

LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE



LSHTM Research Online

Gurol-Urganci, I; Geary, RS; Mamza, JB; Duckett, J; El-Hamamsy, D; Dolan, L; Tincello, DG; van der Meulen, J; (2018) Long-term Rate of Mesh Sling Removal Following Midurethral Mesh Sling Insertion Among Women With Stress Urinary Incontinence. *JAMA*, 320 (16). pp. 1659-1669. ISSN 0098-7484
DOI: <https://doi.org/10.1001/jama.2018.14997>

Downloaded from: <http://researchonline.lshtm.ac.uk/4649901/>

DOI: <https://doi.org/10.1001/jama.2018.14997>

Usage Guidelines:

Please refer to usage guidelines at <https://researchonline.lshtm.ac.uk/policies.html> or alternatively contact researchonline@lshtm.ac.uk.

Available under license: <http://creativecommons.org/licenses/by-nc-nd/2.5/>

<https://researchonline.lshtm.ac.uk>

1 **LONG-TERM RATE OF MESH SLING REMOVAL FOLLOWING MID-**
2 **URETHRAL MESH SLING INSERTION AMONG WOMEN WITH STRESS**
3 **URINARY INCONTINENCE**

4 Ipek Gurol-Urganci PhD^{1,2*}, Rebecca S Geary PhD^{1,2*}, Jil B Mamza PhD^{1,2}, Jonathan Duckett
5 FRCOG³, Dina El-Hamamsy MRCOG⁴, Lucia Dolan MD⁵, Douglas G Tincello MD^{6#}, Jan van der
6 Meulen PhD^{1,2#}

7
8 ¹ Department of Health Services Research and Policy
9 London School of Hygiene & Tropical Medicine
10 15-17 Tavistock Place, London WC1H 9SH, United Kingdom

11
12 ² Lindsay Stewart Centre for Audit and Clinical Informatics
13 Royal College of Obstetricians and Gynaecologists, London, UK

14
15 ³ Medway Hospital
16 Windmill Road, Gillingham, Kent ME7 5N, UK

17
18 ⁴ Leicester General Hospital
19 Department of Obstetrics and Gynaecology
20 University Hospitals of Leicester,
21 Gwendolen Road, Leicester LE5 4PW, UK

22
23 ⁵ Belfast City Hospital
24 Department of Gynaecology
25 Lisburn Road, Belfast BT9 7AB, Northern Ireland, UK

26
27 ⁶ University of Leicester
28 Department of Health Sciences, College of Life Sciences
29 University Road, Leicester LE1 7RH, UK

30
31 ** Joint first authors have made an equal contribution to this study and manuscript*

32 *# Joint senior authors have made an equal contribution to this study and manuscript*

33
34 **Corresponding Author**

35 Ipek Gurol-Urganci
36 Department of Health Services Research and Policy
37 London School of Hygiene & Tropical Medicine
38 15-17 Tavistock Place, London WC1H 9SH, United Kingdom
39 Telephone: +44 (0)20 7927 2266
40 Email: ipek.gurol@lshtm.ac.uk

41 **Word counts:** Abstract (348 words); Main body (3480 words)

42 **KEY POINTS**

43 **Question**

44 What are the long-term mesh removal rates following mid-urethral mesh sling insertion among
45 women with stress urinary incontinence?

46 **Findings**

47 In this retrospective cohort study that included 95,057 women who underwent mid-urethral mesh
48 sling insertion for stress urinary incontinence, the rate of sling removal was 3.3% at 9 years.

49 **Meaning**

50 These findings may inform decision making when choosing treatment for stress urinary incontinence.

51

52 **ABSTRACT**

53 **Importance**

54 There is concern about outcomes of mid-urethral mesh sling insertion for women with stress urinary
55 incontinence. However, there is little evidence on long-term outcomes.

56 **Objective**

57 To examine long-term mesh removal and reoperation rates in women who had a mid-urethral mesh
58 sling insertion for stress urinary incontinence.

59 **Design and participants**

60 Population based retrospective cohort study including 95,057 women aged 18 or older who had a
61 first-ever mid-urethral mesh sling insertion for SUI in the National Health Service hospitals in
62 England between 1 April 2006 and 31 December 2015. Women were followed up until 1 April 2016.

63 **Exposures**

64 Patient and hospital factors and retropubic or transobturator mesh sling insertions.

65 **Main Outcomes**

66 Primary outcome was the risk of mid-urethral mesh sling removal (partial or total) and secondary
67 outcomes were reoperation for stress urinary incontinence, and any reoperation including mesh
68 removal, calculated with death as competing risk. A multivariable Fine-Gray model was used to
69 calculate subdistribution hazard ratios (sdHR) as estimates of relative risk.

70 **Results**

71 The study population consisted of 95,057 women (median age, 51 years, IQR, 44-61 years) with first
72 mid-urethral mesh sling insertion, including 60,194 with retropubic insertion and 34,863 with
73 transobturator insertion. Median follow-up time was 5.5 years (IQR 3.2-7.5 years). Rate of mid-
74 urethral mesh sling removal was 1.4% (95% CI 1.3%-1.4%) at one year, 2.8% (2.7%-2.9%) at five
75 years and 3.3% (3.2%-3.4%) at nine years. Risk of removal declined with age. The 9-year removal
76 risk after transobturator insertion (2.7%; 2.5%-2.9%) was lower risk than after retropubic insertion
77 (3.6%; 3.5%-3.8%; sdHR 0.72, 0.62-0.84). Rate of reoperation for stress urinary incontinence was
78 1.3% (95% CI: 1.3%-1.4%) at one year, 3.5% (95% CI: 3.4%-3.6%) at five years, and 4.5% (95% CI:

79 4.4%-4.6%) at nine years. Rate of any reoperation including mesh removal was 2.7% (2.6%-2.8%) at
80 one year, 5.5% (5.4%-5.7%) at five years and 6.9% (6.7%-7.1%) at nine years.

81 **Conclusions and Relevance:**

82 Among women undergoing mid-urethral mesh sling insertion, the rate of mesh sling removal at 9
83 years was estimated as 3.3%. These findings may guide women and their surgeons when making
84 decisions about surgical treatment of stress urinary incontinence.

85 **INTRODUCTION**

86 Stress urinary incontinence (SUI) affects approximately one in three women over the age of 18 at
87 some point in their lives, with substantial effects on quality of life.^{1,2} It has recently been estimated
88 that a woman who is currently 18 years old has a 14% chance to undergo surgery for SUI during her
89 lifetime, based on claims data covering a period between 2002 and 2011 in the USA.³ Synthetic mid-
90 urethral mesh sling insertion (MUS) was developed as a less invasive alternative to major abdominal
91 surgery for SUI and its use is supported by professional bodies.⁴⁻⁷ In 2010, based on industry
92 estimates, approximately 250,000 MUS operations for SUI were performed in the USA.⁸

93

94 There is concern about problems that some women experience following MUS insertion, including
95 pain, dyspareunia, persistent urinary incontinence, and exposure or erosion.^{9,10} However, there is little
96 randomized clinical trial evidence on these longer term outcomes.¹

97

98 Recent evidence from routine practice in Scotland (1997-2016) and England (2007-2015) suggests
99 about 10% of women who had MUS inserted were admitted for a complication (combining those
100 related to haemorrhage, infection, pain and mesh removal) within five years, with 5% undergoing
101 further continence surgery.^{11,12} Reviews of urogynecologic mesh conducted by the Food and Drug
102 Administration in the USA, the Scottish government and the English National Health Service¹³⁻¹⁵
103 concluded that complications are ‘not rare’ and that there is insufficient evidence on longer term
104 outcomes.^{8,14} The continued use of MUS for SUI was recommended but only with improved
105 communication to patients of the risks and benefits of mesh and non-mesh procedures.

106

107 This study aimed to examine the long-term mesh removal and reoperation rates in women who had a
108 MUS insertion for stress urinary incontinence. The study used administrative hospital data to identify
109 all women who had a first MUS insertion for SUI in English National Health Service (NHS) hospitals
110 between 2006 and 2016, and followed them up for up to 10 years.

