Title

Functional outcomes following surgical management of pain, exposure or extrusion following a sub urethral tape insertion for urinary stress incontinence.

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Abstract

Introduction and Hypothesis: Surgical revision of a tape inserted for urinary stress incontinence may be indicated for pain, or tape exposure or extrusion. This study assesses the clinical outcomes of revision surgery.

Methods: A retrospective review of 47 consecutive women who underwent surgical revision for the indications of pain, tape exposure or tape extrusion.

Results: 47 women underwent revision. 29 women (62%) had initial tape placement at another institution. Mean interval between placement and revision was 30 months. 39 women (83%) had an identifiable tape exposure or extrusion with or without pain, while 8 women (17%) presented with pain alone. 11 (23%) of the tapes were infected clinically and histologically at revision, 10 of the 11 (90%) being of a multifilament type. In 23 (49%) cases, the revision aimed to completely remove the tape. Partial excision 24 (51%) was reserved for localised exposures or extrusions where infection was not suspected. A concomitant continence procedure was performed in 9 (19%) at the time of tape revision. None of these nine women have experienced recurrent stress urinary incontinence (SUI) compared to 11 of 38 (29%) women requiring further stress incontinence surgery when no continence procedure was performed (Fisher's exact $p=0.092$). 8/47 underwent revision surgery for pain with no identifiable exposure or extrusion, pain subsequently resolved in all 8 women.

Conclusions: Excision is an effective treatment for tape exposure and pain whether infection is present or not. Tapes of a multifilament type are strongly associated with infection. When infection is present, complete sling removal is necessary. A concomitant procedure to prevent recurrent SUI should be considered if tape excision is planned and infection is not suspected.

Key words: Tape, Stress urinary incontinence (SUI), surgical revision, exposure, extrusion.

Summary: Surgical excision is an effective treatment for pain, exposure or extrusion associated with tapes, but recurrent stress incontinence occurs in up to 29% of women.

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Introduction

Stress urinary incontinence (SUI) is a troublesome condition affecting up to 30% of women.¹ Minimally invasive synthetic sling devices , such as the TVT (TVT®, Gynecare, Somerville, NJ, USA) has become the first line surgical treatment for female stress urinary incontinence (SUI) in the developed world.^{2,3,4} Current evidence suggests that these operations are as effective as traditional suburethral slings, or Burch colposuspension in the short term, but with less postoperative complications.¹

The commercial and clinical success of the TVT® (Gynecare, Somerville, NJ) , a retropubic midurethral sling of macroporous monofilament polypropylene material, has led to the rapid introduction to the market of numerous, broadly similar, synthetic slings. Many of these slings have introduced variations of surgical approach, along with differences in trocar design, mesh characteristics and mesh attachments. Despite claims of similarity to the TVT®, emerging complications including infection of the sling, pelvic abscess and rejection in certain types of synthetic slings and meshes have led the FDA to give a Public Health Notification to both doctors and the general public.⁵ To improve clinicians understanding of these complications the Standardization and Terminology Committees of the International Urogynaecological Association (IUGA) and the International Continence Society (ICS) and the Joint IUGA/ICS Working Group on Complications Terminology are striving to bring clarity to the description of such complications through standardised terminology and classification. Arising

from the recommendations of this group, a 'tape' is a flat strip of synthetic material used for incontinence surgery, an 'exposure' is a condition of displaying, revealing, exhibiting or making accessible (e.g vaginal mesh visualized through separated vaginal epithelium) and an 'extrusion' is the passage gradually out of a body structure or tissue (e.g a loop of tape protruding into the vaginal cavity.)⁶

Vaginal, urethral or bladder exposure or extrusion can occur after tape placement. Most cases present in the initial few months postoperatively but may occur many years later. These patients can be asymptomatic or present with vaginal discharge, pain or dyspareunia. A meta analysis of mid urethral slings in 2007 suggested a possible trend towards increased vaginal extrusion with the transobturator approach.⁷

We reviewed those women who underwent surgical revision of their tape for the indication of pain, exposure or extrusion. The aim of the study was to identify the types of tapes implicated, the revisional surgery required and the subsequent functional outcomes for the patients.

Materials and Methods

A retrospective review of women who underwent revision surgery in 2 university hospitals from 2000 to 2010. Women who had surgical revision performed for pain, infection and/or tape exposure or extrusion were

identified. Ethical approval for this study was obtained from the Mercy Health Human Research Ethics Committee.

Data gathered from the patients' charts included demographics, a comprehensive medical history, all surgical reports, patient's lower urinary tract symptoms, physical findings and bladder diaries from each visit. When available, results of urodynamic studies done before initial tape placement and on subsequent revisions were included. The extent of surgical revision was at the surgeon's discretion, but in all cases consisted of at least partial excision of tape material. Patients were classified as having an infected tape only if there was confirmed microbiological evidence or frank pus was evident at the time of tape revision and documented in the operative notes.

All revision procedures were carried out by one of seven urogynecologists in the two university hospitals assisted by fellows. All revision procedures carried out in this series were undertaken under general or regional anaesthesia.

