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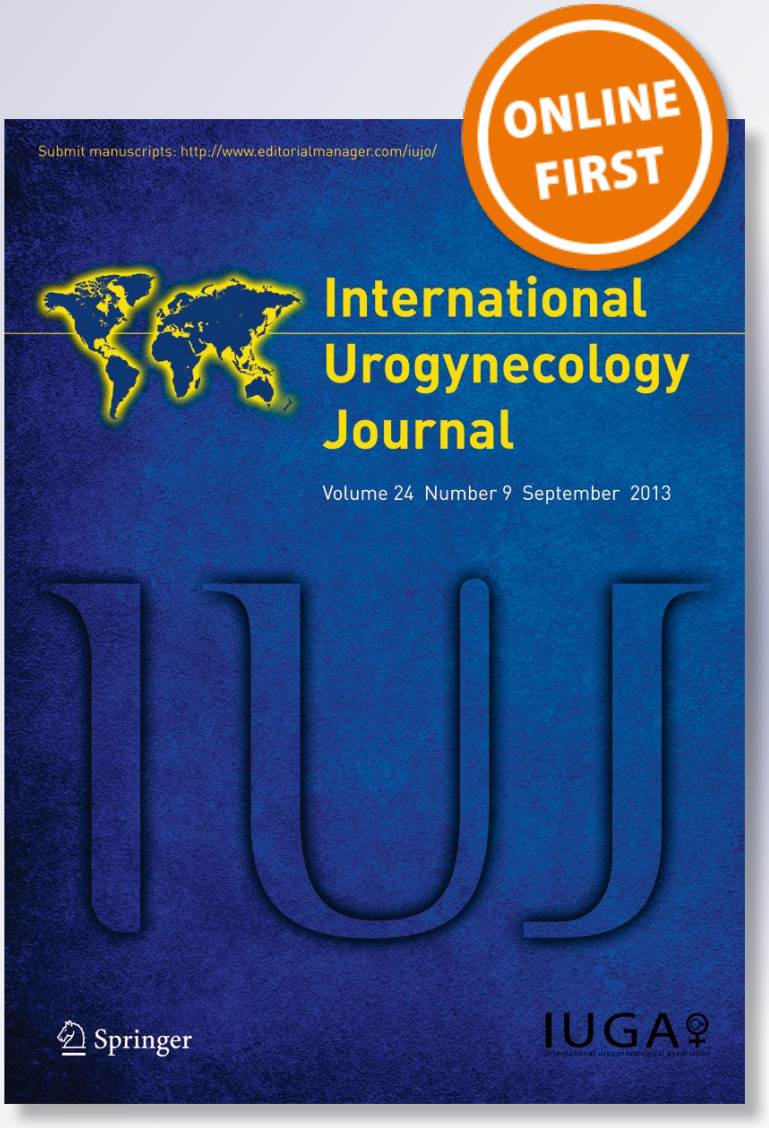

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ORIGINAL ARTICLE

Outcomes after laparoscopic removal of retropubic midurethral slings for chronic pain

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Abstract

Introduction and hypothesis Midurethral slings (MUS) are an established treatment for stress urinary incontinence (SUI), with good objective outcomes and low rates of complications. However, large population-based registry studies highlighted long-term complications from polypropylene slings including erosion, dyspareunia and chronic pain. With recent highly negative media coverage, many women are presenting with chronic pain attributed to the mesh to request complete removal. The available literature provides limited evidence on safety, symptom resolution and incontinence following MUS removal.

Methods We identified all patients who underwent laparoscopic removal of MUS mesh at our hospital between 2011 and 2016. We extracted data from medical records to assess operative safety and contacted all patients by questionnaire that incorporated pain scales, symptom severity and satisfaction.

Results A total of 56 women were assessed. Removal occurred at a median of 44 months following sling insertion (range 3–192). Mean operative time was 74 min (range 44–132). Two patients were returned to theatre (one at 24 hours and one at 14 days) to evacuate a retropubic haematoma, but no visceral injuries occurred. The median inpatient stay was 2 days (range 1–7). Of the 46% of patients who returned the questionnaire ($n = 26$), 88% said they would recommend the procedure. There was a median 6-point decrease in pain scores (10-point numerical scale, $p < 0.0001$); 44.6% reported worsening SUI, more common with removal of the suburethral mesh [odds ratio (OR) 10.72 95% confidence interval (CI) 1.10–104].