111

112
113
114
115
116
117
118
119
120
121
122
123
124
125
126
127
128
129
130
131
132
133
134
135
136
137
138

METHODS

The use of the Hospital Episode Statistics (HES) data for the purpose of national clinical audits and evaluations of care delivered by the NHS was approved by the Confidentiality Advisory Group of the NHS Health Research Authority (15/CAG/0148).

Study design

This study is a national population-based retrospective cohort study using HES data. HES contains records of all inpatient admissions to NHS hospitals in England¹⁶, with data on patient demographics (age, sex and ethnicity), the admission (date of admission and discharge) and clinical information. Diagnostic information is coded using the International Classification of Diseases, 10th revision (ICD-10).¹⁷ Operative procedures are described using the UK Office for Population Censuses and Surveys classification, 4th revision (OPCS-4).¹⁸ It has been demonstrated that the accuracy of HES data is sufficiently robust to support their use for research and managerial decision-making.¹⁹

All women aged 18 years or older who underwent a MUS insertion procedure for SUI for the first time between 1 April 2006 and 31 December 2015 were identified. SUI was defined by the ICD-10 code N39.3. Mesh sling insertions were defined by the OPCS-4 codes M53.3 (introduction of tension-free vaginal tape) and M53.6 (introduction of transobturator tape). These codes to identify retropublic and transobturator mesh sling insertions were introduced in April 2006, the start of the study period, and formed the coding standards in HES for the duration of the study. The procedure was considered to be a first-ever mesh sling insertion ('initial' procedure) if there was no record of a mesh sling procedure in the preceding three years. Follow-up was from date of initial procedure to date of a mesh sling removal, reoperation, or to the end of the follow-up period (31 March 2016), whichever was earlier. As a consequence, the minimum follow-up period was three months and the maximum 10 years.

139 **Outcomes**

140 The primary outcome, ‘mesh sling removal following the initial insertion’, was defined as total or
141 partial removal of retropubic mesh sling insertion (OPCS-4 codes M53.4 and M53.5) or removal of a
142 transobturator insertion (OPCS-4 code M53.7). Further definitions of codes can be found in eTable 1.
143 Due to coding limitations, it was not possible to distinguish partial and total removals following
144 transobturator insertions. The secondary outcomes, ‘reoperation for SUI’ was defined as a further SUI
145 procedure (OPCS-4 codes in eTable 1), and ‘any reoperation’ included both mesh removals and
146 reoperation for SUI. The OPCS -4 codes used to identify the outcomes (MUS removal and
147 reoperation for SUI) were used in HES throughout the study period.

148

149 **Patient factors**

150 Data on patient factors were extracted from HES: age at initial procedure date, Index of Multiple
151 Deprivation (IMD), an area-based measure of economic deprivation based on postcode of residence at
152 the time of the initial procedure²⁰, grouped into quintiles according to the national distribution, ethnic
153 background (white, Asian/Asian-British, black/black-British, or other based on ethnicity information
154 specified by the patients), number of comorbidities (defined using the RCS Charlson Comorbidity
155 Index²¹, grouped as 0 or 1 or more), route of mesh sling insertion (retropubic or transobturator),
156 previous non-mesh SUI procedures in the preceding three years and concurrent prolapse operations
157 (defined using codes listed in eTable 2) in the same episode of care as the initial MUS insertion for
158 SUI. Ethnicity is considered in this study because previous studies have suggested that there are
159 variations in care for women with SUI from different ethnic and socio-economic backgrounds.²² In
160 hospital settings, guidelines state that ethnicity should be self-reported by patients wherever possible,
161 with assistance from relatives, interpreters or advocates as required.²³ The groupings of the 2001
162 Census are used.

163

164 **Organisational factors**

165 Two organisational factors related the hospital where the initial procedure was carried out were also
166 extracted from HES: the number of MUS insertions performed at the year of initial operation (annual

167 ‘volume’; OPCS-4 codes: M53.6 or M53.3); and the hospitals’ status as a specialist urogynecology
168 unit according to whether they were accredited by the British Society of Urogynaecology unit at any
169 point in time during the inclusion period.²⁴

170

171 **Statistical analyses**

172 The cumulative incidence function was used to estimate removal and reoperation risk as a function of
173 time from the initial procedure to first mesh sling removal or first reoperation with death as a
174 competing event and patients reaching the end of the follow-up period as censoring event.²⁵ Because
175 the primary interest of this study was in the absolute risk of mesh sling removal and reoperation to
176 support medical decision, we used a multivariable Fine-Gray model to estimate subdistribution hazard
177 ratios (sdHR) to assess the association between patient and organisational factors and the risk of
178 removal or reoperation and or mesh removal, with robust standard errors to account for within-
179 hospital homogeneity in outcomes.²⁶ A sdHR of 1 implies no association, a sdHR < 1 a decrease of
180 the risk compared to the reference category, and a sdHR > 1 an increase. We tested whether the
181 assumption of proportional subhazards was met by inspecting the cumulative incidence as a function
182 of time for the categories of each of the patient and organisational factors. We also reran the
183 competing risk regression analysis, including time interactions separately for each of the patient and
184 organisational factors.

185

186 Multiple imputation was used to deal with missing values for ethnicity with statistical coefficients
187 obtained from 10 imputed datasets, pooled using Rubin’s rules.²⁷ Estimates are reported with 95%
188 confidence intervals (CI). Wald tests were used to test whether the association of patient and
189 organisational factors with removal or reoperation risks were statistically significant. All reported p
190 values were 2-sided and 0.05 was used as the significance level. All statistical calculations were
191 performed using Stata 14.²⁸ To assess whether the results were robust to coding changes introduced in
192 2006, regression analyses were repeated in two separate sensitivity analyses, first, starting the study
193 period one year later, on 1 April 2007 (rather than 2006), and second, including the previous coding
194 standards to identify procedures.

195

196 **RESULTS**

197 112,152 women were identified as having undergone a first MUS insertion (Figure 1) between 1 April
198 2006 and 31 December 2015. 17,095 patients were excluded because they were not resident in
199 England, did not have a diagnostic code indicating SUI, or had been treated as private patients (many
200 NHS hospitals have private wards where private patients may use the services of the hospital
201 provider)²⁹. Of the included 95,057 women, 60,194 (63.3%) had a retropubic and 34,863 (36.7%) a
202 transobturator insertion and they were all followed up until the end of the follow-up period. Median
203 follow up time was 5.5 years for women who did not have a mesh sling removal and who were alive
204 at the end of follow-up (interquartile range 3.2 and 7.5 years). The median follow-up times for women
205 who had retropubic and transobturator insertion were 5.4 years (IQR 3.1-7.6 years) and 5.6 years
206 (IQR 3.4-7.5 years) respectively. The women's median age was 51 years (IQR 44-61 years), and
207 19.8% had one or more comorbidities. 18.1% had a concurrent prolapse operation in the same episode
208 as their MUS insertion (Table 1).

209

210 **Mesh sling removal**

211 Mesh sling was removed in 1.4% (95% CI: 1.3%-1.4%) of the women at one year, in 2.7% (95% CI:
212 2.6%-2.8%) at five years, and in 3.3% (95% CI: 3.2%-3.4%) at nine years after the initial insertion,
213 accounting for the competing risk of death (Table 1 and Figure 2). The risk of removal was higher (at
214 all time points) in women who had a retropubic insertion than in those who had a transobturator
215 insertion (3.6% compared to 2.7% at nine years after insertion, Table 1, Figure 3). This difference
216 remained after adjusting for other risk factors (sdHR for transobturator insertion: 0.72, 95% CI: 0.62-
217 0.84). The risk of mesh sling removal decreased with age (4.4% for women 18-39 years compared to
218 2.1% for women over 70 years of age at nine years after insertion, sdHR 0.46, 95% CI: 0.38-0.56)
219 (Table 1). We did not find an indication that the assumption of proportional subhazards was violated,
220 except for the route of mesh sling insertion variable. While a visual inspection of Figure 3 does not
221 suggest violation of the assumption, the competing risk regression with a time varying component for

222 route of mesh sling insertion show that the difference between cumulative incidence for removals
223 following retropubic and transobturator insertions declines over time.