Patients who underwent revision of their tape primarily for the indication of bladder outlet obstruction were excluded. Revision of non synthetic biological slings or tapes were also excluded.

Results

A total of 47 women underwent surgery for revision of their tape during the study period for the indication of pain and/or exposure or extrusion of the tape material.

Twenty nine (62%) of these women had their initial tape placed at another institution and were referred when complications developed. The mean interval between tape insertion and its surgical revision was 30 months ranging from 2 weeks to 17 years. Eight women (17%) underwent surgical revision more than 5 years after initial tape placement.

Eighty three percent of the patients (39/47) had an identifiable tape exposure or extrusion. Table 1 illustrates all the tape exposure/extrusion sites.

Of the 47 cases of surgical revision, 17%(8/47) presented with vaginal or pelvic pain which they attributed to their tape and yet no exposure/extrusion was identified on examination or cystourethroscopy. Of these 8 cases, 2 were found to be infected during surgery. While none of the other 6 had tape infection or extrusion/exposure. There was resolution of pain in all 8 cases after surgical revision. (Table 2)

A total of eleven cases (23%) were found to be infected at the time of revision. Of these 11 infected tapes, two, as already mentioned were not associated with an identifiable exposure/extrusion. The remaining 9 infected tapes were associated with exposure/extrusion: . All of the infected tapes were of a multifilament type except for one Lynx® monofilament type tape. (Table 3)

In 23(49%) of cases reviewed the surgical revision aimed to completely remove all the tape material. One patient with an infected multifilament tape required multiple procedures to remove persistent painful infected fragments of tape.

Partial excision 24(51%), was reserved for those women experiencing localised pain, or noted to have a localised tape exposure/extrusion in whom infection was not suspected. 3/24 had localised pain, but no exposure/extrusion, all three were transobturator tapes where the pain was unilateral groin and leg pain. The pain resolved in all three patients on partial excision of the tape from the site of pain. 17 of the 24 partially excised tapes had a localised exposure/extrusion at the lateral vagina; 9 were retropubic and 8 were transobturator tapes. 2 of the 24 had a localised exposure/extrusion through the urethral mucosa; one a retropubic and one was a transobturator tape. In 2 women there was a localised vaginal exposure/extrusion in the midline suburethrally, both of these women had retropubic tapes.

A concomitant anti incontinence procedure was performed in 9(19%) women with the aim to prevent recurrent SUI. Three women had a Burch colposuspension, three had a Pubovaginal sling using autologous fascia, two a retropubic monofilament tape and 1 woman had reapproximation of remaining tape ends with polypropylene suture. The remaining 38 (81%) of the women who underwent tape revision had no concomitant anti incontinence procedure performed. None of the nine women who had a

concomitant anti incontinence procedure experienced recurrent SUI while 29% (11/38) of those who did not have a concomitant anti incontinence procedure did experience recurrent SUI and required a further SUI procedure.

Discussion

Our results concur with previous studies showing that non type 1 multifilament polypropylene meshes appear to be more at risk of infection.⁸ Some of these patients required multiple operations and symptoms were not eradicated until the tape was completely removed. In only one woman, with severe bladder pain, was a type 1, monofilament polypropylene tape found to be associated with infection, this demonstrates that although the risk of infection is low with monofilament tapes, it still may occur. This patient, with a Lynx® tape, presented with severe bladder pain. At cystourethroscopy, the tape was noted to be implanted in the bladder wall. There was marked mucosal oedema and erythema but no obvious mucosal penetration. The Lynx® tape was removed in toto by laparotomy via the retropubic space. Utilising the new classification system⁶, this complication is 4BeT3S3

We found all tape routes and fibre types to be implicated in localised vaginal exposures and extrusions. Going forward and utilising the new classification of complications of tapes⁶ it should be possible in the future to clarify at the time of presentation, which cases are likely exposures of tape and which are extrusions. It is possible that, particularly if infection is present, extrusions may occur over time. There were 21 vaginal and urethral tape

exposures/extrusions over the study period, where infection was not a factor, 12 retropubic and 9 transobturator monofilament tapes. Richter et al. reported mesh exposure rates with the type 1 polypropylene midurethral tapes to be low (<1%) and were more common in the transobturator than the retropubic tapes.⁹ Our findings concur with these low rates of exposure/extrusion for monofilament tapes. The mean interval between tape placement and subsequent revision was 15 months. The majority of these cases were, in our opinion, exposures, rather than extrusions and are related to the tape being placed through the vaginal wall at the time of placement, with the lateral vaginal sulci being at particular risk from the horizontal direction of the transobturator tapes.

There were 8 cases of bladder exposure/extrusions of the tape; all were retropubic multifilament tapes apart from one TVT® tape. This monofilament tape was revised just two weeks after it was placed, while the 7 multifilament tapes presented between 6 months and 10 years later. The TVT® case was a bladder perforation, undetected by cystourethroscopy, while the other 7 cases may have been tape extrusions secondary to infection. These findings again confirm the need for cystourethroscopy following all tape insertions.

