

RESEARCH ARTICLE

Perceived health status after mid-urethral sling revision in 287 women from the VIGI-MESH registry: A cross-sectional study

Hugo Camilli¹  | Brigitte Fatton² | Elise Gand³ | Sandrine Campagne-Loiseau⁴ |
Renaud De Tayrac² | Laurent Wagner² | Christian Saussine⁵ | Jérôme Rigaud⁶ |
Thibault Thubert⁷ | Xavier Deffieux⁸ | Michel Cosson⁹ | Philippe Ferry¹⁰ |
Grégoire Capon¹¹ | Laure Panel¹² | Emmanuel Chartier-Kastler¹³ | Tristan Gauthier¹⁴ |
Xavier Game¹⁵ | Cassandra Bouynat¹⁶ | Romane Bichon¹⁶ | Arnaud Fauconnier¹⁷ |
Anne-Cécile Pizzoferrato¹  | Xavier Fritel¹⁸ 

Correspondence

Hugo Camilli, Service de Gynécologie-
Obstétrique, CHU de Poitiers, Université de
Poitiers, 2 rue de la Milétrie, 86 000 Poitiers,
France.

Email: hugo.camilli@gmail.com

Abstract

Objective: To evaluate the health status and recovery of women after mid-urethral sling (MUS) revision in response to complications.

Design: Cross-sectional study using a questionnaire sent to women from a registry.

Setting: Twenty-two French surgical centres.

Population: A total of 287 women from the VIGI-MESH registry responded, having undergone MUS revision for complications.

Methods: Our sample of women were compared against a representative set of French women taken from the Eurostat database. Multivariate analysis was performed to identify clinical predictors for successful MUS revision. A qualitative analysis was carried out on free-text comments.

Main outcome measures: Health status, defined by the Minimum European Health Module, and recovery, assessed by Patient Global Impression of Improvement.

Results: The response rate was 76% (287/378), with 49% of the women (141/287, 95% CI 43%–55%) reporting good health status, which was 8 points lower than that expected from the comparator French set (57%, 95% CI 55%–58%). Overall, 53% (147/275, 95% CI 47%–59%) of the women reported feeling much better after MUS revision. Just over one-third (35%, 95/275, 95% CI 29%–40%) of respondents reported poor health with little or no improvement. Multivariate analysis showed that being operated on for pain at revision was associated with worse self-perceived health than being operated on for exposure (OR 0.6, 95% CI 0.14–0.95); women with pre-existing comorbidity reported a poorer health status following MUS revision (OR 0.22, 95% CI 0.13–0.38).

Conclusions: Our results suggest that half of the women recovered good health status after MUS revision, whereas a proportion appeared to be seriously affected by an MUS complication despite the revision.

KEYWORDS

cross-sectional study, mid-urethral sling, perceived health status, revision surgery

1 | INTRODUCTION

Stress urinary incontinence (SUI) is a frequent complaint in women and is one of the diseases with the greatest impact on quality of life.^{1,2} During the course of their life, almost 14% of women may undergo SUI surgery.³ Mid-urethral sling (MUS) insertion is the current surgical gold standard. In France, around 32 000 slings are inserted each year.⁴

Following MUS insertion, some women experience complications such as mesh exposure, urinary disorders and chronic pain. Surgical sling revision after MUS insertion may be required in around 4% of patients.^{5,6} The exact number of surgical revisions is poorly known because of the under-reporting of mesh complications.⁷ Although in most cases surgical revision seems to repair the complication efficiently,⁸ some women unfortunately remain symptomatic despite the revision.

The VIGI-MESH registry collects data on complications after surgery for urinary incontinence in France,⁵ and provides a yearly assessment of a woman's health status, including their impression of improvement, self-perceived health, associated comorbidities, perceived limitations, quality of life and free-text descriptions of health concerns.

The aim of the current analysis was to evaluate health status and recovery after MUS revision for complications in women participating in the VIGI-MESH registry. We used global health indicators that enable a comparison between women participating in the VIGI-MESH registry and women in the general French population. Our secondary objective was to identify the clinical predictors of successful MUS revision.

We hypothesised that after MUS revision, women would report poorer health status than the overall French population of the same age. We also hypothesised that women with sling exposure would recover better than women who were in pain.

2 | METHODS

2.1 | Population

Our sample came from the VIGI-MESH registry and only included women who have undergone surgical revision for complications after MUS insertion. Women were included through surgeons indicating their characteristics (age, physical status, surgical history, diabetes, smoking status, menopause and sexual activity) and data relative to MUS insertion and revision (date, indication, surgical procedure, tape characteristics, etc.) on a specific form, including International Continence Society (ICS)–International Urogynecological Association (IUGA) classification.⁹ An independent and standardised review of those reports was carried out by two physicians.

