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Complications after pelvic floor repair surgery (with and without mesh): short-term incidence after 1873 inclusions in the French VIGI-MESH registry.

Xavier Fritel, Sandrine Campagne-Loiseau, Michel Cosson, Philippe Ferry, Christian Saussine, Jean-Philippe Lucot, Delphine Salet-Lizee, Marie-Line Barussaud, Thomas Boisramé, Caroline Carlier-Guérin, et al.

► **To cite this version:**

Xavier Fritel, Sandrine Campagne-Loiseau, Michel Cosson, Philippe Ferry, Christian Saussine, et al.. Complications after pelvic floor repair surgery (with and without mesh): short-term incidence after 1873 inclusions in the French VIGI-MESH registry.. *BJOG: An International Journal of Obstetrics and Gynaecology*, 2019, 10.1111/1471-0528.15956 . inserm-02310221

HAL Id: inserm-02310221

<https://inserm.hal.science/inserm-02310221v1>

Submitted on 10 Oct 2019

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3	incidence after 1873 inclusions in the French VIGI-MESH registry
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56 Running title: Complications after pelvic floor repair surgery

57

58 Word count: 3441

59

60 Abstract

61 Objective: Assess the short-term incidence of serious complications of surgery for
62 urinary incontinence or pelvic organ prolapse

63 Design: Prospective longitudinal cohort study by using a surgical registry

64 Setting: 13 public hospitals in France

65 Population or Sample: 1873 women undergoing surgery between February 2017 and
66 August 2018

67 Methods: Preliminary analysis of serious complications after a mean 7-month follow-
68 up (0–18), according to type of surgery. Surgeons reported procedures and
69 complications, which were verified by the hospitals' information systems.

70 Main Outcome Measures: Serious complication requiring discontinuation of the
71 procedure or subsequent surgical intervention, life-threatening complication requiring
72 resuscitation, or death.

73 Results: 52 women (2.8%, 95% CI 2.1–3.6) experienced a serious complication
74 during either the surgery, requiring discontinuation of the procedure, or the first
75 months of follow-up, necessitating a subsequent reoperation; one case also required
76 resuscitation; no women died. Of 811 midurethral slings (MUS), 11 were removed in
77 part or totally (1.4%, 0.7–2.3), as were 2 of 391 transvaginal meshes (0.5%, 0.1–1.6),
78 and 4 of 611 laparoscopically placed mesh implants (0.7%, 0.2–1.5). The incidence
79 of serious complications 6 months after the surgical procedure was estimated around
80 3.5% (2.0–5.0) after MUS alone, 7.0% (2.8–11.3) after MUS with prolapse surgery,
81 1.7% (0.0–3.8) after vaginal native tissue repair, 2.8% (0.9–4.6) after transvaginal
82 mesh, and 1.0% (0.1–1.9) after laparoscopy with mesh.

83 Conclusions: Early serious complications are relatively rare. Monitoring must be
84 continued and enlarged to assess the long-term risk associated with mesh use and
85 identify its risk factors.

86 Funding: Agence Nationale de Sécurité du Médicament

87 Keywords: Mesh, stress urinary incontinence, pelvic organ prolapse, surgery,
88 longitudinal study, short-term major complication

89 Tweetable abstract: Short-term serious complications are rare after surgery for
90 urinary incontinence or pelvic organ prolapse, even with mesh

91

92 Introduction:

93 Stress urinary incontinence (SUI) and pelvic organ prolapse (POP) are frequent
94 among women older than 50 years and can be functionally disabling.^{1,2} When
95 surgical repair is selected, implanted inert, non-absorbable medical devices (or
96 meshes) are often used.³ Numerous manufacturers offer these devices, which differ
97 in the composition of the materials used (polyester, polypropylene, biological,
98 absorbable, etc.), the manufacturing process (knit, non-woven, welded, coated, etc.),
99 or the technique for fastening them (transfixing, or by glue, absorbable thread, non-
100 absorbent thread, stapled, etc.). The risk of complications may vary with the
101 surgeon's experience, the woman's characteristics, the surgical pathway (vaginal,
102 laparotomic, or laparoscopic, or mixed), the placement technique, and the materials
103 used.^{4,5}

104 The main complications associated with mesh use are exposure or erosion of the
105 material, functional complications, such as pain and urinary obstruction, and their
106 consequences on sexual function (dyspareunia, cessation of intercourse).^{6,7} These
107 complications can have serious functional and psychological repercussions and
108 require surgical revision. The UK regulatory authorities estimate that approximately
109 4% of the 100 000 midurethral slings (MUS) implanted between 2005 and 2013 have
110 been removed.⁸

