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ORIGINAL ARTICLE

Total trans-obturator tape (TOT) removal; a case series including pain and urinary continence outcomes

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Abstract

Introduction and hypothesis For many years, mid-urethral mesh tape (MUT) was the gold-standard procedure for management of stress urinary incontinence (SUI). However, significant concerns were raised over its safety. We present a case series of total trans-obturator tape (TOT) removals, performed in a tertiary unit over a 3-year period. We aim to evaluate improvement of pain and change in urinary continence symptoms following mesh explantation.

Methods This is a retrospective case series of the outcomes of total TOT removal. Primary outcome is the change in pain scores following total removal, assessed preoperatively, at discharge and follow-up. Secondary outcomes were perioperative complications, including return to theatre, re-admission rates and incidence of worsening SUI and overactive bladder symptoms (OAB) postoperatively. Statistical analyses were performed using SPSS 27.0 package (IBM, Chicago, IL) and the GraphPad Prism 9 statistical packages.

Results Nineteen women were identified. Mean age was 52 years and mean BMI was 31. Indications for mesh removal were: chronic pain (95%), vaginal exposure (37%) and pelvic sepsis (5%). No patients had return to theatre. Median intraoperative blood loss was 200 ml (interquartile range [IQR]: 150–288). Mean length of mesh excised was 22 cm. Mean postoperative hospital stay was 2 days. At follow-up, most patients (72%) reported "improvement" of their mesh-related pain at follow-up, while 6% reported "worsening" of pain. Eighty-three per cent of patients reported worsening SUI, and 50% reported worsening OAB symptoms.

Conclusions In the absence of sepsis, significant intraoperative complications are rare during total TOT removals. While 72% of patients reported improvement of their mesh-related pain, 6% still reported worsening pain after total mesh excision.

Keywords Mesh complications · Mesh removal · Mesh excision · Pain · Stress urinary incontinence

Introduction

Pelvic floor disorders, such as urinary incontinence and pelvic organ prolapse (POP), affect up to 25% of women over their lifetime [1], with stress urinary incontinence (SUI) being the most common, affecting 15–17% of women [2]. These conditions have a considerable negative impact on women's quality of life [3]. Many seek treatment options, with up to 20% of them undergoing surgery for SUI or POP [1, 4].

In 1996, synthetic mesh was introduced for use in SUI/POP corrective surgeries and was rapidly adopted in practice. Between 2000–2014, up to 1500 women had mesh implant surgery for SUI and 350 had POP corrective mesh surgery yearly in Scotland alone [5]. Between 2008–2016, NHS England reported 100,000 mesh implant insertions for SUI and 27,000 for POP [6]. However, over the last decade, significant concerns have been raised over the safety and potential complications of synthetic mesh implants. Complications associated with these mesh implants include chronic pain, exposure, perforation into organs, infections and sinus tract formation [7].

The 2020 Independent Medicine and Safety Devices Review recommended the creation of a network of specialist

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centres across the UK, where patients with mesh-related complications would receive specialist multidisciplinary care [8]. A key part of the service provided in these centres across the UK is mesh revision surgery, which includes partial and total mesh removal to manage potential mesh complications. Our Service is one of these centres across the UK commissioned to deliver this multidisciplinary specialised service.

We present a case series of total trans-obturator tape (TOT) removal, including vaginal and extra-vaginal (groin) approaches to achieve total removal, performed in a tertiary mesh complications unit over a 3-year period. We aim to evaluate the patient-related outcomes of the TOT removal via assessing the change in the chronic mesh-related pain and recurrence of incontinence following mesh explanation.

Materials and methods

Identification of patients and data collection

Potential patients were identified from service databases and surgical logs. We retrospectively reviewed the hospital's electronic patients' records (EPR) and surgical logs for all the women who underwent total TOT removal in our unit for mesh-related complication(s) between January 2018 and December 2020.

All of the records reviewed were included in the study after screening them against the inclusion and exclusion criteria in Table 1.

After identification of patients, we performed retrospective review of prospectively collected data by two reviewers independently reviewing the patients' EPR. The data collected included age, BMI and patient-reported co-morbidities (e.g. fibromyalgia, auto-immune disease, diabetes and other relevant co-morbidities). Intra- and postoperative care data were collected, as were follow-up data.