2.2 | Ethical approval

Each woman participating in the VIGI-MESH registry received written information and agreed to the recording of her data and to the completion of follow-up questionnaires. The Comité de Protection des Personnes Ouest III (Institutional Review Board) approved the registry on 9 February 2017 (IDRBC2017-A000308-45), and the study was registered by the Commission Nationale Informatique et Libertés (the national data protection authority) on 16 August 2017 (DR-2017-245).

2.3 | Outcomes

In July 2021, each participant included received a health questionnaire sent by email, if known, or by postal mail if not. One month later, a reminder phone call was made to any women who had not replied.

2.3.1 | Minimum European Health Module

To appraise global health status, we used the Minimum European Health Module (MEHM), which is used by EuroStat to assess health status in European countries every year.¹⁰ This module is composed of three global health questions. The first question is about self-perceived health: 'how is your health in general?' Good health status was defined by the answers 'good' or 'very good'. Fair or poor health status was defined by the answers 'fair', 'bad' or 'very bad'. This constituted our primary end point. The second question asked about chronic morbidity. The third question applied the Global Activity Limitation Indicator (GALI); women were considered disabled if they answered that they were 'severely limited' in their everyday activities.¹¹

2.3.2 | Improvement

A good impression of improvement after MUS revision was defined as 'very much better' or 'much better' on the Patient Global Impression of Improvement (PGI-I) scale.¹² Little or no impression of improvement was defined as 'A little better', 'no change', 'a little worse', 'worse' or 'much worse'. This constituted our secondary end point.

2.3.3 | Open expression

We encouraged women to express themselves freely at the end of the questionnaire: 'we suggest you express yourself freely below, this section is yours, express what seems useful to you, detail your symptoms, your discomforts, what goes well or less well'.

2.4 | Analysis

2.4.1 | Responders versus non-responders

We compared responders and non-responders, considering the characteristics of the women and information related to MUS insertion and revision.

2.4.2 | Description of women characteristics, index surgery, and MUS revision

Single-incision MUS was classified as transobturator. In case of multiple complications, we considered the first occurrence. Comorbidity (yes or no) was assessed by question 2 of the MEHM ('Do you have any longstanding illness or health problem?'). If these data were missing, comorbidity was instead assessed by the American Society of Anesthesiologists (ASA) Physical Status Classification System (women graded as ASA III or higher were considered to have comorbidity).

We considered four classes for the indication of MUS revision: (i) exposure of sling (in the vagina, urethra or bladder); (ii) pelvic pain; (iii) urinary disorder (recurrent urinary tract infection, voiding dysfunction, overactive bladder); and (iv) postoperative collection (abscess or haematoma within 1 month of surgery).

We classified the type of surgical revision into three categories: (i) section of the sling; (ii) partial or total removal of the sling; or (iii) loosening of the sling, vaginal trimming and other procedures.

2.4.3 | Perceived health after MUS revision

First, we compared the self-perceived health observed in our sample of women in the VIGI-MESH registry who underwent MUS revision for complications against the expected self-perceived health from a set of 5540 French women of similar ages from Eurostat.¹³ We also compared the self-perceived health of our sample of women who required MUS revision for complications with that of 1289 women from the VIGI-MESH registry who did not need MUS revision.⁶

Second, in our VIGI-MESH sample of women with MUS revision, we performed a comparison of women in good versus women in fair or poor self-perceived health, using logistic regression, to highlight any predictors of good health status. The multivariate model was planned to include significant variables on univariate analysis and those suspected to be related to perceived health (age, smoking status, comorbidity, type of MUS and indications for revision).^{14,15} The final model retains only significant variables. We performed similar analysis on the secondary end point, the PGI-I scale (good impression of improvement vs little or no impression of improvement), with the objective of highlighting predictors of good recovery.

2.4.4 | Qualitative textual analysis

We chose to perform a qualitative analysis on free-text commentaries from women considering themselves in fair or poor self-perceived health, and with little or no impression of improvement by MUS revision. Their free-text comments were classified into different themes according to their expressed health situation.

2.5 | Statistics

Continuous data were expressed as mean $\pm$ standard deviation (SD). Categorical variables are given as number (percentage) of patients, along with the 95% confidence interval.

We used the Student's *t*-test to compare continuous variables with the normal distribution. The Wilcoxon rank sum test was reported for continuous variables with a skewed distribution; the χ^2 test or Fisher's exact test was reported for comparing categorical variables. Logistic regression models adjusted for known confounding factors were used to identify the predictors of good health. Variables associated with good health ($P < 0.20$) in the univariate logistic model were selected for the multivariate model.

All analyses were performed using SAS® (SAS Institute, Cary, NC, USA).

3 | RESULTS

3.1 | Population and responders versus non-responders

In the VIGI-MESH registry, 378 women who had undergone a surgical revision for MUS complications received our questionnaire. In total, 287 women completed the questionnaire (76%) and constituted our sample (Figure 1). No difference was found between responders and non-responders according to the characteristics of the women (Appendix S1).