111 Medical implant monitoring cannot estimate either exhaustively or precisely the
112 incidence of complications linked to the use of these devices, because the number
113 and type of surgical procedures involving mesh placement are unknown and due to
114 the probable under-reporting of their later complications.⁶ Some incidents of mesh
115 exposure have been observed more than five years after their placement.^{9,10}
116 Randomised trials based on the best trained, most experienced teams present a risk
117 of underestimating the occurrence of complications that are either rare or associated
118 with surgical malpractice;⁴ RCTs are not adequately powered to detect rare but
119 serious adverse events.

120 In 2018 the British government and National Health Service announced the
121 restriction of use of vaginally inserted surgical mesh and recommended high
122 vigilance scrutiny for procedures where there is no alternative to vaginally inserted
123 mesh, procedures offered as alternatives to mesh, and procedures involving
124 abdominally-inserted mesh.¹¹

125 In France, the national medicines agency (Agence Nationale de Sécurité du
126 Médicament et des produits de santé, ANSM) issued a call in 2016 for a surgical
127 registry to collect mesh use in SUI or POP surgery and follow up adverse effects.¹²
128 Our project, funded by the ANSM, began in 2017. The objective of this first analysis
129 is to describe the data collection methods of VIGI-MESH registry and report the
130 results of its first months of operation.

131

132 Methods

133 The surgeons involved in the randomised PROSPERE trial (comparing the
134 complications of laparoscopic sacropexy and of transvaginal mesh implantation to
135 treat cystocele) subsequently collaborated to develop the VIGI-MESH registry.⁴
136 Already trained and experienced in reporting serious adverse effects (PROSPERE's
137 principal outcome criteria) with a reporting process of proven reliability, they have
138 also demonstrated their recruitment capacity. The outcomes developed for the
139 PROSPERE trial, based on the Clavien-Dindo classification for surgical
140 complications, were again used for the VIGI-MESH registry:¹³ grade III complications
141 were defined by the discontinuation of the surgical procedure (mesh planned but not
142 placed or removed immediately) or by the need for subsequent surgical, endoscopic,
143 or radiological intervention, grade IV by a life-threatening complication, and grade V
144 by the woman's death. Grade II complications were recorded but not considered
145 serious; they included suture or mesh removal at office visits or bedside, along with
146 any surgical injury repaired during the procedure with no modification (neither an
147 additional surgical incision nor discontinuation of the procedure). As in the
148 PROSPERE trial, subsequent surgery for failure or recurrence of incontinence or
149 prolapse was reported but not considered a complication.⁴ Complications were also
150 described according to the IUGA/ICS classification.^{14,15} Each investigator collected
151 the complications, described them and their management in detail, and graded them.
152 The severity of complications was cross-checked by the first author from operative
153 reports. This analysis considers only serious complications (grade III and above).

154 The PROSPERE team had an annual volume of around 3000 operations (1300 for
155 SUI and 1700 for POP). Based on PROSPERE's results, we estimated the incidence
156 of serious complications (defined as grade III or higher on the Clavien-Dindo scale) at
157 4% a year, or 120 events.⁴

158 Registration of these surgical procedures began in February 2017. In accordance
159 with French law for studies of usual care (i.e., not involving experimental
160 interventions or treatments), each woman undergoing surgery for SUI, pelvic organ
161 prolapse, or rectal prolapse received thorough written information about the register,
162 was assured that all identifying data would remain confidential, and was asked to
163 consent to the recording of her data and to receiving follow-up questionnaires for the
164 next decade.

165 Eligible surgical procedures included the placement of midurethral slings (MUS),
166 retropubic (Burch) colposuspension, vaginal repair surgery with or without mesh,
167 abdominal or laparoscopic repair and endoanal surgery. Procedures involving
168 artificial sphincters, balloons and periurethral injections were not included.

169 All surgeons reported each operation they performed on a specific case report form
170 that collected the woman's characteristics (age, physical status, surgical history,
171 diabetes, smoking status, menopause, and sexual activity) and the surgical
172 procedures used (with or without mesh, manufacturer's name of the mesh and kit,
173 and type of fixation, approach, additional procedures, duration of surgery and
174 coding). The exhaustiveness of the data collection was verified by reviewing the
175 mesh delivery forms (for each patient) from the hospital pharmacies and the surgical
176 procedure codes recorded by each hospital's medical data department.