Surgical revision for the management of pain associated with no detectable exposure/extrusion is an effective option. We performed total tape excision in those cases where infection was suspected but partial excision for localised pain where infection was not thought to be the cause. Localised pain was the presenting symptom in three transobturator tapes but no retropubic tapes

Monarc® (2) TVT-O® (1). The transobturator tape has been shown to have a higher incidence of groin pain, particularly the in-out approach.¹⁰ In our experience, division of the sling transvaginally, as it passes into the obturator fossa, without complete removal, is effective in relieving pain.

Almost a third (29%) of the women who had no concomitant anti incontinence procedure at tape revision subsequently required further SUI surgery, compared to none of the women who had such a concomitant procedure. If tape revision requires partial or complete removal of sling material then a concomitant procedure to prevent recurrent SUI should be considered. If infection is present, synthetic tapes should not be used, and an autologous graft sling or Burch colposuspension performed. Placement of a new tape at the time of tape removal may also be unwise if the reason for removal is pain. At the very least, patients should be counselled of the risk of developing recurrent SUI after tape revision.

While the placement of a mid urethral tape is a relatively straightforward procedure and undertaken by many gynaecologists, the management of subsequent complications, which require tape removal, can be problematic and requires considerable skill and experience. A number of urethrovaginal fistulas have been referred to our unit in recent years following attempted tape revision elsewhere. Careful cystourethroscopy is necessary following revision surgery to ensure that no urinary tract injury has occurred.

Tape complications include voiding dysfunction, pain, infection, exposure or extrusion of tape material. Tamussino et al found that 1.4% of women in a national Austrian database¹¹ who had undergone a TVT® placement, subsequently required re operation to loosen, remove or divide the sling. Surgeons must strive to minimise complications through careful patient and device selection.

One limitation of this study is its retrospective nature and small sample size. What is clear is that further studies are required to rigorously assess strategies for managing specific complications while minimising the risk of recurrent SUI. The recent introduction of the IUGA/ICS joint terminology and classification of the complications related directly to the insertion of prostheses and grafts in female pelvic floor surgery⁶ will greatly assist in the standardization of complications for future studies of this nature.

Complications such as pain, infection, exposure and extrusion of the tape can occur many years after initial placement which demonstrates the importance of long-term follow up of new tape devices introduced by companies onto the market. In this study 1 in 5 women with complications presented more than 5 years after initial insertion, highlighting the need for long term vigilance. A number of the tapes have been removed from the market because of these complications but not before many thousands have been placed worldwide. These devices will continue to cause complications into the future so it is important that these women are carefully followed up. It is incumbent on the operating surgeon to carefully review the medical evidence for proof of

efficacy and safety prior to inserting any device for the treatment of SUI or vaginal prolapse.

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TABLES

Table 1. Anatomical sites of Tape Exposure/Extrusion Extrusion.

TABLE 1.

Site of Tape Exposure/Extrusion	Number (%)	Route of Insertion Retropubic (RP) or Transobturator (TO)
Vagina alone	29(74%)	TO 8 RP 21
Bladder alone	6(15%)	RP 6
Bladder and Vagina	2(5%)	RP 2
Urethra alone	2(5%)	RP 1 TO 1
TOTAL	39(100%)	39

Table 2. Tapes removed for the indication of Pain alone

Tape Type and number	Number found to be Infected at Revision or histology
IVS (2)	1
Lynx (1)	1
Monarc (2)	0
Sparc (1)	0
TVT-O (1)	0
Safyre (1)	0
Total (8)	Total (2)

IVS ® (Tyco Healthcare, Mansfield, MA, USA)

Lynx ® (Boston Scientific, Natick, MA, USA)

Monarc ® (American Medical Systems, Minnetonka, MN USA)

Safyre® (MedicService AG, Switzerland),

Sparc ® (American Medical Systems, Minnetonka, MN, USA)

TVT-O ® (Gynecare, Somerville, NJ, USA)

Table 3: Tape Filament type and Presence of Infection.

TABLE 3

Tape Type	Numbers of each Tape type revised (% of total)	No. of each Tape type found to be infected on removal
Advantage	2 (4)	-
InFast	2 (4)	2
IVS	17 (36)	8
Lynx	1 (2)	1
Monarc	7 (15)	-
Prolene	1 (2)	-
Safyre	1 (2)	-
SPARC	2 (4)	-
TVT	9 (19)	-
TVT-O	5 (11)	-
TOTAL	47 (100%)	11

Advantage ® (Boston Scientific, Natick, MA, USA)

Lynx ® (Boston Scientific, Natick, MA, USA)

Monarc ® (American Medical Systems, Minnetonka, MN USA)

InFast ® (American Medical Systems, Minnetonka, MN, USA)

Prolene ® (Ethicon, Somerville, NJ, USA)

Safyre® (MedicService AG, Switzerland),

Sparc ® (American Medical Systems, Minnetonka, MN, USA)

TVT-O ® (Gynecare, Somerville, NJ, USA)

IVS ® (Tyco Healthcare, Mansfield, MA, USA)

TVT ® (Gynecare, Somerville, NJ, USA)