3.2 | Revision: indication and surgical procedure

The MUS insertions took place between January 1998 and December 2020, with 51% (95% CI 45%–58%) using retropubic and 49% (95% CI 42%–55%) using transobturator slings. The mean age at the time of MUS insertion was 53 ± 14 years and the MUS revision was performed 5.1 ± 5.9 years (mean $\pm$ SD) after insertion. The questionnaire was filled out 3.1 ± 1.2 years (mean $\pm$ SD) after MUS revision (Table 1).

The three main indications for revision were pain, urinary disorders and exposure of the sling (Figure 2). In total,

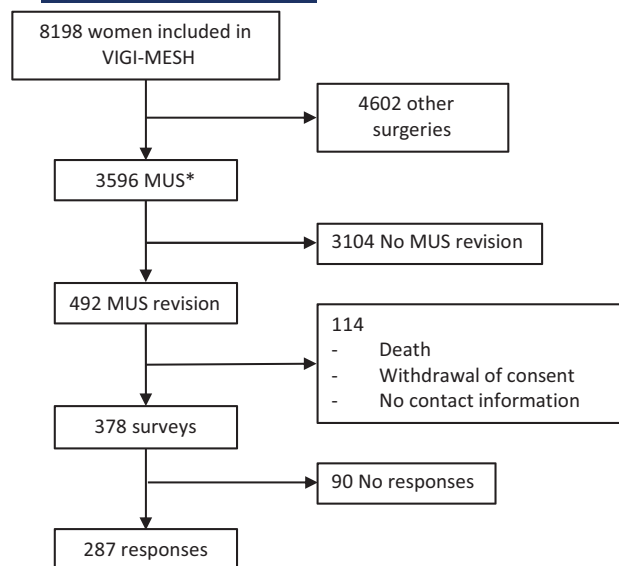


FIGURE 1 Flow chart. *MUS, mid-urethral sling.

TABLE 1 Characteristics of the population.

Variables	All (n = 287)
Age at follow up, year (mean ± SD)	61 ± 12
Age at MUS insertion, year (mean ± SD)	53 ± 14
Time to revision, year (mean ± SD)	5.1 ± 5.9
Time from revision to follow-up, year (mean ± SD)	3.1 ± 1.2
Smoking status, n (%)	35 (13%)
Comorbidity, n (%)	157 (56%)
BMI, kg/m ² (mean ± SD)	25.9 ± 4.8
Menopausal status, n (%)	191 (71%)
Sexual activity, n (%)	160 (69%)
RP MUS, n (%)	134 (51%)
TO MUS, n (%)	127 (49%)
Two or more MUS revisions, n (%)	32 (11%)
Indication for revision	
For exposure only, n (%)	56 (20%)
For pain only, n (%)	37 (13%)
For urinary disorders only, n (%)	86 (30%)
For two reasons or more, n (%)	101 (35%)
For postoperative collection only, n (%)	7 (2%)
Revision procedure	
Section of sling, n (%)	33 (11%)
Partial or total removal of sling, n (%)	188 (66%)
Vaginal trimming, sling loosening or other procedure, n (%)	66 (23%)

Abbreviations: BMI, body mass index; MUS, mid-urethral sling; RP, retropubic; SD, standard deviation; TO, transobturator.

101 women (35%, 95% CI 30%–41%) underwent MUS revision for at least two reasons (pain, exposure or urinary disorder).

Among the 143 women who returned for corrective surgery for exposure, 57 women (40%, 95% CI 32%–48%) were also in pain, 18 women (13%, 95% CI 7%–18%) also had urinary disorder and 12 women (8%, 95% CI 4%–13%) presented with all three indications; we also found 19 women who were asymptomatic (13%, 95% CI 8%–19%).

Among the 120 women who presented with pain, 49 women (41%, 95% CI 32%–50%) complained of dyspareunia, 24 women (20%, 95% CI 13%–27%) reported provoked pain and 50 women (42%, 95% CI 33%–50%) reported spontaneous pain. Thirteen women (11%, 95% CI 5%–16%) returned to the operation room within the first 6 months, including five women within the first 3 months.

Among the 130 women with urinary disorders, 37 women (28%, 95% CI 21%–36%) suffered from recurrent urinary infections, 35 women (27%, 95% CI 19%–35%) had overactive bladder symptoms, 40 women (31%, 95% CI 23%–39%) had immediate voiding dysfunction (within the first postoperative month) and 59 women (45%, 95% CI 37%–54%) had delayed voiding dysfunction.

The MUS revision resulted in total or partial MUS removal for 188/287 women (67%, 95% CI 60%–71%), MUS section for 33 women (11%, 95% CI 9%–17%), MUS loosening for 33 women (11%, 95% CI 8%–15%) and other procedures for 33 women (11%, 95% CI 8%–15%). Among the other procedures, we noted 13 vaginal trimmings and seven drainages (Appendix S2).

