior trainees. There are valid concerns in live surgical training opportunities and assessments impacted by election-related civil unrest, an outbreak of ebolavirus, university staff strikes, junior doctor strikes, and acute shortages of currency and fuel which were among the challenges that trainees and surgeon educators faced during the two-year duration of the SOS trials. These were compounded by not infrequent electricity outages which bring live surgery to an abrupt halt for hours or even days. A China-OLIMPICS trial is planned, as is a UK-based multi-centre

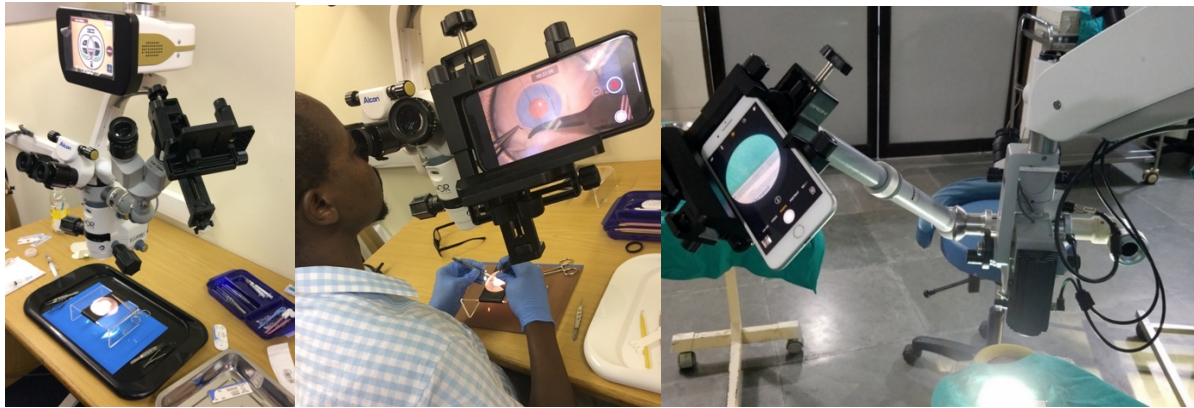


GLASS trial for which both have a primary outcome measure of live surgery competence in a standardised, controlled setting. However, it was an accepted limitation of the OLIMPICS trial that the primary outcome measure was the simulation surgical competency assessment. A systematic review of simulation-based surgical training and assessment in ophthalmology included 118 studies, of which only 2 investigated transfer of skills to the operating theatre.<sup>56</sup>

Other live surgical assessment tools were considered. These are discussed on page 37 of this thesis. However, they were developed for phacoemulsification cataract surgery, and not SICS or glaucoma surgery. The ICO-OSCAR, despite its limitations in the setting of the OLIMPICS trial was therefore selected for live surgical assessment.

The use of the simulation artificial eye afforded a standardization that would not have otherwise been achievable in the live surgical setting. The cataract surgical case mix is itself variable in SSA. Many patients present with mature or hypermature cataracts, and co-morbidities may include corneal scarring, pseudoexfoliation, previous trauma and uveitis. These all impact the complexity of surgery, risk of complications, the supervising surgeon's threshold for taking over surgery, and the trainee's confidence in performing. There is also variability in the location of surgery: university teaching hospital, district hospital, and mobile camp. Instruments and consumables (including surgical blades) also vary in these settings. A further limitation in live surgery assessment was technology. Very few operating theatres in SSA have recording facilities attached to microsurgical operating microscopes. It was only in the very final stages of the SOS trial planning that technology was identified to record live surgery at low-cost. A universal smartphone mount, originally designed for attaching to star-gazing telescopes was used with an iPhone. This Orion SteadyPix Pro (Orion Telescopes, Watsonville, CA, USA) was trialled in Nepal, and used for live surgery assessment recordings in the OLIMPICS trial, however we did not have it in the first months of the trial.

**Figure 27. Orion SteadyPix Pro mount with smartphone**



It would have been impossible for untrained surgeons to be evaluated in a live surgical setting in the GLASS trial, especially where only one of the control trainees performed any live glaucoma surgery. Within this context, it was an accepted limitation that the performance on simulation model eyes may be expected to be better in the intervention group trained with these. However, it was the exact same eyes used in all baseline and subsequent assessments, so control participants would have had some experience with them as well.

Limitations of the study include variability in training opportunities and environment between six training institutions in five countries. Ophthalmology training does vary in terms of curriculum, assessment, faculty, and class size. Training institutions have variable facilities, in terms of clinical and surgical instruments and equipment, pharmaceuticals, and educational facilities. It is an assumption of the SOS trials that this variability would have been offset by the strict randomisation methodology and protocol. Furthermore, analyses involving linear regression models took into account training centre as a fixed effect.

Live surgical training with patients is an important aspect of surgical education. Simulation-based surgical education is not a substitute, but merely an initial boost or addition to this. It is good clinical practice to ensure trainees initially select relatively easy and less complex cases. There is and will be, however, a variability in case-mix. The OLIMPICS trial only collected partial data in terms of case mix, and it appeared similar between intervention and control arms. This is a limitation and a challenge. Every live surgery is different, and it was not possible to standardise the case-complexity and risk-stratification of live supervised cataract surgery performed by participants at the 12-month assessment. Furthermore, a cataract grading

system such as the Lens Opacities Classification System III (LOCS III), Oxford Clinical Cataract Classification and Grading System (OCCCGS), or WHO simplified cataract grading system was not used.<sup>141 142</sup> In retrospect this would have been very good to have; and could have provided a fascinating insight into the case selection, complexity and variation of the total 740 cataract operations performed by both groups in the OLIMPICS trial one-year follow-up period.

The numbers of trabeculectomy procedures in the GLASS study were low, especially in the control group where only one of the participants performed any surgery. Trainee ophthalmologists in the UK have a mean annual trabeculectomy rate of 0.5.<sup>143</sup> Trainees in Australia have a mean annual rate of between 1.1 and 1.6<sup>29 30</sup> Trainees in the USA have completed a mean of 8.6 trabeculectomies by the end of their 3-year residency, however two-thirds of trainees begin operating as primary surgeon performing trabeculectomy only in their final year.<sup>144</sup> The mean of 3.2 trabeculectomies performed by the intervention group in the GLASS trial over the one year follow-up is reasonable. However, this is a limitation and in retrospect perhaps a different ophthalmic surgical procedure could have been chosen for the trial, for example pterygium, corneal trauma surgical repair, evisceration, or lid surgery for trachoma. This is potential material for future work.

Participants in both trials agreed and signed informed consent not to discuss or share any of the educational intervention with control participants. This was agreed by and emphasised by the head of training and local consultant surgeon collaborators. It was furthermore emphasised at the three and twelve-month assessment points. It was stated that if sharing of educational intervention details, or 'contamination bias', was found, then the control participant would lose their opportunity to travel to Cape Town for the training intervention. While this was a strong motivator, and there was no direct evidence of contamination bias found during and after the trials, it is a limitation that trainee participants in either arm of both trials could and would have spoken to each other. However, even if some of the control participants were privy to some of the content or structure of the training intervention, they did not experience any of the instruction, feedback, guided sustained deliberate practice, outcome measurement against the Sim-OSSCARs and reflective learning.

## Surgical education research

A systematic review of trials involving simulation-based education or assessment of ophthalmic surgical skills concluded that studies were heterogeneous, and methodological rigour was inadequate.<sup>56</sup> It concluded that literature on simulation in eye care is inadequate, despite widespread adoption and large investment and expenditure.

There are currently no centralized national or international ophthalmic surgical education research institutions. This is despite supervising consultants and training programmes being held responsible for the quality of care of their trainees. Ophthalmology training programmes are regulated by universities or national regulatory bodies, however there is no uniform or coherent evidence-base or relationship between surgical education research, training, and patient outcomes.

Challenges exist in the design, methodology, conduct and funding of ophthalmic surgical education research. It is an ethical imperative to place patient safety first. Large prospective trials are needed to allow for the inherent variability of individual surgical aptitude. Robust methodology is needed to ensure meaningful levels of evidence are attained.

Within the SOS trials, there were challenges to follow-up and attendance. Trainee surgeons lead busy lives. Examinations, further academic studies, elective training placements as well as personal and family events needed to be worked around within the timeframes of the trial follow-up periods. Visa delays, election violence, general strikes, civil unrest, and an Ebola outbreak also came into consideration. The logistics of conducting two separate RCTs involving 100 trainees in 5 countries, with a matrix of training and assessment timetables, around individual and national dynamics, were challenging.

## Further Research

### *From current data in the SOS Trials:*

Both SOS trials had two independent masked graders. The total scores (out of 40 for the Sim-OSSCARs) were used in the primary and secondary outcome measures. We have 1,500 surgical videos graded, and within this large data set are grading for individual steps. Which steps of surgery are most impacted by intense simulation-based surgical education and sustained-deliberate practice? In the OLIMPICS trials for SICS, is it: scleral tunnel or the capsulotomy? In the GLASS trial for trabeculectomy, is it the steps of scleral flap formation, or the placement of flap sutures, or conjunctival sutures? Further detailed analysis is needed.

Non-technical skills for surgeons (NOTTS) is a behaviour rating system (Appendix 5c). It has been validated for observation and assessment of 4 categories of a surgeon's non-technical skill: situational awareness, decision making, communication and teamwork, and leadership.<sup>145</sup> It became very clear in the early stages of the OLIMPICS trial recruitment that it was impractical to evaluate NOTSS ratings, as many of the trainees were either new to a programme, or the head of training had not directly worked with the participant.

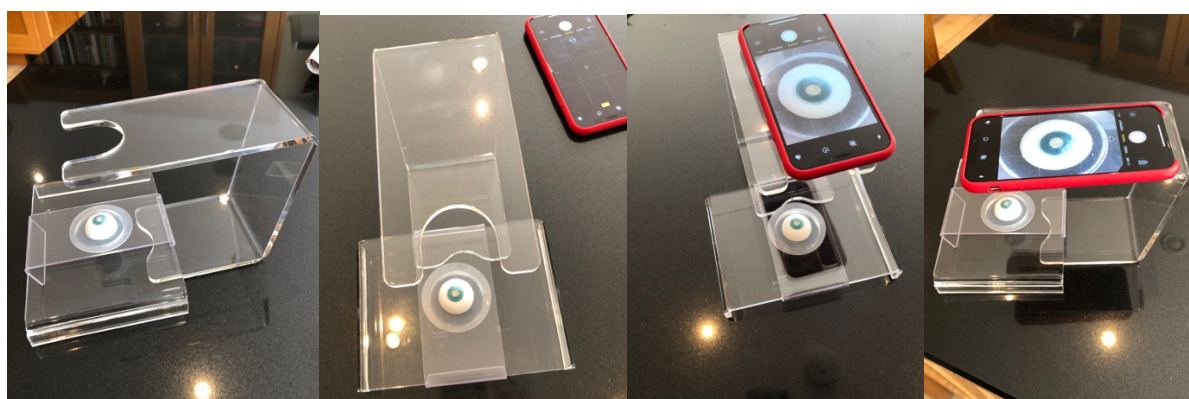
There is a large set of qualitative data from both the OLIMPICS and GLASS trials. Sixty-five interview were conducted with randomly assigned participants at different time-points (Appendix 5a). These have been transcribed, however have not yet been thematised. Further qualitative data were obtained during the self-reported confidence assessments (Appendix 5b). This was in the format of short open-ended questions relating to the basis of confidence in surgical skills. All participants were assessed for confidence at baseline, 3-months and 12-months. Further qualitative research and analysis is needed to inform our understanding of the perceptions of surgical training, motivations, and change in surgical confidence.



*Further research should be explored well beyond the current data sets of the SOS Trials:*

1. All training intervention courses in both SOS trials were conducted by the PI. It will be important to evaluate the effect of locally conducted courses on surgical competence, confidence and short-term patient surgical numbers and outcomes. Research should be undertaken into the acceptability of locally established and run simulation courses. For sustainability, further research could be undertaken in the cost-utility and cost-effectiveness of locally established simulation training units.
2. Prior to the coronavirus pandemic, we had been exploring research ideas around remote set-up, remotely conducted training-the-trainers and surgical education courses, and mentoring. Distinct from tele-medicine, this tele-simulation-surgical-education, or 'Tele-Sim-Ed', is now an area for pressing development, evaluation and research. Perhaps 'WebLab' would be an appropriate term.
3. Leading on from Tele-Sim-Ed or 'WebLab', is research into the impact of self-directed sustained deliberate practice, or perfect targeted practice, homework (Figure 28). The critical hours spent engaging in sustained-deliberate practice need not all be in a relatively expensive simulation surgery training unit. With relatively inexpensive equipment, they could be conducted at home. Video recordings of simulation surgical procedures could be uploaded, and feedback provided remotely by a mentor surgeon.

**Figure 28.      Prototype artificial eye and phone holder for mobile SDP [Phillips Studio, UK]**



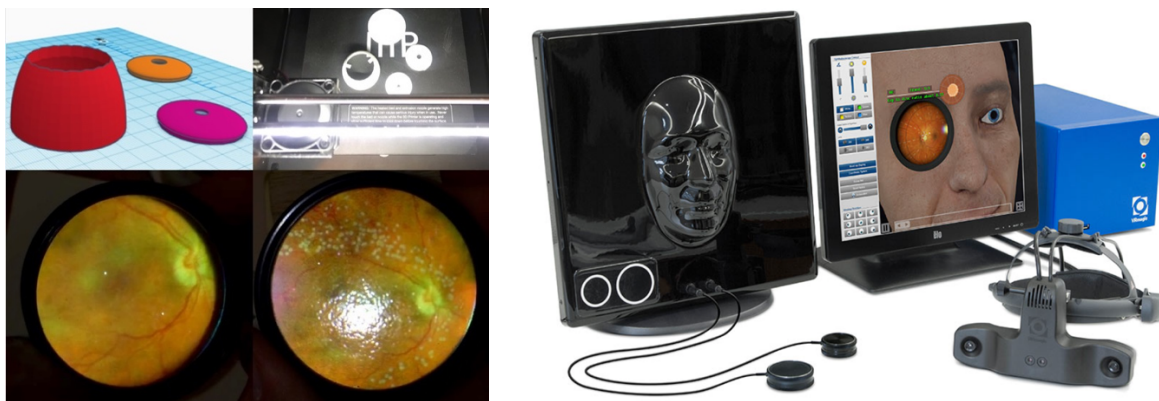
4. Aside from research into the different educational approaches, further research could be conducted into the utility of simulation-based surgical education (SBSE) in other important ophthalmic surgical procedures. Most of the available literature on ophthalmic SBSE explores the utility of computerised simulation for phacoemulsification (phaco) cataract surgery<sup>56 61-63 81 84 85</sup> Most included junior

residents, and many were task-specific rather than assessing the entire cataract surgical procedure. There have been no prospective multi-centre RCTs exploring the effect of intense SBSE for phaco versus conventional training alone, and certainly not for ophthalmologists who are experienced in SICS.

Trachoma is the most common infectious cause of avoidable blindness globally. Although there has been a fair amount of research attention into different surgical procedures for the treatment of trachoma trichiasis, there have been no prospective RCTs comparing different surgical educational approaches.

Diabetic retinopathy is the most common cause of blindness in the working-age adult population in the UK, and is an important global health issue. Research could be conducted into the utility of high-tech and low-tech approaches to simulation-based education for pan-retinal photocoagulation laser skills (Figure 29).<sup>146</sup>

**Figure 29. 3D-Printed model for practicing PRP<sup>146</sup>; and Eyesi Indirect Ophthalmoscope Simulator**



Together with a team from Whipps Cross Hospital in London, and Cheltenham Hospital we have validated an assessment rubric and simulation model for training in repair of eyelid trauma. Further study is needed into training approaches for sporadic and relatively rare trauma procedures.

5. It is crucial for ophthalmologists to be equipped and able to deal with surgical complications. Ophthalmic trainees in the UK complete a median of 592 phaco cataract surgeries by the during their 7-year training.<sup>127</sup> Furthermore, 100% feel confident performing independent phaco surgery from their 4<sup>th</sup> year onwards.<sup>130</sup> However, 9% of final year trainees were not confident in performing an anterior

vitrectomy (the technique required to safely manage the most common complication of cataract surgery) independently.<sup>130</sup> Regular team 'fire-drills' have been documented to practice the management of vitreous loss.<sup>147</sup> Mandatory simulation training and competency assessment has been suggested.<sup>148</sup> However, further educational research is needed to explore the impact of simulation training in surgical complications, and translate this into best practice.

6. With further adoption of ophthalmic SBSE across the globe, long-term research is needed to evaluate the broader impact on visual impairment and blindness. Does the wider adoption of a robust and high-quality SBSE approach have a meaningful effect on surgical output, quality of outcomes, complication rates, and the burden of avoidable blindness and MSVI?
7. Much of good clinical and surgical practice is dependent on a multi-disciplinary team. Team 'fire drills' have been described for simulation-based practice of the management of vitreous loss.<sup>147</sup> The feasibility of high-fidelity immersive simulation training for ophthalmic surgical teams has been described.<sup>149</sup> Further exploration of the utility of interprofessional education would be a valuable and important area for future work. Can simulation training in a practice theatre improve flow, efficiency, and output in a high-volume surgical unit? Can interprofessional education in a practice theatre improve patient safety?
8. Hybrid training is a broad term, encompassing a combination of traditional and simulation surgical education curricula and approaches; combined online and in-person (more commonly referred to as a 'blended' approach). Could a hybrid surgical education curriculum be explored to incorporate online self-directed learning, simulation training in a practice theatre, and sequential live surgical education?

This thesis describes the concept, methodology and results of the OLIMPICS and GLASS trials. We could have published the trial papers, and left it there. However, the proof of concept and availability of data and evidence is not a proof of or measure of implementation.

During the last three months of the trials, consultant surgeons from collaborating institutions were invited to Cape Town during training courses to observe, and be trained as trainers. This 'training-the-trainers' (TTT) was the first step of local ownership of the educational model. Appendices 7 and 8 describe the Trainer's manuals for two courses, having been shortened to 3 days for practicality, and as the research assessment components were not required.

Developing simulation surgery training units within university ophthalmology teaching programmes is ongoing. We have since the final training intervention of the GLASS trial begun to set up simulation Surgery Training Centres in Nairobi, Kigali, Mbarara, Lomé, Dar es Salaam, and Dodoma. We are advising and collaborating with centres in Addis Ababa, Maputo, and Yaoundé; and have recently gained funding for four more Surgery Training Centres in Tanzania and Nigeria.

Within South Africa we are working with the College of Ophthalmologists, within the College of Medicine, to aim towards curriculum integration of SBSE into the national training curriculum for ophthalmology.