Conclusions Laparoscopic removal of MUS is feasible and effective but carries a risk of worsening SUI.

Keywords Laparoscopic removal · Retropubic midurethral slings · Mesh · Chronic pain · Safety · Patient satisfaction

Introduction

Rates of incontinence surgeries for women incorporating polypropylene meshes have increased over the last two decades [1, 2]. Most incontinence procedures utilise synthetic polypropylene slings [3–5]. The earliest studies of pelvic polypropylene mesh use [6, 7] reported few adverse effects, and most women continue to experience good outcomes, with minimal complications. Polypropylene slings consequently remain a very popular operation with both urogynaecologists and patients. However, studies have identified some potentially serious complications, including mesh exposure or extrusion through the vaginal mucosa; erosion into the bladder, urethra or bowel; negative impacts on bladder or bowel function; and pelvic pain or dyspareunia possibly caused by mesh shrinkage or direct nerve impingement. Polypropylene incontinence slings have a 0.9–10% reoperation rate [8–12]. While reoperations for pain remain relatively uncommon (compared with reoperation for erosion, voiding dysfunction or failure), persistent pain remains one of the leading causes of litigation [13]. As media attention has highlighted safety concerns about mesh, more women are requesting total mesh removal. Patients may attribute highly diverse symptoms due to mesh insertion, including chronic pelvic pain, chronic fatigue, fibromyalgia and pain distant from the pelvis. There is limited evidence to support the causality of mesh in these distant symptoms. Patients may also have psychological morbidity rooted in anxieties about long-term harm from mesh. While polypropylene may cause significant chronic inflammation [14], there is little evidence for

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systemic effects of mesh [15] and no evidence for human carcinogenesis [16, 17].

Most mesh erosions into the vagina, urethra or bladder, and most cases of dyspareunia associated with mesh, can be dealt with using an entirely vaginal approach [18]. For women requesting complete mesh excision, an open or laparoscopic approach is needed to dissect out the retropubic arms. The laparoscopic approach provides a superior view of the retropubic space and confers potential advantages for quicker recovery and better cosmesis. While small series have reported good success rates [19, 20], it is unclear which patients are most likely to benefit from mesh removal, and the risks of laparoscopic total mesh removal surgery, including recurrent stress urinary incontinence (SUI), are not well described.

We aimed to report technical feasibility and operative outcomes for complete and partial removal of retropubic MUS for chronic pain and evaluate patients' perceptions of the excision surgery, including its effects on pain and SUI.

Methods

We identified all patients undergoing partial or complete laparoscopic removal of a retropubic MUS for mesh-related pain at our hospital between January 2011 and December 2016. We excluded women who had a sling excision for mesh erosion into the bladder and urethra, vaginal erosion, infection in the absence of pain and removal for voiding difficulties. All patients were operated on by one of two surgeons (NP or SRJ). We linked and collected data from the electronic patient records, physical hospital notes, theatre logs and the national audit database. We specifically recorded age, body mass index (BMI), prior surgical history (including prolapse or continence surgery and attempts to divide or remove the sling), primary and secondary symptoms leading to the presentation, previous conservative measures to alleviate pain, intraoperative findings and operative times. We used the Clavien-Dindo system to grade any intraoperative, early or late complications on a scale of I–V, with I being any deviation from the normal surgical/postoperative course through to severe complications requiring intervention (grade III), life-threatening severity (grade IV) or death (grade V). We contacted all patients using a postal questionnaire (median follow-up 22 months, range 6–60), including items on change in pain scores (10-point numerical scale, where 0 represents no pain and 10 the worst possible pain), SUI recurrence, overall satisfaction, and subsequent continence procedures.