3.3 | Main results

At follow-up, almost half of the women (141/287, 49%, 95% CI 43%–55%) in our sample reported good health status; this result was 8 points (95% CI 7.3–8.7 points) lower than that expected in the French population (57%, 95% CI 55%–58%, according to Eurostat; $P=0.027$); it was also lower than that observed in the VIGI-MESH registry, with 73% (95% CI 71%–75%) of women who had undergone MUS insertion only, without postoperative revision, reporting good health status.

More than half of the women (53%, 95% CI 47%–59%) reported feeling much better after MUS revision. Fifty-two women (19%, 95% CI 14%–23%) reported severe limitations in their everyday activities; this result was 6 points (95% CI 5.4–6.6 points) higher than expected in the French population (13%, 95% CI 12%–14%, according to Eurostat; $P=0.002$).

Among women reporting fair or poor health status (lower row, Figure 3), we noted a sizable level of comorbidity (72%, 95% CI 65%–80%) and severe limitation (34%, 95% CI 26%–42%); the proportion of severe limitation was even greater in those who had presented little or no improvement after MUS revision (40%, 95% CI 30%–50%). Among women who declared that they had good health status (upper row, Figure 3), the rate of comorbidity was lower (38%, 95% CI 30%–46%) and a very low proportion

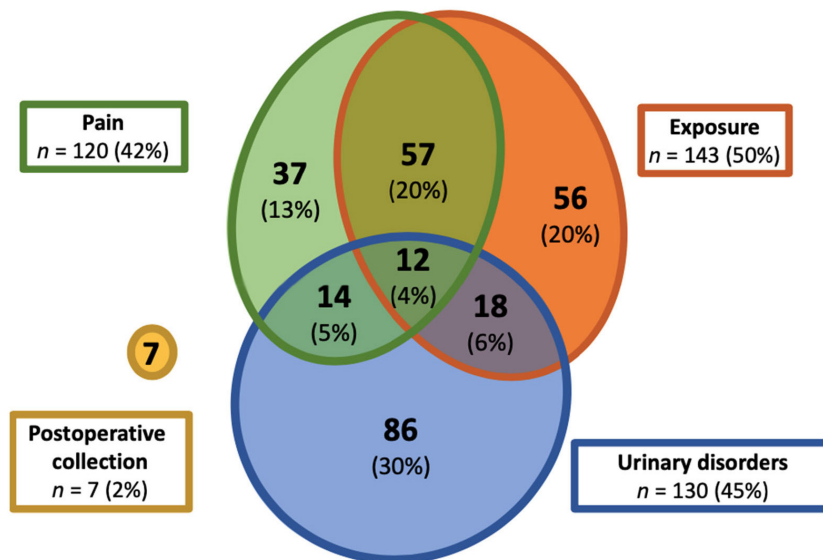


FIGURE 2 Indications for mid-urethral sling revision ($n = 287$).

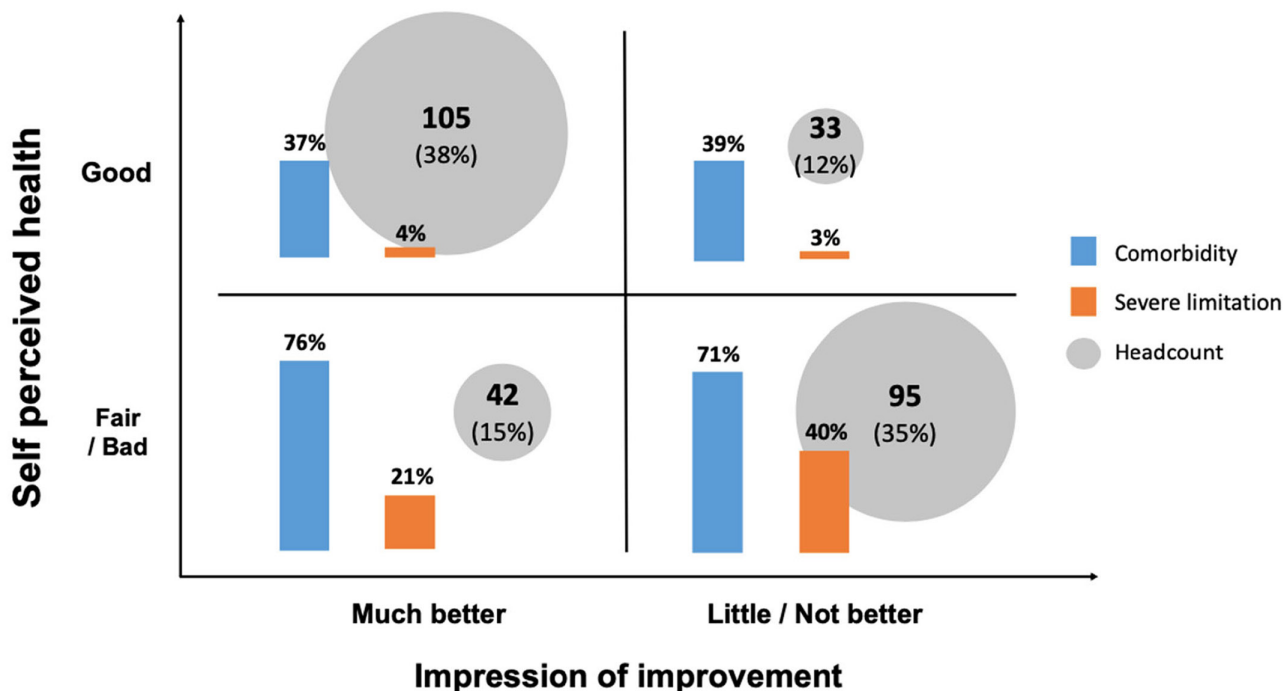


FIGURE 3 Self-perceived health and score for Patient Global Impression of Improvement (PGI-I) after mid-urethral sling revision ($n = 275^*$).