Whether it be initial advocacy of the use of SBSE, curriculum integration and mandating the approach within training, developing simulation Surgery Training Centres, or TTT; the focus is on locally driven, adapted, owned and conducted ophthalmic simulation surgical training.

With the publication of the OLIMPICS and GLASS trials, availability of chapter 8, appendices 7 and 8, the template and evidence is there to successfully roll out ophthalmic simulation Surgery Training Units in sub-Saharan Africa and beyond. However, how can the approach be successfully adopted and adapted ensuring high quality educational impact? I have been thinking around the central ideas of this thesis for ten years, and have been motivated to make it happen. I personally developed and conducted all the training, most of the fundraising, and developed a network of collaborators and partners. If I were to focus my

efforts elsewhere and remove myself completely from further development, how can this be successfully rolled out?

We could begin by highlighting the goal: to impact the burden of avoidable blindness by improving the ophthalmic surgical quality and quantity. The next step would be to Develop a “Theory of Change” to strengthen ophthalmic surgery and training to help identify key activities that need to take place, to shape the sustainable components of the ophthalmic simulation-based surgical education.

**Figure 30.** Purposes and values of a Theory of Change



A Theory of Change must by definition involve other stakeholders. It should be the result of an effective participatory process where stakeholders work together to define and refine the model. The partners will then be more likely to take ownership of the result, increasing the likelihood of a project’s success and sustainability.<sup>150</sup> A Theory of Change model is more effective if it is the result of a participatory process that involves as wide a range of stakeholders as practicable. With this in mind, we could continue to engage with collaborators and stakeholders acknowledged in this thesis (page 14), and include other surgeon educators in the region and internationally, and key development, NGO, industry and government ministry stakeholders interested in ophthalmic surgical education. Once an overall strategy and Theory of Change has been developed, it comes down to local ownership. A request has to come from within, rather than an outside stakeholder simply offering a fully functioning ophthalmic surgical skills centre. Demonstrable local ownership would be crucial in terms of teaching faculty or at least one local nominated and interested consultant surgeon trainer.



Further support would be material, in terms of a room and local technical and administrative support. Once this is achieved, fundraising would be needed for capital and initial running costs, however a long-term strategy should be in place for sustainability. Training courses developed in this thesis have been further refined and are hosted on Orbis International Cybersight. They remain open-access, however local training institutions would be encouraged to adapt them if desired to make them bespoke and fit for local purpose. A framework can be developed for the evaluation of locally run training, and the educational and surgical quality impact.

Ultimately it is the quality of the educational outcome that should motivate the local ophthalmic consultant surgeon trainer. If they take the template for new simulation training units, and adopt the educational framework for the training approach, using the available resources with further support from interested stakeholders: the effectiveness of training novice surgeons and educational quality should be maintained and improved long beyond the absence of Will Dean.

## Quality improvement in Healthcare

Trainee ophthalmologist participants in the OLIMPICS trial performed over two-times more cataract surgeries in the year following training, with 3.5 times fewer complications of PCR. We estimate that there are 5,000 new ophthalmologists trained each year globally, however only half are surgically trained.<sup>9 129</sup> The first 25 cataract cases performed by these 2,500 trainees is a total of 62,500 operations. The control group participants had a PCR rate of 26.2%, equivalent to 16,375 patients; the intervention group 7.4%, 4,625 people with PCRs during their cataract operation. Assuming no other confounders, and replicating the simulation-based educational intervention and results of the OLIMPICS trial, there would be around 11,750 fewer people globally having a surgical complication of a PCR. This is a maximum estimate, as supervised trainees have been shown to have lower complication rates with a range of 2.2 to 14.3%.<sup>61 151 152</sup> It is however safe to conclude that the application of a simulation-based surgical education approach to cataract surgery training for novice cataract surgeons worldwide would have a demonstrable impact on patient safety.

## Economics and Sustainability of Surgical Education

The training of ophthalmic surgeons is expensive. A review of surgical training in the COSECSA (College of Surgeons of Eastern Central & Southern Africa) region in 2011 showed a range of costs for tuition per trainee per annum from US\$1,800 to \$11,500.<sup>153</sup> There are direct costs of tuition fees, as well as indirect costs of extra time taken in theatre or clinics. These extra direct and indirect costs make it challenging to make an accurate determination of total costs. Furthermore, tuition fees and living expenses change over time. In 2015 the International Agency for the Prevention of Blindness (IAPB) estimated the total mean cost (fees and living costs) for training an Ophthalmologist in Africa is US\$43,484; with an extra \$28,000 needed for basic equipment to make the new graduate productive.<sup>27</sup>

Cost is an issue with simulation training in ophthalmology. An analysis in the USA showed cost-reductions and savings of tens of thousands of US Dollars' for residency training programmes using ophthalmic surgical simulators<sup>154</sup>. However, the initial capital expenditure of these high-tech computerised simulators may be prohibitive, especially for smaller training programmes.

Ferris *et al* demonstrated that availability of simulation training on the Eyesi for trainees reduced posterior capsule rupture (PCR) cases by 280 annually in the UK. Aside from the implicit benefit in patient safety, it equated to a saving of approximately £560,000 per annum.<sup>61</sup>

In the SOS Trials, we focused on the use of bespoke high-fidelity, low-tech yet affordable and sustainable models of ophthalmic simulation-based surgical education (Figure 22, page 124).

Costs of the study intervention (intense simulation-based surgical training) will be assessed in terms of capital costs, instruments, consumables, educational materials, time (faculty time, and trainees' time away from work), and incidental costs (local transport, accommodation etc.). This could be added to a more detailed incremental cost effectiveness analysis.

Cost, fidelity and educational impact are often intertwined. High-cost and high-tech does not necessarily mean high fidelity. The Eyesi simulator has been validated for the CCC step of phaco cataract surgery, however it is not possible to perform corneal incisions to any degree

of fidelity. Computer and virtual reality simulators in ophthalmic surgical education play a very important role, however it is easy to be immediately seduced by them. The mere presence of a simulator does not necessarily translate to making a trainee a better surgeon. As discussed previously in this thesis (Chapters 9 and 10, and Discussion pages 196-204), it is an entire educational package underpinned by sound educational theory, and informed by robust research that ensures the intended impact of ophthalmic simulation-based surgical education.

The conduct of the educational intervention within both SOS trials is unsustainable. Flying 100 trainees to Cape Town for a 5-day residential course was necessary for standardisation of the training intervention provided. The total travel carbon footprint of around 82 tonnes of CO<sub>2</sub>, led to over 2,600 trees being planted (Ripple Africa, UK Charity number 1103256).



What is needed is locally-conducted simulation-based surgical education, within ophthalmology training programmes.

## Advocacy

High-tech computerised and full-immersion virtual reality models are attractive. They present well at international conferences, and appear to be a magical answer to the challenges of surgical education. What has been described in this thesis is rather an educational-theory underpinned approach to low-tech high-fidelity and sustainable low-cost simulation-based surgical education. Although evidence and data informing the utility and effect of this training approach, advocacy is needed. Computer and virtual reality simulators in ophthalmic surgical education play a very important role, however it is easy to be immediately seduced by them. The mere presence of a simulator does not necessarily translate to making a trainee a better surgeon. As discussed, it is the comprehensive educational package informed by sound educational theory, and robust research that ensures the intended impact of ophthalmic simulation-based surgical education.

Advocacy on a very local level, where the increase in a trainee's surgical competence prior to any live surgical education with patients can be witnessed by a trainer. The benefits of a rapid and sustained increase in competence using simulation should be explicit. Advocacy may however be needed on a wider scale, informing government health and education departments to encourage investment into the approach.

**Figure 31. HRH The Countess of Wessex; and French Prime Minister, Jean-Marc Ayrault**





## Global Adoption

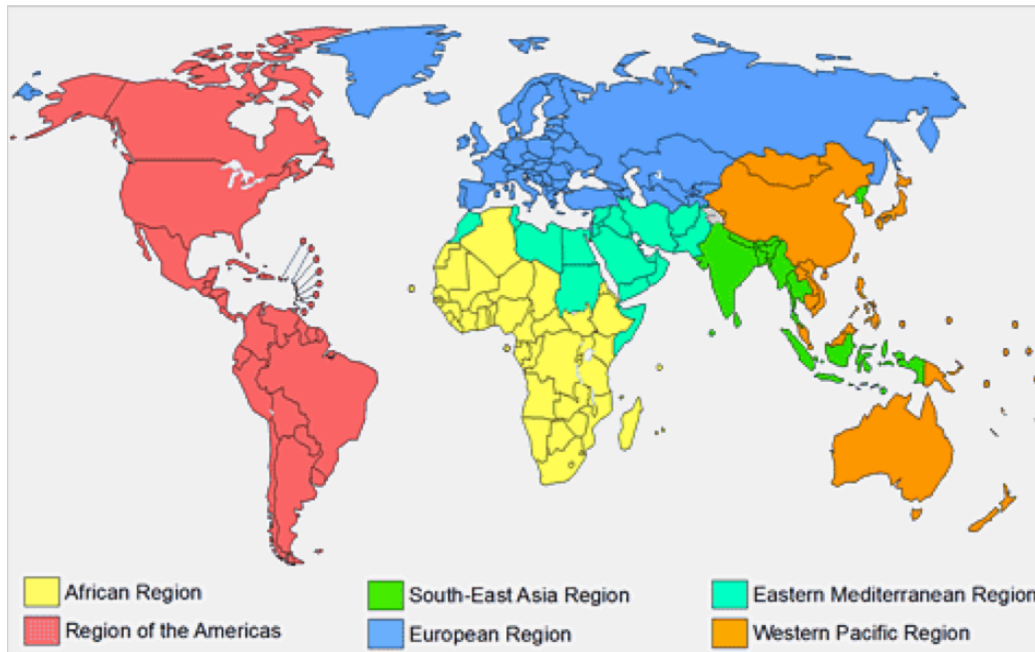
Ophthalmic simulation-based surgical education has been developed and adopted in many parts of the world. Until 5 years ago, the evidence for investment and adoption was sparse and overall evidence for the use of simulation-based training or assessment in ophthalmology was deemed poor.<sup>56</sup> This is changing.

Broad-based ophthalmic surgical education networks and knowledge sharing platforms are well developed. These include the Royal College of Ophthalmology surgical training faculty, the US American Council of Graduate Medical Education and American Academy of Ophthalmology surgical education faculty, among many others. Sub-speciality specific surgical education networks have existed for decades. These include international societies of cataract and refractive surgery, oculo-plastic, glaucoma, paediatrics and strabismus, vitreo-retinal and all others.

Ophthalmic simulation surgical education networks and platforms exist, however not uniformly. These include the Ophthalmic simulation forum<sup>155 156</sup>, the website [www.simulatedocularsurgery.com](http://www.simulatedocularsurgery.com), and the Ophthalmic Surgical Education and Training (OphSET) at the Johns Hopkins Wilmer Eye Institute in Baltimore, USA.<sup>157</sup>

Would it be feasible and useful to aim to form a Global ophthalmology surgical training network (GOSTN)? Is an Ophthalmic Surgical Education Consortium (OSEC) a valid proposal? This Ophthalmic Surgical education and training network (OphSET-NET) could share ideas, evidence, practice and initiatives in ophthalmic surgical education. A consortium could also perhaps better focus efforts to attain funding and support for efforts to fully adopt ophthalmic simulation-based surgical education (SBSE) within training programmes. Subsequent to the SOS trials, and collaboration and partnerships developed therein, we are planning a programme of adoption of ophthalmic SBSE in the WHO Africa Region, Western Pacific Region, and beyond if requested (Figure 32).

**Figure 32. World Health Organisation Member State Regions**



[<http://origin.who.int/about/regions/en/>]

Among the over 115,000 surgical ophthalmologists globally, many thousand teach surgery to future generations of ophthalmic surgeons. Thousands of these will have further educational experience, training and qualifications. These ophthalmic ‘surgeon-educators’ share a wealth of knowledge and expertise. Could a coherent, coordinated, shared, locally-adaptable, educational-theory and educational-evidence underpinned ophthalmic surgical education strategy be developed to lead the way (Figure 33)?

**Figure 33. Strategizing Ophthalmic Simulation-based Surgical Education**

People			Knowledge			Means		
Patients	Trainees	Trainers	Experience	Evidence	Evaluation	Educational	Instruments	Advocacy

Finally, as much as we might talk about the millions blind in the world and the two hundred-thousand ophthalmologists globally; surgery and surgical education is an individual experience. Blindness is an individual experience. Perhaps the best approach would be to

simply add to the discussion, increase the evidence-base, and engage in further educational research.

You cannot save the world, you cannot save a region, but you can focus on the patient, the person and family in front of you to ensure they have the best chances of blindness prevention. A consortium or forum will not per-se be the solution. Microsurgical ophthalmic education is such a dynamic yet razor-focused, complex yet utterly explicit and clear, team-based and yet completely individual landscape; that perhaps the best we can hope for is simply sharing the evidence and experiences we have, in the hope that Mr Luka's grandchildren will have the expert eye surgical care they deserve when they need it.

Andragogy refers to the principles and methods used in adult education.<sup>135</sup> One of the key assumptions and principles of adult learning is that of self-concept, and a more self-directed learning. I believe this to be true not only of adult learners, but also of the ophthalmic surgeons who engage in teaching surgery. Ophthalmic surgeon-educators across the globe possess self-determination of their surgical education approach. The evidence, knowledge and means are there. It remains to be seen if this translates into a robust and sustainable adoption of simulation-based surgical education.

If we as surgeon educators are to sustain a healthy and happy 35-year career with reduced incidence of systemic hypertension and gastric ulcers, we owe it to ourselves to enable trainees to attain a benchmarked level of competence before being allowed to operate under supervision in theatre. If we want our and future trainees to learn in a calm and enabling environment, grow in confidence and competence, we must enable them engage in deliberate practice away from patients. If we as healthcare professionals are to protect our patients from harm, the cornerstone of good clinical practice and the Hippocratic oath, we have an ethical imperative to improve the quality of surgical education and reduce initial complication rates in trainees' initial learning curves. We owe this to ourselves, our trainees, our patients. We owe this to Mr Luka.

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## 13. Appendices

- Appendix 1 Informed Consent Forms & Participant Information Sheets
- Appendix 2 Budget
- Appendix 3 Sim-OSSCARs and OSCAR
- Appendix 4 Trainee Survey Questionnaire
- Appendix 5 Semi-structured Interview, Confidence Scoring, NOTTS
- Appendix 6 Patient Consent to Clinical Photography Forms
- Appendix 7 OLIMPICS Cybersight SICS Course Trainer's Manual
- Appendix 8 GLASS Cybersight Trabeculectomy Course Trainer's Manual



## Appendix 1a Participant Consent Form (OLIMPICS Trial)

The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East Africa. OLIMPICS Trial (Ophthalmic Learning & Improvement Initiative in Cataract Surgery)

International Centre for Eye Health, London School of Hygiene & Tropical Medicine, UK  
University of Cape Town, South Africa  
Mbarara University of Science and Technology, Uganda  
University of Nairobi, Kenya  
Kilimanjaro Christian Medical Centre, Tanzania  
Makerere University, Uganda  
University of Zimbabwe, Harare

I \_\_\_\_\_  
(name) have been invited to participate in a trial of surgical training, involving a five day intense training and education course for cataract surgery in Cape Town, South Africa and ongoing assessment for the following 15 months. I understand there is no fee for the course, and all educational materials are given free of charge. I understand that the course is for my personal educational benefit.

Study Reference Number: 

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Please initial box	
1. I confirm that I have read and understand the participant information sheet dated ..... (version ..... ) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered fully.	<input type="checkbox"/>
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without training or legal rights being affected.	<input type="checkbox"/>
3. I give my permission for anonymised data from this course to be published in peer-reviewed literature as part of broader research into surgical training techniques, including the placement of an anonymized data set in a data repository.	<input type="checkbox"/>
4. I understand that <b>no personal identifiable information</b> will be included in any published output.	<input type="checkbox"/>
5. I understand that interviews, opinions, or recordings of the education and training will only be used for academic purposes.	<input type="checkbox"/>
6. I understand that no formal feedback will be given to any of my colleagues or surgical supervisors	<input type="checkbox"/>
7. I understand that no data will be made available to work/training institutions or be used for any future job selection.	<input type="checkbox"/>
8. I agree to anonymised video recording and assessment at baseline, three / twelve / fifteen months of my surgery	<input type="checkbox"/>
9. I commit to ensuring that <b>all</b> surgical outcome data for patients operated by myself (supervised or other) for SICS, that this data (day 1 VA and complications of PCR) is captured onto a recording sheet (with no patient identifiable data),	<input type="checkbox"/>



and reported for a fifteen-month period (from initial intervention to fifteen months).	
10. I finally understand, agree, and wholly commit to NOT discussing or sharing any of the details in any way with the 'control' group of peers in this study for at least the first three months after the Cape Town training.	<input type="checkbox"/>

Signed \_\_\_\_\_ Date: \_\_\_\_\_

\_\_\_\_\_

Countersigned by Principal Investigator (Dr Will Dean)

Principle Investigator (Africa) / PhD Student: Dr William H Dean FRCOphth MEd MBChB BSc

Principle Investigator (LSHTM): Prof. Matthew Burton PhD FRCOphth

Co-Investigators:

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Dr Juliet Otiti MBChB MMed(Ophth)

Any queries should be directed in the first instance to the Principal Investigator Dr Will Dean:

Will.Dean@lshtm.ac.uk

Phone: UK +44(0)7899 753 953 RSA +27(0)710 701 272

***Please refer to Participant Information Sheet (OLIMPICS Version 1.1)***

## Appendix 1b Participant Consent Form (GLASS Trial)

The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East Africa. GLASS Trial (Glaucoma Simulated Surgery Trial)

International Centre for Eye Health, London School of Hygiene & Tropical Medicine, UK  
University of Cape Town, South Africa  
Mbarara University of Science and Technology, Uganda  
University of Nairobi, Kenya  
Kilimanjaro Christian Medical Centre, Tanzania  
Makerere University, Uganda  
University of Zimbabwe, Harare

I \_\_\_\_\_  
(name) have been invited to participate in a trial of surgical training, involving a five day intense training and education course for cataract surgery in Cape Town, South Africa and ongoing assessment for the following 15 months. I understand there is no fee for the course, and all educational materials are given free of charge. I understand that the course is for my personal educational benefit.