177 We used several sources to identify complications: the monitoring of specific surgical
178 procedures for complications by the data departments, surgeons' spontaneous
179 reports, and a questionnaire sent to the women a year later. These annual follow-up

180 questionnaires collected information about perceived health and improvement (WHO,
181 EQ5D, and PGI-I questionnaires) and can be considered patient-reported outcomes.
182 Complications were analysed, based on the surgeon's case report forms, the surgical
183 reports, and the women's responses to the one-year follow-up, on a centralised
184 basis.

185 We planned to describe the surgical procedures and classify them by mesh use
186 (yes/no), approach (vaginal, laparoscopic, or laparotomic), and indication
187 (incontinence or prolapse). A preliminary examination of the first inclusions allowed
188 us to list the principal surgical procedures and the expected complications.¹⁶ This
189 analysis distinguished five groups: isolated MUS (retropubic, transobturator, or
190 single-incision) with no procedure for prolapse, MUS with surgical treatment of
191 prolapse, transvaginal repair with at least one mesh, vaginal native tissue repair and
192 laparoscopy with mesh. We built a Kaplan-Meier survival curve to represent the
193 incidence of short-term complications by surgical group, according to the dates of the
194 surgery and the complication. For all women, the last date of follow-up for this initial
195 short-term analysis was set at 9 August, 2018. Complications after that date are not
196 considered here. For women with more than one complication, we have considered
197 the first classified as grade III or higher.

198 Complications are described according to the surgical procedure involved as well as
199 their nature, their management and the interval between the procedure and its
200 occurrence. The incidence of complications associated with MUS procedures was
201 analysed by a multivariate logistic regression that considered the type of MUS
202 (retropubic, transobturator, or single-incision), concomitant hysterectomy and any
203 concomitant procedure for POP. The incidence of complications associated with POP
204 procedures was analysed by considering the surgical group (transvaginal mesh,
205 vaginal native tissue repair or laparoscopy with mesh), concomitant hysterectomy
206 and concomitant MUS. Multivariate analyses were adjusted for age, smoking, and
207 recurrent surgery for IU or POP.

208 Patients were not involved in the development of the VIGI-MESH registry. No core
209 outcome sets were used. This registry-based study is listed on clinicaltrials.gov
210 (NCT03052985).

211

212 Results:

213 Between February 2017 and August 2018, the 13 participating surgical centres
214 prospectively included 1887 women (9–365 per centre). The procedures for 14
215 women did not correspond to the predefined surgical groups: 4 Altemeier or Delorme
216 procedures, 1 laparotomic Burch colposuspension, 2 laparoscopy without mesh, and
217 8 laparotomies with mesh. These were not included in the analysis. We estimated
218 that 79% of the eligible patients consented to participate (Table S1).

219 The index surgery (at inclusion) was for SUI alone (all with MUS) without surgery for
220 prolapse (n=658); for prolapse alone (n=1062, including 888 with at least one mesh);
221 and combined MUS and prolapse surgery (n=153) (see Table 1). The associated
222 hysterectomies (total or subtotal) were not counted as procedures to correct
223 prolapse.

224 Mean age was 62 (29–93) years and mean BMI 26 kg/m² (16–61). Overall, 75.9%
225 were postmenopausal, 45.9% sexually active, 9.2% smokers, and 6.8% had
226 diabetes. Previous gynaecological history included a hysterectomy (17.5%) and
227 surgery for SUI or prolapse (20.4%). The physical status (ASA score) was rated 1 for
228 628 women (33.5%), 2 for 950 (50.6%), 3 for 143 (7.6%) and 4 for 2 (0.1%) (see
229 Table 2). Mean length of follow-up was 7.3 months (0–18).

230 Half the women with isolated SUI treated by MUS underwent a retropubic procedure
231 (n=338, 51.4%); the others had a transobturator procedure (n=177) or a single-
232 incision sling (n=142) (data missing for one). MUS was combined with prolapse
233 surgery for 153 women: 76 laparoscopic mesh sacropexies, 7 laparoscopic mesh
234 rectopexies (3 rectopexies were associated with a sacropexy), 34 transvaginal mesh
235 and 39 vaginal native tissue repairs; the MUS placement was retropubic for 67
236 women, transobturator for 64, and a single-incision for 16 (six missing data).