Extensive preoperative counselling addressed patient expectations in order to set realistic goals for improvement in pain given the uncertainty in the existing literature. If the sling was providing a good therapeutic effect, if appropriate, the patient was counselled about the option of partial mesh removal. This was to allow preservation of the suburethral component of the sling. The informed consent process covered not only removal surgery but alternatives including vaginal oestrogen use, specialist physiotherapy and medications to optimise bladder and bowel function. We counselled patients about the risk of major immediate complications and potential for recurrent incontinence and performed preoperative urodynamics for patients with recurrent incontinence. All patients either had a flexible outpatient cystoscopy to enable surgical planning or a rigid cystoscopy immediately prior to laparoscopy to exclude lower urinary tract mesh erosion.

When patients opted for total excision, the vaginal portion of the tape was excised first through a suburethral incision before undertaking the laparoscopy, as this helps define the limit of the laparoscopic dissection. A three-port laparoscopy was then performed using a 0° laparoscope (see Fig. 1a–d). The bladder was instilled with 300 ml normal saline with methylene blue to help delineate the dome. With the patient in the Trendelenberg position, the retropubic space was opened using a monopolar hook at 2 cm above the bladder reflection. A plane of loose areolar tissue was developed with careful blunt dissection from this correct incision point to open the space of Retzius. The bladder was reflected down bilaterally to expose the urethra and sphincter complex in the midline and the obturator vessels and nerves bilaterally. The arms of the mesh were identified, and the relation of the mesh to the important structures in the retropubic space were assessed at this stage. The most proximal portion visible was dissected from the abdominal wall using monopolar hook or scissors. The free edge was then grasped with a toothed grasper, and under traction, the mesh was sharply dissected from the surrounding structures. This was continued down to the level of the vagina where the tape was divided. Once haemostasis was secured in the retropubic space, the peritoneal edges were sutured using a single continuous polyglactin suture. Excised mesh was retained for microbiological culture [21] and histological examination [22].

Results

From 2011 to 2016, 56 patients had laparoscopic removal of a retropubic MUS for chronic pain. Mean patient age was 48.5 years (range 30–71); mean BMI was 28.4 (range 18 – 40) (Table 1). Most frequently reported pain was vaginal (n = 30, 53.6%), abdominal (n = 28, 50.0%) and groin (n = 22, 39.3%) pain, but most women reported pain at multiple sites (n = 42, 75.0%). Twenty-two women had additional pain-free symptoms they attributed to the mesh, including recurrent urinary tract infection (UTI) (n = 20, 35.7%), lower-limb