Study Reference Number: 

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Please initial box	
1. I confirm that I have read and understand the participant information sheet dated ..... (version .....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered fully.	<input type="checkbox"/>
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without training or legal rights being affected.	<input type="checkbox"/>
3. I give my permission for anonymised data from this course to be published in peer-reviewed literature as part of broader research into surgical training techniques, including the placement of an anonymized data set in a data repository.	<input type="checkbox"/>
4. I understand that <b>no personal identifiable information</b> will be included in any published output.	<input type="checkbox"/>
5. I understand that interviews, opinions, or recordings of the education and training will only be used for academic purposes.	<input type="checkbox"/>
6. I understand that no formal feedback will be given to any of my colleagues or surgical supervisors	<input type="checkbox"/>
7. I understand that no data will be made available to work/training institutions or be used for any future job selection.	<input type="checkbox"/>
8. I agree to anonymised video recording and assessment at baseline, three / twelve / fifteen months of my surgery	<input type="checkbox"/>
9. I commit to ensuring that <b>all</b> surgical outcome data for patients operated by myself (assisted, performed supervised or other) for trabeculectomy, that this data (baseline and month 3 VA; pre-operative, month 1 and 3 IOP; complications necessitating a return-to-theatre within the first post-operative month; and further topical glaucoma medications needed) is captured onto a	<input type="checkbox"/>

recording sheet (with no patient identifiable data), and reported for a fifteen-month period (from initial intervention to fifteen months)	
10. I finally understand, agree, and wholly commit to NOT discussing or sharing any of the details in any way with the 'control' group of peers in this study for at least the first three months after the Cape Town training.	<input type="checkbox"/>

Signed \_\_\_\_\_ Date: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Countersigned by Principal Investigator (Dr Will Dean)

Principle Investigator (Africa) / PhD Student: Dr William H Dean FRCOphth MEd MBChB BSc

Principle Investigator (LSHTM): Prof. Matthew Burton PhD FRCOphth

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Dr Simon Arunga FCOECSA MMed(Oph) MBChB

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Dr Agrippa Mukome MBChB MMed

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Any queries should be directed in the first instance to the Principal Investigator Dr Will Dean:

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***Please refer to Participant Information Sheet (GLASS Version 1.1)***

## Appendix 1c Participant Information Sheet – SICS Training

The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East Africa. The OLIMPICS Trial (Ophthalmic Learning & Improvement Initiative in Cataract Surgery).

### Participant Information Sheet (OLIMPICS Version 1.1)

International Centre for Eye Health, London School of Hygiene & Tropical Medicine, UK  
Mbarara University of Science and Technology, Uganda  
University of Nairobi, Kenya  
Kilimanjaro Christian Medical Centre, Tanzania  
Makerere University, Uganda  
University of Zimbabwe, Harare  
University of Cape Town, South Africa

LSHTM Principal Investigator:	Dr William Dean FRCOphth MEd MBChB BSc
Kenya Principal Investigator:	Dr Stephen Gichuhi PhD
Tanzania Principal Investigator:	Dr William Makupa MD, MMed Ophth, FCOphth ECSA
Uganda Principal Investigators:	Dr Simon Arunga MMed Dr Juliet Oti MMed
Zimbabwe Principal Investigator:	Dr Agrippa Mukome MBChB MMed

### Introduction

You are being invited to take part in an educational-intervention research study. Before you decide whether or not you will be a participant, it is important for you to understand why this research is being done and what it will involve.

Please take time to read the following information carefully. Talk to others about the study, including your training programme Director, if you wish. Ask us if there is anything that is not clear or if you would like more information.

This form is designed to tell you everything you need to think about before you decide whether or not you agree to be in the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the study. The decision to join or not join the study will not cause you to lose any of your usual training opportunities within your MMed Ophthalmology Training Institution course.

You can take a copy of this information sheet, to keep. Do not sign the consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

### **Do you have to take part in this study?**

No. You do not have to take part in this study. Even if you do not take part in this study you will still be offered exactly the same training as per your training institution and curriculum.

## **Study Overview**

### **What is the study about?**

Globally there are an estimated 36 million people who are blind and a further 216 million with significant visual impairment (excluding uncorrected refractive error). Approximately 80% of blindness is preventable or treatable, and 90% of the burden is in Low and Middle Income Countries (LMIC). Sub-Saharan Africa (SSA) has the highest prevalence of blindness of any region at 9% in >50 year olds. Age-related cataract accounts for about a third of this blindness. Small incision cataract surgery (SICS) is a widely accepted, appropriate and affordable procedure with high quality visual outcomes. Glaucoma is the second leading cause of blindness in SSA (8%), and surgical trabeculectomy is often the primary treatment, partly due to the challenges of sustaining medical therapy. Together, cataract and glaucoma account for a half of blindness in SSA, and both require surgical management. However, SSA is the region with the lowest number of ophthalmologists per capita, with about 2.7 per million.

The College of Ophthalmology of Eastern Central and Southern Africa (COECSA) has adopted a competency-based curriculum for ophthalmic trainees in the region. There are a number of learning domains, one of which is surgical skills (SS). Of the seventeen separate surgical skills to be learnt, the very first, 'SS1', is 'Simulation and Wetlab'. This illustrates the importance placed within COECSA on the use of simulation in surgical training. It has been acknowledged however that the curriculum-integration of simulation is only in its infancy, as with many ophthalmology training programmes around the world. There is no coherent, sustainable, standardised and educationally-underpinned regional training programme employing simulation. Furthermore, there is no robust evidence or significant data testing the efficacy of simulation-based surgical education in cataract and glaucoma surgery.

Of the more than two hundred thousand ophthalmologists in the world, a disproportionately low number are trained and work in sub-Saharan Africa. The shortage of expert eye surgeons in SSA is well documented in the literature. This leads to a number of challenges, including the amount of time is available for training. There is a need to develop innovative, efficient, well-evidenced, and cost-effective strategies for ophthalmic training in the SSA Region, and Globally.

This is a prospective, single-masked randomised controlled education-intervention trials of intense simulation-based surgical education versus current standard training of ophthalmologists-in-training in four East African countries. The aim is to investigate whether simulation-based surgical education improves competence, surgical outcomes, and confidence. All participants will (by the end of the study) receive the educational intervention of 'five-days intense simulation-based training' at the Surgical Training Unit, University of Cape Town. The intervention groups will receive this training at week one; and the matched controls after a period of one year. The 'intervention training' specifically is an five-day intense course of lectures, small-group teaching, practical surgical simulation training, videos, and assessments. This training is in addition to the trainees' normal current standard training, and not designed to replace it.

### **Why have you been chosen?**

You are being invited to join the study because you are an ophthalmologist in training at one of the collaborating Institutions in East Africa, and you may meet all the eligibility criteria.

**How many people are taking part in this trial?**

We plan to recruit 50 trainees in total: 25 for the SICS intervention training arm, and 25 in the standard (control) SICS training arm.

**Procedures****What will we ask you to do?*****Baseline assessment:***

We will ask you some basic questions cataract and cataract surgery. We will ask you about your previous surgical experience.

***Randomisation:***

Immediately after baseline assessment, we will randomise you to either the first SICS “intervention” training group, or the second SICS “control” training group.

***Further Baseline assessment:***

Whether you have been randomised to the first (“Intervention”) or second (“Control”) group, we will show you some of the basics of the procedure of SICS, and the performing of a procedure using simulation (artificial eyes). We will then invite you to perform three simulation SICS procedures, which we will record (these recordings will be anonymised).

***Educational Intervention:***

Once you are allocated to one of the groups, you will receive clear instruction on how the timetable will run. If you are allocated to the first “Intervention” group, then you will be invited to the Surgical Training Unit in Cape Town for an intense five-day simulation-based training course. Your flights, accommodation, meals, training (together with all consumables, instruments, and educational materials) will be provided free of charge. If you are allocated to the second “Control” group, then you will be invited to the Surgical Training Unit in Cape Town for the same intense five-day simulation-based training course (over a period of ten days); only this will take place after a period of one year.

***Follow-up assessments:***

We will revisit you at your Training Institution at 3 and 12, and 15 months after your enrolment to the study. We will invite you to perform three further simulation SICS procedures (which again we will record and anonymise) at 3, 12 and 15 months. We will also, invite you to perform three live SICS surgeries (which again we will record and anonymise). During the period between three to fifteen months (total one year), we will ask you to monitor, record and report all of the outcomes of SICS surgery that you perform in your hospital (in terms of day 1 visual acuity, and incidences of peri-operative complications of posterior capsule rupture).

It is critically important to emphasise that you should ***not share any of the learning, lessons, materials or experiences in any way between colleagues who are in a different “Intervention” or “Control” group*** for at least the first three months (after the first ‘Intervention’ group’s training in Cape Town). If you feel this will not be possible, then please to tell us, and we will work with you to try to make this possible or if necessary to exclude you from this study. It is also important to emphasise that if sharing of the education between



the first “Intervention” or second “Control” is found, then both individuals will be excluded from the study, and the second “control” individual would forfeit their simulation training course in Cape Town at year one. This is really important for the integrity of the trial.

### **What is the educational intervention that is being tested?**

The surgical education that is being investigated is intense simulation-based surgical training. This involves a comprehensive eight-day course, and subsequent three months of practice back home. No patients are involved in this training. This training is not meant to replace standard training, but to augment it.

### **Benefits**

#### **What benefits are there to taking part in the study?**

You will be offered free simulation-based surgical training in Cape Town. This will be followed up with three months of practice and feedback (remotely via internet) at your normal place of work. All of this training, and the expenses involved will be offered free of charge. No study has been done to investigate the efficacy of simulated ophthalmic surgical education for SICS to this level. You will be helping to answer this question.

### **Risks**

#### **What are the risks of taking part?**

There are very low risks associated with participating in this study. You will be away from normal work and training for one week in Cape Town, South Africa. You will have a colleague who is in the same stage of training, with whom you will not be able to share (initially for at least three months) the learning from this educational intervention. There is a danger that if you are in the “Intervention” group, and you do share some or any of the learning from this course with your matched “Control” colleague, that they will forfeit their training in Cape Town (at year one).

There is however no risk that this training will affect, or reflect on, your current training course marks, future employment, or be reported to your training programme Director.

#### **What will happen to the assessment recordings, interviews, feedback, and surgical outcomes data I give?**

The video recordings will be made using the same blue latex-free gloves for all participants, using the same instruments, and the same standard recording equipment. They will also be anonymised so that none of your personal information will be identifiable. These recordings will be stored on an encrypted hard drive in Cape Town and London. Interviews will be recorded and transcribed, anonymised, and thematised: again, no personal identifiable information will be kept. Surgical outcomes of your SICS procedures that you record during the one year period will need to be documented in such a way so they do not include any patient-identifying information. Once this data is reported, none of your personal related information will be made available. Summarised, anonymised data will be including the placement of an anonymized data set in a data repository.

#### **Are there any other alternative educational interventions available?**

There is growing evidence that simulation-based surgical education is a valid way to augment surgical training. It is envisaged that in years to come, there will be further local, national, and regional opportunities to engage in this.

### **Withdrawal from the Study**

You have the right to leave a study at any time without penalty. The researchers and sponsor also have the right to stop your participation in this study without your consent if, for example:

- They believe there has been ‘contamination’ between “Intervention” and “Control” individuals
- You were not to agree to any future changes that may be made in the study plan

### **New Information**

#### **What will we do if we find if one educational-intervention is better than the other?**

If we find that intense simulation-based surgical training is better than none, we will publish this finding and envisage that it will lead to further funding for such training.

### **Payment**

You will not be offered payment for being in this study.

### **Costs**

There will be no costs to you for participating in this study. You will not be charged for any of the research activities. All transport, accommodation, meals, and materials will be provided free of charge. You will not receive any additional payments or per diems for participating, beyond your normal stipend or salary from your training unit.

### **Confidentiality**

#### **What will happen to the records/interview, and videos we keep of your (simulation) operations?**

All the information and videos we collect will be kept confidential. It will be kept securely and only the primary investigator, or expert markers will have access to it. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might identify you will not appear when we present this study or publish its results. No information from this study will be placed into your ophthalmology training record.

### **In Case of Complaint**

#### **What if there is a problem?**

Any complaint about the way you have been treated during the study will be addressed. Please use the addresses below to contact the study coordinators.

### **Who sponsored this study?**

The study is sponsored through the London School of Hygiene and Tropical Medicine.

### **Who has reviewed the study?**

This study was reviewed by the British Council for the Prevention of Blindness, the Ulverscroft Foundation (Leicester, UK), CBM-USA, the LSHTM Ethics Review Committee, the University of Cape Town ethics committee, the Nairobi University Ethics Committee, the College of Medicine Malawi Ethics Committee, The KCMC and Tanzania Ethics Committees, and the MURHEC and Makerere Universities Ethics Committees.

**Who is doing this study?**

The study will be coordinated by Dr Will Dean who is an ophthalmology consultant who has a MEd (Masters in Education) in Surgical Education at Imperial College, London; a Fellowship of the Royal College of Ophthalmology (UK); over 15 years of experience in ophthalmology and training ophthalmologists in Malawi, Southern Africa and the UK. The recruitment, assessments, and training will be conducted by him, and a small team of specialist ophthalmology consultants.

**Contact Information**

**If you have any questions please ask us:**

- if you have any questions about this study or your part in it, or
- if you have questions, concerns or complaints about the research

Dr. Will Dean at +44 7899 753 953 or +27 710 701 272 or [will.dean@lshtm.ac.uk](mailto:will.dean@lshtm.ac.uk)

Prof. Matthew Burton at +44 20 7636 8636 or [matthew.burton@lshtm.ac.uk](mailto:matthew.burton@lshtm.ac.uk)

**You will be given a copy of the information sheet.  
Thank you for considering taking the time to read this sheet.**

## Appendix 1d Participant Information Sheet – Trabeculectomy

The Simulated Ocular Surgery (SOS) Trials: Randomised-Controlled Trials Comparing Intense Simulation-Based Surgical Education for Cataract and Glaucoma Surgery to Conventional Training Alone in East Africa. The GLASS Trial (Glaucoma Simulated Surgery Trial)

### Participant Information Sheet (GLASS Version 1.1)

International Centre for Eye Health, London School of Hygiene & Tropical Medicine, UK  
Mbarara University of Science and Technology, Uganda  
University of Nairobi, Kenya  
Kilimanjaro Christian Medical Centre, Tanzania  
Makerere University, Uganda  
University of Zimbabwe, Harare  
University of Cape Town, South Africa

LSHTM Principal Investigator:	Dr William Dean FRCOphth MEd MBChB BSc
Kenya Principal Investigator:	Dr Stephen Gichuhi PhD
Tanzania Principal Investigator:	Dr William Makupa MD, MMed Ophth, FCOphth ECSA
Uganda Principal Investigators:	Dr Simon Arunga MMed Dr Juliet Otiti MMed
Zimbabwe Principal Investigator:	Dr Agrippa Mukome MBChB MMed

### Introduction

You are being invited to take part in an educational-intervention research study. Before you decide whether or not you will be a participant, it is important for you to understand why this research is being done and what it will involve.

Please take time to read the following information carefully. Talk to others about the study, including your training programme Director, if you wish. Ask us if there is anything that is not clear or if you would like more information.

This form is designed to tell you everything you need to think about before you decide whether or not you agree to be in the study. It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the study. The decision to join or not join the study will not cause you to lose any of your usual training opportunities within your MMed Ophthalmology Training Institution course.

You can take a copy of this information sheet, to keep. Do not sign the consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

### **Do you have to take part in this study?**

No. You do not have to take part in this study. Even if you do not take part in this study you will still be offered exactly the same training as per your training institution and curriculum.

## **Study Overview**

### **What is the study about?**

Globally there are an estimated 36 million people who are blind and a further 216 million with significant visual impairment (excluding uncorrected refractive error). Approximately 80% of blindness is preventable or treatable, and 90% of the burden is in Low and Middle Income Countries (LMIC). Sub-Saharan Africa (SSA) has the highest prevalence of blindness of any region at 9% in >50 year olds. Age-related cataract accounts for about a third of this blindness. Small incision cataract surgery (SICS) is a widely accepted, appropriate and affordable procedure with high quality visual outcomes. Glaucoma is the second leading cause of blindness globally (8%), and surgical trabeculectomy is often the primary treatment, partly due to the challenges of sustaining medical therapy. Together, cataract and glaucoma account for half of blindness in SSA, and both require surgical management. However, SSA is the region with the lowest number of ophthalmologists per capita, with about 2.7 per million.

The College of Ophthalmology of Eastern Central and Southern Africa (COECSA) has adopted a competency-based curriculum for ophthalmic trainees in the region. There are a number of learning domains, one of which is surgical skills (SS). Of the seventeen separate surgical skills to be learnt, the very first, 'SS1', is 'Simulation and Wetlab'. This illustrates the importance placed within COECSA on the use of simulation in surgical training. It has been acknowledged however that the curriculum-integration of simulation is only in its infancy, as with many ophthalmology training programmes around the world. There is no coherent, sustainable, standardised and educationally-underpinned regional training programme employing simulation. Furthermore, there is no robust evidence or significant data testing the efficacy of simulation-based surgical education in cataract and glaucoma surgery.

Of the more than two hundred thousand ophthalmologists in the world, a disproportionately low amount are trained and work in sub-Saharan Africa. The shortage of expert eye surgeon human resources in SSA is well documented in the literature. This leads to a number of challenges, including the amount of time is available for training. There is a need to develop innovative, efficient, well-evidenced, and cost-effective strategies for ophthalmic training in the SSA Region, and Globally.

This is a prospective, single-masked randomised controlled education-intervention trials of intense simulation-based surgical education versus current standard training of ophthalmologists-in-training in four East African countries. The aim is to investigate whether simulation-based surgical education improves competence, knowledge, surgical outcomes, and confidence. All participants will (by the end of the study) receive the educational intervention of 'five-days intense simulation-based training' at the Surgical Training Unit, University of Cape Town. The intervention groups will receive this training at week one; and the matched controls after a period of one year. The 'intervention training' specifically is an five-day intense course of lectures, small-group teaching, practical surgical simulation training, videos, and assessments. This training is in addition to the trainees' normal current standard training, and not designed to replace it.

### **Why have you been chosen?**

You are being invited to join the study because you are a training ophthalmologist in one of the collaborating Institutions in East Africa, and you may meet all the eligibility criteria.

**How many people are taking part in this trial?**

We plan to recruit 100 trainees in total: 25 for the first SICS training arm, 25 for the first glaucoma surgery training arm; then 25 in the second (control) SICS training arm; and a final 25 (controls) in the second glaucoma surgery training arm. You would not be involved with the cataract surgery training trial.

**Procedures****What will we ask you to do?*****Baseline assessment:***

We will ask you some basic questions glaucoma and glaucoma surgery. We will ask you about your previous surgical experience.

***Randomisation:***

Immediately after baseline assessment, we will randomise you to either the first trabeculectomy “intervention” training group, or the second trabeculectomy “control” training group.

***Further Baseline assessment:***

Whether you have been randomised to the first (“Intervention”) or second (“Control”) group, we will show you some of the basics of the procedure of trabeculectomy, and the performing of a procedure using simulation (artificial eyes). We will then invite you to perform three simulation trabeculectomy procedures, which we will record (these recordings will be anonymised).