237 The vaginal native tissue repair group included 17 obliterative procedures
238 (colpocleises). The laparoscopy mesh group included 490 sacropexies
239 (sacrohysteropexy or sacrocolpopexy), 91 rectopexies (55 associated with a
240 sacropexy), and 5 other laparoscopic mesh procedures; a single mesh was implanted
241 in the vesicovaginal space in 161 women, in the rectovaginal space in 47, and a
242 double mesh in both for 316 (seven missing data); in the laparoscopy mesh group,
243 the mesh procedure was combined with a laparoscopic Burch colposuspension 38
244 times, a subtotal hysterectomy 217 times, a total hysterectomy 11 times, and a
245 vaginal amputation of the uteri cervix twice.

246 The surgeons reported 63 intraoperative surgical injuries (3.4%) including 34 of the
247 bladder, 2 of the urethra, 2 of the rectum, and 19 accidental openings of the vagina.
248 In most (all but eight) cases, these injuries did not lead to discontinuation of mesh
249 implantation or MUS placement and were not counted as serious complications. In
250 one case, the inaccessibility of the sacral promontory required conversion of the
251 planned laparoscopic sacropexy to vaginal placement of a subvesical mesh (not
252 considered a serious complication).

253 Among the 1873 women included in this analysis, 52 (2.8%) experienced a serious
254 complication during the surgery or its first months of follow-up (Table 3); 31
255 complications were related to a MUS, 4 to a vaginal native tissue repair, 12 to a
256 transvaginal mesh, and 5 to a laparoscopy with mesh. As Figure 1 shows, the
257 incidence of serious complication six months after the procedure was estimated
258 around 3.5% (95% CI 2.0–5.0) after MUS alone (red curve), 7.0% (2.8–11.3) after

259 MUS associated with surgery for prolapse (green curve), 1.7% (0.0–3.8) for vaginal
260 native tissue repair (grey curve), 2.8% (0.9–4.6) after transvaginal mesh (orange
261 curve) and 1.0% (0.1–1.8) after laparoscopy with mesh (blue curve).

262 Most of these complications were graded IIIb (surgical revision under general
263 anaesthesia), one case required intensive care, and no deaths occurred. The most
264 frequent complication was obstructed micturition (18 cases all related to MUS, 2.2%)
265 and the second mesh exposure (9 cases related to MUS, 1.1%; 5 to transvaginal
266 mesh, 1.3%; and 2 to laparoscopic mesh, 0.3%).

267 Of the 31 complications (3.8%, 2.7–5.3) related to MUS surgery, 5 occurred during
268 surgery or in the first 48 hours: 1 bladder injury, 2 urethral injuries, 1 haemorrhage
269 and 1 complete urinary retention. Placement of the MUS was stopped or it was
270 removed four times because of the complication (three injuries and one intraoperative
271 haemorrhage); in the last case, the sling was loosened vaginally on day 1 (Table 4).
272 There were 17 complications treated from two days to two months after the initial
273 intervention: obstructed micturition resulted in loosening the sling in 12 women and
274 dividing it in 2; 1 woman needed to return to the operative room (OR) to evacuate a
275 suburethral thrombus that had resulted in obstructed micturition; and a part of the
276 MUS had to be removed in 2 women because of early vaginal exposure (associated
277 with pain in one case). Between 2 and 12 postoperative months, 9 complications
278 were managed, due to 1 late urinary retention, 5 vaginal MUS exposures (1 with
279 pain), 2 urethral MUS exposures (1 with pain), and 1 painful subcutaneous
280 tumefaction of an incision opening after a retropubic MUS. These complications
281 required MUS division (one case), partial removal of the MUS (seven cases), and
282 vaginal trimming without MUS resection (one case). The risk of MUS complication
283 was higher in women with concomitant POP surgery (Figure 1), but not statistically
284 significantly (aOR 2.12, 95% CI 0.88–5.12) (Table S2).