224

225 **Reoperation for SUI**

226 Risk of reoperation for SUI was 1.3% (95% CI: 1.3%-1.4%) of the women at one year, in 3.5% (95%
227 CI: 3.4%-3.6%) at five years, and in 4.5% (95% CI: 4.4%-4.6%) at nine years after the initial
228 insertion, accounting for the competing risk of death (Table 2 and Figure 2). The risk of reoperation
229 was higher (at all time points) in women who had transobturator insertion than in those who had a
230 retropubic insertion (5.3% compared to 4.1% at nine years after insertion, Table 2, Figure 3). This
231 difference remained after adjusting for other risk factors (sdHR for transobturator insertion: 1.31, 95%
232 CI: 1.14-1.51). Higher risk of reoperation for SUI was associated with having undergone a non-mesh
233 continence procedure prior to the initial MUS insertion in this study (8.1% for women who had a
234 bulking injection and 4.5% for women who did not, sdHR 1.74, 95% CI: 1.32-2.29; 11.1% for women
235 who had another non-mesh SUI procedures and 4.5% for women did not, sdHR 2.60, 95% CI: 1.85-
236 3.65) (Table 2). We did not find an indication that the assumption of proportional subhazards was
237 violated.

238

239 **Any reoperation (mesh removal and/or reoperation for SUI)**

240 The risk of any reoperation (mesh removal and/or reoperation for SUI) following the initial MUS
241 insertion was 2.6% at 1 year (95% CI: 2.5%-2.7%), 5.5% at five years (95% CI: 5.4%-5.7%) and
242 6.9% at nine years (95% CI: 6.7%-7.1%, Table 3). The risk of any reoperation was not statistically
243 significantly different after retropubic or transobturator insertion (Table 3) Asian/Asian-British had a
244 lower risk of reoperation than women from a white ethnic background (5.4% compared to 7.0% at
245 nine years after insertion, sdHR 0.75, 95% CI: 0.59-0.96). Higher risk of any reoperation was
246 associated with having undergone a non-mesh continence procedure prior to the initial MUS insertion
247 in this study (10.3% for women who had a bulking injection and 6.9% for women who did not, sdHR
248 1.55, 95% CI: 1.20-1.99; 14.5% for women who had another non-mesh SUI procedures and 6.9% for
249 women did not, sdHR 2.29, 95% CI: 1.66-3.14) (Table 3). We did not find an indication that the

250 assumption of proportional subhazards was violated, except for the route of mesh sling insertion
251 variable. The competing risk regression with a time varying component for route of mesh sling
252 insertion show that the difference between cumulative incidence for any reoperations following
253 retropubic and transobturator insertions declines over time.

254

255 Of the 95,057 women in the cohort, 5,328 (5.6%) had at least one reoperation (for mesh removal
256 and/or reoperation for SUI) (eTable 3). As their first reoperation, 2,276 (2.4%) women had a sling
257 removal operation, 1,957 (2.2%) had a repeat mesh sling insertion, and 1,075 (1.1%) had a non-mesh
258 SUI operation. The risk of sling removal as the first reoperation following the initial MUS insertion
259 was 1.3% at 1 year (95% CI: 1.2%-1.3%), 2.4% at five years (95% CI: 2.3%-2.5%) and 2.9% at nine
260 years (95% CI: 2.8%-3.1%). Amongst the 1,957 women who had a repeat mesh sling insertions, 1592
261 (81.3%) were without sling removal as compared with 143 (7.3%) with concurrent sling removal.
262 Remaining 244 (12.5%) of repeat mesh sling insertions were recorded with an additional unspecified
263 revisional procedure code (one of 12 non-specific OPCS-4 codes, eTable 1). The risk of repeat sling
264 insertion as the first reoperation for SUI following the initial MUS insertion was 0.9% at 1 year (95%
265 CI: 0.8%-0.9%), 2.1% at five years (95% CI: 2.0%-2.2%) and 2.7% at nine years (95% CI: 2.5%-
266 2.8%). The risk of a non-mesh SUI operation as the first reoperation for SUI was 0.4% at 1 year (95%
267 CI: 0.4%-0.5%), 1.2% at five years (95% CI: 1.1%-1.2%) and 1.5% at nine years (95% CI: 1.4%-
268 1.6%) (Table 3).

269

270 Types of subsequent operations by initial route of insertion are provided in eTable 4. Of the 95,057
271 women in the cohort, 1832 (1.9%) had only removal operations and 1681 (1.8%) had only insertion
272 operations in the follow-up period. 0.9% of women had multiple types of operations (removals,
273 insertion and non-mesh SUI operations).

274

275 By April 2016, 490 women who had initially received a retropubic mesh sling had undergone a total
276 removal operation during the study period. Of these 490 women, 56 (11.4%) had a repeat MUS
277 insertion following the total removal operation. Therefore, only 434 (0.7%) of the 60,194 women who

278 had an initial retropubic insertion had their mesh sling fully removed without any subsequent insertion
279 (eTable 4). Presented as the cumulative incidence according to time from the initial procedure, the
280 total removal rates of a retropubic mesh sling without a reinsertion were 0.4% (95% CI: 0.3%-0.4%)
281 at one year, 0.7% (95% CI: 0.7% - 0.8%) at five years and 0.9% (95% CI: 0.8%-1.0%) at nine years
282 (Figure 4).

283

284 **DISCUSSION**

285 Within nine years of an MUS insertion, 3.3% of women had a removal procedure, 4.5% had a
286 reoperation for SUI and 6.9% had any reoperation (mesh removal and/or reoperation for SUI).

287 Removal rates were lower following transobturator insertions than following retropubic insertions,
288 and rates of reoperation for SUI were lower following retropubic insertions than following
289 transobturator insertions. Risks of removal and any reoperation (mesh removal and/or reoperation for
290 SUI) were higher among young women and among women from a white ethnic background. These
291 findings, showing lower removal rates after transobturator insertions, are in line with earlier studies
292 from Scotland and England.^{11,12} However, these studies did not provide cumulative incidence results
293 for removal and reoperation (mesh removal and/or reoperation for SUI) as a function of time after
294 reoperation¹¹ or include admissions for complication without surgery¹², which complicates a direct
295 comparison.

296

297 In routine practice in the English NHS, risks of MUS removal were 2.7% at five years and 3.3% at
298 nine years, however, 99.3% of women who had an initial retropubic MUS insertion between 1 April
299 2006 and 31 December 2015 still had a full or partial MUS in situ at the end of the study period. This
300 can be understood because most removals were partial removals and many women had another mesh
301 sling inserted (eTable 4 and Figure 5). Due to coding limitations, the proportion of women who had at
302 least a partial MUS in situ after a sling insertion and removal could only be estimated for women who
303 had a retropubic insertion, but it is unlikely that these results would be markedly different for women
304 who had a transobturator insertion.

305

306 The present results demonstrate that removal and reoperation risks were associated with the insertion
307 route and patient factors. The risk of a removal was about 30% lower if the mesh sling had been
308 inserted via the transobturator route, which may be explained by the removal of transobturator sling
309 being a more complicated procedure. However, the risk of any reoperation, also including partial or
310 total mesh sling removals, was not associated with the route of insertion which, albeit indirectly,
311 indicates that risk of a reoperation for SUI is higher in women who had a transobturator insertion. A
312 Cochrane review also found that the risk of reoperation is higher after a transobturator mesh sling
313 insertion, but this came from four small trials including only 695 women.¹

314

315 The risk of mesh removal or any reoperation (mesh removal and/or reoperation for SUI) was
316 considerably lower in older patients and in women from non-white ethnic backgrounds, but an
317 association with socio-economic deprivation was not observed. These findings demonstrate that
318 removal and reoperation risks may be associated with women's background. However, it is not
319 possible to disentangle potential explanations for these difference in risks, which range from higher
320 morbidity to differences in severity of the underlying condition that led to surgery as well as to how
321 women perceived possible issues related to having a mesh sling inserted and their choices about
322 seeking further clinical advice and treatment.

323

324 The use of mesh sling as a treatment for female SUI is rapidly decreasing in the UK with a reduction
325 by about 50% between 2008 and 2017.³⁰ This highlights a change in patient choice and surgical
326 practice which is likely to reflect concerns about longer-term complications, outcomes and risk of
327 further surgery after MUS insertion.