All data included in this study were obtained through retrospective review of case notes for patients who received standard NHS care; therefore, an ethical/institutional approval was not deemed necessary.

All patients completed a 10-point pain visual analogue scale (VAS) and a 4-point Likert scale assessing patients' impression of improvement preoperatively, at discharge and at follow-up.

Surgical procedure

All patients in this cohort had been assessed by the multidisciplinary team (MDT) and completed conservative (non-surgical) management. All patients were offered optimisation of their pain medication and their chronic pain management strategies through pain management services, targeted physiotherapy and/or local infiltration of steroids and local anaesthetics. All patients included in our cohort had opted for surgical management in the form of total TOT mesh removal as their chosen procedure. All cases were discussed at the specialist mesh MDT meeting in line with national guidelines before being listed for surgery.

All surgeries were performed in our unit by two experienced mesh removal surgeons. The surgery was performed through a combination of a vaginal and extra-vaginal routes, i.e. vaginal and bilateral groin incisions, to ensure total removal.

Surgical technique

The surgical approaches and excision technique used in our unit and for this case series are described below.

A sub-urethral incision is performed and the mesh tape is identified. Utilising careful dissection the tape is mobilised off the urethra and then cut in the middle to form two segments (right and left). This then allows access for lateral dissection. The mesh tape is mobilised and dissected free off the vagina and underlying paraurethral tissues along its route until it reaches the obturator internus. It is then mobilised free from surrounding muscle fibres through the obturator foramen into the groins.

A vertical 5-cm incision is made in each groin, approximately 1–2 cm lateral to the skin crease, extending downwards from the lower border of adductor longus. The overlying fascia is divided exposing the adductor muscle complex. The lateral ends of the mesh tape are then identified and dissected free from surrounding structures medially, towards the obturator foramen, where this groin

Table 1 Screening criteria used for data selection

	Screening criteria
Inclusion criteria	- Patient referred to our unit with suspected mesh-related complication and history of a single trans-obturator tape (TOT) insertion - Patient had total TOT removal in the period between 2018 and 2020
Exclusion criteria	- Patients who had more than one mesh implant inserted - Patients who had previous mesh revision surgery (i.e. partial removal) - Patients with confirmed urinary tract perforation of their TOT*

*This cohort of patients was excluded as their data were already reported by Saidan et al. 2019 [9]

mobilisation of the tape meets the already dissected and freed vaginal segment of the tape.

The tapes are thus removed in two segments: right and left. Non-suction surgical drains are left in the groin sites at surgical discretion. Wound closures (vaginal and groin) were performed in layers using absorbable sutures (Polysorb™, Covidien, Mansfield, MA, USA).

All explanted mesh specimens are photographed in line with our nationally agreed protocol, with a measurement tape, and uploaded onto individual electronic patient records (EPR) prior to insertion into histopathology transport medium for further analysis (Fig. 1).

Patients aim for discharge after day 1. Postoperative outpatient follow-up was scheduled for 3–6 months.

Outcomes

Our primary outcome is the change in chronic mesh-related pain after total TOT removal, assessed by the pain VAS and the 4-point Likert scale assessing patients' impression of improvement.

Secondary outcomes include intraoperative complications, return to theatre, postoperative complications, readmission rates and prevalence of stress urinary incontinence (SUI) and overactive bladder symptoms (OAB) after total TOT removal.

Statistical analysis

Statistical analyses were performed with the SPSS 27.0 package (IBM, Chicago, IL) and the GraphPad Prism 9 statistical packages. Comparison between the pre- and postoperative scores was performed using Wilcoxon matched pairs test. $P < 0.05$ was considered statistically significant. Descriptive statistics were used to characterise the patient population.

Results

We identified a total of 19 eligible patients over this time period. Mean patient age was 52 (range 45–68) years. Mean BMI was 31 (range 21–44); 74% (14/19) of patients were post-menopausal; 37% of patients self-reported suffering from pre-existing fibromyalgia and 11% from auto-immune disease.

The most common indication for mesh removal was chronic mesh-related pain, 95% (18/19) of women, followed by mesh exposure in 37% (7/19). One patient (5%) suffered from offensive vaginal discharge and pelvic abscess extending into the right buttock (Table 2).