285 There were 21 complications related to POP surgery (1.7%, 1.1–2.6). Among them, 8
286 occurred during surgery or in the first 48 hours: 5 bladder injuries, and 3
287 haemorrhages (Table 4). Placement of the transvaginal mesh (or concomitant MUS)
288 was stopped or it was removed four times; three haemorrhages required return to the
289 OR for secondary haemostasis (two vaginal native tissue repairs and one
290 transvaginal mesh for a woman who also required a blood transfusion and intensive
291 care); a transvaginal mesh was removed vaginally on day 1 because of bladder
292 exposure discovered during an early reoperation indicated for pain and obstructed
293 micturition. Seven more complications were treated at two days to two months after
294 the initial intervention: in three cases (one laparoscopic sacrohysteropexy and two
295 transvaginal mesh procedures), painful ureteral obstruction was treated with a
296 double-J stent or nephrostomy; in two others, the patient needed to return to the OR
297 to evacuate a haematoma or restore haemostasis (one bleeding after vaginal
298 amputation of the uteri cervix associated with a laparoscopic sacrocolpopexy, and
299 one painful subvesical haematoma after vaginal native tissue repair); in two more
300 cases, the mesh was removed laparoscopically because of a pelvic abscess (one
301 after a laparoscopic sacrocolpopexy and one after a laparoscopic rectopexy). Six
302 vaginal mesh exposures were managed between 2 and 12 postoperative months,
303 four transvaginal placements (one with pain) and two laparoscopic sacrocolpopexies
304 (among women with a previous hysterectomy). These complications required partial
305 removal of the mesh (one transvaginal mesh and two laparoscopic) in three cases,
306 while the other three required vaginal trimming of a transvaginally placed vaginal
307 mesh without resection (Table 4). The risk of a POP surgery complication was lower

308 in women with laparoscopic procedures (aOR 0.67, 95% CI 0.16–2.80) and higher for
309 transvaginal mesh placement (aOR 2.18, 0.5–6.22) than for vaginal native tissue
310 repair (Figure 1), but these differences were not statistically significant (Table S3).

311 Management of complications in seven women necessitated multiple procedures. In
312 3 of 13 cases, loosening the sling was not sufficient to improve micturition; return to
313 the OR was needed to divide the MUS (1 case) or remove its suburethral portion (2
314 cases). In two of the cases requiring return to the OR for haemostatic surgery, a
315 second return was necessary, in one case for consolidation and in another to remove
316 the haemostatic compresses. In the sixth case, the placement of a double-J stent,
317 due to urethral blockage after sacrohysteropexy, was completed secondarily by a
318 laparoscopic urethral release. In the seventh, the nephrostomy was replaced by a
319 double-J stent.

320 Of 811 MUS placed, 11 were removed, in part or totally (1.4%, 0.7–2.3), as were 2 of
321 the 391 transvaginal meshes (0.5%, 0.1–1.6) and 4 of the 611 meshes placed
322 laparoscopically (0.7%, 0.2–1.5).

323 We also observed 29 surgical revisions (1.6%) for recurrent SUI (n=24) or POP
324 (n=5). The most frequent revision was MUS placement after laparoscopic sacropexy
325 (n=14, 3.6%). Finally, 70 women (3.7%) underwent at least one subsequent
326 reoperation for serious complications or recurrent SUI or POP (Table 3).

327

328

329 Discussion

330 Main findings

331 In the first months after surgery, we observed an incidence of serious complications
332 of 2.8% — 3.8% for MUS procedures and 1.7% for POP procedures. The type of
333 complication differs according to type of and time since surgery. Intraoperative
334 complications were principally intraoperative bladder injuries during vaginal surgery
335 that led to discontinuation of the mesh or sling placement. Half of the early
336 complications were for difficulties in bladder voiding after MUS. The later
337 complications were mainly vaginal exposure of either MUS or mesh, whether they
338 had been placed vaginally or less often, by laparoscopy. The most frequent
339 complications occurred in surgery combining MUS and prolapse repair.

340 Strengths and limitations

341 The number of complications reported in this early short-term analysis is too low to
342 enable a powerful explanatory analysis according to the characteristics of the
343 woman, the mesh, the combination of surgical procedures, the surgeon or the centre.
344 For example, the risk of complication appeared higher in combined MUS and POP
345 procedures and in cases of transvaginal mesh placement, but these differences were
346 not statistically significant. Our short-term follow-up does not yet allow us to estimate
347 the long-term incidence of mesh removal for mesh-related pain, which appear to
348 occur most frequently after an interval of two years.¹⁷

349 VIGI-MESH was designed to obtain a complete overview of daily practice and help to
350 draw conclusions about the harm-benefit ratio of mesh procedures. The prospective
351 nature of our registry makes it possible to capture a large proportion of eligible
352 surgeries. The quality of the information collected is ensured by cross-checking
353 pharmacy dispensing data and surgical procedure codes. The hospital data systems
354 allow medical events after surgery to be chained and monitored so that complications
355 are not missed.