***Educational Intervention:***

Once you are allocated to one of the groups, you will receive clear instruction on how the timetable will run. If you are allocated to the first “Intervention” group, then you will be invited to the Surgical Training Unit in Cape Town for an intense five-day simulation-based training course. Your flights, accommodation, meals, training (together with all consumables, instruments, and educational materials) will be provided free of charge. If you are allocated to the second “Control” group, then you will be invited to the Surgical Training Unit in Cape Town for the same intense five day simulation-based training course; only this will occur after a period of one year.

***Follow-up assessments:***

We will revisit you at your Training Institution at 3 and 12, and 15 months after your enrolment to the study. We will invite you to perform three further simulation trabeculectomy procedures (which again we will record and anonymise) at 3, 12 and 15 months. We will also, invite you to perform up to three live trabeculectomy surgeries (which again we will record and anonymise). During the period between three to fifteen months (total one year), we will ask you to monitor, record and report all of the outcomes of trabeculectomy surgery that you perform in your hospital (in terms of: intra-ocular pressure at week 4 and week 12; post-operative Complications (indicating by a return-to-theatre within the first post-operative month); further medical treatments for raised intra-ocular pressure; and week 12 VA (un-corrected & best corrected) compared to Pre-operative VA).



It is critically important to emphasise that you should ***not share any of the learning, lessons, materials or experiences in any way between colleagues who are in a different “Intervention” or “Control” group*** for at least the first three months (after the first ‘Intervention’ group’s training in Cape Town). If you feel this will not be possible, then please to tell us, and we will exclude you from this study. It is also important to emphasise that if sharing of the education between the first “Intervention” or second “Control” is found, then both individuals will be excluded from the study, and the second “control” individual would forfeit their simulation training course in Cape Town at year one.

### **What is the educational intervention that is being tested?**

The surgical education that is being investigated is intense simulation-based surgical training. This involves a comprehensive five-day course, and subsequent three months of practice back home. No patients are involved in this training. This training is not meant to replace standard training, but to augment it.

### **Benefits**

#### **What benefits are there to taking part in the study?**

You will be offered free simulation-based surgical training in Cape Town. This will be followed up with three months of practice and feedback (remotely via internet) at your normal place of work. All of this training, and the expenses involved will be offered free of charge. No study has been done to investigate the efficacy of simulated ophthalmic surgical education for glaucoma surgery to this level. You will be helping to answer this question.

### **Risks**

#### **What are the risks of taking part?**

The risks of taking part in this study are that you will be away from normal work and training for ten days. You will have a colleague who is in the same stage of training, which whom you will not be able to share (initially for at least three months) the learning from this educational intervention. There is a danger that if you are in the “Intervention” group, and you do share some or any of the learning from this course with your matched “Control” colleague, that they will forfeit their training in Cape Town (at year one).

There is however no risk that this training will affect, or reflect on, your current training course marks, future employment, or be reported to your training programme Director.

#### **What will happen to the assessment recordings, interviews, feedback, and surgical outcomes data I give?**

The video recordings will be made using the same blue latex-free gloves for all participants, using the same instruments, and the same standard recording equipment. They will also be anonymised so that none of your personal information will be identifiable. These recordings will be stored on an encrypted hard drive in Cape Town and London. Interviews will be recorded and transcribed, anonymised, and thematised: again, no personal identifiable information will be kept. Surgical outcomes of your trabeculectomy procedures that you record during the one year period will need to be recorded to not include any patient-identifying information. Once this data is reported, none of your personal related information

will be made available. Summarised, anonymised data will be including the placement of an anonymized data set in a data repository.

### **Other Treatment Outside this Study**

#### **Are there any other alternative educational interventions available?**

There is growing evidence that simulation-based surgical education is a valid way to augment surgical training. It is envisaged that in years to come, there will be further local, national, and regional opportunities to engage in this.

### **Withdrawal from the Study**

You have the right to leave a study at any time without penalty. The researchers and sponsor also have the right to stop your participation in this study without your consent if, for example:

- They believe there has been 'contamination' between "Intervention" and "Control" individuals
- You were not to agree to any future changes that may be made in the study plan

### **New Information**

#### **What will we do if we find if one educational-intervention is better than the other?**

If we find that intense simulation-based surgical training is better than none, we will publish this finding and envisage that it will lead to further funding for such training.

### **Payment**

You will not be offered payment for being in this study.

### **Costs**

There will be no costs to you for participating in this study. You will not be charged for any of the research activities. All transport, accommodation, meals, and materials will be provided free of charge.

### **Confidentiality**

#### **What will happen to the records/interview, and videos we keep of your (simulation) operations?**

All the information and videos we collect will be kept confidential. It will be kept securely and only the primary investigator, or expert markers will have access to it. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might identify you will not appear when we present this study or publish its results. No information from this study will be placed into your ophthalmology training record.

### **In Case of Complaint**

#### **What if there is a problem?**

Any complaint about the way you have been treated during the study will be addressed. Please use the addresses below to contact the study coordinators.

**Who sponsored this study?**

The study is sponsored through the London School of Hygiene and Tropical Medicine.

**Who has reviewed the study?**

This study was reviewed by the British Council for the Prevention of Blindness, the Ulverscroft Foundation (Leicester, UK), CBM-USA, the LSHTM Ethics Review Committee, the University of Cape Town ethics committee, the Nairobi University Ethics Committee, the College of Medicine Malawi Ethics Committee, The KCMC and Tanzania Ethics Committees, and the MURHEC and Makerere Universities Ethics Committees.

**Who is doing this study?**

The study will be coordinated by Dr Will Dean who is an ophthalmology consultant, with a specialist interest in glaucoma, who has a MEd (Masters in Education) in Surgical Education at Imperial College, London; a Fellowship of the Royal College of Ophthalmology (UK); over 15 years of experience in ophthalmology in Malawi, Southern Africa and the UK; and is working at LSHTM for a PhD. The recruitment, assessments, and training will be conducted by him, and a small team of specialist ophthalmology consultants.

**Contact Information**

**If you have any questions please ask us:**

- if you have any questions about this study or your part in it, or
- if you have questions, concerns or complaints about the research

Dr. Will Dean at +44 7899 753 953 or +27 710 701 272 or [will.dean@lshtm.ac.uk](mailto:will.dean@lshtm.ac.uk)

Prof. Matthew Burton at +44 20 7636 8636 or [matthew.burton@lshtm.ac.uk](mailto:matthew.burton@lshtm.ac.uk)

**You will be given a copy of the information sheet.  
Thank you for considering taking the time to read this sheet.**

This study was funded by:

- The British Council for the Prevention of Blindness, London, UK  
<http://www.bcpb.org>  
British Council for Prevention of Blindness  
4 Bloomsbury Square  
London  
WC1A 2RP
- Ulverscroft Foundation, Leicester, UK  
<https://www.ulverscroft-foundation.org.uk>  
The Ulverscroft Foundation  
The Green  
Bradgate Road  
Anstey  
Leicester  
LE7 7FU
- CBM-USA, Greenville, SC, USA  
<https://www.cbm.org>  
CBM International  
Stubenwald-Allee 5  
64625 Bensheim  
Germany
- Queen Elizabeth Diamond Jubilee Trust  
<https://www.jubileetribute.org>  
The Queen Elizabeth Diamond Jubilee Trust  
128 Buckingham Palace Road  
London  
SW1W 9SA
- Lavelle Fund for the Blind  
<https://lavellefund.org>  
Lavelle Fund for the Blind, Inc.  
307 West 38th Street, Suite 1905  
New York, NY 10018  
USA
- L'Occitane Foundation  
<https://fondation.loccitane.com>
- Orbis International  
<https://www.orbis.org/en>

Orbis  
520 8th Avenue, 12th Floor  
New York, NY 10018  
USA

- Lions Knysna, South Africa

<https://lionsclubs.co.za/410w/knysna.htm>  
Lions Den  
Trotter Street  
Knysna  
South Africa

Contributions were made by:

- Alcon ZA
- Duckworth & Kent

Central costs were covered, and run through the LSHTM.

Trainee: \_\_\_\_\_ Evaluator: \_\_\_\_\_ Date: \_\_\_\_\_

Ophthalmic Simulated Surgical Competency Assessment Rubric – Sutureless ECCE (OSSCAR-SICS)					
		Novice (score = 0)	Advanced Beginner (score = 1)	Competent (score = 2)	Score (Not done score = 0)
1	<b>Scleral fixation</b>	No scleral fixation; inappropriate place; tissue trauma	Appropriate position of scleral fixation, but needs to re-grip. Mild tissue trauma	Good position of fixation, no need to re-grip, no trauma	
2	<b>Paracentesis</b>	Chamber collapses on performing paracentesis. Inappropriate width, length and location. Pierces anterior capsule on entry.	Inappropriate location, width or length. Anterior chamber almost stable.	Wound of adequate length, width, and correct location.	
3	<b>Viscoelastic insertion</b>	Unsure of when and how much viscoelastic to use. Has difficulty accessing anterior chamber through paracentesis.	Administers viscoelastic at appropriate time, amount, and cannula position.	Viscoelastics administered in appropriate amount, at appropriate time, with cannula tip clear of lens capsule and endothelium.	
4	<b>Scleral incision</b>	Inappropriate location, shape and size; hesitant incision.	Either one of the incision location, shape or size is incorrect.	Good incision location, shape and size. Firm and stable scleral fixation throughout.	
5	<b>Scleral tunnel</b>	Inappropriate tunnel depth, hesitant dissection. Button-hole and/or premature entry.	Able to dissect forward, and understands that tunnel depth is incorrect but unable to correct.	Tunnel constructed at correct place. If inappropriate place, able to rectify.	
6	<b>Sclero-corneal tunnel</b>	Does not extend into clear cornea. Button-hole and/or premature entry.	Does not extend >1mm into clear cornea. Internal tunnel not wider than external.	Extends tunnel into clear cornea >1mm, wider limbal corneal tunnel than at scleral incision.	
7	<b>Corneal entry</b>	Hesitant keratome entry into AC. Significant shallowing of anterior chamber. Require wound extension or suturing.	Entry at mostly right plane. Able to extend but with repeated use of viscoelastic. Internal valve irregular. Require wound extension or suturing.	Fluently enters in right plane. Wound length adequate with no further need for extension. Retains viscoelastic during extension.	
8	<b>Capsulotomy / Capsulorhexis start</b>	Tentative; size and position are inadequate for nucleus density; incorrect capsulotomy position.	Mostly in control, slow initial start. Capsulotomy in correct position.	Correct and smooth start to capsulorhexis. Delicate approach and confident control of cystotome.	
9	<b>Capsulotomy / Capsulorhexis completion</b>	Tentative; size and position are inadequate for nucleus density; incorrect capsulotomy position. Radial tear	Mostly in control, few awkward or repositioning movements. Capsulotomy in correct position. Radial tear corrected.	Adequate size and position for nucleus density, no tears. AC depth throughout the capsulorhexis.	
10	<b>Hydrodissection: Visible fluid wave and free prolapse of one pole of nucleus</b>	Hydrodissection fluid not injected in quantity or place to achieve nucleus rotation or prolapse.	Fluid injected in appropriate location, able to prolapse one pole of nucleus but encounters more than minimal resistance.	Ideally see free fluid wave, adequate for free nuclear hydroprolapse or mechanical prolapse with minimal resistance.	
11	<b>Injection of visco-elastic</b>	Doesn't inject visco-elastic into eye	Injects insufficient visco-elastic. Injects only into PC or AC	Injects adequate visco-elastic into capsule bag behind nucleus, and AC	
12	<b>Prolapse of nucleus partially into AC</b>	Unable to dial nucleus into AC. Hooks anterior or posterior nuclear surface, nucleus rotates in the bag. Iris and corneal touch.	Multiple attempts required to prolapse upper equator of nucleus into AC with more than minimal resistance. No corneal touch.	Prolapse of upper equator with minimal resistance. No damage to pupil and iris.	
13	<b>Nucleus extraction</b>	Damages endothelium, iris or capsule, unable to hold and extract nucleus, movements not coordinated. Pierces posterior capsule.	Removes nucleus after repeated attempts, more than one piece, might need wound extension prior to extraction.	Extracts nucleus with one or two attempts; proper wound size in relation to nuclear density.	
14	<b>IOL insertion</b>	Grips IOL incorrectly, inserts IOL incorrectly, multiple attempts.	Hesitant insertion of IOL, more than one attempt to insert	Inserts IOL into capsular bag efficiently, correctly, and in first attempt	
<b>GLOBAL INDICES</b>					
15	<b>Wound Neutrality and Minimizing Eye Rolling and Corneal Distortion</b>	Nearly constant eye movement and corneal distortion.	Eye usually in primary position, mild corneal distortion folds occur.	The eye is kept in primary position during the surgery. No distortion folds are produced. The length and location of incisions prevents distortion of the cornea.	
16	<b>Eye Positioned Centrally Within Microscope View</b>	Constantly requires repositioning.	Mild fluctuation in pupil position.	The pupil is kept centered during the surgery.	
17	<b>Scleral and Corneal Tissue Handling</b>	Tissue handling is rough and damage occurs.	Tissue handling decent but potential for damage exists.	Tissue is not damaged nor at risk by handling.	
18	<b>Intraocular Spatial Awareness</b>	Instruments often in contact with capsule, iris, corneal endothelium; blunt second instrument not kept in appropriate position.	Rare contact with capsule, iris, endothelium. Often has blunt second hand instrument in appropriate position.	No accidental contact with capsule, iris, corneal endothelium. Blunt, second hand instrument, is kept in appropriate position.	
19	<b>Overall Fluidity of Procedure</b>	Hesitant, frequent starts and stops, not at all fluid.	Occasional inefficient and/or unnecessary manipulations occur	Inefficient and/or unnecessary manipulations are avoided	
20	<b>Overall Speed of Procedure</b>	Case duration more than 15 minutes.	Case duration about 10-15 minutes.	Case duration about 5-10 minutes.	
<b>TOTAL</b>					

Good Points: \_\_\_\_\_

Suggestions for development: \_\_\_\_\_

*Based on the International Council of Ophthalmology (ICO) Ophthalmology Surgical Competency Assessment Rubric-SICS (ICO-OSSCAR-SICS)*



Trainer: \_\_\_\_\_ Evaluator: \_\_\_\_\_ Date: \_\_\_\_\_

Ophthalmic Simulated Surgical Competency Assessment Rubric - Trabeculectomy (Advanced eye)					
		Novice (score = 0)	Advanced Beginner (score = 1)	Competent (score = 2)	Score (Not done score = 0)
1	Globe stabilization	Unable to perform clear corneal traction suture placement.	Is able to place a corneal traction suture with hesitation or multiple attempts, and is able to tape suture to ensure correct globe positioning	Is able to perform a corneal traction suture placement with ease at one attempt, and is able to tape suture efficiently to ensure correct globe positioning.	
2	Conjunctival peritomy	Peritomy in inappropriate place. Jagged edge, tears in conjunctiva	Peritomy of reasonable size, one or two small tears or jagged edges	Peritomy of good size and position. No tears or uneven jagged edges	
3	Scleral incision	Hesitant/multiple attempts required to make scleral partial thickness incision. Inaccurate placement/inadequate depth of scleral incision. Corneal grooves inaccurately placed/too deep.	Scleral partial thickness incision efficiently performed, though hesitant, in correct position, inaccurate/inadequate depth of scleral incision.	Scleral partial thickness incision efficiently performed, in correct position. Correct depth of scleral incision. Corneal grooves accurately placed, correct depth.	
4	Corneal groove to allow buried releasable suture	Corneal grooves inaccurately placed/too deep, or not performed at all	Corneal grooves accurately placed. Slightly too deep or too shallow.	Corneal grooves accurately placed, correct depth.	
5	Paracentesis	Hesitant/multiple attempts required to make paracentesis. Damage to iris/lens from paracentesis incision.	Paracentesis efficiently performed, though hesitant, in correct position, without inadvertent injury to iris/lens.	Paracentesis efficiently performed, without inadvertent injury to iris/lens.	
6	Formation of scleral flap	Unable to form a scleral flap safely without unintended changes in thickness of flap/risk of overly thin flap/risk of entering anterior chamber (AC) too posteriorly.	Able to form a scleral flap safely without unintended changes in thickness of flap/risk of overly thin flap/risk of entering AC too posteriorly, but hesitant, and not efficiently	Able to form a scleral flap safely without unintended changes in thickness of flap/risk of overly thin flap/risk of entering AC too posteriorly, efficiently.	
7	Full thickness corneal incision into AC	Unable to efficiently enter AC	Able to perform a full-thickness corneal incision, though hesitant	Able to make full-thickness corneal incision into AC efficiently, and at first attempt.	
8	Formation of sclerostomy with punch.	Unable to insert Kelly's punch to perform sclerostomy.	Able to use punch to form sclerostomy, though hesitant, with multiple attempts.	Able to use punch efficiently to form a full thickness sclerostomy.	
9	Peripheral iridectomy	Unable to retract iris and perform full thickness iridectomy.	Able to retract iris, but unable to complete full-thickness iridectomy.	Able to retract iris, perform full-thickness iridectomy efficiently, and first attempt on most occasions.	
10	Placement of one fixed suture.	Is unable to place and tie scleral flap fixed suture.	Is able to eventually place and tie fixed flap suture, but inefficient/multiple attempts.	Is able to efficiently place and tie scleral flap suture. Checks IOP before locking suture.	
11	Placement of one releasable scleral flap suture	Is unable to place and tie scleral flap releasable suture.	Is able to eventually place and tie releasable flap suture, but inefficient/multiple attempts. Comes loops of releasable suture not buried in cornea. Failure to reform AC.	Is able to efficiently place and tie releasable suture. Corneal loops of releasable sutures fully buried in cornea via corneal grooves. Prompt, efficient reformation of AC via paracentesis, digital estimation of IOP to ensure not too high	
12	Reformation of AC using BSS via paracentesis, titration of IOP to ensure watertight scleral flap, but IOP not excessively high.	Failure to reform AC, because of too loose, poorly placed releasable sutures. Failure to tighten releasable sutures adequately.	AC successfully reformed, but failure to render scleral flap watertight and/or failure to appreciate that IOP too high (via digital IOP estimation), and need to release IOP via paracentesis.	AC efficiently reformed, scleral flap confirmed to be watertight efficiently, IOP not excessive (efficient estimation of IOP via digital pressure), but if so, IOP reduced via efficient release of aqueous via paracentesis.	
13	Conjunctival suturing	Unable to place and tie conjunctival sutures.	Is able to eventually place and tie conjunctival sutures, but inefficient/multiple attempts	Is able to efficiently place and conjunctival sutures. Places three or more mattress sutures.	
<b>GLOBAL INDICES</b>					
14	Tissue handling	Tissue handling is often unsafe with inadvertent damage, or excessively aggressive or timid.	Tissue handling is safe but sometimes requires multiple attempts to achieve desired manipulation of tissue.	Tissue handling is efficient, fluid and almost always achieves desired tissue manipulation on first attempt.	
15	Surgical field positioned centrally within microscope view	Very limited or delayed repositioning. Surgical field often at periphery of microscope view.	Surgical field occasionally at periphery of microscope view.	Surgical field at centre of microscope view. Adjusts microscope as needed and without delay	
16	Technique of holding suture needle in needle holder	Loads needle in proper direction for a forehand pass but sometimes loads incorrectly for backhand pass. Loads too close or too far from the swaged end of the needle.	Loads needle properly for forehand and backhand needle pass but is inefficient and often requires multiple attempts.	Loads needle properly and efficiently for forehand and backhand needle passes.	
17	Technique of surgical knot tying	Require multiple extra hand maneuvers to make first throw lay flat and/or loosens first throw while attempting to perform the second throw.	Is able to tie a flat surgeon's knot first throw but second and third throws are inefficient. Does not inadvertently loosen the first throw.	Is able to efficiently tie a flat, square surgeon's knot.	
18	Intraocular spatial awareness	Instruments often in inappropriate contact with iris, or cornea	Rare inappropriate contact with iris or cornea	No accidental damage or contact with iris or cornea	
19	Overall fluidity of procedure	Hesitant, frequent starts and stops. Not at all fluid	Occasional inefficient and/or unnecessary movements or manipulations occur	Inefficient and/or unnecessary manipulations are avoided	
20	Overall speed of procedure	Case duration more than 30 minutes	Case duration 20-30 minutes	Case duration under 20 minutes	
<b>TOTAL</b>					