*Twelve missing values from PGI-I scale.

of women felt severely limited in their everyday activities (4%, 95% CI 0%–7%).

3.4 | Explanatory analysis

In the group with good self-perceived health, the women were younger, had fewer comorbidities, smoked less often and were more likely to still be sexually active. We did not find any difference between women with good versus fair or

poor self-perceived health concerning the type of MUS, type of complication and type of surgical procedure (univariate analysis) (Table 2).

We performed a multivariable analysis. The type of surgical procedure for revision was not included in this model. The final parameters that could explain a poorer health status were active smoker, comorbidity and older age (Table 3). Being operated on for pain at revision was associated with poorer self-perceived health than being operated on for exposure. All other variables included in the model were not significant.

TABLE 2 Univariate analysis: women with good self-perceived health versus women with fair or poor self-perceived health status and women who felt much better versus women who felt little or not improved.

Variables	Self-perceived health: very good or good			Impression of improvement: very much better or much better		
	Good (N=140)	Fair/bad (N=147)	Unadjusted OR (95% CI)	Much better (N=147)	Little/not improved (N=128)	Unadjusted OR (95% CI)
Age at follow-up, by year, mean $\pm$ SD	60 $\pm$ 12	63 $\pm$ 13	0.98 (0.96–0.99)	60 $\pm$ 12	63 $\pm$ 13	0.98 (0.96–1.00)
Age at MUS insertion, by year, mean $\pm$ SD	51 $\pm$ 15	54 $\pm$ 13	0.99 (0.97–1.00)	51 $\pm$ 15	54 $\pm$ 13	0.98 (0.97–1.00)
Time from insertion to revision, by year, mean $\pm$ SD	4.4 $\pm$ 5.3	5.7 $\pm$ 6.4	0.97 (0.93–1.00)	4.9 $\pm$ 5.5	5.2 $\pm$ 6.5	0.99 (0.95–1.03)
Time from revision to follow-up, by year, mean $\pm$ SD	3.1 $\pm$ 1.1	3.1 $\pm$ 1.3	0.99 (0.96–1.02)	3.1 $\pm$ 1.3	3.2 $\pm$ 1.2	0.94 (0.78–1.14)
Smoking status, yes vs no, <i>n</i> (%)	10 (31%)	25 (69%)	0.40 (0.19–0.84)	14 (42%)	19 (58%)	0.60 (0.29–1.25)
Comorbidity, yes vs no, <i>n</i> (%)	55 (35%)	102 (65%)	0.25 (0.15–0.42)	70 (47%)	79 (53%)	0.56 (0.35–0.92)
BMI (kg/m ²), mean $\pm$ SD	25.3 $\pm$ 4.5	26.4 $\pm$ 5.0	0.95 (0.90–1.00)	25.2 $\pm$ 4.5	26.7 $\pm$ 5.0	0.94 (0.89–0.99)
Menopausal status, yes vs no, <i>n</i> (%)	87 (46%)	104 (54%)	0.57 (0.33–0.97)	90 (49%)	92 (51%)	0.60 (0.34–1.04)
Sexual activity, yes vs no, <i>n</i> (%)	88 (56%)	72 (44%)	1.90 (1.08–3.34)	89 (58%)	65 (42%)	1.96 (1.10–3.49)
Two or more MUS revisions, yes vs no, <i>n</i> (%)	12 (38%)	20 (62%)	0.59 (0.28–1.25)	10 (32%)	21 (68%)	0.37 (0.17–0.82)
Type of MUS						
RP, <i>n</i> (%)	67 (50%)	67 (50%)	1	71 (55%)	58 (45%)	1
TO, <i>n</i> (%)	56 (44%)	71 (56%)	1.27 (0.78–2.06)	64 (52%)	59 (48%)	1.13 (0.69–1.85)
Indication for revision						
For exposure only, <i>n</i> (%)	29 (52%)	27 (48%)	1	34 (64%)	19 (36%)	1
For pain only, <i>n</i> (%)	15 (41%)	22 (59%)	0.64 (0.27–1.47)	13 (39%)	20 (61%)	0.36 (0.15–0.89)
For urinary disorders only, <i>n</i> (%)	48 (56%)	38 (44%)	1.18 (0.60–2.31)	43 (52%)	40 (48%)	0.60 (0.30–1.22)
For postoperative collection only, <i>n</i> (%)	3 (43%)	4 (57%)	0.70 (0.14–3.41)	4 (57%)	3 (43%)	0.75 (0.15–3.69)
For two reasons or more, <i>n</i> (%)	46 (46%)	55 (54%)	0.78 (0.41–1.50)	53 (54%)	46 (46%)	0.64 (0.31–1.28)
Revision procedure						
Section of sling, <i>n</i> (%)	19 (58%)	14 (42%)	1	22 (67%)	11 (33%)	1
Partial or total removal of sling, <i>n</i> (%)	88 (47%)	100 (53%)	0.65 (0.31–1.37)	92 (51%)	88 (49%)	0.52 (0.24–1.14)
Vaginal trimming, sling loosening or other procedure, <i>n</i> (%)	34 (52%)	32 (48%)	0.78 (0.34–1.82)	33 (53%)	29 (47%)	0.57 (0.24–1.37)