356 Interpretation

357 Our early results concerning the incidence of complications are similar to those of
358 other recent work. We observed 6 grade III complications after 531 mesh
359 laparoscopies (1.1%), compared with the PROSPERE trial, where we found only one
360 among 129 laparoscopies (0.8%). We observed 11 MUS excisions among 811
361 placed (1.4%) while a large retrospective English study found an excision rate of
362 1.4% at one year.¹⁸

363 In our first results, the mesh was removed for pain seven times. In a series of
364 transvaginal mesh-related complications, half were symptomatic before eight
365 months.¹⁹ Another study with a five-year follow-up showed that more than half the
366 transvaginal mesh-related complications took place during the first year.²⁰ It will be
367 necessary to continue the monitoring to identify the incidence of late complications. It
368 would also be useful to be able to specify if these surgeries lead to chronic pain as
369 sequelae. One limitation of the Clavien-Dindo classification is that it does not
370 consider chronic pain. We plan to work with patients on developing a survey about
371 sequelae and chronic pain among the women in this registry.

372 If we suppose that expert centres have fewer complications, using only such centres
373 for the registry may result in underestimating the risk of complications in everyday
374 practice. On the other hand, the expert centres are probably more likely to diagnose

375 these complications early, which may raise their rates of early incidence. We assume
376 that the risk of loss to follow-up, because of disappointment with initial care, should
377 be low in the participating hospitals, because of their experience and ability to identify
378 complications early.

379 Several additional surgical procedures classified here as serious complications were
380 related to sling adjustments (its loosening or division). One of the advantages of MUS
381 for the treatment of incontinence is precisely the possibility of subsequent adjustment
382 of the sling, which is not possible for other surgical procedures for SUI (retropubic
383 colposuspension or traditional sling). Around 30 000 midurethral slings are placed
384 annually in France.²¹ The number of surgical revisions seen in our registry in the
385 early months after the placement of MUS alone was around 3.8% and may thus
386 indicate that there are around 1100 reoperations for this procedure each year in
387 France. Note that in our registry half the MUS were retropubic, although in France in
388 2017 (data from the Agence Technique de l'Information sur l'Hospitalisation) this
389 pathway accounted for only 20% of the MUS placed.

390 It seems essential to continue long-term monitoring after surgical pelvic floor repair,
391 whether or not mesh is used, to ensure comparison and follow changes in practice as
392 women and surgeons' opinions of mesh evolves.¹¹ The registry will allow us to
393 compare the different types of materials and the different methods of placement, to
394 identify those that could present problems and to propose guidelines for the
395 prevention and management of these complications and their sequelae.²² Answers to
396 these questions interest clinicians, women, manufacturers, and the public health
397 authorities.

398 Conclusions

399 Short-term serious complications are rare after surgery for urinary incontinence or
400 pelvic organ prolapse, even with mesh use. Monitoring must be continued and
401 enlarged to assess more exactly the long-term risk associated with mesh use and
402 identify the associated risk factors.

403

404

405 *Acknowledgements*

406 The authors thank the VIGI-MESH team, Lucie Merlet, Florence Tartarin, Elodie
407 Migault, and Pierre-Jean Saulnier; and Jo Ann Cahn for editing.

408 We thank also all the surgeons who contributed cases to the registry: A.
409 Aboukassem, C. Akladios, E. Arsene, S. Aucouturier, E. Bailly, J-J. Baldauf, G.
410 Bader, S. Bartolo, M-L. Barussaud, F. Béchard, K. Ben Naoum, S. Bernardeau, R.
411 Boohdun, T. Boisramé, F. Borie, R. Botchorichvili, M. Boukaram, A. Brams, C.
412 Bruhat, S. Campagne-Loiseau, C. Carlier-Guérin, O. Celhay, T. Charles, A.
413 Charvériat, P. Chauvet, A. Chevrot, P. Collinet, M. Cosson, P. Costa, S. Curinier, P.
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424 *Disclosure of interest*

425 XF, SCL, CS, DSL, MLB, TB, CCG, TC, XD, PD, ACP, SC, SR, VR, and AF have no
426 direct or indirect commercial financial incentive associated with publishing the article.

427 MC, JPL and RdT have received honoraria from Boston Scientific. MC, PF, JPL and
428 RdT have received honoraria from Coloplast.

429 *Contribution to Authorship*

430 XF, SCL, MC, PF, CS, JPL, DSL, MLB, TB, CG, TC, PD, XD, ACP, SC, RdT and AF
431 included women, collected and completed data. XF, SR, VR, and AF contributed to
432 the conception, design, analysis, interpretation of data and article writing. Each
433 author had access to the data analysis, participated in revising the manuscript and
434 approved the final submitted version.