Good Points: \_\_\_\_\_

Suggestions for development: \_\_\_\_\_

Based on the International Council of Ophthalmology (ICO)-Ophthalmology Surgical Competency Assessment Rubric

ICO-Ophthalmology Surgical Competency Assessment Rubric-SICS (ICO-OSCAR: SICS)					
Date _____ Resident _____	Novice (score = 2)	Beginner (score = 3)	Advanced Beginner (score = 4)	Competent (score = 5)	Not done. Done by preceptor (score= 0)
1 <b>Draping</b>	Unable to start draping without help.	Drapes with minimal verbal instruction. Incomplete lash coverage.	Lashes mostly covered, drape at most minimally obstructing view.	Lashes completely covered and clear of incision site, drape not obstructing view.	
2 <b>Scleral access &amp; Cauterization</b>	Unable to successfully access sclera. Cauterization insufficient or excessive both in intensity and localization.	Accesses sclera but with difficulty and hesitation. Cauterization insufficient or excessive in location or intensity.	Achieves good scleral access with mild difficulty. Adequate cauterization.	Precisely and deftly accesses sclera. Appropriate and precise cauterization.	
3 <b>Sclerocorneal Tunnel</b>	Inappropriate incision depth, location, and size, hesitant dissection. Iris prolapse may occur	One of the following correct: incision depth, location or size. Able to dissect forward but not able to perceive depth	Two of the following are correct: incision depth, location or size. Understands that tunnel depth is incorrect but unable to correct.	Good incision depth, location and size. Tunnel constructed at right plane, if inappropriate plane, able to rectify.	
4 <b>Corneal entry</b>	Hesitant keratome entry into AC. Unable to extend the internal valve. Significant shallowing of anterior chamber. Require wound extension or suturing.	Enters into AC but difficulty in extension. Follows a different plane. Entry either anterior or posterior to dissection site. Mild AC shallowing. Require wound extension or suturing.	Entry at right plane. Able to extend but with repeated use of viscoelastic. Internal valve irregular. Require wound extension or suturing.	Fluently enters in right plane. Wound length adequate with no further need for extension. Retains viscoelastic during extension. Self-sealing, provides good access for surgical maneuvering.	
5 <b>Paracentesis &amp; Viscoelastic Insertion</b>	Chamber collapses on performing paracentesis. Inappropriate width, length and location. Pierces anterior capsule on entry. Unsure of when, what type and how much viscoelastic to use. Has difficulty accessing anterior chamber through paracentesis.	Appropriate incision width, location or length. Anterior chamber shallows mildly. Requires minimal instruction. Knows when to use but administers incorrect amount or type of viscoelastic.	Inappropriate location, width or length. Anterior chamber almost stable. Requires no instruction. Administers viscoelastic at appropriate time, amount, type, and cantula position.	Wound of adequate length, width, and correct location. Viscoelastics administered in appropriate amount, at appropriate time, with cantula tip clear of lens capsule and endothelium.	
6 <b>Capsulorhexis: Commencement of Flap &amp; follow-through.</b>	Instruction required, tentative, chases rather than controls rhexis, cortex disruption may occur.	Minimal instruction, occasional loss of control of rhexis, cortex disruption may occur.	In control, few awkward or repositioning movements, no cortex disruption.	Delicate approach and confident control of the rhexis, no cortex disruption.	
7 <b>Capsulorhexis: Formation and Circular Completion</b>	Size and position are inadequate for nucleus density, tear may occur.	Size and position are barely adequate for nucleus density, difficulty achieving circular rhexis, tear may occur.	Size and position are almost exact for nucleus density, shows control, and requires only minimal instruction.	Adequate size and position for nucleus density, no tears, rapid, unaided control of radialization, maintains control of the flap and AC depth throughout the capsulorhexis.	
8 <b>Hydrodissection: Visible Fluid Wave and Free prolapse of one pole of nucleus</b>	Hydrodissection fluid not injected in quantity or place to achieve nucleus rotation or prolapse.	Multiple attempts required, able to prolapse nuclear pole after multiple efforts. Manually forces nucleus prolapse before adequate hydrodissection, cheese wiring.	Fluid injected in appropriate location, able to prolapse one pole of nucleus but encounters more than minimal resistance.	Ideally see free fluid wave, adequate for free nuclear hydroprolapse or mechanical prolapse with minimal resistance. Aware of contraindications to hydrodissection.	
9 <b>Prolapse of nucleus completely into AC</b>	Unable to dial nucleus into AC. Hooks anterior or posterior nuclear surface, nucleus rotates in the bag, iris and corneal touch, pupillary constriction, may damage capsule or zonules.	Prolapses nucleus after repeated awkward attempts, needs instruction, churns cortex causing reduced visibility; iris or corneal touch; no damage to capsule or zonules.	Prolapses nucleus into AC with more than minimal resistance. No corneal touch.	Prolapse with minimal resistance. No damage to pupil and iris.	
10 <b>Nucleus extraction</b>	Damages endothelium, iris or capsule, unable to hold and extract nucleus, movements not coordinated.	Movements coordinated but unable to extract nucleus, iris or corneal damage, unable to assess wound size in relation to nuclear density.	Removes nucleus after repeated attempts, more than one piece, might need wound extension prior to extraction.	Extracts nucleus with one or two attempts, proper wound size in relation to nuclear density.	
11 <b>Irrigation and Aspiration Technique With Adequate Removal of Cortex</b>	Great difficulty introducing the aspiration tip under the capsulorhexis border, aspiration hole position not controlled, cannot regulate aspiration flow as needed, cannot peel cortical material adequately, engages capsule or iris with aspiration port.	Moderate difficulty introducing aspiration tip under capsulorhexis and maintaining hole up position, attempts to aspirate without occluding tip, shows poor comprehension of aspiration dynamics, cortical peeling is not well controlled, jerky and slow, capsule potentially compromised. Prolonged attempts result in minimal residual cortical material.	Minimal difficulty introducing the aspiration tip under the capsulorhexis, aspiration hole usually up, cortex will engage for 360 degrees, cortical peeling slow, few technical errors, minimal residual cortical material. Some difficulty in removing sub incisional cortex	Aspiration tip is introduced under the free border of the capsulorhexis in irrigation mode with the aspiration hole up. Aspiration is activated in just enough flow as to occlude the tip, efficiently removes all cortex. The cortical material is peeled gently towards the center of the pupil, tangentially in cases of zonular weakness. No difficulty in removing subincisional cortex	
12 <b>Lens Insertion, Rotation, and Final Position of Intraocular Lens</b>	Unable to insert IOL.	Difficult insertion, manipulation of IOL, rough handling, unstable anterior chamber. Repeated hesitant attempts placing lower haptic in capsule, repeated attempts rotate upper haptic d into place with excessive force.	Insertion and manipulation of IOL accomplished with minimal anterior chamber instability, the lower haptic is placed with some difficulty, upper haptic is rotated with some stress.	Insertion and manipulation of IOL is performed in a deep, and stable anterior chamber and capsular bag, with incision appropriate for implant type. The lower haptic is smoothly placed inside the capsular bag; the upper haptic is rotated or gently bent and inserted into place without exerting excessive stress to the capsulorhexis or the zonule fibers.	
13 <b>Wound Closure (including Suturing, Hydration, and Checking Security as Required)</b>	If suturing is needed, instruction is required and stitches are placed in an awkward, slow fashion with much difficulty, assignation, best needles, incomplete suture rotation and wound leakage may result, unable to remove viscoelastics thoroughly, unable to make incision watertight or does not check wound for seal. Improper final IOP.	If suturing is needed, stitches are placed with some difficulty, resuturing may be needed, questionable wound closure with probable assignation, instruction may be needed, questionable whether all viscoelastics are thoroughly removed. Extra maneuvers are required to make the incision water tight at the end of the surgery. May have improper IOP.	If suturing is needed, stitches are placed with minimal difficulty tight enough to maintain the wound closed, may have slight assignation, viscoelastics are adequately removed after this step with some difficulty. The incision is checked and is water tight or needs minimal adjustment at the end of the surgery. May have improper IOP.	If suturing is needed, stitches are placed tight enough to maintain the wound closed, but not too tight as to induce assignation, viscoelastics are thoroughly removed after this step, the incision is checked and is water tight at the end of the surgery. Proper final IOP.	
14 <b>Global Indices Wound Neutrality and Minimizing Eye Rolling and Corneal Distortion</b>	Nearly constant eye movement and corneal distortion.	Eye often not in primary position, frequent distortion folds.	Eye usually in primary position, mild corneal distortion folds occur.	The eye is kept in primary position during the surgery. No distortion folds are produced. The length and location of incisions prevents distortion of the cornea.	
15 <b>Eye Positioned Centrally Within Microscope View</b>	Constantly requires repositioning.	Occasional repositioning required.	Mild fluctuation in pupil position.	The pupil is kept centered during the surgery.	
16 <b>Conjunctival and Corneal Tissue Handling</b>	Tissue handling is rough and damage occurs.	Tissue handling borderline, minimal damage occurs.	Tissue handling decent but potential for damage exists.	Tissue is not damaged nor at risk by handling.	
17 <b>Intraocular Spatial Awareness</b>	Instruments often in contact with capsule, iris, corneal endothelium; blunt second instrument not kept in appropriate position.	Occasional contact with capsule, iris, corneal endothelium; sometimes has blunt second instrument in appropriate position.	Rare contact with capsule, iris, endothelium. Often has blunt second hand instrument in appropriate position.	No accidental contact with capsule, iris, corneal endothelium. Blunt, second hand instrument, is kept in appropriate position.	
18 <b>Iris Protection</b>	Iris constantly at risk, handled roughly.	Iris occasionally at risk. Needs help in deciding when and how to use hooks, ring or other methods of iris protection.	Iris generally well protected. Slight difficulty with iris hooks, ring or other methods of iris protection.	Iris is uninjured. Iris hooks, ring, or other methods are used as needed to protect the iris.	
19 <b>Overall Speed and Fluidity of Procedure</b>	Hesitant, frequent starts and stops, not at all fluid.	Occasional starts and stops, inefficient and unnecessary manipulations common, case duration about 60 minutes.	Occasional inefficient and/or unnecessary manipulations occur, case duration about 45 minutes.	Inefficient and/or unnecessary manipulations are avoided, case duration is appropriate for case difficulty. In general, 30 minutes should be adequate.	
Comments: _____					TOTAL: _____



## Appendix 3d Trabeculectomy ICO-OSCAR

ICO-Ophthalmology Surgical Competency Assessment Rubric-Trabeculectomy (ICO-OSCAR:Trabeculectomy)					
Date _____ Resident: _____	Novice (score = 2)	Beginner (score = 3)	Advanced Beginner (score = 4)	Competent (score = 5)	Not applicable. Done by preceptor (score= 6)
1	<b>Draping:</b> Is unable to prepare or drape the patient using sterile technique without instruction. Unaware of importance of identifying correct eye and procedure prior to draping.	Is able to prepare and drape the patient but sterile technique is inconsistent. Difficulty attaining proper head position.	Is able to consistently prepare and drape patients using sterile technique however steps are performed inefficiently. Attains proper head position.	Is able to consistently and efficiently prepare and drape patients with appropriate head position.	
2	<b>Corneal Traction Suture</b> Is unaware of the use of corneal traction suture for trabeculectomy.	Is familiar with the step but is unaware of its relevance, timing and is unable to perform it.	Is able to state the purpose of the step and is able to perform the step at the appropriate time.	Is able to consistently perform the step with the appropriate length of bite, depth of suture and achieve the desired rotation of the eye for exposure	
3	<b>Conjunctival Incision</b> Is unable to describe limbal or fornix conjunctival incision for trabeculectomy surgery and fornix versus limbus based flaps.	Is able to describe but not able to perform limbal or fornix conjunctival incision for trabeculectomy surgery.	Is able to perform limbal or fornix conjunctival incisions but is inefficient and requires guidance.	Is able to efficiently perform either limbal or fornix conjunctival incision.	
4	<b>Conjunctival Incision &amp; Tenon's dissection</b> Is unable to describe technique of limbal or fornix conjunctival incision for trabeculectomy surgery.	Is able to describe but not able to perform limbal or fornix conjunctival incision for trabeculectomy surgery.	Is able to perform limbal or fornix conjunctival incisions but is inefficient and requires guidance. Has difficulty with judging appropriate length of incision, dissection down to sclera of both conjunctiva and tenon's and the necessary force to apply to the tissue	Is able to efficiently perform either limbal or fornix conjunctival incision. Judges appropriately the length of incision, adequately dissects down to sclera of both conjunctiva and tenon's and handles the tissue with the necessary force	
5	<b>Hemostasis</b> Is unable to describe the need for hemostasis, type of cautery required, appropriate technique. Is unable to perform	Is able to describe the need for hemostasis, type of cautery required, appropriate technique. Has difficulty performing proper technique	Is able to apply cautery but has difficulty with scleral burns, shrinkage of tissue, obtaining hemostasis	Is able to efficiently and precisely apply hemostasis without significant scleral burns, shrinkage of tissues and obtains hemostasis.	
6	<b>Creation of scleral flap</b> Is unable to describe proper technique of scleral flap creation.	Is able to describe dissection technique for flap creation but requires constant guidance to perform the basic steps. Needs reminding to grasp sclera outside flap construction area	Is able to perform basic flap creation but is inefficient and/or creates flaps that are too thin or too deep	Is able to efficiently create flap to the appropriate length and depth without constant guidance	
7	<b>Application of antimetabolite</b> Is unable to accurately describe role of antimetabolites in trabeculectomy, types of antimetabolites and the relative indication for use of each type, safety considerations and use of pledget material	Is able to accurately describe role of antimetabolites in trabeculectomy, types of antimetabolites and the relative indication for use of each type, safety considerations and use of pledget material.	Is able to safely apply antimetabolite onto eye but may have difficulty creating pledget material to appropriate size and thickness. Appropriately discards materials into toxic waste and rinses eye of residual antimetabolite material.	Is able to safely, efficiently and accurately, apply antimetabolite onto eye and has no difficulty creating pledget material to appropriate size and thickness. Appropriately discards materials into toxic waste and rinses eye of residual antimetabolite material.	
8	<b>Paracentesis</b> Inappropriate incision architecture, location, and size.	Leakage and/or iris prolapse with local pressure, provides poor surgical access and puts anterior capsule at risk.	Incision either well-placed or non-leaking but not both.	Incision parallel to iris, self sealing, adequate size, provides good access for surgical maneuvering.	
9	<b>Sclerostomy</b> Is unable to describe the role of sclerostomy and its creation.	Is able to create an entry plane into anterior chamber but has significant difficulty with using Kelly punch. Damages scleral flap. Makes sclerostomies too large or too small for appropriate filtration.	Is able to create an appropriate entry plane into the anterior chamber and is able to use Kelly punch with dexterity. Makes sclerostomies too large or too small for appropriate filtration.	Is able to create an appropriate entry plane into the anterior chamber and is able to use Kelly punch with dexterity. Makes sclerostomies appropriate size for filtration.	
10	<b>Scleral Flap suturing/ anterior chamber reformation</b> Instruction is required and stitches are placed in an awkward, slow fashion with much difficulty, loosens prior placed scleral flap sutures, bends needles, incomplete suture rotation. Cannot cannulate anterior chamber via paracentesis. Improper final IOP.	Stitches are placed with some difficulty, resuturing may be needed, questionable wound closure with probable loosening of prior placed scleral flap sutures, instruction may be needed. Has difficulty cannulating anterior chamber via paracentesis to reform anterior chamber. May have improper IOP.	Stitches are placed with minimal difficulty tight enough to maintain the wound closed but to allow for appropriate filtration, may have slight loosening of prior placed scleral flap sutures. Cannulates anterior chamber with ease to reform anterior chamber. May have improper IOP.	Stitches are placed tight enough to maintain the wound closed but to allow for appropriate filtration. Not too tight as to induce loosening of prior placed scleral flap sutures, Proper final IOP.	
11	<b>Conjunctival closure</b> Is unable to close conjunctiva. Unable to differentiate Tenon's capsule from conjunctiva. Unable to differentiate wing sutures from mattress sutures and running sutures and when appropriate to place.	Is able to perform basic conjunctival closure technique but is inefficient and requires significant guidance. Additional sutures are required. Significant bleb leak at the end of surgery with unstable, shallow anterior chamber. May have buttonhole of conjunctiva.	Is able to safely close conjunctiva with good tissue approximation but is inefficient. May have bleb leak or unstable, shallow anterior chamber.	Is able to safely and efficiently close conjunctiva with good tissue approximation and no bleb leak and stable anterior chamber.	
<b>Global Indices</b>					
12	<b>Maintaining hemostasis</b> Is unable to describe types of cautery, settings for cautery and/or unable to describe electrocautery technique.	Can describe techniques for avoiding and controlling bleeding but requires significant guidance to perform proper cautery to minimize bleeding.	Usually applies proper tissue technique to avoid bleeding and is able to control bleeding using cautery but requires multiple attempts to cauterize and may leave burnt carbon marks.	Consistently applies proper tissue technique to avoid bleeding and is able to efficiently control bleeding using cautery.	