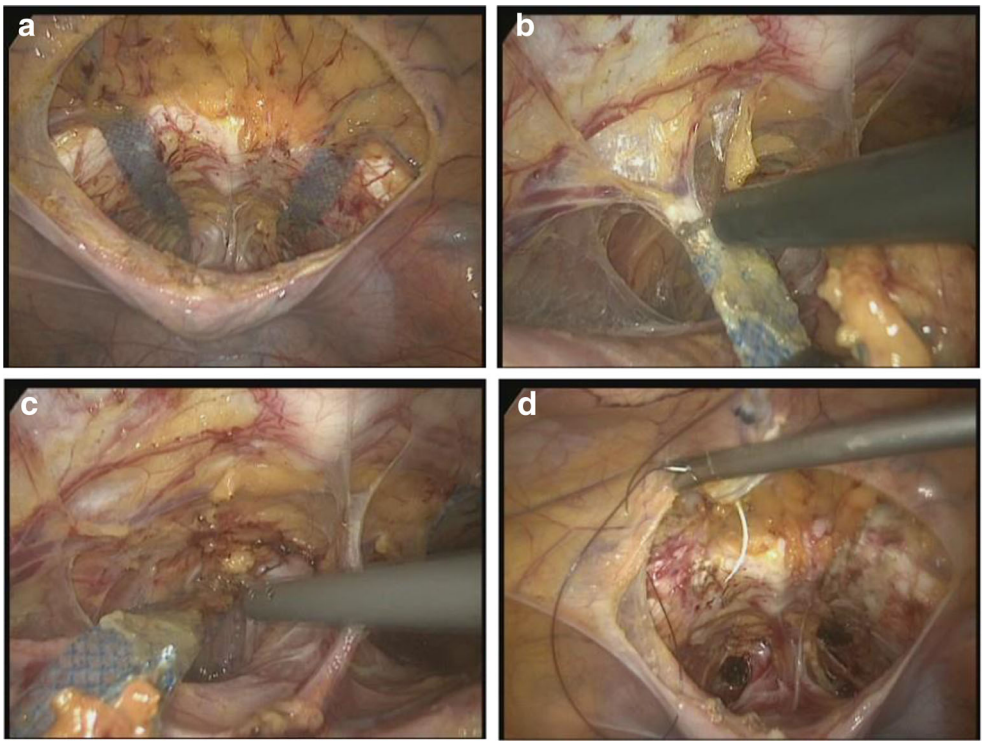

Fig. 1 **a**–**d** Laparoscopic removal of retropubic sling arm. **a** Cave of Retzius is opened showing the course of both arms. **b** With traction on the end of one arm, dissection commences using monopolar hook. **c** Dissection is extended to the suburethral portion. **d** After removal of the second arm, the peritoneal incision is closed using monofilament suture

swelling ($n = 1$, 1.7%) and chronic fatigue ($n = 1$, 1.7%). Bothersome lower urinary tract symptoms were common, including persistent or recurrent SUI ($n = 11$, 19.6%), urgency ($n = 21$, 37.5%) or voiding difficulties ($n = 10$, 17.8%). Of nine women who had undergone prior attempts to remove the suburethral mesh, three reported existing SUI. The main presenting complaint sites, types, duration, associated factors and anatomic distributions are summarised using the International Continence Society/International Urogynaecological Association (ICS/IUGA) mesh complications classifier (Fig. 2).

Conservative measures were initiated for all patients before offering surgery. Use of analgaesic medications were recorded in 55% ($n = 31$) of patients, including opioids ($n = 10$) and neuromodulatory agents such as gabapentin ($n = 18$). Four patients were under the care of a pain specialist, and eight had previously tried local anaesthetic or steroid injections for localised pain. Nine women had undergone a prior attempt to remove or trim the suburethral mesh using a vaginal approach. Median time from mesh insertion to laparoscopic excision was 44 months (range 3–192).

Table 1 Patient demographics

$N = 56$	Mean/median[a]	Range
Age (years)	48.5	30–71
Body mass index (kg/m^2)	28.4	18.0–40.1
Length of time sling in situ (months)	44[a]	3–192

[a] Indicates the median value

Findings and procedure

Forty-six patients (82%) underwent complete retropubic MUS mesh removal via a combined laparoscopic and vaginal approach; ten patients (18%) underwent a laparoscopic partial removal with preservation of at least the suburethral component (one patient had the left arm preserved also, as her pain was situated on the right). Most slings appeared to have been anatomically correctly placed. Although these were all retropubic slings, in four patients, there was impingement on the obturator neurovascular bundle, and in one patient, the mesh had completely transected the left obturator nerve [23]. Other findings were mesh exposure at the suprapubic trocar site, a single chronic retropubic abscess and one case in which the middle of sling was beneath the urethra but both arms were positioned to the right side of the symphysis pubis. No case was converted to laparotomy. Mean duration of surgery was 74 min (range 44–132) and median hospital stay was 2 days (range 1–7).

Safety of procedure

All procedures were completed laparoscopically, as intended. Two patients returned to theatre: one within 24 h of the procedure for laparoscopic evacuation of an 8-cm retropubic haematoma and one 2 weeks after the procedure for laparoscopic evacuation of a 5-cm retropubic haematoma. There was one case of urinary sepsis requiring treatment with antibiotics intravenously in a patient who presented with recurrent UTI as

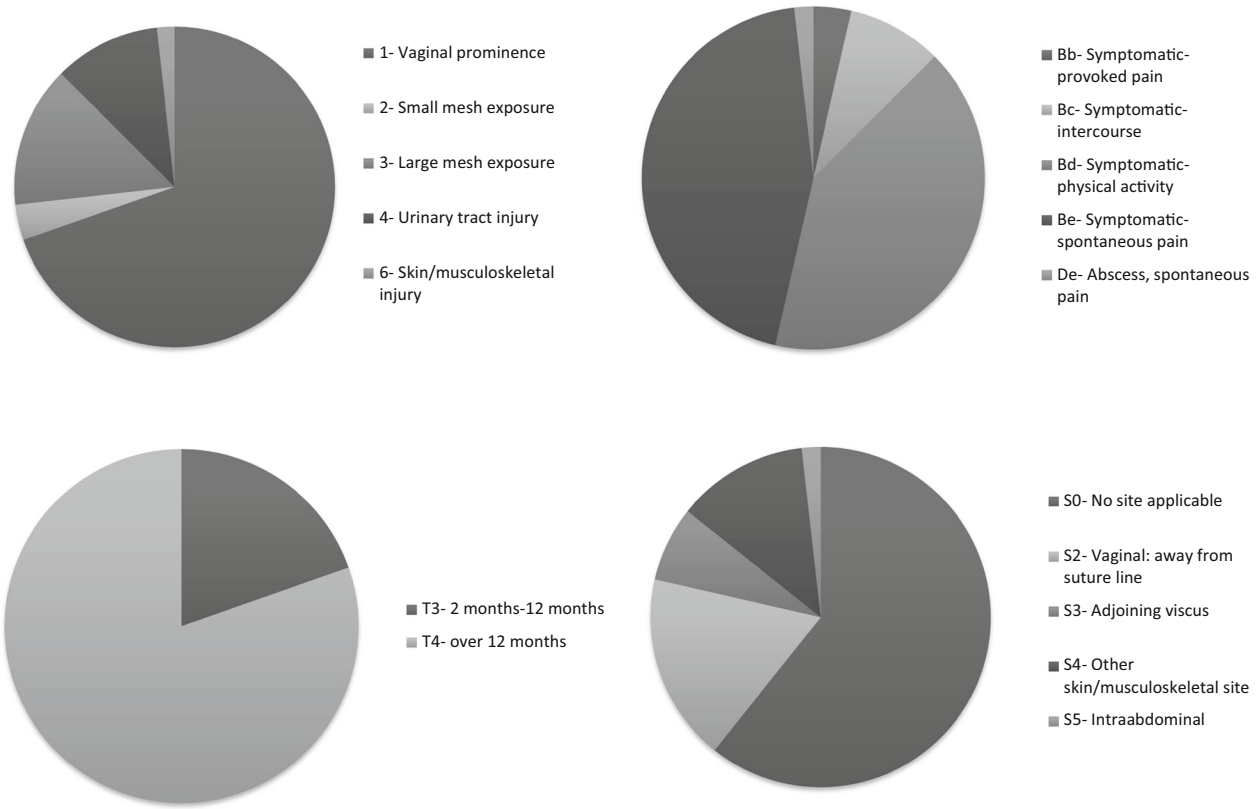

Fig. 2 International Continence Society/International Urogynaecological Association (ICS/IUGA) mesh complications classification of main presenting complaint

a primary complaint. Two patients developed surgical-site infections; both were treated with antibiotics. Incisional hernias occurred in three patients, with two requiring surgical correction. Another patient developed a fibroma at the left port site, which was excised.

At follow-up 12 weeks post-procedure, 27 patients (48%) reported complete improvement in their presenting complaint. A further 17 (30%) had partial improvement, and six (11%) reported no improvement. At median follow-up of 22 months (range 1–60 months), 46% of patients ($n = 26$) returned the postal questionnaire. Of these, 88% said they would recommend the procedure. There was a median 6-point decrease in pain scores (10-point numerical rating scale, $p < 0.0001$). Subjective SUI was present in 40 patients following removal; this was recorded as moderate to severe in 12. Twelve patients reported urgency or urgency urinary incontinence.

In mutually adjusted binary logistic regression analysis of pain improvement or resolution at follow-up, there was no impact of age [odds ratio (OR) 0.99/year; 95% confidence interval (CI) 0.91–1.09), length of time the sling was in situ (OR 1.02/months; 95% CI 0.99–1.04) or prior attempt at surgical removal (OR 2.70; 95% CI 0.29–25.8), although the latter with limited power. In mutually adjusted binary logistic regression of worsening or new-onset SUI at follow-up, there was no impact of age (OR 0.98/year; 95% CI 0.91–1.06), length of time in situ (OR 1.01/month; 95% CI 0.99–1.02) or prior attempt at surgical removal (OR 2.44; 95% CI 0.48–12.22). Excision of the suburethral portion of the mesh was, however, strongly associated with de novo or worse SUI (OR 10.72; 95% CI 1.10–104.00). There was limited power to explore whether symptoms of vaginal, pelvic or groin pain were more likely to resolve.

Discussion

In the current media climate regarding vaginal mesh, the decision to remove mesh is frequently patient driven. There is little data to help guide patients in these decisions and little evidence to guide surgeons undertaking the procedure. For this patient group, extensive conservative treatments had typically been tried elsewhere before referral to our unit, and patients had made the decision for removal despite the uncertain outcome and lack of safety data. Our data demonstrate that laparoscopic removal of a retropubic MUS is a feasible technique for use in women with chronic pain but can have some serious complications. In this consecutive series of 56 patients, mean duration of surgery was 74 min and median

Table 2 Previous series reporting outcomes after laparoscopic removal of midurethral slings

Study	No. patients	Median follow-up (months)	Cure or improvement in pain *n* (%)	Recurrent urinary incontinence *n* (%)
Pikaart (2006) [24]	2	3	2 (100%)	1 (50%)
Roupret (2010) [20]	38	38	38 (100%)	25 (65.7%)
Rigaud (2010) [19]	17	13	12 (70.5%)	13 (76.5%)
Braun (2010) [25]	4	6	Not recorded	1 (25%)
Sinha (2014)	1	5	1 (100%)	0 (0%)

length of hospital stay of 2 days. Two patients had early Clavien–Dindo grade IIIb complications, both with a return to theatre for evacuation of retropubic haematoma. There were, however, no conversions to laparotomy and no cases of bowel, bladder or ureteric injury. Most patients who completed the clinic or questionnaire follow-up were satisfied with the procedure, with highly clinically and statistically significant decreases in pain.

The mechanism through which pain is reduced is usually unclear. In most cases, the sling was apparently correctly situated, with no direct nerve impingement; 71% of patients were left with persistent SUI, which was more likely if they had opted for removal of the suburethral portion of mesh. Previous series of similar procedures are summarised in Table 2. The 78% rate of cure or improvement in pain in this series falls within the range of the previous literature (70.5–100%). Similarly, the 71% rate of recurrent incontinence lies within the range of prior estimates (0–76.5%). Our data add to this earlier work, demonstrating that removal of the suburethral portion of the sling directly impacts negatively on the chance of recurrent incontinence.

Ours is the largest reported series of patients having undergone laparoscopic removal of retropubic MUS for pain symptoms. Although we are confident of complete case ascertainment through the use of a procedure registry, data quality is dependent on accurate and complete contemporary documentation. Recording of concomitant analgesia, for example, was often limited in hospital notes and letters held for the patient. Secondly, response and recall bias may have affected patient evaluation of their postoperative symptoms and degree of satisfaction. Data are also limited by a lack of before-and-after validated pain and SUI scores. The generalisability of these results may be limited, as we only included women seeing one of two surgeons at this one centre. It is difficult to judge the risk of selection bias, as patients frequently attended our centre as tertiary or quaternary referrals.

Conclusion

Failure to respond to conservative measures for pain following insertion of a retropubic MUS should prompt discussion about the pros and cons of laparoscopic mesh removal. Although laparoscopic removal is feasible, there were significant early and late complications. These risks must be balanced against unpredictable efficacy; we identified no factors associated with pain resolution, although most patients reported cure or improvements in pain. De novo or worsening SUI was also common and was strongly associated with removal of the suburethral portion of mesh. Subsequent management of this SUI may be challenging. Such patients will not consider further polypropylene slings, and retropubic scarring from excision may make repeat surgery more complex. We also know that surgery for recurrent SUI is less efficacious than primary surgery. Despite the methodological limitations of this case series, most respondents would recommend the procedure to women experiencing a similar problem after MUS insertion.

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Compliance with ethical standards

Conflicts of interest None.

Ethical/review board approval Not required (Local Audit and service development project).

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