Note: Entries set in bold indicate significant difference.

Abbreviations: BMI, body mass index; CI, confidence interval; MUS, mid-urethral sling; OR, odds ratio; RP, retropubic; SD, standard deviation; TO, transobturator.

Concerning the impression of improvement, older age, comorbidity and several revisions (two or more) were associated with a poorer impression of improvement (Table 3). Being operated on for pain alone was associated with a poorer impression of improvement than being operated on for exposure alone. All other variables included in the model were not significant.

3.5 | Qualitative analysis

Of the women included in the study, 87% (249/287) expressed themselves freely.

Qualitative analysis of spontaneous declarations from the 95 women who considered themselves in fair or poor health with little or no improvement found six health themes

potentially related to MUS surgery and revision: (i) pain and sexual issues; (ii) urinary disorders; (iii) failure of surgery; (iv) despair; (v) lack of information; (vi) success of surgery; and (vii) other health issues (Table 4). If a woman expressed pain or despair, for example, we considered that the MUS contributed to her poor health status. On the contrary, if a woman expressed improvement or mentioned other health problems, we considered that her poor health status was not related to MUS insertion or revision. Out of these 95 women, 59 women (62%, 95% CI 52%–72%) attributed their poor health status to MUS insertion or revision, eight women (8%, 95% CI 3%–14%) expressed success concerning MUS revision, 19 women (20%, 95% CI 12%–28%) mentioned other health issues that could explain their health status and nine women (9%, 95% CI 4%–15%) did not express any explanation.

TABLE 3 Multiple regression logistic model to predict good health status after mid-urethral sling (MUS) revision for complications.

Variables	Self-perceived health	Impression of improvement
	Very good or good	Very much better or much better
	Multivariable adjusted OR (95% CI) ^a	Multivariable adjusted OR (95% CI) ^b
Age at follow-up, by year	0.77 (0.61–0.96)	0.78 (0.63–0.96)
Smoking status, yes vs no	0.31 (0.13–0.71)	–
Comorbidity, yes vs no	0.22 (0.13–0.38)	0.58 (0.35–0.97)
Two or more revisions, yes vs no	–	0.34 (0.15–0.78)
Revision		
For exposure only	1	1
For pain only	0.36 (0.14–0.95)	0.28 (0.11–0.72)
For urinary disorder only	0.88 (0.40–1.91)	0.56 (0.27–1.16)
For two reasons or more	0.77 (0.37–1.60)	0.66 (0.32–1.34)
For postoperative collection	1.17 (0.17–8.27)	0.72 (0.12–4.43)

Note: Entries set in bold indicate significant difference.

Abbreviations: CI, confidence interval; OR, odds ratio.

^aOther variables introduced in the model and not significant were number of MUS revisions (one vs two or more), type of MUS (retropubic vs transobturator) and body mass index.

^bOther variables introduced in the model and not significant were smoking status, type of MUS (retropubic vs transobturator) and body mass index.

TABLE 4 Samples and themes from the qualitative textual analysis of free-text comments collected from 95 women in fair or poor self-perceived health, with little or no impression of improvement.

Themes	Quotations	n ^a
Pain or sexual issues	'Burns and severe pain', 'The pain has remained', '... very important vaginal pains during my sexual intercourse involve today a new form of disability', 'I can't have sex', 'It is difficult for my husband and I to conceive of a normal sex life'	20
Urinary disorders	'Urinary tract problems', 'I still have to use underwear protection to avoid getting dirty all the time', 'Overactive bladder has not changed, it remains and is disabling'	20
Failure	'It didn't work', 'No changes', 'I expected much more improvement', 'So few results', 'Since the removal, urine leakage is still there, but I have no more pain at all'	12
Despair	'This operation destroyed my life', 'My life has been a long descent into hell', 'I even thought about suicide ... my life is hell', 'The mesh ... destroyed my sports life, sex life, etc.', 'Quality of life degraded', 'Broken life', 'I feel mutilated', 'My life is in brackets'	5
Lack of information	'Information has to be gathered, only the media has warned about the complications', 'I feel like I've been manipulated by surgeons'	2
Success	'I have my dignity back', 'I have been able to ride again since the last operation', 'My concerns about bladder leakage were resolved after the tape was removed'	8
Other issues	'On chemo ...', 'My health is bad because of my severe emphysema', 'Perceived health at 80 because in rehabilitation for total knee prosthesis'	19

^aNumber of women expressing themselves in this theme (nine women did not comment).