Perioperative complications

Urinary tract injury only occurred in 1/19 (5%). A urethral injury was sustained during the excision of an infected suburethral sinus tract, after the mesh tape had been removed, which extended into the right buttock. It was repaired with a Martius graft with no persistent defect on follow-up.

The median measured intraoperative blood loss was 200 ml (interquartile range [IQR]: 150–288). None of the

Table 2 Indications for mesh removal

Indications for removal	Number (n = 19)	Percentage
Pain (with no mesh exposure or clinical signs of infection)	11	58%
Mesh exposure (and pain)[a]	6	32%
Mesh exposure (with no reported pain)	1	5%
Sinus tract/sepsis and mesh exposure[b]	1	5%

Pain was reported in 95% (18/19) of patients

[a]Vaginal mesh exposure identified ± vaginal discharge reported, [b] patient presented with signs of sepsis, pain and vaginal discharge

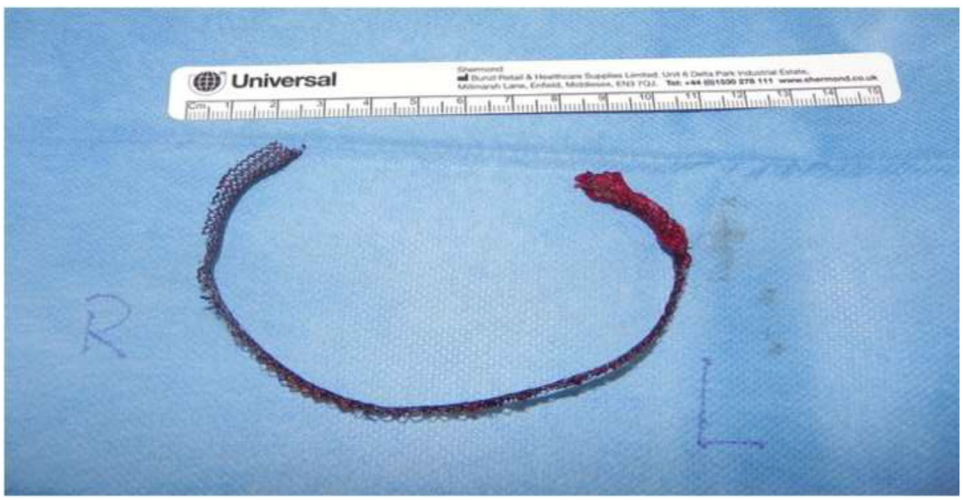

Fig. 1 Removed TOT mesh photographed in line with our nationally agreed protocol, with a measurement tape

patients had a return to theatre. None required blood transfusion. The mean length of the mesh tape excised was 22 (range 19–29) cm. In our centre, the insertion of the groin drains is at the discretion of the surgical team. However, these were used liberally with 15/19 patients having had them inserted. The mean blood collected in both drains was 118 (range 0–550) ml. Most of the drains were removed on day 1 postoperatively.

All excised mesh and tissue were sent for histopathological examination. All confirmed the presence of an inflammatory foreign body reaction, most commonly giant cell reaction, surrounding embedded foreign material.

Due to the geographical nature of our service, discharge is sometimes delayed because of travel limitations. Despite this, the mean stay postoperatively was only 2 (range 1–6) days. There was no return to theatres or hospital readmissions in this case series.

Follow-up

Eighteen of 19 (95%) patients have attended for a further face-to-face follow-up to date. Due to COVID-19 restrictions and suspension of elective services, the follow-up period was variable, with follow-up taking place between 3–16 months postoperatively (average: 7.5 months).

Primary outcome

All patients completed their pain assessment at discharge. In the immediate postoperative period, most patients reported significant improvement in their mesh-related chronic pain. Fifteen of 19 (79%) patients reported significant drop in their pain VAS score [with a clinically significant decrease in the mean pain score from 8.368 (95% CI 7.47, 9.26) preoperatively to 2.875 (95% CI 0.99, 4.75) (Fig. 2)].

At follow-up, all 18 patients completed the pain VAS. The significant decrease in the mean pain score from baseline seen at discharge appeared to persist with a mean pain VAS score of 3.611 (95% CI 2.05, 5.16) at follow-up, which is a clinically and statistically significant (p-value: 0.0003) reduction (Fig. 2).