328

329 To our knowledge, this is the largest study of outcomes following MUS insertions for SUI in almost
330 100,000 women. The administrative hospital dataset had near-100% coverage of patients treated in the
331 English NHS, reducing the risk of selection bias. Furthermore, it is likely that at least 90% of all
332 incontinence procedures carried out in England are provided by the NHS, given that the total annual
333 spending on private health care in England is about 5% of the total annual spending on the NHS.³¹

334
335
336
337
338
339
340
341
342
343
344
345
346
347
348
349
350
351
352
353
354
355
356
357
358
359
360

Limitations

This study has several limitations. First, some relevant clinical and patient characteristics (e.g. smoking, severity of incontinence, obesity) and the reasons why removal or reoperations were carried out were not available.

Second, this study only reported on women who underwent a surgical intervention after the mesh sling insertion.³² The advantage of this approach is that within administrative hospital data the accuracy for procedural coding is greater than for diagnostic coding.¹⁹ In this way, this study avoided overestimation of the complication rate or inconsistency in coding, problems that are recognised when diagnosis codes are being used for this purpose or when outpatient visit are being used as an indicator of further healthcare use.³³ However, this approach did not capture any problems that did not lead to surgical treatment.

Third, new procedure codes for retropubic and transobturator mesh sling insertions were introduced in April 2006, the start of the study period. Prior to this, these procedures were recorded along with other non-classified procedures. Some inaccuracies may have resulted where certain units continued to use the old coding standard in the first year of the study period. However, the findings were robust to sensitivity analyses starting the study period one year later and to including the previous coding standards.

Fourth, three times as many partial removals as total removals were performed following retropubic mesh sling insertions. This study was unable to explore the type of the removal following transobturator insertions because removal type was not captured for these insertions. Therefore, the effect of the more challenging operative procedure to remove transobturator slings cannot be commented on.

361 Fifth, coding limitations mean that this study cannot provide insight into why MUS slings were
362 removed. The most common diagnostic code recorded in removals episodes is T83 (Complications of
363 genitourinary prosthetic devices, implants and grafts) which is unable to capture the commonly
364 reported problems following MUS insertion such as mesh exposure, pain, voiding dysfunction and
365 other diagnoses. The finding that mesh removal is more common after retropubic MUS insertions may
366 suggest that voiding problems are a leading reason for removals, although patient-reported data is
367 required to provide insight into the reasons for MUS removal.

368

369

370 **Conclusions**

371 Among women undergoing mid-urethral mesh sling insertion, the rate of mesh sling removal at 9
372 years was estimated as 3.3%. These findings may guide women and their surgeons when making
373 decisions about surgical treatment of stress urinary incontinence.

374

375 **Funding**

376 This study was supported by a grant from the National Institute for Health Research (NIHR) Health
377 Services and Delivery Research (HS&DR) Programme (14/70/162). Independent scientific review of
378 the proposal has been undertaken by NIHR. JvdM was partly supported by the NHS National Institute
379 for Health Research Collaboration for Leadership in Applied Health Research and Care North Thames
380 at Bart's Health NHS Trust. The funders did not contribute to design and conduct of the study;
381 collection, management, analysis, and interpretation of the data; preparation, review, or approval of
382 the manuscript; or decision to submit the manuscript for publication. The authors are solely
383 responsible for any errors or omissions as well as the opinions expressed.

384

385 **Contribution to Authorship**

386 The study was conceived and designed by all authors. IGU and JBM performed the statistical
387 analyses. JvdM, DGT, JD, DE-H and LD assisted with the interpretation of results. RSG, IGU, JBM,
388 DE-H and JvdM wrote the manuscript, with input from all other authors. Joint senior authors (DGT
389 and JvdM) and joint first authors (IGU and RSG) have made an equal contribution to this study and
390 manuscript.

391

392 **Disclosure of Interests**

393 All authors declare no competing interests.

394

395 **Acknowledgements**

396 We would like to thank Lynn Copley MSc and Natalie Eugene MSc (for data extraction) and David
397 Cromwell PhD (for methodological advice on competing risk models) of the Clinical Effectiveness
398 Unit of the Royal College of Surgeons of England and London School of Hygiene and Tropical
399 Medicine. They did not receive any compensation for this work.

400

401 **Access to Data**

402 Ipek Gurol-Urganci had full access to all the data in the study and takes responsibility for the integrity
403 of the data and the accuracy of the data analysis.

404

405 **Details of Ethics Approval**

406 Not required for the analysis of anonymised routinely collected administrative data.

407 **REFERENCES**

408 1. Ford A, Rogerson L, Cody DJ, Aluko P, Ogah J. Mid-urethral sling operations for stress
409 urinary incontinence in women. *The Cochrane database of systematic reviews*. 2017(7).
410 2. Coyne KS, Kvasz M, Ireland AM, Milsom I, Kopp ZS, Chapple CR. Urinary incontinence
411 and its relationship to mental health and health-related quality of life in men and women in
412 Sweden, the United Kingdom, and the United States. *Eur Urol*. 2012;61(1):88-95. doi:
413 10.1016/j.eururo.2011.1007.1049. Epub 2011 Jul 1026.
414 3. Wu JM, Matthews CA, Conover MM, Pate V, Jonsson Funk M. Lifetime risk of stress urinary
415 incontinence or pelvic organ prolapse surgery. *Obstetrics and gynecology*. 2014;123(6):1201-
416 1206.
417 4. Aigmueller T, Trutnovsky G, Tamussino K, et al. Ten-year follow-up after the tension-free
418 vaginal tape procedure. *American journal of obstetrics and gynecology*.
419 2011;205(5):496.e491-495.
420 5. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under
421 local anesthesia for treatment of female urinary incontinence. *International urogynecology
422 journal and pelvic floor dysfunction*. 1996;7(2):81-85; discussion 85-86.
423 6. Ward K, Hilton P, The United Kingdom and Ireland Tension-free Vaginal Tape Trial Group.
424 Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as
425 primary treatment for stress incontinence. *Bmj*. 2002;325:67.
426 7. AUGS-SUFU. *Position Statement: Mesh Midurethral Slings for Stress Urinary Incontinence*.
427 2018.
428 8. U.S. Food & Drug Administration. Considerations about Surgical Mesh for SUI. 2018;
429 [https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics](https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345219.htm)
430 [/UroGynSurgicalMesh/ucm345219.htm](https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345219.htm).
431 9. NHS England. Mesh complications. 2017.
432 10. Maggoire U, Agrò E, Soligo M, Li Marzi V, Digesu A, Serati M. Long-term outcomes of
433 TOT and TVT procedures for the treatment of female stress urinary incontinence: a
434 systematic review and meta-analysis. *International urogynecology journal*. 2017;28(8):1119-
435 1130.
436 11. Morling J, McAllister D, Agur W, et al. Adverse events after first, single, mesh and non-mesh
437 surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland,
438 1997–2016: a population-based cohort study. *The Lancet*. 2017;389(10069):629-640.
439 12. Keltie K, Elneil S, Monga A, et al. Complications following vaginal mesh procedures for
440 stress urinary incontinence: an 8 year study of 92,246 women. *Scientific Reports*.
441 2017;7(1):12015.
442 13. NHS England. Mesh Oversight Group Report. 2017.
443 14. Scottish Government. Scottish Independent Review of the use, safety and efficacy of
444 transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ
445 prolapse in women. 2017; <http://www.gov.scot/Resource/0051/00515856.pdf>. Accessed
446 16/09/2017.
447 15. U.S. Food & Drug Administration. FDA public health notification: serious complications
448 associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and
449 stress urinary incontinence 2008.
450 16. NHS Digital. Hospital Episode Statistics. 2010; <http://content.digital.nhs.uk/hes>. Accessed
451 10/08/2017.
452 17. World Health Organization. International Statistical Classification of Diseases and Related
453 Health Problems 10th Revision. 2010;
454 <http://apps.who.int/classifications/icd10/browse/2010/en>. Accessed 05/08/2017.
455 18. NHS Digital. OPCS Classification of Interventions and Procedures. 2006;
456 [http://www.datadictionary.nhs.uk/web_site_content/supporting_information/clinical_coding/o](http://www.datadictionary.nhs.uk/web_site_content/supporting_information/clinical_coding/ops_classification_of_interventions_and_procedures.asp)
457 [pcs_classification_of_interventions_and_procedures.asp](http://www.datadictionary.nhs.uk/web_site_content/supporting_information/clinical_coding/ops_classification_of_interventions_and_procedures.asp). Accessed 05/08/2017.
458 19. Burns E, Rigby E, Mamidanna R, et al. Systematic review of discharge coding accuracy.
459 *Journal of public health (Oxford, England)*. 2012;34(1):138-148.