4 | DISCUSSION

4.1 | Main findings

In our sample of women undergoing revision for complications after MUS insertion, around half reported 'very good' or 'good' health status and around half felt 'very much better' or 'much better' after MUS revision.

A major finding from our study is that women with pre-existing comorbidity had a poorer health status following MUS complication and revision. Poor health status or no improvement were more likely to occur in the case of revision for pain.

4.2 | Strengths and limitations

One strength of our cross-sectional study is its multicentricity, with 287 women included from 22 centres in France, receiving treatment from no fewer than 54 different surgeons. Each operative report and medical file was appraised by two independent physicians (XF and AC). All data relative to MUS revision were collected prospectively.

To appraise the health status reported by women who had experienced a complication after MUS insertion, we used several methods.

1. Global patient reported outcome measure, such as MEHM enabled us to compare our sample with the self-perceived health expected in the French population of the same age.
2. We also compared our sample with a sample of women from VIGI-MESH who had an MUS insertion alone (without any concomitant repair of pelvic organ prolapse and with no revision). These two comparisons, using the MEHM, enabled us to place our population on a precise scale. Our sample of women appears to be in poorer health compared with that of the general population and with that of women from VIGI-MESH having undergone MUS without complications.
3. We also carried out qualitative analysis of the free-text comments, as the majority of women expressed themselves about their poor health. We distinguished between situations potentially attributable to MUS insertion, or its revision, and those attributed by women to another health problem.

These complementary methods enabled us to better describe the health status of our population, which is known to be subjective and complex information and therefore difficult to evaluate by a simple numerical assessment.

The method of comparing health status between our sample and the set of French women may be a limitation because women were not surveyed using exactly the same media. We consider that the results are interpretable because they are consistent with the comparison made in the VIGI-MESH register between women with revision and women without revision.

4.3 | External validity

Two other studies using the same definition of improvement with PGI-I found similar results: there was 47% improvement among the 59 patients studied by Kowalik et al. (they had undergone mesh removal of vaginal mesh, abdominal mesh or MUS);¹⁶ in the population of 101 women who underwent MUS revision for urinary disorders, studied by Kim-fine et al., 49% of the patients reported improvement.¹⁷ Concerning variation in improvement depending upon indication for revision, our results are in accordance with those of a prospective study conducted by Pace et al.,¹⁸ who highlighted a greater impression of improvement after revision for mesh exposure than after revision for pain only (74% vs 33%; 64% vs 39% in our sample).

Few previous studies have collected the experiences of women after MUS revision. The strength of the words used by some women in their responses showed us the impact that such complications can have. Uberoï et al. noted that patients were unprepared for the potential failure of surgery and, as we also highlighted, expressed despair, with a strong sense of failure after MUS complications.¹⁹

4.4 | Interpretation

Poor health status in our sample was related to older age, more comorbidities and severe limitations. This result is consistent with our clinical experience and can also be compared with the findings of Greer et al.,²⁰ who in 2013 had shown that women with an ASA III score had more perioperative complications after prolapse surgery. In our sample, the group of women in fair or poor self-perceived health declared double the level of comorbidity than the group in good self-perceived health. Having a pre-existing comorbidity appears to amplify the health consequences of a complication.

Our results show that, in the case of pain, poor health status may persist despite surgical revision. Women reoperated upon for pain had poorer self-perceived health and a lower impression of improvement than women reoperated upon for exposure of the sling. The women with sling exposure were less often symptomatic prior to revision; furthermore, we know that chronic pain may be resistant to surgical revision and require alternative treatments.²¹

Nearly two-thirds of the women in our sample reported good perceived health or great improvement after the revision, whereas just over one-third reported poor health with little or no improvement. In the group of women with the worst health status (in fair or poor health, with little or no improvement), 62% associated their poor condition with their experience of MUS insertion or revision. The identification of women at risk of long-term sequelae seems to be essential before MUS insertion. Although our study design does not enable us to define a typical patient profile, it seems that the women most affected by a complication of MUS would be those with comorbidities. Likewise, Pace et al. suggest that the women most affected are those with a chronic pain condition;¹⁸ in the work by Jong et al., 46% of women revised for pain after MUS were in chronic pain.²² Smoking also appears to be a risk factor in this context: we found it to be associated with poorer self-perceived health after MUS revision. Smoking was previously known as a risk factor for sling revision (Clancy et al.).²³

Our sample is derived from the 4% of women who underwent MUS revision after MUS insertion. MUS revision results in total failure for 21% of our sample. Therefore, total failure is a rare occurrence for women with MUS insertion. The impact of sequelae despite revision on these women is considerable: urinary disorders, pain and sexual issues were the most frequent explanations in their poor health. This situation should be known by surgeons, especially insofar as it can lead to a breakdown of trust between the practitioner and the patient, as a few women have clearly explained to us (Table 4).