435 *Details of Ethics Approval*

436 Our study complies with French law. The Institutional Review Board (Comité de
437 Protection des Personnes Ouest III) approved the protocol 9 February 2017 (IDRBC
438 2017-A000308-45), and the study was registered by the national data protection
439 authority (Commission Nationale Informatique et Libertés, CNIL) on 16 August, 2017
440 (DR-2017-245).

441 *Funding*

442 The national medicines agency (Agence Nationale de Sécurité du Médicament et des
443 produits de santé, ANSM) provided funding for the study, but played no role in data
444 collection or analysis, assessment of the complications, or interpretation of the
445 results.

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Figure 1. Survival without serious complication (Kaplan-Meier survival curve) by type of surgical group (MUS alone in red, MUS + POP surgery in green, vaginal native tissue repair in grey, transvaginal mesh in orange, and laparoscopy with mesh in blue) (MUS: Midurethral sling; POP: pelvic organ prolapse).

Table 1. Several combinations of surgical procedures in 1873 women.

Surgical group, N	Procedures MUS	Laparoscopy with mesh				Vaginal native tissue repair				Transvaginal mesh			Hysterectomy	
		Burch (laparoscopy)	Sacropexy with mesh	Rectopexy with mesh	Other with mesh	Anterior repair	Apical suspension	Posterior repair	Obliterative	Anterior mesh	Apical mesh	Posterior mesh		
MUS alone, 658	658	-	-	-	-	-	-	-	-	-	-	-	-	10
MUS + POP surgery, 153	153	-	76	7	-	14	23	45	-	28	22	5	37	
Vaginal native tissue repair, 174	-	-	-	-	-	63	106	121	17	-	-	-	67	
Transvaginal mesh, 357	-	-	-	-	-	3	39	126	-	324	273	53	33	
Laparoscopy with mesh, 531	-	38	490	91	5	-	-	2	-	-	-	-	228	
Overall, 1873	811	38	566	98	5	80	168	294	17	352	295	58	375	

MUS: Midurethral sling; POP: pelvic organ prolapse.

Table 2. Characteristics of the women and surgeries included in the analysis (N=1873)

Surgical group, N	Age		Menopausal n (%)	Sexually active n (%)	Smoking n (%)	Diabetes n (%)	Previous hysterectomy n (%)	Previous SUI or prolapse surgery n (%)	Operative time (min) mean (sd)	Operative blood loss (ml) mean (sd)
	mean (sd)	n (%)								
MUS alone, 658	57 (13)	364 (55.3)	367 (55.8)	90 (13.7)	31 (4.7)	98 (14.9)	112 (17.0)	28 (21)	37 (54)	
MUS + POP surgery, 153	63 (11)	121 (79.1)	68 (44.4)	13 (8.5)	8 (5.2)	28 (18.3)	27 (17.6)	139 (73)	96 (100)	
Vaginal native tissue repair, 174	68 (13)	151 (86.8)	53 (30.5)	11 (6.3)	17 (9.8)	41 (23.6)	47 (27.0)	80 (40)	78 (78)	
Transvaginal mesh, 357	70 (7)	352 (98.6)	103 (28.9)	17 (4.8)	34 (9.5)	78 (21.8)	94 (26.3)	74 (42)	90 (90)	
Laparoscopy with mesh, 531	62 (10)	433 (81.5)	270 (50.8)	41 (7.7)	37 (7.0)	81 (15.3)	100 (18.8)	152 (50)	59 (77)	
Overall, 1873	62 (12)	1421 (75.9)	861 (46.0)	172 (9.2)	127 (6.8)	326 (17.4)	380 (20.3)	86 (67)	59 (77)	

MUS: midurethral sling; POP: pelvic organ prolapse; sd: standard deviation.

Surgical groups differed significantly for age (ANOVA, $p < 0.001$), menopausal status (Chi^2 , $P < 0.001$), sexual activity (Chi^2 , $P < 0.001$), smoking (Chi^2 , $P < 0.001$), diabetes (Chi^2 , $P = 0.01$), previous hysterectomy (Chi^2 , $P = 0.004$), previous SUI or POP surgery (Chi^2 , $P = 0.006$), operative blood loss (ANOVA, $P < 0.001$), and operative time (ANOVA, $P < 0.001$).

Table 3. Incidence of serious complications (Grade III or more), relapse surgery (for stress urinary incontinence or prolapse), and any subsequent surgical procedure for relapse or complication (intraoperative complications excluded).