- 460 20. Department for Communities and Local Government. The English indices of deprivation
461 2015; <https://www.gov.uk/government/collections/english-indices-of-deprivation>.
- 462 21. Armitage JN, van der Meulen JH, Royal College of Surgeons Co-morbidity Consensus G.
463 Identifying co-morbidity in surgical patients using administrative data with the Royal College
464 of Surgeons Charlson Score. *The British journal of surgery*. 2010;97(5):772-781.
- 465 22. Siddiqui NY, Levin PJ, Phadtare A, Pietrobon R, Ammarell N. Perceptions about female
466 urinary incontinence: a systematic review. *International urogynecology journal*. 2013.
- 467 23. Mathur R, Bhaskaran K, Chaturvedi N, et al. Completeness and usability of ethnicity data in
468 UK-based primary care and hospital databases. *Journal of public health (Oxford, England)*.
469 2013.
- 470 24. BSUG. Accreditation of Units: Standards for Service Provision in Urogynaecology Units:
471 Certification of Units. 2017; <http://bsug.org.uk/pages/information/accreditation-of-units/102>.
- 472 25. Putter H, Fiocco M, Geskus R. Tutorial in biostatistics: competing risks and multi-state
473 models. *Stat Med*. 2006;26(11):2389-2430.
- 474 26. Austin PC. A Tutorial on Multilevel Survival Analysis: Methods, Models and Applications.
475 *Int Stat Rev*. 2017;85(2):185-203.
- 476 27. White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and
477 guidance for practice. *Stat Med*. 2011;30(4):377-399.
- 478 28. *Stata Statistical Software* [computer program]. Version Release 14. College Station, TX:
479 StataCorp LP; 2014.
- 480 29. NHS Digital. *HES Data Dictionary: Admitted Patient Care*. 2018.
- 481 30. NHS Digital. Retrospective Review of Surgery for Urogynaecological Prolapse and Stress
482 Urinary Incontinence using Tape or Mesh 2018; [https://digital.nhs.uk/data-and-](https://digital.nhs.uk/data-and-information/publications/statistical/mesh/apr08-mar17/retrospective-review-of-surgery-for-vaginal-prolapse-and-stress-urinary-incontinence-using-tape-or-mesh-copy)
483 [information/publications/statistical/mesh/apr08-mar17/retrospective-review-of-surgery-for-](https://digital.nhs.uk/data-and-information/publications/statistical/mesh/apr08-mar17/retrospective-review-of-surgery-for-vaginal-prolapse-and-stress-urinary-incontinence-using-tape-or-mesh-copy)
484 [vaginal-prolapse-and-stress-urinary-incontinence-using-tape-or-mesh-copy](https://digital.nhs.uk/data-and-information/publications/statistical/mesh/apr08-mar17/retrospective-review-of-surgery-for-vaginal-prolapse-and-stress-urinary-incontinence-using-tape-or-mesh-copy).
- 485 31. King's Fund. *The UK private health market*. 2014.
- 486 32. Mitropoulos D, Artibani W, Graefen M, et al. Reporting and Grading of Complications After
487 Urologic Surgical Procedures: An ad hoc EAU Guidelines Panel Assessment and
488 Recommendations. *European urology*. 2011;61(2):341-349.
- 489 33. Keltie K, Cole H, Arber M, et al. Identifying complications of interventional procedures from
490 UK routine healthcare databases: a systematic search for methods using clinical codes. *BMC*
491 *medical research methodology*. 2014;14(126).
- 492 34. Fine J, Gray R. A proportional hazards model for the subdistribution of a competing risk.
493 *Journal of American Statistical Association*. 1999;94:496-509.

494

495 **Table 1:** Risk of mesh sling removal following initial mesh sling insertion

	Risk of removal ¹ (%)					Subdistribution hazard ratio (95% CI) ²	P-value ³
	Number (%)	1-year (95% CI)	5-year (95% CI)	9-year (95% CI)			
All: crude risk (n/N, %)		1275/90215 (1.4)	1508/52715 (2.9)	240/6981 (3.4)			
All: adjusted risk	95057 (100)	1.4 (1.3, 1.4)	2.7 (2.6, 2.8)	3.3 (3.2, 3.4)			
Age at initial surgery (years)							
18-39	10292 (10.8)	2.0 (1.7, 2.2)	3.6 (3.2, 4.0)	4.4 (3.9, 4.9)	Reference	<0.001	
40-49	33094 (34.8)	1.5 (1.4, 1.6)	2.9 (2.8, 3.1)	3.7 (3.4, 4.0)	0.83 (0.74, 0.93)		
50-59	24664 (26.0)	1.4 (1.2, 1.5)	2.8 (2.6, 3.1)	3.4 (3.1, 3.6)	0.77 (0.68, 0.87)		
60-69	16877 (17.8)	1.0 (0.8, 1.1)	2.1 (1.9, 2.3)	2.5 (2.2, 2.8)	0.56 (0.48, 0.66)		
70+	10130 (10.7)	0.9 (0.8, 1.1)	1.7 (1.5, 2.0)	2.1 (1.7, 2.5)	0.46 (0.38, 0.56)		
Index of multiple deprivation							
1 Most deprived quintile	16136 (17.0)	1.3 (1.1, 1.5)	2.7 (2.4, 2.9)	3.2 (2.9, 3.5)	Reference	0.12	
2	18277 (19.2)	1.5 (1.3, 1.7)	2.9 (2.7, 3.2)	3.5 (3.2, 3.8)	1.12 (0.97, 1.30)		
3	20468 (21.5)	1.3 (1.1, 1.5)	2.5 (2.3, 2.8)	3.0 (2.7, 3.3)	0.96 (0.83, 1.12)		
4	20779 (21.9)	1.3 (1.1, 1.4)	2.6 (2.4, 2.9)	3.2 (2.9, 3.6)	1.01 (0.87, 1.18)		
5 Least deprived quintile	19397 (20.4)	1.5 (1.3, 1.7)	2.8 (2.5, 3)	3.5 (3.2, 3.9)	1.08 (0.92, 1.25)		
Ethnic background ⁴							
White	83451 (95.8)	1.4 (1.3, 1.5)	2.7 (2.6, 2.8)	3.3 (3.2, 3.4)	Reference	0.08	
Asian/Asian-British	2049 (2.4)	0.9 (0.5, 1.3)	2.1 (1.6, 2.9)	2.9 (2.0, 4.1)	0.73 (0.51, 1.05)		
Black/black-British	576 (0.6)	1.7 (0.9, 3.0)	2.3 (1.3, 3.7)	2.3 (1.3, 3.7)	0.71 (0.42, 1.19)		
Other	1057 (1.2)	0.9 (0.5, 1.6)	1.9 (1.2, 2.9)	2.8 (1.6, 4.5)	0.73 (0.49, 1.09)		
Missing (n=7924, 8.3%)							
Route of mesh sling insertion							
Retropubic	60194 (63.3)	1.6 (1.5, 1.7)	3.0 (2.9, 3.2)	3.6 (3.5, 3.8)	Reference	<0.001	
Transobturator	34863 (36.7)	0.9 (0.8, 1.0)	2.2 (2.0, 2.3)	2.7 (2.4, 2.9)	0.72 (0.62, 0.84)		