13	<b>Tissue handling</b>	Is excessively aggressive or timid in manipulating tissue. Inadvertent tissue damage occurs to conjunctiva or sclera. Needs direction to grasp sclera outside margins of intended scleral flap.	Aware of techniques for avoidance of tissue damage and bleeding but needs supervision to accomplish proper handling. Needs direction to grasp sclera outside margins of intended scleral flap.	Tissue handling is safe but sometimes requires multiple attempts to achieve desired manipulation of tissue. No direction required to avoid grasping sclera within margins of intended scleral flap.	Tissue handling is efficient, fluid and almost always achieves desired tissue manipulation on first attempt.	
14	<b>Knowledge of instruments</b>	Can only identify instruments in simple terms such as "scissors" and "forceps" but no knowledge of necessary sutures or needle types.	Can identify some but not most of the surgical instruments by proper names and can identify necessary suture sizes and materials but not needle types.	Can identify most but not all of the surgical instruments by proper name and can identify necessary suture sizes/materials but not needle types.	Can identify all surgical instruments by proper names and can identify necessary suture sizes/materials and needle types.	
15	<b>Technique of holding suture needle in needle holder</b>	Frequently loads needle incorrectly.	Loads needle in proper direction for a forehand pass but sometimes loads incorrectly for backhand pass. Loads too close or too far from the swaged end of the needle.	Loads needle properly for forehand and backhand needle pass but is inefficient and often requires multiple attempts.	Loads needle properly and efficiently for forehand and backhand needle passes.	
16	<b>Technique of surgical knot tying</b>	Unable to tie knots.	Require multiple extra hand maneuvers to make first throw lay flat and/or loosens first throw while attempting to perform the second throw.	Is able to tie a flat surgeon's knot first throw but second and third throws are inefficient. Does not inadvertently loosen the first throw.	Is able to efficiently tie a flat, square surgeon's knot.	
17	<b>Communication with surgical team</b>	Does not know role of surgical team members. Lacks confidence or has too much. Does not establish good rapport with team. Unable to request instruments from scrub nurse using proper instrument and suture names and/or instructions to surgical assistant are vague or nonexistent.	Knows role of most surgical team members. Lacks confidence. Has difficulty establishing good rapport with team members. Able to request most instruments from scrub nurse using proper instrument and suture names but instructions to surgical assistant are inadequate to perform procedure safely.	Knows role of each surgical team member. Is somewhat confident and usually treats team with respect. Establishes good working relationship. Able to request most instruments from scrub nurse using proper instrument and suture names in correct order. Instructions to surgical assistant are adequate for a skilled assistant but inadequate for an unskilled assistant.	Knows role of each surgical team member. Is confident and treats team with respect. Establishes good working relationship. Able to efficiently request instruments from scrub nurse using proper names in correct order. Able to consistently give clear instructions to surgical assistant.	
Overall Difficulty of Procedure:    Simple    Intermediate    Difficult Good Points: _____ Suggestions for development: _____ Agreed action: _____						<b>TOTAL SCORE</b>

**General Considerations****Inclusion and Randomisation**

Trainee eye doctors from collaborating training institutions in Eastern and Southern Africa will be assessed for eligibility to either the OLIMPICS, or GLASS trials. Trainees will not be eligible for both. Once eligibility criteria are met, trainee eye doctor participants will be randomised within institutions.

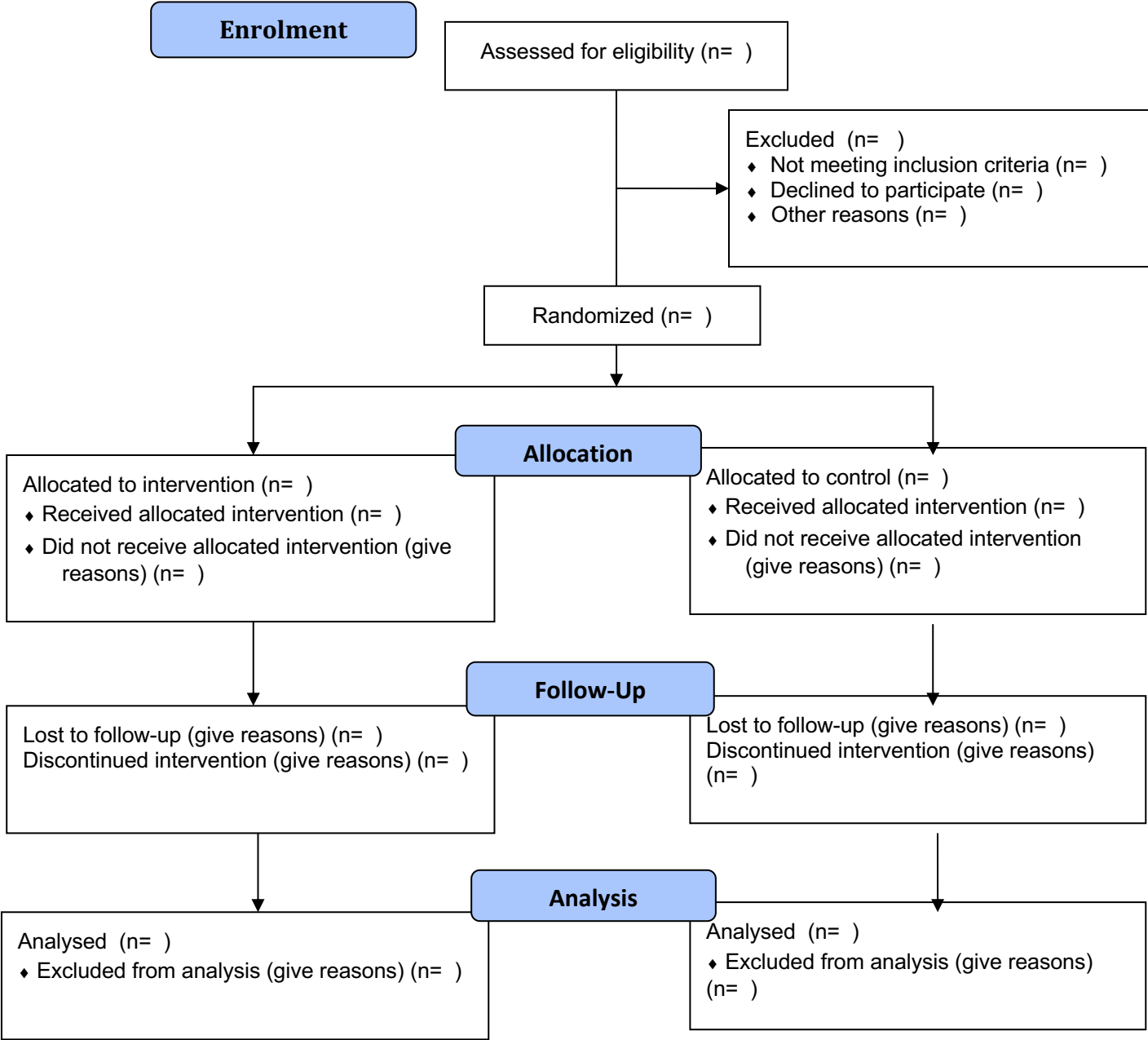
**Intention to Treat**

All participants' data will be analysed according to their randomisation allocation irrespective of whether or not they completed all the follow-up assessments.

**Participant flow**

The following will be shown by trial arm in a **flowchart** following 2010 CONSORT statement.<sup>158</sup> Numbers eligible, excluded for different reasons, consenting to take part, randomized, and who received and did not received the intended treatment. The numbers still in follow-up, censored, defaulting, and permanently lost-to-follow-up respectively at each visit and the final number of participants included in the analyses will also be shown by arm. Reasons for declining to take part, not having the allocated surgery, or discontinuing follow-up and exclusion from analysis will be summarized by arm.

Flow Diagram





## **Data Integrity, Consistency and Range checks**

All surgical videos will be graded by two independent masked expert surgeon assessors. A randomly selected 5% of all videos will be independently marked by the primary investigator. The randomly-selected 5% of videos will be re-marked by each grader after a two-month time period. Inter- and intra-observer will be analysed using kappa correlation.

A collaborator with no prior access to raw video data will be invited to select more than ten random videos from libraries of the OLIMPICS and GLASS trial, and correlate these with the anonymised videos (given a randomly allocated seven-digit number) to ensure data integrity. Further random checks will be made on raw data sheets and computerised data.

For numerical variables, such as Sim-OSSCAR scores and confidence ratings, range checks will be performed using maximum checks. Identified outliers will be double-checked by the primary investigator.

## **Description of baseline data**

The following characteristics of participants at baseline will be tabulated by arm:

- a. Number of participants
- b. Age (years)
- c. Sex, female (%)
- d. Geographic Region / City of collaborating institution: Cape Town / Harare / Kampala / Mbarara / Moshi / Nairobi
- e. Knowledge score (30 question standardised MCQ)
- f. Pre-intervention surgical experience:
  - Total numbers of procedures (performed) (by inclusion criteria should = 0)
  - Parts of procedures performed (number)

The distributions of these variables by treatment arm will be compared, to assess whether there is imbalance at baseline in these potential confounding factors.

## **Primary Analysis**

### **Primary outcome measure**

Mean global competency assessment score (as a percentage), using the ophthalmic simulation surgical competency assessment rubric (Sim-OSSCAR) at three-months post-training intervention. The primary outcome measure is the mean score of three masked assessments of simulation surgical performance using the Sim-OSSCAR. If data is missing from one assessment, then the mean of two or one will be used.

### **Analysis of primary outcome measure**

Intention to treat analysis of the Sim-OSSCAR score by arm.

### **Primary analysis of primary outcome:**

It is expected that the important baseline characteristics will be balanced between the two arms by stratified (for training centre) randomisation. This will be reported using a Rank Sum or Chi squared test. If this is the case, the outcome in the two arms will be compared by linear regression model for Sim-OSSCAR at three months, adjusted for surgical training centre as a fixed effect. Adjustment will be made for baseline mean Sim-OSSCAR score in the model.

### **Secondary analysis of primary outcome:**

*a. Effect modification*

We will assess effect modification of the intervention on Sim-OSSCAR score at three months with the following factors by including an interaction term with treatment arm in the linear regression model.

- a. Surgical training centre
- b. Sex
  - Male
  - Female
- c. Age of trainee: will be classified based on the distribution

*b. Analysis of determinants of Sim-OSSCAR score:*

A multivariable linear regression model will be used to identify potential explanatory factors for higher scores by three months, adjusting for arm (intervention/control). Other factors which will be examined in a model of Sim-OSSCAR score will include

- a. Age
- b. Sex
- c. Training centre

*c. Sim-OSSCAR score at end of intervention, at one year and 15-months*

Intention-to-treat analysis will be used to assess the impact of the intervention on OSSCAR score at end-intervention, one-year and 15-months, using linear regression adjusted for training centre, as per the approach used for the primary analysis.

## **Secondary Analyses**

### **Secondary outcome measures**

- a. Mean live ICO-OSCAR score at one year post-training for OLIMPICS trial. These will be analysed by linear regression, adjusting for training centre, as per the approach used for the primary outcome.
- b. Number of surgeries performed over one year (from 0 to 12 months). Analysed using a Poisson regression, with trial arm as the exposure of interest, adjusting for training centre.
- c. Patient-specific outcomes for all surgeries performed during 0-12 months for OLIMPICS Trial:
  - i. Day 1 Visual acuity (LogMAR): uncorrected and pin-hole. VA will be categorised as a binary outcome (percentage good, or poor) and analysed using logistic regression.
  - ii. Operative complications of posterior capsule rupture. Analysed using linear regression.
- d. Confidence rating scores (Assessed at baseline, three and twelve months), analysed using Wilcoxon Rank Sum test.

### **Training Record**

An accurate training record will be maintained and analysed by arm:

- a. Data will be collected for the duration of the trials (15 months for each participant) for conventional training: Surgical sessions attended / Numbers of surgeries performed (supervised and un-supervised) / Assisted. Descriptive (no formal analysis)

### **Adverse events**

The OLIMPICS and GLASS trials are 'educational-intervention' trials. All the educational intervention is using simulation. Data will be collected for all participants in both arms of both trials for all live surgeries performed (under local supervision, as part of conventional regulated and accredited training).

Complications will occur during surgery, these complications will be recorded by all participants (and subsequently summarised and reported to the PI). No patient identifiable data will be available:

For the OLIMPICS trial:

- Posterior capsule rupture (with or without vitreous loss)

For the GLASS trial:

- Conjunctival button hole
- Bleb leak
- Hyphaema

Within each trial the proportion of surgeries resulting in an adverse event will be compared using a logistic regression with trial arm as the primary exposure, adjusting for training centre.

**Qualitative analysis**

Semi-structured interviews (conducted as per Appendix 5a) will be recorded, transcribed, thematised and analysed. Thematisaion will be performed manually and electronically using nVivo software (QRS International, Burlington MA, USA). Confidence ratings do contain elements of open-ended questions which will be analysed per participant, and per stage of assessment.

**In-Depth Interviews**

Date: \_\_\_\_\_

ID. : \_\_\_\_\_

**1> *Baseline Interview (at selection, pre-randomisation)***

- What are the main challenges (in your area) in surgical training?
- What areas could you use most help with in surgical training?
  - Why?
- Does anything motivate you as a surgeon?

.....

Date: \_\_\_\_\_

**2> *During Intervention Training in Cape Town***

- What do training surgeons say are the most important ways to learn surgery?
- How do you, or how have you, learnt surgery?
- What are the main challenges (in your area) in surgical training?
- How do you think surgeons can continually improve their surgical skills?
- Think about the best surgical trainer you have worked with. What made them so good?
- Think about the worst surgical trainer you have worked with. What made them bad?
- What, if any, are the main benefits of simulated ocular surgery training?
- Does anything motivate you as a surgeon?

.....

Date: \_\_\_\_\_

**3> At Year one assessment**

- How, if at all, has the simulation surgical training affected your overall practice as a surgeon over the past year?
  - What aspects of the training?
- Does anything motivate you as a surgeon?

***Interviews will be recorded and transcribed, anonymised, and thematised.  
No personal identifiable information will be kept.***



**Ophthalmology Surgical Training** I.D.....

Date.....

*We invite you to answer a few simple questions relating to your own views about your surgery and training. Please be as honest as possible. Your answers will be kept completely anonymous, and will not be made available to anyone in any identifiable way. Please refer to the Participant Information Sheet, and do feel free to ask any questions.*

On a scale from one to ten, with 1 being “not confident at all” and 10 being “very confident”, please circle the level you most feel at this time:

How do you feel about yourself as a surgeon?

1	2	3	4	5	6	7	8	9	10
Not confident at all					Very confident				

How do you feel about your own surgical skills?

1	2	3	4	5	6	7	8	9	10
Not confident at all					Very confident				

What has impacted your level of confidence?

--

How do you feel about your cataract/glaucoma surgical skills?

1	2	3	4	5	6	7	8	9	10
Not confident at all					Very confident				

What are you most confident about regarding your surgical ability?

--

What specifically has led to this level of confidence?

--

**Ophthalmology Surgical Training**

Consultant Initials.....

Date.....

NOTSS is a behaviour rating system for surgeons. The system was developed using task analysis with subject matter experts. It allows Consultant surgeons to give feedback to colleagues and trainees based on structured observations of non-technical aspects of performance during intraoperative surgery.

We invite you to answer a few simple questions relating to your assessment of a trainee participant: Reference:  (Confidential Number)

*Please be as honest as possible. Your answers will be kept completely confidential, anonymous, and will not be made available public in any identifiable way. Please refer to the Participant Information Sheet, and do feel free to ask any questions.*

On a scale from one to four, with 1 being poor, 2 marginal, 3 acceptable, 4 good, and “NO” if not observed.

How would you rate the trainee in terms of **situational awareness**?

NO	1	2	3	4
Not observed	Poor	Marginal	Acceptable	Good

How would you rate the trainee in terms of **decision making**?

NO	1	2	3	4
Not observed	Poor	Marginal	Acceptable	Good

How would you rate the trainee in terms of **communication & teamwork**?

NO	1	2	3	4
Not observed	Poor	Marginal	Acceptable	Good

How would you rate the trainee in terms of **leadership**?

NO	1	2	3	4
Not observed	Poor	Marginal	Acceptable	Good

How would you rate the trainee in terms of general **surgical competency**?

NO	1	2	3	4
Not observed	Poor	Marginal	Acceptable	Good

*See overleaf for clarification if needed.*

**THIS ASSESSMENT IS FOR ANONYMISED RESEARCH PURPOSES ONLY, AND FORMS NO PART OF THE TRAINEES OFFICIAL TRAINING RECORD**

### **Situational awareness**

Gathering information (e.g. ensures biometry is available), understands information, anticipating (e.g. verbalises what may be required later in operation, plans operating list well)

*(Poor = Arrives in theatre late, overlooks clinical notes (or biometry), asks questions which demonstrate lack of understanding, operates beyond level of experience)*

### **Decision making**

Considers options, selects & communicates these options, implements and reviews decisions well

*(Poor = Unable to consider options, or unable to communicate options. Rigidly stays with decisions even if not working)*

### **Communication & teamwork**

Exchanges information well, establishes a shared understanding, co-ordinating team activities (in theatre)

*(Poor = Struggles to exchange information, cannot co-ordinate teams)*

### **Leadership**

Setting & maintaining standards, supporting others, coping with pressure.

*(Poor = Unaware of clinical standards, ignores others, cannot cope with pressure)*

### **Competence**

Can cope with "crowdedness" (multiple activities, accumulation of information), has some perception of actions in relation to goals, deliberate planning and formulates routines

*(Poor = very hesitant or incapable, rigid adherence to taught rules or plans, no exercise of "discretionary judgment")*

## PATIENT INFORMATION

### Consenting to Clinical Photography or Video recording

The Eye Hospital has a policy to give you the right to control the use of photographs or video recordings, which may be taken during the course of your treatment.

**You can refuse to have photographs or videos taken for any reason other than for your health records. This will not affect your treatment in any way.**

You have been asked to have medical video recordings taken. These will be for:

Anonymous assessment of your surgery, as part of ongoing evaluation of eye surgery and surgery training.

The videos of your surgery will not themselves be published or made available in any way to the public.

You will be given information about what the recordings will be used, and will be asked to sign a consent form.

**Further Information: If you have any further questions please speak to your doctor.**

**This leaflet is available in large print and other languages on request.**

# Consent to Clinical Photography/Video and Consent Form

## Patient Details

Initials .....

Date of Birth .....

Hospital No.....

I have explained the purpose of clinical photography/recordings to the patient and how the images will be used.