Surgical group		Included N	Serious complications n (%; 95% CI)	Relapse surgery n (%; 95% CI)	Subsequent surgery n (%; 95% CI)
MUS	MUS alone	658	23 (3.5, 2.3–5.1)	4 (0.6, 0.0–1.4)	25 (3.8, 2.5–5.5)
	+ POP surgery*	153	10 (6.5, 3.4–11.3)	4 (2.6, 0.9–6.1)	9 (5.9, 3.0–10.5)
Vaginal native tissue repair	no MUS	174	3 (1.7, 0.5–4.5)	2 (1.1, 0.2–3.6)	5 (2.9, 1.1–6.2)
	+ MUS*	39	2 (5.1, 1.1–15.4)	1 (2.6, 0.3–11.4)	2 (5.1, 1.1–15.4)
Transvaginal mesh	no MUS	357	10 (2.8, 1.4–4.9)	4 (1.1, 0.4–2.6)	10 (2.8, 1.4–4.9)
	+ MUS*	34	4 (11.8, 4.1–25.6)	1 (2.9, 0.3–12.9)	3 (8.8, 2.5–21.7)
Laparoscopy with mesh	no MUS	531	6 (1.1, 0.5–2.3)	15 (2.8, 1.7–4.5)	21 (4.0, 2.5–5.9)
	+ MUS*	80	4 (5.0, 1.7–11.4)	2 (2.5, 0.5–7.8)	4 (5.0, 1.7–11.4)
Overall		1873	52 (2.8, 2.1–3.6)	29 (1.5, 1.1–2.2)	70 (3.7, 2.9–4.7)

CI: confidence interval; MUS: Midurethral sling; POP: pelvic organ prolapse.

*In the group with both MUS and surgery for prolapse, eight complications were related to MUS (incidence: 5.2%, 2.5-9.6) and two to a transvaginal mesh (incidence: 5.9%, 1.2-17.6).

Table 4. Type, timing and management of the serious complications (N = 52). The number exceeds 52 because some women had more than one type of complication.

Surgical group	Complication type, n (%)						Time, n (%)			Care for complication, n (%)								
	Intraoperative injury*	Haemorrhage/haematoma*	Obstructed micturition*	Ureteral obstruction	Mesh exposure	Pelvic abscess	Pain	T1: 0-48 h	T2: D2-M2	T3: M2-M12	MUS/mesh intraoperative stop or removal*	OR for haemostasis	Upper urinary tract procedure	MUS loosening	MUS division	MUS removal	Mesh removal	Vaginal trimming (without excision)
MUS alone	1 (0.2)	1 (0.2)	13 (2.0)	-	7 (1.1)	-	4 (0.6)	3 (0.5)	12 (1.8)	8 (1.2)	2 (0.3)	-	-	10 (1.5)	3 (0.5)	7 (1.1)	-	1 (0.2)
MUS + POP surgery	3 (2.0)	1 (0.7)	4 (2.6)	-	3 (2.0)	-	1 (0.7)	3 (2.0)	5 (3.3)	2 (1.3)	3 (2.0)	1 (0.7)	-	3 (2.0)	-	2 (1.3)	-	1 (0.7)
Vaginal native tissue repair	-	3 (1.7)	-	-	-	-	1 (0.6)	2 (1.1)	1 (0.6)	-	-	3 (1.7)	-	-	-	-	-	-
Transvaginal mesh	3 (0.8)	1 (0.3)	1 (0.3)	2 (0.6)	4 (1.1)	-	3 (0.8)	5 (1.4)	2 (0.6)	3 (0.8)	3 (0.8)	1 (0.3)	2 (0.6)	-	-	-	2 (0.6)	2 (0.6)
Laparoscopy with mesh	-	1 (0.2)	-	1 (0.2)	2 (0.4)	2 (0.4)	1 (0.2)	-	4 (0.8)	2 (0.4)	-	1 (0.2)	1 (0.2)	-	-	-	4 (0.8)	-
Overall	7 (0.4)	7 (0.4)	18 (1.0)	3 (0.2)	16 (0.9)	2 (0.1)	10 (0.5)	13 (0.7)	24 (1.3)	15 (0.8)	8 (0.4)	6 (0.3)	3 (0.2)	13 (0.7)	3 (0.2)	9 (0.5)	6 (0.3)	4 (0.2)

MUS: midurethral sling; POP: pelvic organ prolapse; OR: operative room.

*The comparison between surgical groups was significant for intraoperative injury (Chi^2 , $P=0.003$), haemorrhage/haematoma (Chi^2 , $P=0.04$), obstructed micturition (Chi^2 , $P<0.001$), and MUS/mesh intraoperative stop or removal (Chi^2 , $P=0.01$).