Improvement of the chronic mesh-related pain was also assessed using the 4-point Likert scale (Table 3).

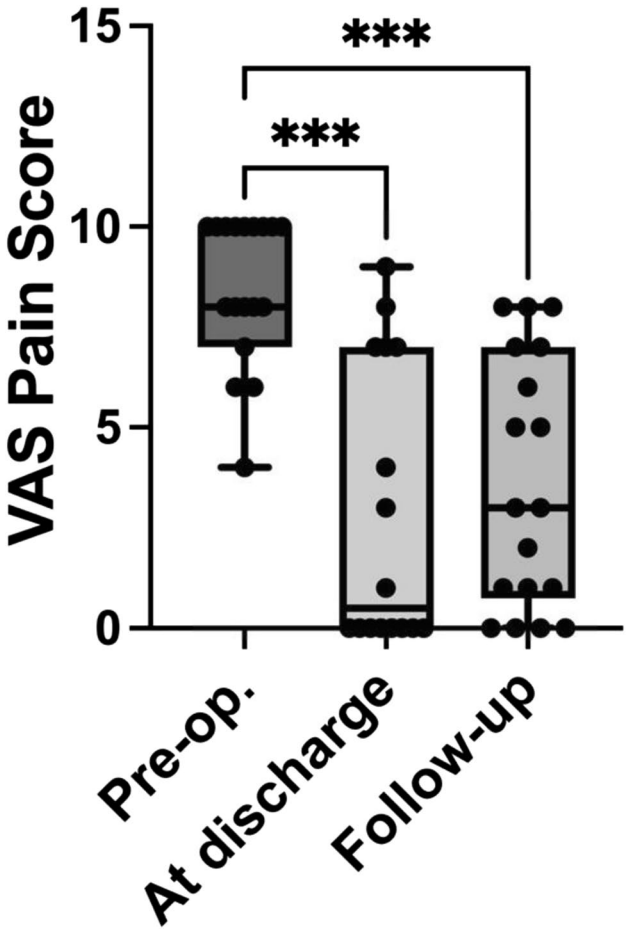

Fig. 2 Mean VAS pain scores pre- and postoperatively and at follow-up. The patients' VAS pain scores were shown to be significantly reduced postoperatively and at follow-up compared to the preoperative (pre-op) pain scores. ***$P \leq 0.05$

Table 3 Patient impression of improvement (at follow-up) using 4-point Likert scale for assessment of pain

Change in pain	Number ($n = 18$)	Percentage
Cured[a]	4	22%
Improved	9	50%
No change	4	22%
Worse	1	6%

[a]Patients reporting complete resolution of pain

Secondary outcomes

Urinary symptoms

Stress urinary incontinence (SUI)

At follow-up, 15/18 (83%) of patients reported worse or de-novo stress urinary incontinence (SUI), 40% (6/15) of which had previously been dry. Fifty per cent (9/18) of patients reported worsening of their pre-existing SUI. Only 17% (3/18) of patients did not suffer from worsening stress urinary incontinence within the first year after mesh removal (Table 4).

To date, 33% (5/15) of patients suffering from worsening SUI have gone on to have further surgical management of their SUI, after failure of conservative therapies including

Table 4 Change in urinary symptoms at follow-up

Incontinence	Change in symptoms	Number (n = 18)	Percentage
Stress urinary incontinence (SUI)	New onset	6	33%
	Pre-existing - worse	9	50%
	Pre-existing - no change	1	6%
	Pre-existing - improved	0	0%
	No SUI reported	2	11%
Overactive bladder symptoms (OAB)	New onset	1	6%
	Pre-existing - worse	8	44%
	Pre-existing - no change	6	33%
	Pre-existing - improved	2	11%
	No OAB reported	1	6%

formal supervised pelvic floor muscle training by our dedicated physiotherapy team.

Overactive bladder symptoms

Only 50% (9/18) of patients reported de novo or worsening of their pre-existing overactive bladder symptoms (OAB) (Table 4). To date, 4/9 (44%) of these patients are considering intravesical Botox injection after unsuccessful trials of anticholinergics and/or Mirabegron.