Patient information leaflet has been given.

I am a health professional requesting clinical photography/ video recording.

I will ensure that the appropriate video images are taken in a manner as to ensure that the patient **cannot be identified**.


**Signature of health professional**.....

**Print Name** .....

**Job Title** .....

**Contact details**..... **Date**..... / ..... / .....

**Patient statement** (please circle your answer) I agree to have clinical video recordings done. The request for the same has been explained to me and I fully understand what it entails.

**Yes**

**No**

**Signature of patient** ..... **Date** ...../...../.....

## Statement of Independent Witness / Interpreter

I have interpreted the above information to the patient to the best of my ability and in a way which I believe she or he can understand.

**Interpreter's signature** ..... **Name**..... **Date** ...../...../.....

**Hati ya Fomu ya Kupiga picha ya Kliniki****INFORMATION PATIENT****Kukubaliana na Upigaji picha wa Kliniki au Kurekodi Video**

Hospitali ya Jicho ina sera kukupa haki ya kudhibiti matumizi ya picha au rekodi za video, ambazo zinaweza kuchukuliwa wakati wa matibabu yako.

**Unaweza kukataa kuwa na picha au video zilizochukuliwa kwa sababu yoyote isipokuwa kwa kumbukumbu zako za afya. Hii haiathiri matibabu yako kwa njia yoyote.**

Umeulizwa kuwa na rekodi za video za matibabu zilizochukuliwa. Hizi zitakuwa kwa:

Tathmini isiyojulikana ya upasuaji wako, kama sehemu ya tathmini inayoendelea ya upasuaji wa macho na mafunzo ya upasuaji.

Video za upasuaji wako hazitasambazwa au zinapatikana kwa njia yoyote kwa umma.

Utapewa taarifa kuhusu kile ambacho rekodi zitatumika, na utaombwa kusaini fomu ya idhini.

**Maelezo zaidi: Kama una maswali zaidi tafadhali sungumza na daktari wako.**

**Kipeperushi hiki kinapatikana katika lugha kubwa na magazeti mengine kwa ombi.**



## Ruhusa kwa Upigaji picha / Video na Fomu ya Ruhusa

### Maelezo ya Mgonjwa

Jina .....

Tarehe ya kuzaliwa .....

Nambari ya hospitali .....

Nimeelezea madhumuni ya kupiga picha / rekodi za kliniki kwa mgonjwa na jinsi picha zitatumika.

Taarifa ya subira ya wagonjwa imetolewa.

Mimi ni mtaalamu wa afya anaomba kuandika picha za kliniki / video.

Nitahakikisha kuwa picha za video zinazofaa zinachukuliwa kwa namna ya kuhakikisha kwamba **mgonjwa hawezi kutambuliwa**.


Saini ya mtaalamu wa afya .....

Chapa jina .....

Jina la kazi .....

Maelezo ya mawasiliano .....

Tarehe ..... / ..... / .....

**Taarifa ya subira** (tafadhali duru jibu lako) Nakubali kuwa na rekodi za video za kliniki zilizofanywa. Ombi la sawa limeelezwa kwangu na ninaelewa kikamilifu kile kinachohusu.

**Ndiyo**

**Hapana**

**Saini ya mgonjwa** ..... **Tarehe** ...../...../.....

### Taarifa ya Shahidi wa Uhuru / Mtafsiri

Nimetafsiri maelezo ya juu kwa mgonjwa kwa uwezo wangu wote na kwa njia ambayo ninaamini yeye au anaweza kuelewa.

**Saini ya mkalimani** ..... **Jina** ..... **Tarehe** ...../...../.....

## OLIMPICS Small Incision Cataract Surgery course Trainer's Manual

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## Facility

Location: Ophthalmology Simulation Surgery Training Unit, H53 Old Main Building, Groote Schuur Hospital

Online registration: <https://consult.cybersight.org/web/guest/orbisprescreening>

Network: Wifi internal network linked software: [network name \[Tenda\]](#)

Microscopes X 5 (Zeiss Stemi 305 with dedicated cameras)

SICS simulation eyes (Philips studio®)

Cataract surgery instruments and consumables for 5 students per course

## Pre-course

All students should be registered on the Cybersight website. This must be arranged by the course organiser by emailing Lawrence Sica at [lawrence.sica@orbis.org](mailto:lawrence.sica@orbis.org) and providing names and email addresses of participants.

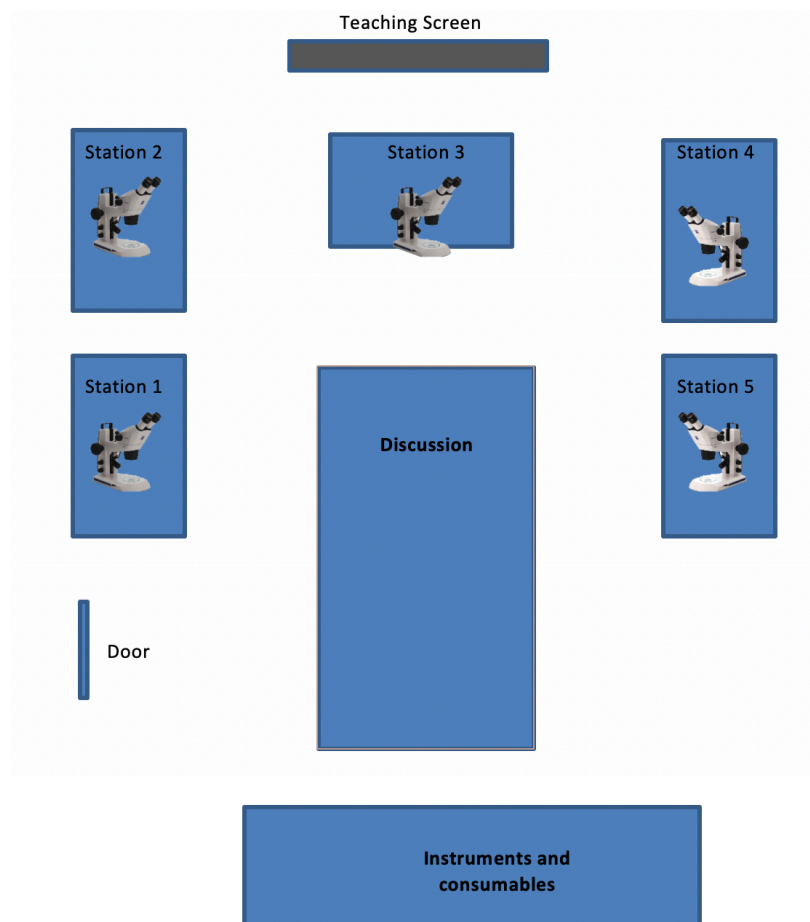
Students should watch the complete SICS procedure available through the Cybersight Website.

The screenshot displays the Cybersight website interface for 'OLIMPICS Cataract Surgery Training - Dr. Will Dean'. The user is logged in as 'Will Dean'. The interface is divided into a left sidebar and a main content area. The sidebar shows 'Curriculum Progress' at 1/7, 'STATUS: IN PROGRESS', and a 'Resources' section. The main content area is organized by day. 'Before Course' shows 1/1 progress and a message: 'You have completed the requirements for this group.' Below this is a 'Launch' button for 'OLIMPICS Cataract Training - Before Course Materials'. 'Day 1' shows 0/2 progress and a requirement to complete 2 courses. It lists 'Module 2: Manual Small Incision Cataract Surgery (4 hours)' and 'OLIMPICS Cataract Training - Day 1 Materials', both with 'Launch' buttons. 'Day 2' also shows 0/2 progress and a requirement to complete 2 courses. It lists 'Module 1: Evaluation of Adult Cataract and Preoperative Assessment (4 hours)' and 'OLIMPICS Cataract Training - Day 2 Materials', both with 'Launch' buttons. 'Day 3' shows 0/2 progress and a requirement to complete 2 courses. It lists 'Module 3: Postoperative Care of the Cataract Patient (4 hours)' and 'OLIMPICS Cataract Training - Day 3 Materials', both with 'Launch' buttons.

### **Teaching Room setup:**

Keys available from Chervon van der Ross (Division secretary)

[chervon.vanderross@uct.ac.za](mailto:chervon.vanderross@uct.ac.za)



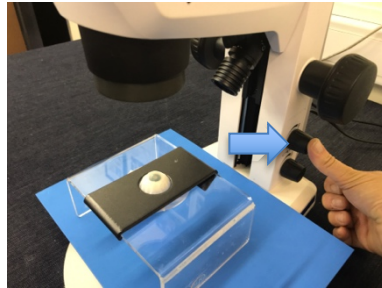
## Preparation of audio-visual equipment

Turn on the Teaching Screen

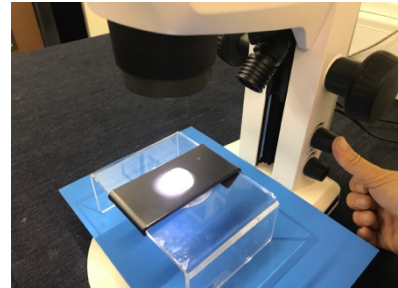
Attach the teaching laptop with lectures to the HDMI/VGA input cable for the teaching screen



Turn on all microscopes



and microscope cameras



Turn on all Apple iPads and open the Labscope App.



Ensure that all devices are connected to the local Wi-Fi network: [Tenda](#)

Ensure that all iPads have **enough charge** and the videos from the previous course are **deleted** from the Labscope app and the Photos app (see below)

Lectures from the laptop will appear on the Teaching Screen. If not, check the **source** input on the Teaching Screen TV.

### Use of the Labscope software:



How to view the surgery of a selected microscope on the teaching screen:

- Tap on the microscope icon (top left) and then tap on the selected microscope icon.
- The view of the selected microscope will open automatically
- Plug the iPad in to the HDMI cable attached to the teaching screen (check input).

How to use the laser pointer:

- Tap on the central icon
- Tap on laser pointer

How to record the surgery of a selected station:

- Tap on the microscope icon (top left) and then tap on the selected microscope icon.
- The view of the selected microscope will open automatically
- Check the dropdown icon: select video

- Exit and tap on the record button: a blue ring will appear, and clock will start

How to transfer the recording to the Photos app and then review the recording:

- Tap on the record button and the blue circle will disappear (and the recording will stop)
- Click the file icon (left)
- Select the last file on the list
- Tap on the export icon
- Select 'export to camera roll'
- Close the Labscope App and open 'Pictures'
- The video will appear, select it. It is possible to fast-forward and rewind (bottom scroll bar)

How to delete the video contents of the Labscope App and Photos app:

- Tap on the file icon in Labscope App
- Select the boxes of the files you want to delete
- Tap the Trash icon and confirm

Select the videos in the Photos App

- Select delete
- Click on the 'Recently Deleted' icon. Select all files and confirm delete

### Suggested Timetable

Day	Morning 8:00 – 10:30	Midday 11:00 – 1:00	Afternoon 2:00 – 5:00	Evening (Homework)
<b>Sunday</b>	<i>Candidates arrive in Cape Town</i>			Free
<b>Monday</b>	Introductions. Burden of disease exercise. Basic suturing / microsurgical skills.	Scleral tunnel. Scleral fixation Paracentesis. Learning theory & expertise lecture.	SICS video & lecture Capsulotomy Sim-OSSCAR.	<i>SICS Video. Suturing. Scleral tunnel.</i>
<b>Tuesday</b>	Review. Corneal entry. Hydrodissection. Nucleus extraction.	Pre-operative assessment lecture. Intra-ocular lens. Demonstration of SICS SOS. SICS Video.	Small group discussion review of entire SICS procedure. SICS SOS (with sim-OSSCAR)	<i>Scleral Tunnel.</i>
<b>Wednesday</b>	Review. Complications. Management of complications. SICS SOS (with sim-OSSCAR)	SICS SOS (with sim-OSSCAR) Post-operative care and audit	SICS SOS (with sim-OSSCAR)	<i>SICS Video.</i>
<b>Thursday</b>	<i>Candidates depart Cape Town</i>			



## **Day 1**

### **Introduction**

Student introductions

Introduce the layout and the use of the Labscope app

Plan competence, not experience etc.

Each student to perform a complete SICS procedure and record. This will be reviewed later and compared to later surgeries.

Pearl:

Students to wear gloves for all procedures.

### **Burden of disease exercise**

50% of world blindness is due to cataract

Burden of disease in your area:

Total population of the region served

Blind = 1%

Blind from cataract = 50% of this (point prevalence) (incidence is about 1/8<sup>th</sup> of this)

Number of ophthalmologists serving this?

Cataracts per ophthalmologist (to clear the current backlog)

Visual impairment from cataract is 3 x this amount

Therefore, burden is:

Then times 2 for 2 eyes.

### **Basic suturing**

Equipment:

Foam x 2

Needle holder

Straight tying forceps x 2

Iris scissors

Number 15 blade

Suture (start with 6/0)

Make a clean cut in the top piece of foam and place on second piece

Practice suturing under the microscope, wearing gloves. Ensure correct techniques (watch videos if necessary)

Interrupted sutures, burying the knot

Consider demonstrating on the teaching screen

### **Scleral tunnel**

Use of apples (suggested number: 3-5 apples, 10-20 tunnels on each apple)

Demonstrate on teaching screen or on whiteboard

Tunnel dimensions:

8mm (known relative to the corneal diameter)

Draw first, then 15 degree, then crescent blade

Frown shape, closest 2mm from limbus

Pearl:

Crescent blade sideways sweeping, the importance of hand/finger rotation

Demonstrate on an apple

Apple placed on a ring holder

Draw the cornea and the incision before cutting

Consider using the hand rests over the apple. Without the ring holder the fixation forceps need to stabilise the apple  
Observe the students and correct  
Suggested number of scleral tunnels: >50

### **Scleral fixation**

Discuss location and technique

Pearl:  
Use at each stage of scleral tunnel and for paracentesis

### **Paracentesis**

Discuss and demonstrate  
Timing of incision

Pearl:  
Large enough for Simcoe cannula

### **Lecture on learning theory**

**Introduction to the Sim-OSSCAR**

**Hand out colour copies of the Sim-OSSCAR**

### **Plans for lunch – see appendix**

During lunch, all watch the SICS video again

### **Capsulotomy**

Tomatoes: suggested number xxx  
Microwave tomatoes (1 min per tomatoes) to loosen skin  
Cooked tomatoes to rest on a tissue / gauze to absorb juice  
Draw small circle on the tomato and aim to tear at the edge of the circle  
Use of needle (cystotome) and capsulorhexis forceps  
Continuous curvilinear technique  
Linear capsulotomy technique

Pearl:  
Consider using a ½ paperclip / wire loop to limit the access of the forceps to the surgeon side only  
Linear capsulotomy must be made proximal enough to allow easy access to the proximal nucleus

NOT can-opener technique

## **Day 2**

### **Room preparation**

Have *used* simulation eyes setup at each station

Revise scleral tunnel and capsulotomy theory

### **Corneal entry**

Use of the keratome AFTER viscoelastic fill of AC (see **Preparation of viscoelastic**)

Pearls:

Slide in through the tunnel sideways

Always advance when cutting

Students to practice on *used* eyes

Ask the student to demonstrate and describe the technique

### **Hydrodissection**

Pearls:

Stress the checking of cannula attachment of the syringe and that cannula is not blocked

Stress thorough hydrodissection

Cannula to remain above the nucleus at all times

Press down with the heel of the cannula to allow fluid to easily escape from the eye

### **Nucleus extraction**

Discuss the theory of viscoelastic injection and use of the cannula tip to raise the proximal nucleus

Pearls:

Ensure that the capsulotomy is proximal enough

Avoid pressing down on the nucleus

Discuss fish-hook extraction

How to prepare the fish-hook, watch video?

Technique of fish-hook introduction, rotation, extraction

Pearls:

Stress enough viscoelastic beneath the nucleus to protect the capsule

Students to practice nucleus removal on used eyes. Reinsert the nucleus and perform again.

Discuss use of the Vectus or irrigating Vectus

### **Intraocular lens insertion**

Re-use the lenses. They can be removed and reinserted.

Pearls:

Ensure that the IOLs are inserted the correct way up

### **Plans for lunch**

### **Procedure revision**

Students to list the steps of the procedure from preparation of the patient to subconjunctival injection. List these on the white board.

Revise the order of instruments to be prepared on the tray (see photo)

All students gather at each student station and describe the procedure and demonstrate the correct order of the instruments (this is therefore done 5 times).

During this, the instructor is to replace the blades with new ones ready for the first complete procedure.

Revise how the students will record the operation using Labscope.

Pearls:

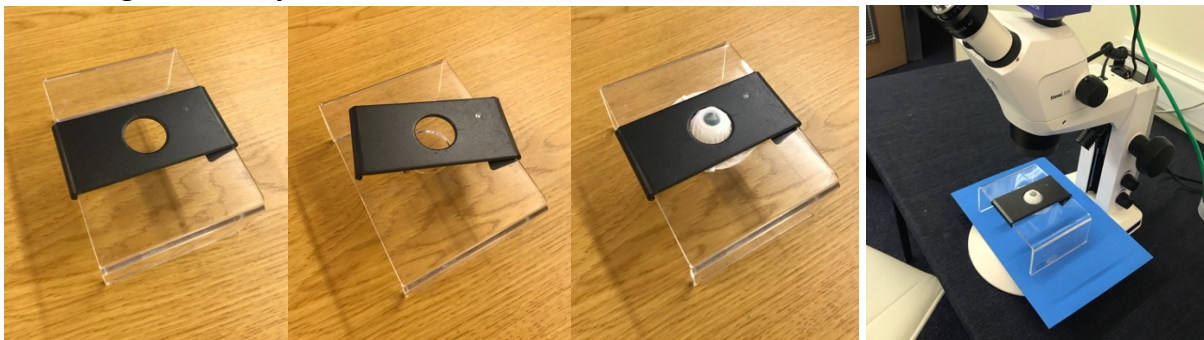
Students should check the recording from time to time to ensure image centration

The Sim-OSSCAR should be open as a cheat sheet so students can review what is expected at each step

### Complete procedures

Students are to perform complete procedures on new eyes. Each procedure is recorded by the student and reviewed after the surgery. It is marked out of 40 marks based on the Sim-OSSCAR. Areas for improvement are identified and discussed with the student.

### Mounting the SICS eyes



### Instrument set for SICS



*From left to right [bottom row]:* Hoskins fixation forceps, 15° blade, 2mL syringe with ultrasound gel (for use as ophthalmic viscosurgical device (OVD)), crescent blade (2.5mm, angled, bevel-up), keratome blade (3mm), 1mL insulin needle bent in to cystotome, 10mL syringe with water and canula, 2mL syringe fish-hook (bent 30G needle), 5mL syringe with irrigating Vectis cannula and water, curved tying forceps (for IOL implantation), IOL dialler, straight Vannas scissors, capsule forceps; *[top right]:* IOL, needle holder.