Even though the preoperative profile of patients unlikely to experience improvement after MUS revision needs to be better established, the circumstances of revision failure must be actively sought out, with the objective of proposing adequate, at times multidisciplinary, therapies. Abraham et al. have highlighted the importance of multidisciplinary

management of patients with persisting pain after their surgery, particularly with physiotherapy.²⁴

5 | CONCLUSION

In our registry, half of the women who had undergone surgical revision for complications after MUS insertion felt much better, whereas half reported fair or poor health status. The health status in our sample was poorer than expected in the French population. Risk factors for poor health status or no improvement after MUS revision were higher age, comorbidities and pain.

AUTHOR CONTRIBUTIONS

Study concept and design: HC, BF and XF. Acquisition of data: HC, BF, EG, SC-L, RDT, LW, CS, JR, TT, XD, MC, PF, GC, LP, EC-K, TG, XG, CB, RB, AF, A-CP and XF. Analysis and interpretation of data: HC, BF, EG and XF. Drafting of the article: HC and XF. Statistical analysis: HC, EG and XF. Obtaining funding: XF. HC and XF had full access to all data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. They attest that all authors listed meet the authorship criteria and that no others meeting the criteria have been omitted. We affirm that our article is an honest, accurate and transparent report of the VIGI-MESH registry, that no important aspects of the registry have been omitted, and that any discrepancies from the registry as originally planned and registered have been explained.

AFFILIATIONS

¹Service de Gynécologie-Obstétrique, CHU de Poitiers, Université de Poitiers, Poitiers, France

²Service de Gynécologie-Obstétrique, CHU Carémieu, Université de Nîmes, Nîmes, France

³INSERM CIC 1402, Université de Poitiers, Poitiers, France

⁴Service de Gynécologie-Obstétrique, CHU Estaing, Clermont-Ferrand, France

⁵Service d'Urologie, CHU de Strasbourg, Université de Strasbourg, Strasbourg, France

⁶Service d'Urologie, CHU de Nantes, Nantes, France

⁷Service de Gynécologie, CHU de Nantes, Nantes, France

⁸APHP Antoine-Béclère, Service de Gynécologie-Obstétrique, Université Paris-Sud, Clamart, France

⁹Service de Gynécologie-Obstétrique, CHU de Lille, Université de Lille, Lille, France

¹⁰Service de Gynécologie-Obstétrique, CH de La Rochelle, La Rochelle, France

¹¹Service d'Urologie, CHU de Bordeaux, Université de Bordeaux, Bordeaux, France

¹²Service de Gynécologie, Clinique Beau-Soleil, Montpellier, France

¹³CHU de la Pitié-Salpêtrière, AP-HP, Université de la Sorbonne, Paris, France

¹⁴Service de Gynécologie-Obstétrique, CHU de Limoges, Université de Limoges, Limoges, France

¹⁵Service d'Urologie, CHU de Toulouse, Université de Toulouse, Toulouse, France

¹⁶Université de Poitiers, Poitiers, France

¹⁷Service de Gynécologie-Obstétrique, CHI Poissy-Saint-Germain, UVSQ, Poissy, France

¹⁸INSERM CIC 1402, Service de Gynécologie-Obstétrique, CHU de Poitiers, Université de Poitiers, Poitiers, France

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CONFLICT OF INTEREST STATEMENT

HC, BF, EG, SC-L, CS, JR, TT, XD, MC, PF, GC, LP, EC-K, TG, XG, CB, RB, AF, A-CP and XF have no conflicts of interest. Prof. Renaud de Tayrac reports grants, personal fees or other recompense from Neomedic and ABMedica. Prof. Laurent Wagner reports grants, personal fees or other recompense from Coloplast, Neomedic and ABMedica. Prof. Michel Cosson reports personal fees from Promedon, ABMedica and Syliva Proveday. Dr Philippe Ferry and Prof. Xavier Game report grants, personal fees or other recompense from Coloplast.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author, upon reasonable request.

ETHICS APPROVAL

The Comité de Protection des Personnes Ouest III (Institutional Review Board) approved the registry on 9 February 2017 (IDRBC2017-A000308-45), and the study was registered by the Commission Nationale Informatique et Libertés (the national data protection authority) on 16 August 2017 (DR-2017-245).

ORCID

Hugo Camilli  <https://orcid.org/0009-0005-9841-8804>

Anne-Cécile Pizzoferrato  <https://orcid.org/0000-0003-3973-6018>

[org/0000-0003-3973-6018](https://orcid.org/0000-0003-3973-6018)

Xavier Fritel  <https://orcid.org/0000-0002-4987-8127>

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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