Discussion

The complications and benefits associated with the mesh use in SUI/POP surgery are still controversial. And there is variability in the rates of reported mesh-associated complications in the literature. In two reviews of patients with mesh implants, rates of complications attributed to transobturator tapes (TOT) varied between 1.4%–2% [9, 10]. Another trial reported TOT-associated pain to be present in 4.3% of women and tape erosion in 4.5% [11]. However, recognition of mesh-associated complications and its impact on patients' quality of life has increased over the past few years. The 9-year risk of TOT removal in women who had a first mesh implant for SUI under NHS England between 2006 and 2016 was reported to be 2.7% [12]. Nonetheless, there is limited evidence on the indications for and benefits of partial or total mesh removal [13, 14] and on long-term outcomes following mesh removal [13, 15]. Therefore, it has become essential to perform a risk-benefit evaluation of mesh removal to help aid the clinicians and patients in decision making and to improve patient care.

We report a case series of patients having total TOT mesh removal. Indication of removal was predominantly due to pain (95%). In the absence of infection, significant intraoperative complications were rare during total TOT removals.

At the postoperative follow-up, 72% (13/18) of patients reported significant improvement or complete resolution of their chronic mesh-related pain at follow-up after total mesh removal. Similar patterns of pain improvement have previously been reported in the literature [16–18]. It is however worth noting that 28% (5/18) of patients in this study still suffered from ongoing or worsening pain despite total mesh excision.

Nearly 83% of patients developed significant worsening of stress urinary incontinence in the first year after mesh removal, which was significant enough to require further surgical management in over a third of these patients to date. This number is likely to increase as more patients complete their conservative management. Similar results of worsening incontinence after mesh removal were previously reported in the literature [16–19].

Impact of total mesh removal on patients' overactive bladder symptoms is still unclear with 50% of patients reporting worsening symptoms and 44% reporting improvement of no change of their OAB symptoms.

The main limitation to our study is the small number of patients. This is partly due to the COVID-19 pandemic and the suspension of elective services in 2020 which affected our follow-up time interval. This can also be attributed to our attempt to avoid the heterogeneity in data by including only patients with one mid-urethral TOT mesh tape and no previous excision and no preoperative urinary tract perforation. One other limitation is the lack of long-term data, which makes it difficult to assess whether the improvement of mesh-related pain is maintained or not.

This study reports specific outcomes in an important cohort of patients undergoing a standardised described surgical procedure for TOT removal who have been suffering from mesh-associated complications. These results will aid the clinicians in the counselling and management of patients with such a life-devastating problem and enable patients to make an informed decision about proceeding with TOT mesh tape excision surgery. Further research is need to

explore different surgical approaches of mesh removal and long-term outcomes.

Conclusion

In the absence of sepsis, significant intraoperative complications are rare during Total TOT removals.

While 72% of patients reported disappearance/significant improvement of their chronic-pain, 28% still reported pain despite total mesh excision; 83% of patients developed significant worsening incontinence at follow-up after total mesh removal, with one third of these women opting for further surgery.

Author's participation in the manuscript Sami Shawer (SS): project development, data collection and analysis, manuscript writing.

Vijna Boodhoo (VB): project development, data collection and analysis, manuscript writing

Oliver Licari (OL): project development, revision of the manuscript and supervision.

Stewart Pringle (SP): supervision of the project and final approval.

Veenu Tyagi (VT): supervision of the project and final approval.

Vladimir Revicky (VR): supervision of the project and final approval.

Karen Guerrero (KG): project development, data collection and analysis, revision of the manuscript and overall supervision.

Declarations

Conflicts of interest Sami Shawer (SS), Vijna Boodhoo (VB), Oliver Licari (OL) and Stewart Pringle (SP): no conflict of interest for any of the authors.
Veenu Tyagi (VT): Executive member and/or member of the British Society of Urogynaecology (BSUG), the UK Continence Society (UKCS) and the Scottish Pelvic Floor Network (SPFN).
Vladimir Revicky (VR): Member of the British Society of Urogynaecology (BSUG) and the UK Continence Society (UKCS)
Karen Guerrero (KG): Executive member of the British Society of Urogynaecology (BSUG) and the UK Continence Society (UKCS). Chair of the RCOG sub-speciality training committee.

Conference presentations Extracts of data included in this review were previously presented at the UK Continence Society annual scientific meeting held virtually in March 2021 and the International Continence Society conference held virtually in October 2021.

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