## **Day 3**

### **Lectures**

#### **Post-op care**

#### **Post-op complications - endophthalmitis**

During this discussion, students are asked to prepare the treatment for managing endophthalmitis. What antibiotics, how to mix, doses, how best to have this available (all in a single box) in a known location

#### **Audit**

Continue with **complete procedures** with recording and Sim-**OSSCAR review** for the remainder of the day.

After a few cases, students are to review the FIRST case they performed on Day 1 and mark with an Sim-OSSCAR. They can compare their latest scores.

Aim to perform 5-6 complete procedures.

### **Appendix 1: Instruments and consumables**

Philips Studio SICS simulation model eyes are kept in the cupboard in the office adjacent to the training unit. They are supplied in a box of six.

Consumables are ordered 6 monthly and stocks are kept in the store cupboards in the teaching room. Discuss any shortages with Will Dean or Deon Minnies.

List of available instruments:

### **Appendix 2: Viscoelastic substitute:**

Use ultrasound gel (5 litre containers)

Mix with equal amount of water the day before and shake to mix. Allow to stand overnight for bubbles to lessen

## GLASS Glaucoma Surgery course Trainer's Manual

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## Facility

Location: Ophthalmology Simulation Surgery Training Unit, H53 Old Main Building, Groote Schuur Hospital

Online registration: <https://consult.cybersight.org/web/guest/orbisprescreening>

Network: Wifi internal network linked software: [Tenda](#)

Microscopes X 5 (Zeiss Stemi 305 with dedicated cameras)

SICS simulation eyes (Philips studio®)

Cataract surgery instruments and consumables for 5 students per course

## Pre-course

All students should be registered on the Cybersight website. This must be arranged by the course organiser by emailing Lawrence Sica at [lawrence.sica@orbis.org](mailto:lawrence.sica@orbis.org) and providing names and email addresses of participants.

Students should watch the complete SICS procedure available through the Cybersight Website.

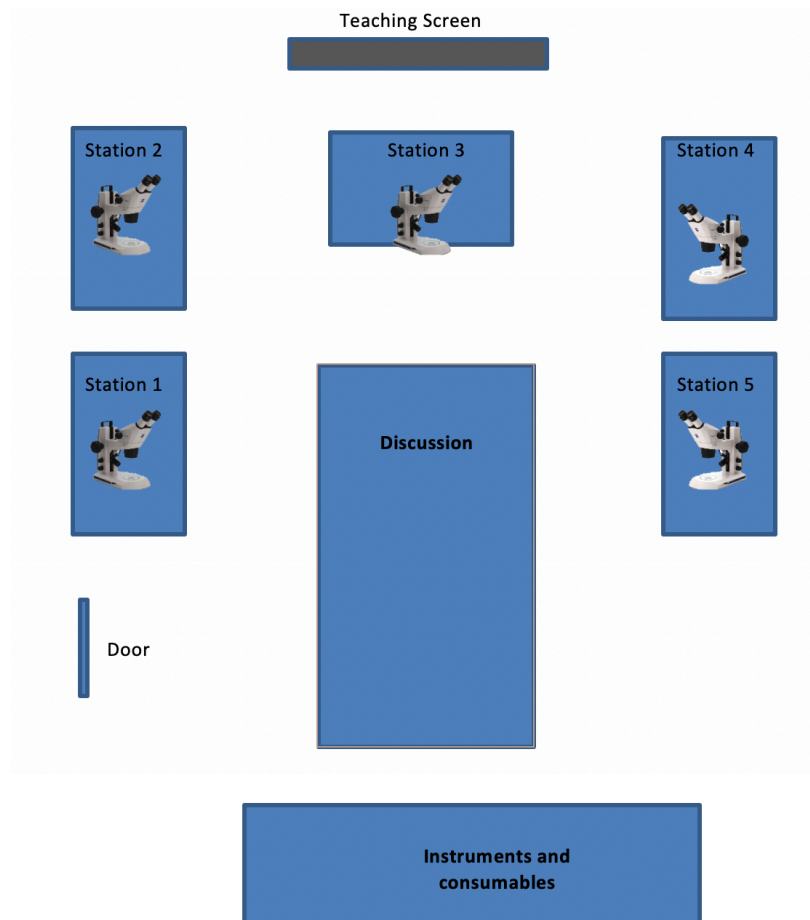
The screenshot displays the Cybersight website interface for the GLASS Trabeculectomy Training course. The top navigation bar shows the user is logged in as 'Will Dean'. The main content area is titled 'GLASS Trabeculectomy Training - Dr. Will Dean'. On the left sidebar, there is a 'GLASS' logo with the tagline 'Glaucoma Simulated Surgery', a 'Lesson Progress' indicator showing '3/28', a 'STATUS: IN PROGRESS' button, and a 'Resources' link. The main content area is organized into sections for 'Before Course Materials', 'Day 1 Materials', 'Day 2 Materials', and 'Day 3 Materials'. Each section contains a list of materials with a 'Launch' button next to each item.

Section	Material	Action
Before Course Materials	Modern Trabeculectomy Presentation	Launch
	Basic Sciences - Trabeculectomy	Launch
	OSCAR Rubric - Trabeculectomy	Launch
	OSSCAR - Trabeculectomy	Launch
	Trabeculectomy 30 min Video	Launch
Day 1 Materials	Burden of Disease	Launch
	Basic Suturing	Launch
	Suturing ESHC Video	Launch
	Suturing Richard Caesar Video	Launch
	Modern Trabeculectomy Presentation	Launch
	Trabeculectomy 12 min Video	Launch
	Trabeculectomy 30 min Video	Launch
	Learning & Expertise	Launch
Day 2 Materials	Scleral Flap	Launch
	Demonstration of Trab SOS	Launch
	Trabeculectomy Video	Launch
	Pre-op Assessment (trab)	Launch
	Pre-op Assessment (trab) Presentation	Launch
	Anti-metabolites	Launch
	Releasable & Conj Suturing	Launch
Day 3 Materials	Complications of Glaucoma Surgery	Launch
	Post-operative Care following Trabeculectomy	Launch
	Bleb-associated Infections	Launch
	Cefuroxime: for Intra-cameral Injection	Launch
	Endophthalmitis Protocol	Launch
	Post-operative Complications (trab)	Launch
	Peng Khaw Video	Launch
	Trab Outcomes Template	Launch

### **Teaching Room setup:**

Keys available from Chervon van der Ross (Division secretary)

[chervon.vanderross@uct.ac.za](mailto:chervon.vanderross@uct.ac.za)



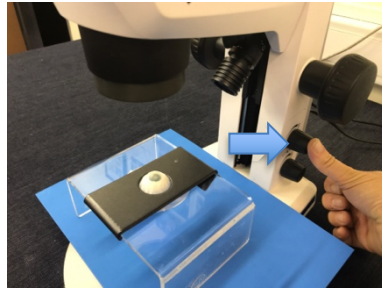
## Preparation of audio-visual equipment

Turn on the Teaching Screen

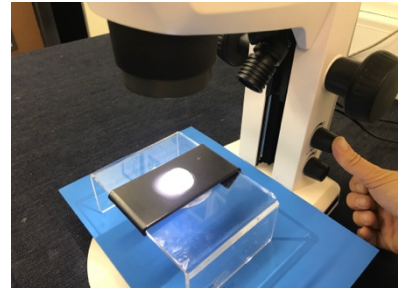
Attach the teaching laptop with lectures to the HDMI/VGA input cable for the teaching screen



Turn on all microscopes



and microscope cameras



Turn on all Apple iPads and open the Labscope App.



Ensure that all devices are connected to the local Wi-Fi network: [Tenda](#)

Ensure that all iPads have **enough charge** and the videos from the previous course are **deleted** from the Labscope app and the Photos app (see below)

Lectures from the laptop will appear on the Teaching Screen. If not, check the **source** input on the Teaching Screen TV.

### Use of the Labscope software:



How to view the surgery of a selected microscope on the teaching screen:

- Tap on the microscope icon (top left) and then tap on the selected microscope icon.
- The view of the selected microscope will open automatically
- Plug the iPad in to the HDMI cable attached to the teaching screen (check input).

How to use the laser pointer:

- Tap on the central icon
- Tap on laser pointer

How to record the surgery of a selected station:

- Tap on the microscope icon (top left) and then tap on the selected microscope icon.
- The view of the selected microscope will open automatically
- Check the dropdown icon: select video
- Exit and tap on the record button: a blue ring will appear, and clock will start

How to transfer the recording to the Photos app and then review the recording:

- Tap on the record button and the blue circle will disappear (and the recording will stop)
- Click the file icon (left)
- Select the last file on the list
- Tap on the export icon
- Select 'export to camera roll'
- Close the Labscope App and open 'Pictures'
- The video will appear, select it. It is possible to fast-forward and rewind (bottom scroll bar)

How to delete the video contents of the Labscope App and Photos app:

- Tap on the file icon in Labscope App
- Select the boxes of the files you want to delete
- Tap the Trash icon and confirm

Select the videos in the Photos App

- Select delete
- Click on the 'Recently Deleted' icon. Select all files and confirm delete

#### Suggested Timetable

Day	Morning 8:00 – 10:30	Midday 11:00 – 1:00	Afternoon 2:00 – 5:00	Evening (Homework)
Sunday	<i>Candidates arrive in Cape Town</i>			Free
Monday	Introductions. Burden of disease. Basic suturing.	Scleral flap. Clear corneal traction suture. Paracentesis. Learning theory & expertise lecture.	Modern trabeculectomy lecture Releasable sutures. Conjunctival sutures. Sim-OSSCAR.	<i>Trab Video. Scleral flap. Releasable sutures.</i>
Tuesday	Review. Corneal entry. Sclerostomy. Peripheral iridectomy.	Pre-operative assessment lecture. Demonstration of trab SOS. Trab Video.	Small group discussion review of entire trab procedure. Trab SOS (with sim- OSSCAR)	<i>Scleral Flap. Conjunctival sutures.</i>
Wednesday	Review. Complications. Management of complications. Trab SOS (with sim- OSSCAR)	Trab SOS (with sim- OSSCAR)	Trab SOS (with sim- OSSCAR)	<i>Trab Video.</i>
Thursday	<i>Candidates depart Cape Town</i>			

## **Day 1**

### **Introduction**

Student introductions

Introduce the layout and the use of the Labscope app

Plan competence, not experience etc.

Each student to perform a complete trabeculectomy procedure and record. This will be reviewed later and compared to later surgeries.

Pearl:

Students to wear gloves for all procedures.

### **Burden of disease exercise**

50% of world blindness is due to cataract

Burden of disease in your area:

Total population of the region served

Blind = 1%

Blind from cataract = 50% of this (point prevalence) (incidence is about 1/8<sup>th</sup> of this)

Number of ophthalmologists serving this?

Cataracts per ophthalmologist (to clear the current backlog)

Visual impairment from cataract is 3 x this amount

Therefore, burden is:

Then times 2 for 2 eyes.

Blind from glaucoma = 10%: but number of patients with glaucoma who need treatment is higher.

### **Basic suturing**

Equipment:

Foam x 2

Needle holder

Straight tying forceps x 2

Iris scissors

Number 15 blade

Suture (start with 6/0)

Make a clean cut in the top piece of foam and place on second piece

Practice suturing under the microscope, wearing gloves. Ensure correct techniques (watch videos if necessary)

Interrupted sutures, burying the knot

Consider demonstrating on the teaching screen

Mattress suture: long and close to clean cut

### **Scleral flap**

Use of apples (suggested number: 3-5 apples, 10-20 flaps on each apple)

Demonstrate on teaching screen or on whiteboard

Scleral flap dimensions:

3 x 4 mm (known relative to the corneal diameter)

Draw limbus first, then 15 degree for horizontal incision, then crescent blade 'tunnel', then complete side vertical incisions (but not all the way to the limbus)

Pearl:

Crescent blade sideways sweeping, the importance of hand/finger rotation

Demonstrate on an apple

Apple placed on a ring holder

Draw the corneal limbus and the incision dimensions before cutting

Consider using the hand rests over the apple. Without the ring holder the fixation forceps need to stabilise the apple

Observe the students and give feedback

Suggested number of scleral flaps: >40

### **Clear corneal traction suture**

Discuss location and technique

Practice on used eyes (use 6/0 suture)

Pearl:

Place needle flat on cornea, then depress and advance

### **Paracentesis**

Discuss and demonstrate

Timing and position of incision

Pearl:

Large enough for Rycroft cannula

### **Lecture on learning theory**

#### **Introduction to the Sim-OSSCAR**

Hand out colour copies of the Sim-OSSCAR

#### **Plans for lunch – see appendix**

During lunch, all watch the Trabeculectomy video again

### **Lecture on Modern Trabeculectomy**

Discuss entire technique

### **Releasable scleral flap suture**

Discuss location and technique

Practice on foam (use 8/0 suture)

Pearl:

Create a reasonable size flap on the foam. Use a second piece of foam underneath to protect the microscope

### **Conjunctival sutures**

Discuss location, technique, and number

Practice on used eyes (use 9/0 suture)

Pearl:

Aim for meticulous suturing

Use 'non-plastic' bags cut in a semi-crescent to suture to foam



## **Day 2**

### **Room preparation**

Have *used* simulation eyes setup at each station

Revise scleral flap and suturing theory

### **Corneal entry**

Use of the 15 degree blade AFTER pre-placement of scleral flap sutures

Pearls:

Very careful use of blade to avoid cutting sutures. Use a drop of water to place the suture ends in

Students to practice on *used* eyes

Ask the student to demonstrate and describe the technique

### **Sclerostomy**

Pearls:

Kelly's punch needs to be rotated vertically to cut a hole for the sclerostomy, not just a shelved incision

### **Peripheral Iridectomy**

Discuss the dimensions

Pearls:

For the artificial eyes, a toothed forceps is needed to grip the (rubber) iris.

Vannas scissors held parallel to the limbus (not into the anterior chamber)

### **Plans for lunch**

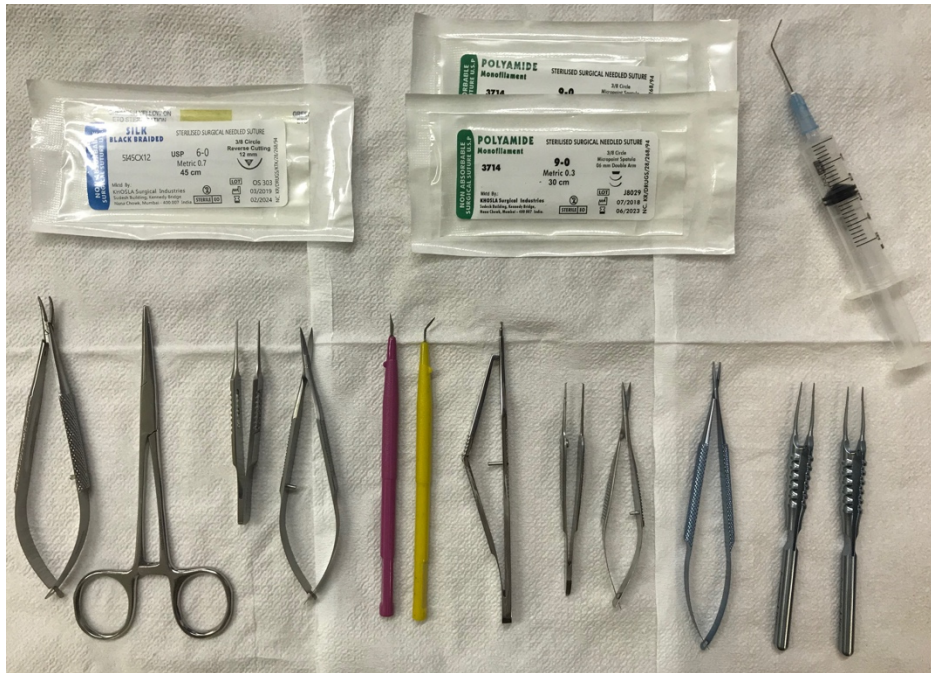
### **Watch trabeculectomy video (Prof Peng Khaw)**

### **Procedure revision**

Students to list the steps of the procedure from preparation of the patient to conjunctival suturing. List these on the white board.

Revise the order of instruments to be prepared on the tray (see photo)

## Instrument set and consumables for trabeculectomy



*From left to right [bottom row]: Curved needle holders, artery forceps, micro-notched forceps, Westcotts scissors, 15° blade, crescent blade, Kelly's punch, Hoskins toothed forceps, Vannas scissors, fine needle holder, straight suture tying forceps; [top row]: 6/0 silk clear-corneal-traction suture, 9/0 nylon suture for scleral flap and conjunctiva, 5mL syringe with water and cannula.*

All students gather at each student station and describe the procedure and demonstrate the correct order of the instruments (this 'mental rehearsal' is therefore done 5 times). During this, the instructor is to replace the blades with new ones ready for the first complete procedure. Ensure CCTS and 9/0 flap/conjunctival sutures are also replenished

Revise how the students will record the operation using Labscope.

Pearls:

Students should check the recording from time to time to ensure image centration. The Sim-OSSCAR should be open as a cheat sheet so students can review what is expected at each step

### **Mounting the artificial trabeculectomy eyes**

Remove the plastic cover, place the eye over the hole, ensure the scleral patch is facing



Gently replace the conjunctiva. Replace the plastic cover, position the mount under the microscope



### **Complete procedures**

Students are to perform complete procedures on new eyes. Each procedure is recorded by the student and reviewed after the surgery. It is marked out of 40 marks based on the Sim-OSSCAR. Areas for improvement are identified and discussed with the student.

### **Lecture on Pre-operative Assessment for Trabeculectomy**

Discuss selection for surgery and screening, pre-operative clinical management

## **Day 3**

### **Lectures**

#### **Post-op care and management of trabeculectomy bleb; Audit of trabeculectomy Post-op complications – including endophthalmitis**

During this discussion, students are asked to prepare the treatment for managing endophthalmitis. What antibiotics, how to mix, doses, how best to have this available (all in a single box) in a known location

### **Audit**

Continue with **complete procedures** with recording and Sim-**OSSCAR review** for the remainder of the day.

After a few cases, students are to review the FIRST case they performed on Day 1 and mark with an Sim-OSSCAR. They can compare their latest scores.

Aim to perform 5-6 complete procedures.

### **Appendix 1: Instruments and consumables**

Philips Studio advanced trabeculectomy simulation model eyes are kept in the cupboard in the office adjacent to the training unit. They are supplied in a box of six.

Consumables are ordered 6 monthly and stocks are kept in the store cupboards in the teaching room. Discuss any shortages with Will Dean or Deon Minnies.

List of available instruments: