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ORIGINAL ARTICLE

Functional outcomes of synthetic tape and mesh revision surgeries: a monocentric experience

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Abstract

Introduction and hypothesis Synthetic tapes and meshes used for the treatment of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) can lead to complications that require additional surgical procedures. The objective of this study was to report the functional outcomes following tape/mesh removal procedures.

Methods This retrospective study included all consecutive women who underwent a tape/mesh surgical revision in a single tertiary referral center from January 2008 to September 2016. Descriptive statistics were performed to assess outcomes.

Results Overall 140 women, with a mean age of 60.5 (range 35-91) years, had a tape/mesh surgical revision. Patients underwent the following surgeries: tape removal ($n = 95/140$, 67.9%), tape division ($n = 23/140$, 16.4%), mesh removal ($n = 18/140$, 12.9%) and concomitant tape and mesh removal ($n = 4/140$, 2.9%). Tape removals were mainly performed for voiding symptoms ($n = 34/95$, 35.8%) and vaginal erosion/extrusion ($n = 16/95$, 16.8%). Most mesh removals were performed for vaginal erosion/extrusion ($n = 9/18$, 50.0%). Mean interval between tape/mesh insertion and its surgical revision was 52.1 months (range 5.0 days-16.0 years). Mean follow-up time was 20.4 months (range 6.0 days–7.8 years). Voiding and storage symptoms resolved completely in 37/59 (62.7%) patients and in 14/37 (37.8%) patients, respectively; 42/81 (51.9%) patients with postoperative SUI recurrence or persistence underwent an additional surgical procedure. Among the 18 patients who had a mesh removal, only 1 (5.6%) had POP recurrence.

Conclusion Although most symptoms resolved after tape and mesh surgical revisions, patients must be informed that symptoms may persist. Recurrent or persistent SUI or POP may require a subsequent surgical procedure.

Keywords Mesh · Pain · Prolapse · Stress urinary incontinence

Abbreviations

FDA	Food and Drug Administration
POP	Pelvic organ prolapse
PVR	Post-void residual
SUI	Stress urinary incontinence
UTI	Urinary tract infections

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Introduction

An overall prevalence of 26.8% of urinary incontinence, distributed as stress urinary incontinence (SUI) in 45.2% of cases and mixed urinary incontinence in 42.1% of cases, has been reported in French women [1]. Synthetic midurethral tapes are the most frequent surgical procedures performed in Europe for the treatment of SUI [2]. Moreover, the prevalence of symptomatic pelvic organ prolapses (POP) in European countries ranges between 8.3–11.4% [3, 4], and synthetic meshes, placed abdominally or vaginally, are widely used for their surgical treatment [5]. The simplicity of these surgical interventions and high success rates make them very attractive [6, 7].

The use of synthetic material has generated novel complications including tape/mesh erosion/extrusion, contraction and pelvic and vaginal pain [8]. It is difficult to determine the exact incidence of mesh/tape complications because of a lack of a true denominator, lack of a systematic registration of mesh-related complications (underreporting) and lack of studies with

adequate length of follow-up and high attrition rates [9–11]. What is certain is that tape/mesh complications can be serious and require additional surgeries. Abott et al. [12] identified 347 women with tape/mesh complications, among which 77% were grade three or four (severe) complications (Accordion Expanded Classification). These complications required a median of two revision surgeries (range 1–9). Moreover, several authors agree that the surgical management of such complications can be complex and challenging [8, 9, 13, 14].

Two Food and Drug Administration (FDA) safety warnings were issued in 2008 and 2011 regarding the complications associated with synthetic vaginal meshes [15]. More recently, in 2016, the FDA issued an order to reclassify transvaginal surgical meshes for POP from class II (special controls) to class III (pre-market approval) [16]. These warnings and reclassification reiterate the serious risk of complications that may be associated with transvaginal surgical meshes.

As the main objective of the present study was to assess the surgical indications and clinical outcomes of tape and mesh revision surgeries in an expert center, we wanted to obtain unknown data on the functional voiding/continence status of patients after surgical revision. We hypothesized that while these revision surgeries would improve the majority of preoperative symptoms, some would persist. We also hypothesized that these revision surgeries could lead to complications such as SUI recurrence.

Materials and methods

After institutional review board approval, a retrospective study was conducted in a tertiary referral center and included all consecutive women who underwent synthetic tape/mesh revision surgeries from January 2008 to September 2016. Patients who had previous tape/mesh revision surgeries in other institutions and patients with neurogenic diseases were also included. Retrieved data regarding patient demographics and past medical history included age, body mass index, hormonal status, number of deliveries, comorbidities and bladder drainage method. We also identified the date, exact surgical procedure and approach of the initial synthetic tape/mesh surgery.

Revision surgeries were classified into four groups: tape division, tape removal (partial or complete), mesh removal (partial or complete) and concomitant tape and mesh removal. Surgical indications were categorized as the following: vaginal erosion/extrusion, urethral erosion, bladder erosion, voiding symptoms [abnormally slow and/or incomplete micturition with elevated post-void residual (PVR) and/or straining at micturition], storage symptoms (frequency, urgency with or without urge urinary incontinence), chronic pelvic pain/dyspareunia (diffuse pelvic pain, vaginal pain, dyspareunia, pain at micturition, inner thigh pain and lower abdominal pain) and mixed urinary symptoms/pain (several of the previously mentioned symptoms). Whenever a patient had more than one surgical indication, the following order was used to stratify them: erosion/extrusion followed by voiding symptoms, storage symptoms, chronic pelvic pain/dyspareunia and, finally, mixed urinary symptoms. Moreover, complications of the initial synthetic tape/mesh were classified according to the ICS/IUGA prosthesis complication classification [17]. Mean operative time and time interval between initial tape/mesh surgery and revision surgery were collected.

We also looked into whether preoperative symptoms [voiding symptoms, pelvic pain/dyspareunia, storage symptoms, recurrent urinary tract infections (UTIs)] were completely resolved, improved or unchanged after revision surgery. Recurrent UTIs were defined as ≥ 3 episodes per year. The final symptom status (resolved, improved or unchanged) was strictly based on the surgeons' medical notes mainly based on questions asked to the patients, but also on uroflowmetry, PVR, bladder diary and number of UTIs, when applicable.

Finally, complications after the latter were collected, namely SUI recurrence or persistence, POP recurrence or persistence, mixed urinary incontinence and other. Surgical management and outcomes of these complications, when applicable, were reported. Statistical analyses were performed using SPSS (IBM SPSS Statistics, version 20.0.0).

Surgical decision making

Being a referral center, the majority of patients were referred to our urology department for the management of their tape/mesh complications. Upon consultation, the operative report of the initial surgery was ordered, whenever possible, to better understand the procedure that had been performed. All patients also had a complete pelvic floor examination, cystoscopy and urodynamic study. Some also had a transvaginal ultrasound to locate the tape. Based on the patient interview, physical examination and paraclinical evaluation, surgeons were able to clearly identify the surgical indication during a multidisciplinary meeting (including urologists dedicated to functional urology, rehab physicians, pain team, gynecologists, colorectal surgeons) and plan the appropriate surgery. Operative reports in our center tend to contain all valuable elements of the surgical decision making; therefore, there were no missing data.

Vaginal erosions were initially treated with local hormonal therapy. When this failed or in cases of vaginal extrusion, a local surgical excision was performed. The later was also entitled for urethral erosions. The tape/mesh was removed subsequently in cases of recurrence. As for urinary symptoms, the surgical decision making algorithm was the following. When a urodynamic study confirmed urinary obstruction, a tape division was performed. Storage symptoms, mixed urinary symptoms, bladder erosions and chronic pelvic pain/dyspareunia required the removal of the entire tape/mesh. Meshes inserted by

a vaginal approach and TOT/TVT-O were removed via a vaginal approach. Meshes inserted laparoscopically and TVT tapes were removed laparoscopically. An informed consent was obtained from all patients after explaining the revision surgery procedure and its risks in detail.

Results

Patients' baseline characteristics

Overall, 140 women who underwent a tape/mesh revision surgery were included in our study. The majority of women ($n = 116/140$, 82.9%) had been referred to our urology department for the management of their tape/mesh complication. Table 1 depicts their baseline characteristics. Mean age at revision surgery was 60.5 (range 35–91) years. Thirty (21.4%) patients had previously undergone one or more tape/mesh revision surgeries, of which 27/30 (90.0%) occurred in another center prior to referral. Data regarding the exact types of tapes/meshes were rarely mentioned in the operative protocols and therefore were only available for 24 (17.1%) patients. More than ten different types of tapes/meshes were inserted among these patients, the Gynecare™ tape being the most frequent (6/24, 25%).

Revision surgery indications

Patients underwent the following revision surgeries: tape removal ($n = 95/140$, 67.9%), tape division ($n = 23/140$, 16.4%), mesh removal ($n = 18/140$, 12.9%) and concomitant tape and mesh removal ($n = 4/140$, 2.9%). Indications of revision surgeries are listed in Fig. 1. Tape removals were mainly performed for voiding symptoms ($n = 34/95$, 35.8%) and vaginal erosion/extrusion ($n = 16/95$, 16.8%). The majority of mesh removal surgeries were performed for vaginal erosion/extrusion ($n = 9/18$, 50.0%) and pelvic pain/dyspareunia ($n = 5/18$, 27.8%). Tape/mesh vaginal erosions and extrusions were asymptomatic in 20/140 (14.3%) patients. Tape/mesh complications are classified according to the ICS/IUGA prosthesis complication classification in Fig. 2. The majority of tape complications were related to the urinary tract, were asymptomatic and occurred more than 12 months following the initial surgery. As for mesh complications, the majority were associated with a vaginal exposure > 1 cm that occurred more than 12 months following the implant and that could be either symptomatic or asymptomatic.

Revision surgery procedures

Revision surgery-related data are provided in Table 2. Mean interval between tape/mesh insertion and its revision surgery in our center was 52.1 months (range 5.0 days–16.0 years). Removal and division of tapes were mainly performed using a vaginal approach in 65/95 (68.4%) and 22/23 (95.7%) patients, respectively. More specifically, among the 53 patients who had a revision surgery for a TVT tape, 19/53 (35.8%) were completely removed through a laparoscopic approach, 14/53 (26.4%) were removed through a vaginal approach, 13/53 (24.5%) were incised through a vaginal approach, 4/53 (7.5%) were removed through a combined laparoscopic and vaginal approach, and 3/53 (5.7%) were removed through an abdominal open approach. Mesh revision surgeries were performed using a vaginal, laparoscopic or open approach in 10/18 (55.5%), 5/18 (27.8%) and 3/18 (16.7%) patients, respectively. More precisely, among the ten patients who had a transvaginal mesh, nine (90.0%) were removed with a vaginal approach and one (10.0%) with an open approach. Together with the revision surgeries, three (2.1%) patients had a laparoscopic anterior and posterior sacrocolpopexy and one (0.7%) patient a TVT insertion.

Revision surgery outcomes

Mean follow-up up time was 20.4 months (range 6.0 days–7.8 years). Eleven of 140 (7.9%) patients were lost to follow-up immediately after revision surgery. Voiding and storage symptoms resolved completely in 37/59 (62.7%) and in 14/37 (37.8%) patients, respectively (Table 3).

Preoperatively, 47 patients had reported pelvic pain/dyspareunia. More specifically, 23/47 (48.9%) patients had complained of diffuse pelvic pain, 9/47 (19.1%) of vaginal pain, 8/47 (17.0%) of dyspareunia, 3/47 (6.4%) of pain at micturition, 2 (4.3%) of inner thigh pain and 2 (4.3%) of lower abdominal pain. In 21/47 (44.7%) of these patients, pain was associated with vaginal, urethral or bladder erosion. Pelvic pain/dyspareunia resolved completely after revision surgery in 30/47 (63.8%) patients (Table 3). Final pain status was strictly based on what was reported by the patients.

Figure 3 demonstrates the results post revision surgery. One patient developed a vesico-vaginal fistula after a laparoscopic and vaginal tape removal. This patient later benefited from a Martius flap. Cases of persistent SUI occurred when patients reported having SUI before their revision surgery, while cases of recurrent SUI occurred when patients only had SUI after their revision surgery. Rates of SUI recurrence were of 34.8 and 36.8% following tape section and removal, respectively. In very few cases, patients reported a worsening of their SUI symptoms. Of 81 patients with postoperative SUI recurrence or persistence, 42 (51.9%) patients underwent an additional surgical procedure: 18/81 (22.2%) tapes, 17/81 (21.0%) artificial urinary sphincters, 6/81 (7.4%) adjustable continence ACT balloons and 1/81 (1.2%) fascial slings. Only 1 (4.5%) patient of the 22 who had a partial or complete mesh removal (with or without tape removal) had a

Table 1 Baseline patient characteristics at revision surgery ($n = 140$)

Variable	Total (n = 140)	Tape complication ($n = 118$)	Mesh complication ($n = 18$)	Tape and mesh complications ($n = 4$)
Median age, years (range)	60.5 (35–91)	60.0 (35–91)	66.5 (47–77)	61.0 (50–63)
BMI, n (%)				
- < 18.5	4 (2.9)	4 (3.4)	0	0
- ≥ 18.5 to < 25	51 (36.4)	41 (34.7)	9 (50.0)	1 (25.0)
- ≥ 25 to < 30	47 (33.6)	40 (33.9)	5 (27.8)	2 (50.0)
- ≥ 30	30 (21.4)	27 (22.9)	2 (11.1)	1 (25.0)
- Unavailable	8 (5.7)	6 (5.1)	2 (11.1)	0
Neurologic disorder, n (%)				
- None	134 (95.7)	114 (96.6)	16 (88.9)	4 (100)
- Cauda equinae syndrome	3 (2.1)	2 (1.7)	1 (5.6)	0
- Spinal cord injury	1 (0.7)	0	1 (5.6)	0
- Stroke and Parkinson's disease	2 (1.4)	2 (1.7)	0	0
Median parity (range)	4.7 (0-12)	3 (0-12)	3 (0-10)	6 (2-10)
Hormonal status, n (%)				
- Premenopausal	33 (23.6)	31 (26.3)	2 (11.1)	0
- Postmenopausal	107 (76.4)	87 (73.7)	16 (88.9)	4 (100)
Bladder drainage method, n (%)				
- Spontaneous voiding	123 (87.9)	103 (87.3)	16 (88.9)	4 (100)
- ISC	17 (12.1)	15 (12.7)	2 (11.1)	0
Smoking status, n (%)				
- Never smoker	94 (67.1)	75 (63.6)	15 (83.3)	4 (100)
- Former smoker	11 (7.9)	11 (9.3)	0	0
- Current smoker	20 (14.3)	20 (16.9)	0	0
- Not reported	15 (10.7)	12 (10.2)	3 (16.7)	0
Previous pelvic radiotherapy	4 (2.9)	4 (3.4)	0	0
Diabetes	11 (7.9)	9 (7.6)	2 (11.1)	0
History of tape/mesh revision surgery, n (%)	30 (21.4)			
- Tape division	18 (60.0)			
- Tape removal	8 (26.7)	–	–	–
Vaginal approach	5 (16.7)			
Abdominal approach	3 (10.0)			
- Partial or complete mesh removal (vaginal approach)	3 (10.0)			
Tape distention	1 (3.3)			

ISC: Intermittent self-catheterization

symptomatic POP recurrence that was confirmed at the pelvic floor examination and this patient opted for observation.

Discussion

The purpose of this study was to evaluate indications and clinical outcomes of tape/mesh revision surgeries. The most common surgical indications of tape and mesh revision surgeries were voiding symptoms (35.8–60.9%) and vaginal erosion/extrusion (44.4%), respectively. These surgeries often succeeded in improving voiding and pain symptoms (62.7–63.8%); however, their outcomes regarding storage symptom improvement (37.8%) remained low. We have also demonstrated that SUI and POP may recur after revision surgeries. These data reiterate the importance but also the complexity of revision surgeries.

The most frequent surgical indication for tape division/removal in our study was chronic voiding symptoms. This is one of the most frequent complication of tapes, with reported rates ranging between 2.8 and 34.7%. Mesh removal surgeries were mostly performed for vaginal erosion/extrusion in our study. This corroborates what has been previously reported in the literature [10, 12]. Similar to other studies [18, 19], the majority of tape/mesh complications in our study occurred at periods of

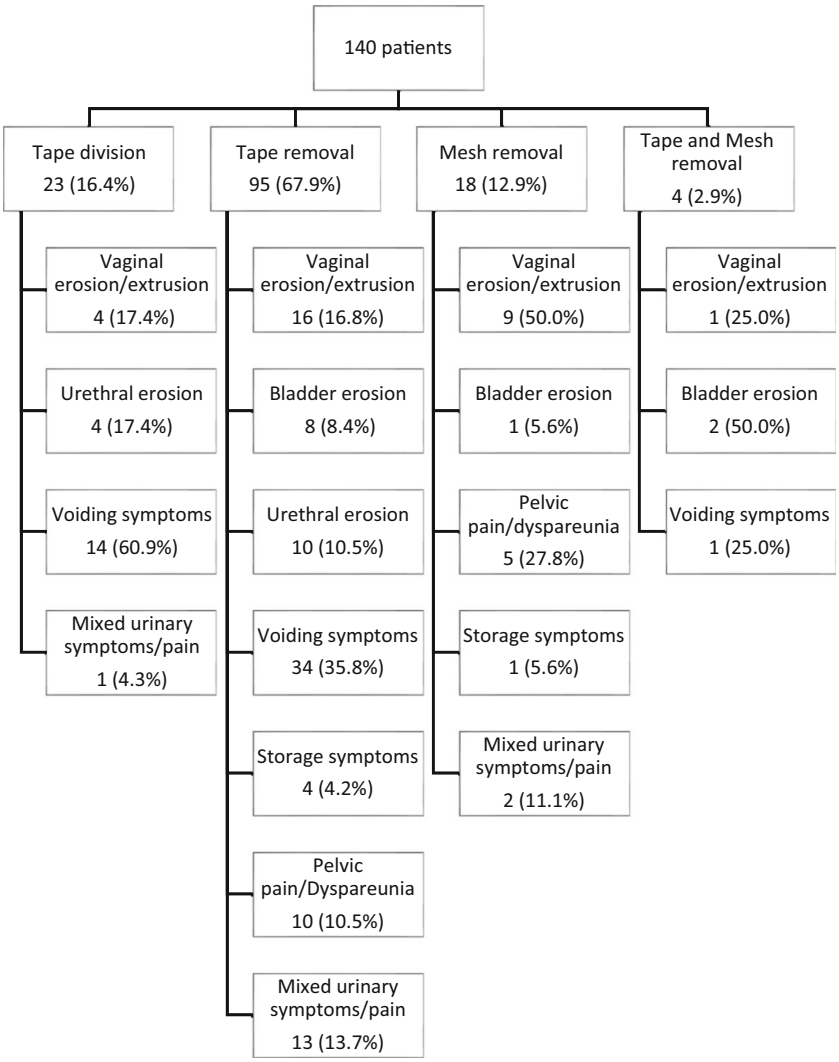

Fig. 1 Surgical indications of revision surgeries

time classified as T3 (between 2 to 12 months) and T4 (over 12 months).

There is major lack of evidence regarding the surgical management of tape/mesh complications [8, 9]. Whether an obstructive tape should be incised or excised, whether a minor vaginal erosion should be treated with estrogen or be excised and how a urinary tract erosion should be managed are all questions that remain partially unanswered [9]. The surgical algorithm for pain management is somewhat clearer as it is advised to excise only the portion where the pain is localized and to remove more material later if the pain persists [20]. Some authors [21, 22] have suggested performing a local anesthetic/steroid infiltration test prior to tape removal. In our center, whenever possible, we tend to opt for a more minimalistic surgical procedure for the first revision surgery to reduce the rates and severity of possible complications. However, when subsequent revision surgeries are required, we prefer a more radical procedure.

Tape/mesh revision surgeries led to a complete resolution of symptoms in about 60% of cases in our study, except for chronic storage symptoms (urgency, frequency, urge urinary incontinence) (37.8%). Similar success rates have been described in the literature (51–57.3%) [18, 23]. Pelvic pain, which included vaginal, micturition, inner thigh, lower abdominal and diffuse pelvic pain as well as dyspareunia, was resolved or improved in 72.3% of patients in this current study. Data in the literature regarding pain status are quite inconsistent. Similar rates have been previously described with a pain-free status achieved in 81 and 67% of patients after tape and mesh revision surgeries, respectively [20]. Another group has reported that among women undergoing a transvaginal mesh revision surgery for pain, only 51% were successfully treated [23]. Worsening of pain has also been described [13]. It must be noted that studies reporting complications of tapes and meshes in the literature are quite heterogeneous, namely regarding methodology and outcome measures. All in all, the presented data reiterate the importance of informing patients with symptoms related to previous tape/mesh surgery complications, no matter their symptoms, that these may persist after revision surgery.

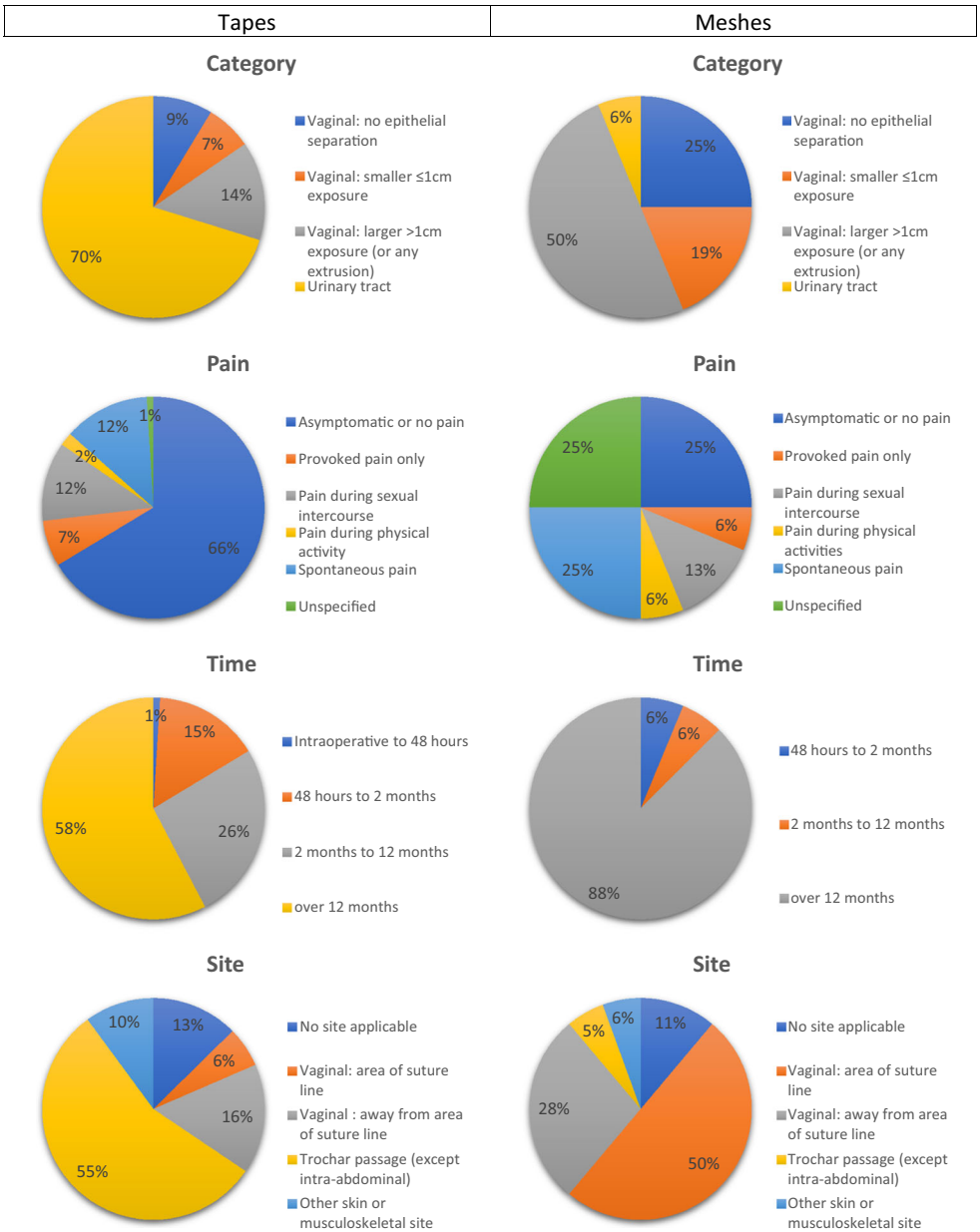

Fig. 2 Tape/mesh complications according to the ICS/IUGA prosthesis/graft complication classification code

In this current study, SUI recurred in 34.8 and 36.8% patients after tape division and tape removal, respectively. Singla et al. [24] reported that in their cohort of 99 patients who underwent a tape revision surgery, 19 reported de novo SUI and 19 reported de novo mixed urinary incontinence. Moreover, among the nine patients who underwent a concomitant SUI surgery at the time of revision in their study, none presented with SUI recurrence. Whether a concomitant surgery for SUI should be performed at the time of the revision surgery is controversial. We prefer to fully reassess patients at a distance from their revision surgery, after complete healing, to recommend the most appropriate SUI surgery case by case. POP recurred in only one (5.6%) patient after partial or complete mesh removal surgery in our study. Similar rates have been reported in the literature (7%) [25].

As previously stated in the literature [8, 9, 11], complications of tapes/meshes are currently underreported, and there is a lack of long-term follow-ups. It is of utmost importance to establish registries that would allow ascertaining the true incidence of such complications and therefore better inform patients of the risks and benefits of the synthetic tape/mesh surgeries they will be undergoing. In the same line of thought, we recommend avoiding the use of multiple tapes/meshes to decrease the risk of complications.

The main limitation of this current study is that it is retrospective, and therefore no validated questionnaire could be used. The description of symptoms was also limited to "complete resolution, improvement or no improvement." Other studies have faced similar limitations [13, 23]. The large referral of patients to our center for the management of

Table 2 Revision surgery related data

	n (%)
Tape/mesh initial surgery	
Tape only	118 (84.3)
- TVT	53 (44.9)
- TOT/TVT-O	60 (50.8)
- TOT/TVT-O and TVT	5 (4.2)
Mesh only	18 (12.9)
- Vaginal approach	10 (55.6)
- Abdominal approach	7 (38.9)
- Not specified	1 (5.6)
Tape and mesh	4 (2.9)
- Mesh with vaginal approach and tape	2 (1.4)
- Mesh with abdominal approach and tape	2 (1.4)
Tape/mesh revision surgery	
Tapes only	118 (84.3)
- Laparoscopic tape removal	21 (15.0)
- Laparoscopic and vaginal tape removal	6 (4.3)
- Abdominal open tape removal	3 (2.1)
- Vaginal tape removal	65 (46.4)
- Vaginal tape division	23 (16.4)
Meshes only	18 (12.9)
- Laparoscopic mesh removal	5 (3.6)
- Abdominal open mesh removal	3 (2.1)
- Vaginal mesh removal	10 (7.1)
Tapes and meshes	4 (2.9)
- Abdominal open mesh removal and vaginal tape removal	2 (1.4)
- Vaginal mesh and tape removal	2 (1.4)
Concomitant surgical intervention	
- None	128 (91.4)
- Laparoscopic anterior and posterior sacrocolpopexy	3 (2.1)
- Meatoplasty	2 (1.4)
- Bladder stone removal	2 (1.4)
- Martius flap	2 (1.4)
- Pelvicol flap	1 (0.7)
- TVT tape insertion	1 (0.7)
- Iliac vein repair*	1 (0.7)
Mean time interval between initial surgery and revision surgery	
(Months)	52.1
(Range)	(5.0 days–16.0 years)

*TVT tape was inserted through the iliac vein

their mesh/tape complications disabled us to control for surgeon-related factors (academic center vs. non-academic center, urologist vs. urogynecologist), as previously reported [10]. Being a referral center and therefore having an unknown denominator of the total number of implants, we were unable to calculate the incidence of complications from synthetic tapes and meshes. Others shared this same limitation [18]. Prospective registries and/or national health system databases could provide these valuable data. The implants and therapy heterogeneity are also a weak point of this study. Since the initial tape/mesh implant surgeries were performed in different hospitals, the surgical techniques were inconsistent. Revision surgeries were heterogeneous because they were performed by several surgeons but also mainly because of the variety of surgical indications and the lack of guidelines regarding their management. Lastly, the exact type of tapes and meshes that were initially implanted was rarely mentioned in the operative reports.

Table 3 Clinical outcomes of tape/mesh revision surgeries

	n = 140 (%)
Outcomes of patients with voiding symptoms	59 (42.1)
- Complete resolution	37 (62.7)
- Improvement	10 (16.9)
- No improvement	5 (8.5)
- Unavailable data	7 (11.9)
Outcomes of patients with pelvic pain/dyspareunia	47 (33.6)
- Complete resolution	30 (63.8)
- Improvement	4 (8.5)
- No improvement	7 (14.9)
- Unavailable data	6 (12.8)
Outcomes of patients with storage symptoms	37 (26.4)
- Complete resolution	14 (37.8)
- No improvement	16 (43.2)
- Unavailable data	7 (18.9)
Outcomes of patients with recurrent UTI	32 (22.9)
- Complete resolution	19 (59.4)
- No improvement	9 (28.1)
- Unavailable data	4 (12.5)

Conclusion

All in all, tape/mesh-related complications may require surgical revisions. In this current study, the most common surgical indications of tape and mesh revision surgeries were voiding symptoms and vaginal erosion/extrusion. These surgeries often succeeded in improving voiding and pain symptoms; however, their outcomes regarding storage symptoms improvement remained low. Therefore, patients must absolutely be informed that symptoms may persist after revision surgery and that recurrent or persistent SUI or POP may require a subsequent surgical procedure. These findings should raise awareness regarding the serious complications that may be caused by tapes/meshes, without calling into question their use in the surgical management of SUI and POP.

Compliance with ethical standards

Conflicts of interest S. Ismail: The author declares that she has no conflict of interest.

E. Chartier-Kastler is a consultant/speaker/investigator for Axonics, Medtronic, Allergan, Pfizer, Lilly, Pierre Fabre, Astellas, Coloplast, Promedon and Uromedica.

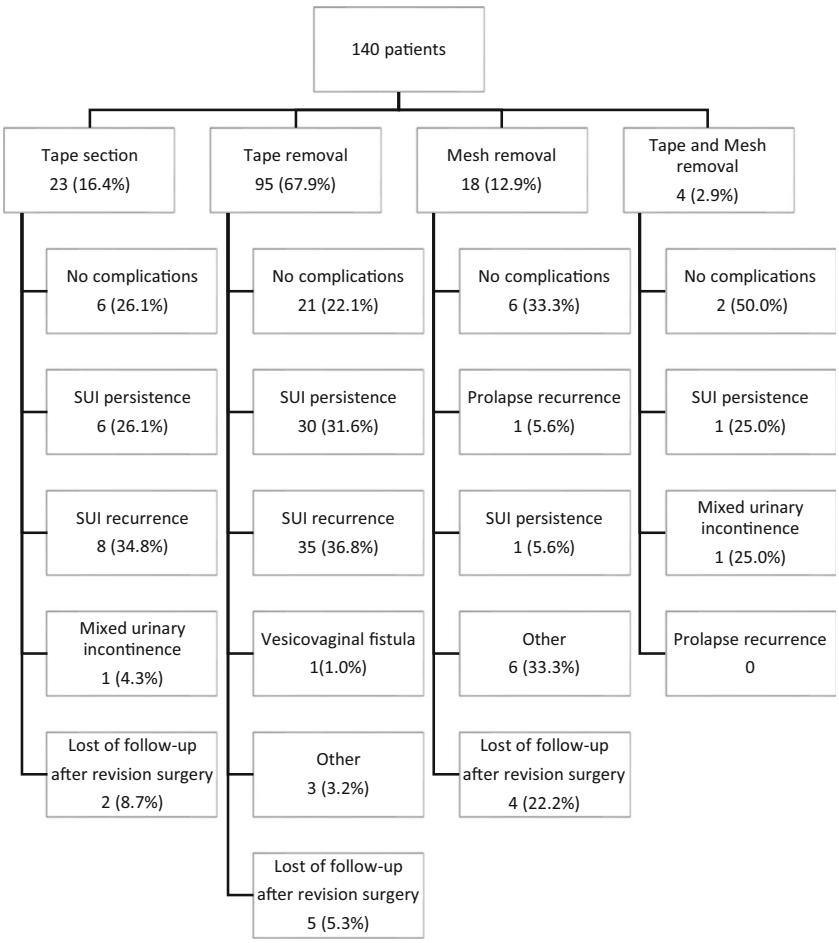

Fig. 3 Results of tape/mesh revision surgeries

C. Reus: The author declares that she has no conflict of interest.
J. Cohen: The author declares that he has no conflict of interest.
T. Seisen: The author declares that he has no conflict of interest.
V. Phé is a consultant for Astellas, Boston Scientific and Pierre Fabre. She is also an investigator for Ipsen.

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