Table 1 (continued)	Risk of removal ¹					
	Number (%)	1-year (95% CI)	5-year (95% CI)	9-year (95% CI)	Subdistribution hazard ratio (95% CI) ²	P-value ³
Comorbidities ⁵						
None	76252 (80.2)	1.4 (1.3, 1.5)	2.7 (2.6, 2.8)	3.3 (3.2, 3.5)	Reference	0.37
1 or more	18805 (19.8)	1.3 (1.1, 1.5)	2.7 (2.4, 2.9)	3.0 (2.7, 3.3)	1.05 (0.94, 1.17)	
Previous bulking injection						
No	94349 (99.2)	1.4 (1.3, 1.5)	2.7 (2.6, 2.8)	3.3 (3.1, 3.4)	Reference	0.36
Yes	709 (0.8)	0.7 (0.3, 1.6)	3.0 (1.9, 4.6)	3.3 (2.1, 5.0)	1.21 (0.80, 1.83)	
Previous other stress urinary incontinence procedure						
No	94710 (99.6)	1.4 (1.3, 1.4)	2.7 (2.6, 2.8)	3.3 (3.1, 3.4)	Reference	0.13
Yes	347 (0.4)	2.6 (1.3, 4.7)	4.2 (2.4, 6.8)	4.2 (2.4, 6.8)	1.50 (0.89, 2.52)	
Concurrent prolapse repair						
No	77932 (82.0)	1.4 (1.3, 1.4)	2.7 (2.6, 2.8)	3.3 (3.1, 3.4)	Reference	0.09
Repair with mesh	817 (0.9)	1.7 (1.0, 2.8)	3.4 (2.3, 4.9)	3.9 (2.6, 5.6)	1.43 (0.98, 2.08)	
Repair without mesh	16308 (17.2)	1.4 (1.2, 1.6)	2.7 (2.5, 3.0)	3.3 (2.9, 3.6)	1.07 (0.93, 1.22)	
Specialist urogynecology unit						
No	75695 (79.6)	1.3 (1.2, 1.4)	2.6 (2.5, 2.7)	3.1 (3.0, 3.3)	Reference	0.17
Yes	19362 (20.4)	1.7 (1.6, 1.9)	3.2 (2.9, 3.4)	3.8 (3.5, 4.2)	1.17 (0.94, 1.47)	
Annual volume of mesh sling insertions						
< 60	28939 (30.3)	1.3 (1.2, 1.4)	2.5 (2.3, 2.7)	3.0 (2.8, 3.3)	Reference	0.21
60-119	44228 (46.5)	1.4 (1.3, 1.5)	2.7 (2.6, 2.9)	3.4 (3.2, 3.6)	1.07 (0.92, 1.24)	
≥120	21990 (23.1)	1.5 (1.3, 1.6)	2.8 (2.6, 3.0)	3.4 (3.1, 3.7)	1.02 (0.82, 1.28)	

496
497 ¹Cumulative incidence function and corresponding 95% confidence interval (95% CI) according to time after initial insertion.
498 ²Sub-hazard ratios calculated with competing risks regression model (Fine & Gray³⁴) adjusted for all patient and hospital factors in table.
499 ³P value obtained from Wald test
500 ⁴Ethnicity percentages calculated for non-missing data
501 ⁵Number of comorbidities derived from Royal College of Surgeons Charlson Comorbidity Index

502
503
504

Table 2: Risk of reoperation for stress urinary incontinence following initial mesh sling insertion

	Risk of reoperation for stress urinary incontinence ¹ (%)				Subdistribution hazard ratio (95%CI) ²	P-value ³
	Number (%)	1-year (95% CI)	5-year (95% CI)	9-year (95% CI)		
All: crude risk (n/N, %)		1252/90215 (1.4)	2087/52715 (3.9)	391/6981 (5.6)		
All: adjusted risk	95057 (100)	1.3 (1.3, 1.4)	3.5 (3.4, 3.6)	4.5 (4.3, 4.7)		
Age at initial surgery (years)						
18-39	10292 (10.8)	1.1 (1.0, 1.3)	3.3 (3.1, 3.5)	4.5 (4.2, 4.8)	Reference	0.29
40-49	33094 (34.8)	1.3 (1.1, 1.4)	3.4 (3.2, 3.7)	4.2 (3.9, 4.6)	0.91 (0.80, 1.03)	
50-59	24664 (26.0)	1.6 (1.4, 1.8)	3.7 (3.4, 4.1)	4.6 (4.2, 5.0)	0.92 (0.81, 1.05)	
60-69	16877 (17.8)	1.7 (1.4, 1.9)	3.8 (3.4, 4.2)	4.3 (3.9, 4.8)	1.00 (0.86, 1.16)	
70+	10130 (10.7)	1.1 (1.0, 1.3)	3.3 (3.1, 3.5)	4.5 (4.2, 4.8)	0.99 (0.83, 1.18)	
Index of multiple deprivation						
1 Most deprived quintile	16136 (17.0)	1.3 (1.1, 1.5)	3.5 (3.2, 3.8)	4.2 (3.9, 4.6)	Reference	
2	18277 (19.2)	1.4 (1.2, 1.5)	3.7 (3.4, 4.0)	4.9 (4.5, 5.4)	1.08 (0.96, 1.23)	
3	20468 (21.5)	1.3 (1.2, 1.5)	3.5 (3.2, 3.7)	4.3 (4.0, 4.7)	0.99 (0.87, 1.13)	
4	20779 (21.9)	1.4 (1.2, 1.5)	3.8 (3.5, 4.1)	4.9 (4.5, 5.3)	1.09 (0.94, 1.26)	
5 Least deprived quintile	19397 (20.4)	1.3 (1.1, 1.4)	3.1 (2.8, 3.3)	4.1 (3.8, 4.5)	0.92 (0.78, 1.09)	
Ethnic background ⁴						
White	83451 (95.8)	1.4 (1.3, 1.4)	3.5 (3.4, 3.7)	4.6 (4.4, 4.8)	Reference	
Asian/Asian-British	2049 (2.4)	0.8 (0.5, 1.2)	2.5 (1.9, 3.3)	3.1 (2.3, 4.0)	0.74 (0.54, 1.01)	
Black/black-British	576 (0.6)	1.0 (0.4, 2.1)	3.1 (1.8, 4.9)	3.4 (2.0, 5.3)	0.71 (0.46, 1.10)	
Other	1057 (1.2)	0.8 (0.4, 1.5)	2.4 (1.5, 3.5)	2.8 (1.7, 4.2)	0.70 (0.45, 1.07)	
Missing (n=7924, 8.3%)						
Route of mesh sling insertion						
retropubic	60194 (63.3)	1.2 (1.1, 1.3)	3.1 (3.0, 3.3)	4.1 (3.8, 4.3)	Reference	<0.001
transobturator	34863 (36.7)	1.5 (1.4, 1.6)	4.1 (3.9, 4.4)	5.3 (5.0, 5.7)	1.31 (1.14, 1.51)	

Table 2 (continued)		Risk of reoperation for stress urinary incontinence ¹ (%)				Subdistribution hazard ratio (95%CI) ²	P-value ³
	Number (%)	1-year (95% CI)	5-year (95% CI)	9-year (95% CI)			
Comorbidities ⁵							
None	76252 (80.2)	1.3 (1.2, 1.4)	3.4 (3.3, 3.6)	4.5 (4.3, 4.7)	Reference	0.35	
1 or more	18805 (19.8)	1.5 (1.3, 1.7)	3.8 (3.5, 4.1)	4.4 (4.0, 4.8)	1.04 (0.95, 1.14)		
Previous bulking injection							
No	94349 (99.2)	1.3 (1.2, 1.4)	3.5 (3.3, 3.6)	4.5 (4.3, 4.7)	Reference	<0.001	
Yes	709 (0.8)	2.9 (1.8, 4.3)	6.9 (5.1, 9.1)	8.1 (5.9, 10.6)	1.74 (1.32, 2.29)		
Previous other stress urinary incontinence procedure							
No	94710 (99.6)	1.3 (1.2, 1.4)	3.5 (3.3, 3.6)	4.5 (4.3, 4.7)	Reference	<0.001	
Yes	347 (0.4)	4.9 (3.0, 7.6)	9.1 (6.3, 12.6)	11.1 (7.8, 15.1)	2.60 (1.85, 3.65)		
Concurrent prolapse repair							
No	77932 (82.0)	1.4 (1.3, 1.4)	3.6 (3.5, 3.7)	4.7 (4.5, 4.9)	Reference	0.001	
Repair with mesh	817 (0.9)	2.8 (1.9, 4.2)	4.9 (3.5, 6.6)	6.2 (3.9, 9.3)	1.32 (0.94, 1.84)		
Repair without mesh	16308 (17.2)	1.1 (0.9, 1.3)	3.0 (2.7, 3.3)	3.7 (3.3, 4.1)	0.80 (0.69, 0.93)		
Specialist urogynecology unit							
No	75695 (79.6)	1.3 (1.2, 1.4)	3.5 (3.4, 3.6)	4.5 (4.3, 4.8)	Reference	0.84	
Yes	19362 (20.4)	1.4 (1.2, 1.5)	3.5 (3.2, 3.8)	4.4 (4.0, 4.8)	1.02 (0.81, 1.29)		
Annual volume of mesh sling insertions							
< 60	28939 (30.3)	1.2 (1.1, 1.4)	3.4 (3.2, 3.6)	4.4 (4.1, 4.8)	Reference	0.37	
60-119	44228 (46.5)	1.4 (1.3, 1.5)	3.6 (3.5, 3.8)	4.7 (4.4, 4.9)	1.09 (0.96, 1.24)		
≥120	21990 (23.1)	1.3 (1.1, 1.4)	3.4 (3.1, 3.6)	4.3 (4.0, 4.7)	1.03 (0.83, 1.28)		

505
506 ¹Cumulative incidence function and corresponding 95% confidence interval (95% CI) according to time after initial insertion.
507 ²Sub-hazard ratios calculated with competing risks regression model (Fine & Gray³⁴) adjusted for all patient and hospital factors in table.
508 ³P value obtained from Wald test
509 ⁴Ethnicity percentages calculated for non-missing data
510 ⁵Number of comorbidities derived from Royal College of Surgeons Charlson Comorbidity Index

511 **Table 3:** Risk of mesh removal or reoperation for stress urinary incontinence following initial mesh sling insertion
 512

	Risk of any reoperation ¹ (%)					Subdistribution hazard ratio (95%CI) ²	P-value ³
	Number (%)	1-year (95% CI)	5-year (95% CI)	9-year (95% CI)			
All: crude risk (n/N, %)		2415/90215 (2.7)	3216/52715 (6.1)	553/6981 (7.9)			
All: adjusted risk		2.6 (2.5, 2.7)	5.5 (5.4, 5.7)	6.9 (6.7, 7.1)			
Age at initial surgery (years)							
18-39	10292 (10.8)	3.1 (2.8, 3.4)	6.3 (5.8, 6.9)	8.3 (7.6, 9.2)	Reference	0.01	
40-49	33094 (34.8)	2.5 (2.3, 2.7)	5.4 (5.2, 5.7)	7.1 (6.7, 7.4)	0.86 (0.79, 0.94)		
50-59	24664 (26.0)	2.5 (2.3, 2.7)	5.6 (5.3, 5.9)	6.8 (6.4, 7.2)	0.86 (0.78, 0.95)		
60-69	16877 (17.8)	2.5 (2.3, 2.7)	5.4 (5.1, 5.8)	6.6 (6.1, 7.1)	0.83 (0.74, 0.94)		
70+	10130 (10.7)	2.5 (2.2, 2.9)	5.3 (4.9, 5.8)	6.1 (5.5, 6.7)	0.79 (0.68, 0.91)		
Index of multiple deprivation							
1 Most deprived quintile	16136 (17.0)	2.5 (2.2, 2.7)	5.5 (5.1, 5.9)	6.6 (6.1, 7.1)	Reference	0.13	
2	18277 (19.2)	2.7 (2.4, 2.9)	5.8 (5.5, 6.2)	7.3 (6.8, 7.8)	1.08 (0.97, 1.20)		
3	20468 (21.5)	2.5 (2.3, 2.7)	5.4 (5.0, 5.7)	6.5 (6.1, 7.0)	0.98 (0.88, 1.08)		
4	20779 (21.9)	2.6 (2.3, 2.8)	5.7 (5.3, 6.0)	7.2 (6.8, 7.7)	1.05 (0.94, 1.17)		
5 Least deprived quintile	19397 (20.4)	2.6 (2.4, 2.9)	5.3 (5.0, 5.7)	6.9 (6.4, 7.4)	1.00 (0.88, 1.13)		
Ethnic background ⁴							
White	83451 (95.8)	2.6 (2.5, 2.7)	5.6 (5.4, 5.8)	7.0 (6.8, 7.2)	Reference	0.01	
Asian/Asian-British	2049 (2.4)	1.5 (1.1, 2.1)	4.3 (3.5, 5.3)	5.4 (4.2, 6.8)	0.75 (0.59, 0.96)		
Black/black-British	576 (0.6)	2.7 (1.6, 4.2)	5.0 (3.4, 7.1)	5.0 (3.4, 7.1)	0.73 (0.51, 1.05)		
Other	1057 (1.2)	1.7 (1.1, 2.6)	3.9 (2.8, 5.2)	5.2 (3.6, 7.3)	0.74 (0.54, 1.01)		
Missing (n=7924, 8.3%)							
Route of mesh sling insertion							
retropubic	60194 (63.3)	2.7 (2.6, 2.9)	5.5 (5.3, 5.7)	6.8 (6.5, 7.0)	Reference	0.61	
transobturator	34863 (36.7)	2.3 (2.1, 2.4)	5.7 (5.4, 5.9)	7.2 (6.8, 7.5)	1.03 (0.92, 1.16)		

Table 3 (continued)	Risk of reoperation ¹ (%)					
	Number (%)	1-year (95% CI)	5-year (95% CI)	9-year (95% CI)	Subdistribution hazard ratio (95%CI) ²	P-value ³
Comorbidities ⁵						
None	76252 (80.2)	2.5 (2.4, 2.6)	5.5 (5.3, 5.7)	7.0 (6.7, 7.2)	Reference	0.22
1 or more	18805 (19.8)	2.7 (2.5, 2.9)	5.8 (5.4, 6.1)	6.6 (6.2, 7.1)	1.05 (0.97, 1.13)	
Previous bulking injection						
No	94349 (99.2)	2.6 (2.5, 2.7)	5.5 (5.4, 5.7)	6.9 (6.7, 7.1)	Reference	0.001
Yes	709 (0.8)	3.6 (2.4, 5.2)	8.9 (6.8, 11.4)	10.3 (7.9, 13.2)	1.55 (1.20, 1.99)	
Previous other stress urinary incontinence procedure						
No	94710 (99.6)	2.6 (2.5, 2.7)	5.5 (5.4, 5.7)	6.9 (6.7, 7.1)	Reference	<0.001
Yes	347 (0.4)	7.0 (4.6, 10.0)	12.5 (9.2, 16.3)	14.5 (10.7, 18.8)	2.29 (1.66, 3.14)	
Concurrent prolapse repair						
No	77932 (82.0)	2.6 (2.5, 2.7)	5.6 (5.4, 5.8)	7.0 (6.8, 7.3)	Reference	0.001
Repair with mesh	817 (0.9)	4.3 (3.1, 5.9)	7.8 (6.0, 9.8)	9.6 (6.9, 12.8)	1.43 (1.09, 1.87)	
Repair without mesh	16308 (17.2)	2.4 (2.2, 2.7)	5.2 (4.8, 5.6)	6.3 (5.8, 6.8)	0.92 (0.83, 1.01)	
Specialist urogynecology unit						
No	75695 (79.6)	2.5 (2.4, 2.6)	5.5 (5.3, 5.6)	6.8 (6.6, 7.1)	Reference	0.37
Yes	19362 (20.4)	3.0 (2.8, 3.2)	5.9 (5.6, 6.3)	7.2 (6.7, 7.7)	1.08 (0.91, 1.29)	
Annual volume of mesh sling insertions						
< 60	28939 (30.3)	2.4 (2.2, 2.6)	5.3 (5.0, 5.6)	6.7 (6.3, 7.1)	Reference	0.4
60-119	44228 (46.5)	2.7 (2.5, 2.8)	5.7 (5.5, 6.0)	7.1 (6.8, 7.4)	1.07 (0.96, 1.20)	
≥120	21990 (23.1)	2.6 (2.4, 2.8)	5.5 (5.2, 5.8)	6.8 (6.4, 7.3)	1.02 (0.86, 1.20)	

513

514 ¹Cumulative incidence function and corresponding 95% confidence interval (95% CI) according to time after initial insertion.515 ²Sub-hazard ratios calculated with competing risks regression model (Fine & Gray³⁴) adjusted for all patient and hospital factors in table.516 ³P value obtained from Wald test517 ⁴Ethnicity percentages calculated for non-missing data518 ⁵Number of comorbidities derived from Royal College of Surgeons Charlson Comorbidity Index

519
520
521
522
523
524
525
526
527
528
529
530
531
532
533
534
535
536
537
538
539
540
541
542
543
544
545
546
547
548

List of Figures & Legends

Figure 1: Study cohort selection process of women aged 18 and above who had a first-ever mesh sling insertion in the English National Health Service

Figure Legend: Study cohort selection process of women aged 18 years and above who had a first-ever mesh insertion in the English National Health Service from 2006-2015. ICD-10 indicates International Classification of Diseases, version 10.

Figure 2: Mesh sling removal, reoperation for stress urinary incontinence and any reoperation according to time after initial mesh insertion in 95,057 women

Figure Legend: Cumulative incidence of mid-urethral sling removal, reoperation for stress urinary incontinence and any reoperation (mesh removal and/or reoperation for stress urinary incontinence), with death from any cause as a competing risk. The median time of follow-up was 5.5 years (interquartile range 3.2 and 7.5 years) in women who did not have a mesh sling removal and were alive at the end of follow-up.

Figure 3: Mesh sling removal and reoperation for stress urinary incontinence according to time after initial insertion in 95,057 women by route of insertion

Figure Legend: Cumulative incidence of mid-urethral sling removal and reoperation for stress urinary incontinence by route of initial mesh insertion with death from any cause as a competing risk. The median time of follow-up was 5.4 years (interquartile range 3.1 to 7.6 years) in women who had an retropubic insertion and 5.6 years (interquartile range 3.4 to 7.5 years) in those who had a transobturator insertion.

Figure 4: Total sling removal with no subsequent mid-urethral sling insertion according to time after initial insertion in 60,194 women who had mesh sling inserted via retropubic route

Figure Legend: Cumulative incidence of mid-urethral sling removal surgery without subsequent insertion in 60,194 women who had mid-urethral mesh sling inserted via retropubic route, with death from any cause as a competing risk.

112,152 women with a first mid-urethral mesh tape insertion between 1 April 2006 and 31 December 2015

17,095 women excluded*

- Resident outside England: n=510
- No relevant ICD-10 code for stress urinary incontinence (N39.3): n=12,563
- Private sector: n=5,045

95,057 women included

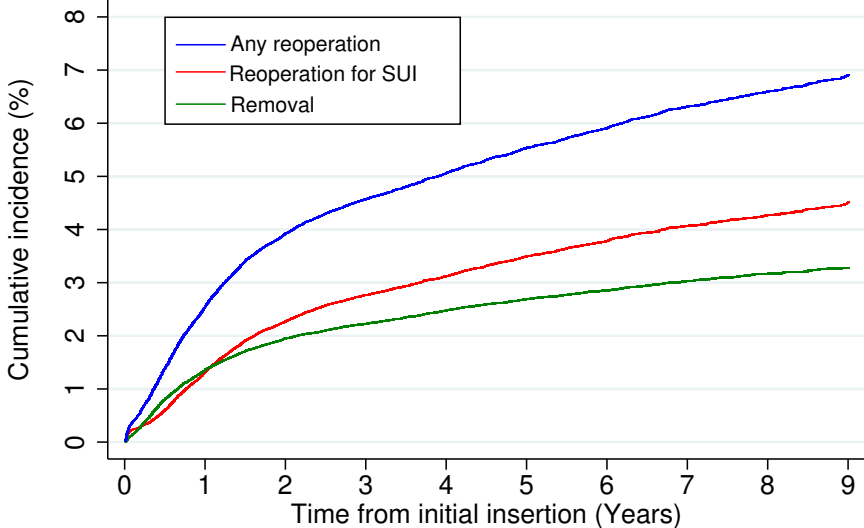
60,194 women with initial retropubic insertion

1,820 women had at least one removal operation

34,863 women with initial transobturator insertion

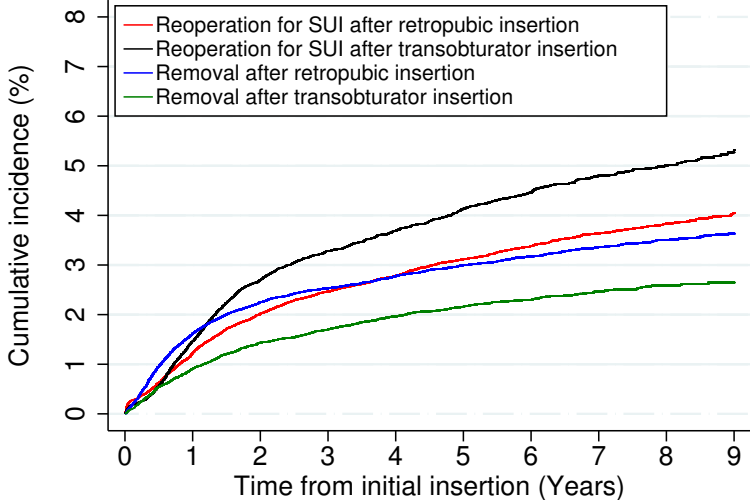
755 women had at least one removal operation

*1,023 episodes failed on multiple criteria



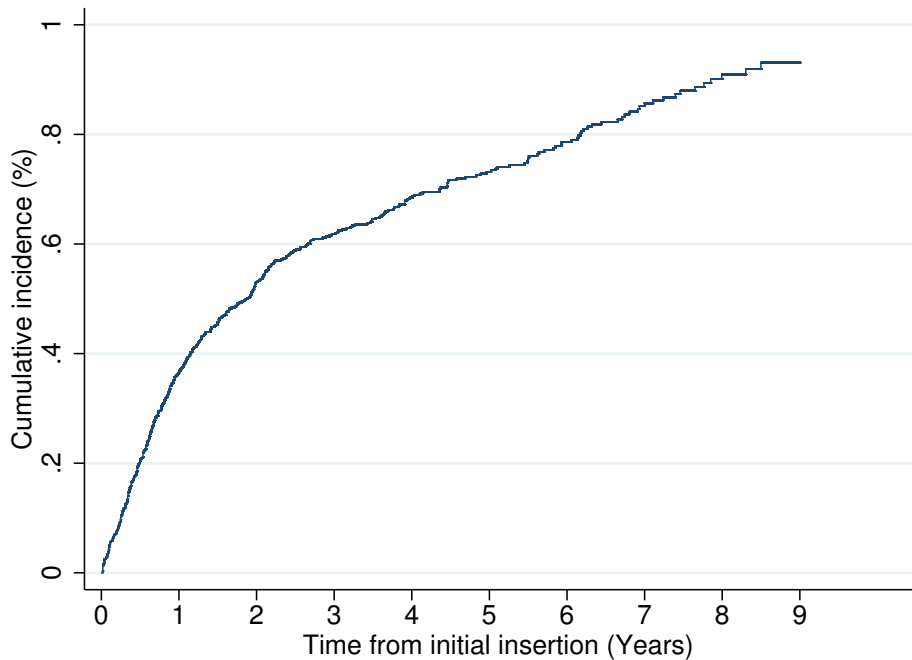
Number at risk

Any reoperation:	95057	87800	79221	69654	59871	49499	38802	27821	16708	6428
Reoperation for SUI:	95057	88963	80661	71050	61170	50628	39730	28535	17148	6590
Removal:	95057	88940	80955	71514	61664	51207	40308	29058	17502	6741



Number at risk

Reoperation after retropubic:	60194	56153	50864	44624	38297	31650	25101	18294	11440	4662
Reoperation after transobturator:	34863	32810	29797	26426	22873	18978	14629	10241	5708	1928
Removal after retropubic:	60194	55920	50732	44620	38330	31751	25230	18466	11546	4710
Removal after transobturator:	34863	33020	30223	26894	23334	19456	15078	10592	5956	2031



Number at risk

Removals: 60194 55920 50732 44620 38330 31751 25230 18466 11546 4710