Results of collagen sling placement following the partial removal of a synthetic mid-urethral sling

Cornelis R. C. Hogewoning[1]
Henk W. Elzevier[1]
Rob. C. M. Pelger[1]
Cornelis J.A. Hogewoning[2]

5

1. Department of Urology, Leiden University Medical Center
2. Department of Obstetrics and Gynecology, Albert Schweitzer Medical Center

(International Journal of Gynecology and Obstetrics (2016 Sep);134(3):286-9)

Introduction

Urinary incontinence among women is a common problem that places a large demand on healthcare resources in high-income countries (1;2). Stress urinary incontinence (SUI) is described as the involuntary leakage of urine on a rise in abdominal pressure and is associated with a negative impact on sexual, psychological, and social functioning (3;4). In 1995, the tension-free vaginal tape (TVT), a polypropylene sling used through a minimally invasive technique to cure SUI, was introduced by Ulmsten and Petros (5). Because of its high success rates and few complications, the TVT soon became the leading surgical treatment for SUI. Following the successful application of the TVT, the trans-obturator tape was introduced in 2001, followed by the TVT Obturator in 2004 and mini-slings in 2006 (6;7). In the past decade, a vast number of mid-urethral slings (MUS) have been developed, with millions of (mostly successful) interventions having been performed worldwide (8:9).

Although most vaginal slings boast low complication rates, serious complications have nevertheless been associated with their use; such complications should always be taken into consideration by both physicians and patients (8). According to the 4th International Consultation on Incontinence (10), vaginal sling complications can occur during surgery (mostly hemorrhage and injury to the lower urinary tract) or after the procedure (much more diverse in nature).

Available data on the rate of (late) postoperative complications following MUS surgery indicates that the frequency of these complications is generally low (8). The most commonly occurring postoperative complications are erosion of the mesh material, displacement of the tape, infection, and pain. Although local treatment of these complications is possible in some patients, in others, eventual complete or partial removal of the mesh is unavoidable. Since the introduction of MUS in the treatment of SUI, multiple reports have described the results and complications, but only a limited number have concerned the treatment of (late) postoperative complications. More importantly, in the current literature, no consensus has yet been reached on the proper treatment of these complications.

The Pelvilace collagen sling is a porcine xenograft acellular matrix bio-implant that can be chosen as a secondary sling to minimize the risk of rejection and to fill in the anatomical defect caused by removal of the primary sling (11). The present study evaluates the results of Pelvilace collagen sling placement directly following partial removal of a primary sling because of late complications.

Materials and methods

A retrospective study was undertaken of patients experiencing late complications following MUS surgery who underwent placement of a Pelvilace collagen sling (C.R. Bard Inc., Murray Hill, NJ, USA) after partial removal of a primary sling at the Albert Schweitzer Medical Center Dordrecht, the Netherlands, between January 1, 2006, and January 31, 2011. The study center is a tertiary referral center treating MUS complications from all around the Netherlands. Exclusion criteria were the placement of the Pelvilace collagen sling as primary treatment or receiving a third suburethral sling within the follow-up period. The study protocol was approved in March 2012 by the medical ethics review board of the Albert Schweitzer Hospital. Participants provided written informed consent.

All surgery had been performed by the same urogynecologist (C.J.A.H.) in the specialized pelvic floor center of the Albert Schweitzer Medical Center. The primary tapes involved were the Intra-Vaginal Sling (Tyco Healthcare, Dublin, Ireland [Covidien from 2007]), TOT Intramesh Softlift (Cousin Biotech, Wervicq-Sud, France), Uretex-TO (C.R. Bard Inc, Murray Hill, NJ, USA), and the TVT and TVT Obturator (Ethicon Women's Health and Urology, Johnson and Johnson, New Brunswick, NJ, USA).

All patients received spinal anesthesia and were placed in the lithotomy position. The first step consisted of the dissection of the anterior vaginal wall, after which the sling was bilaterally removed as far as the internal obturator muscle for trans-obturator slings and the pubic bone for retropubic slings. Following partial removal, the remaining mesh and adjacent tissue were examined for signs of infection or erosion and a routine cystoscopy was performed. Next, the Pelvilace collagen sling was placed in the defect left by the removed tape in the case of erosion or in the correct suburethral position in the case of displacement, followed by a cough stress test to tune the tension of the tape. The tape was placed outside-in through the obturator foramen using a similar technique as described by Delorme et al. (7). The sling was superficially fixated on the suburethral tissue using a slow resorbable stitch (PDS 3-0) and the anterior vaginal wall was closed. Patients were given a transurethral catheter for at least 1 day and prophylactic antibiotics were administered during the first postoperative week.

Between April 2012 and October 2014, identified patients were sent questionnaires that had been designed specifically for the present study. Questionnaires were sent at different times to minimize variation in the length of time since surgery. Patients who had not responded to the previous request were re-contacted the next time questionnaires were sent.

Urodynamics were conducted when urethral instability was suspected before the secondary surgery, including a measurement of the maximum urethral closure pressure (MUCP), before and at least 6 months after repair, as well as an evaluative cystoscopy.

The questionnaire was assembled using a combination of various validated and non-validated questionnaires. It consisted of 44 questions divided into 6 sections evaluating improvement/deterioration, physical condition (health status), micturition, coping behavior (emotional status), and sexual functioning. The Patient Global Impression of Improvement (PGI-I) represented the first part of the questionnaire and assessed the subjective improvement/deterioration after surgery; patients stating their incontinence status as either being "very much better" or "much better" were considered improved. The second part included a visual analogue scale (VAS) and QoL scale to evaluate overall health status. Micturition status and pelvic floor dysfunction were assessed in the third part of the questionnaire using sections of the Urinary Distress Inventory (UDI) and Pelvic Floor Distress Inventory (12-14). Patients scoring 0 in the UDI stress symptoms section were considered cured (as recommended by the International Continence Society). The fourth part scored the coping behavior using the Incontinence Impact Questionnaire (IIQ) (12;13). Both the IIQ and UDI were scored using the different domains as described by van der Vaart et al. (15). Sexual functioning was assessed using 14 non-validated questions designed by the Pelvic Floor and Sexuality Research Group in Leiden. The last question asked the patient whether she would recommend this intervention to patients experiencing similar problems.

The results were statistically evaluated using paired and independent samples *t*-tests in SPSS release 21 (IBM, Armonk, NY, USA). P ≥0.05 was considered statistically significant.

Results

Between January 2006 and January 2011, 38 patients received the Pelvilace collagen sling after partial sling removal and were included in the study (Figure 1). The patients' baseline characteristics are shown in Table 1. The primary sling types and the complications leading to the placement of Pelvilace are described in Table 2. No adverse events were observed during or directly following the placement of the Pelvilace collagen sling.

Table 1 Baseline characteristics (N=38)

Age (years)	54.7 ± 10.5 (27-81)
BMI (kg/m^2)[a]	27.6 ± 4.4 (18.2-37.4)
Mean follow-up[b]	54.3 ± 17.1 (17-89)

a: Derived from questionnaire, n=32 and calculated as weight in kilograms divided by the square of height in meters. b: Period between surgery and questionnaire, n=29,

The questionnaire was completed and returned by 32 (84%) patients. No significant differences were observed in baseline characteristics between responders and non-responders (data not shown). Three patients were excluded from further analysis following the placement of a third sling during the follow-up period because of persistent SUI (Figure 1). These patients were included in the success/failure rates as failures to avoid bias.

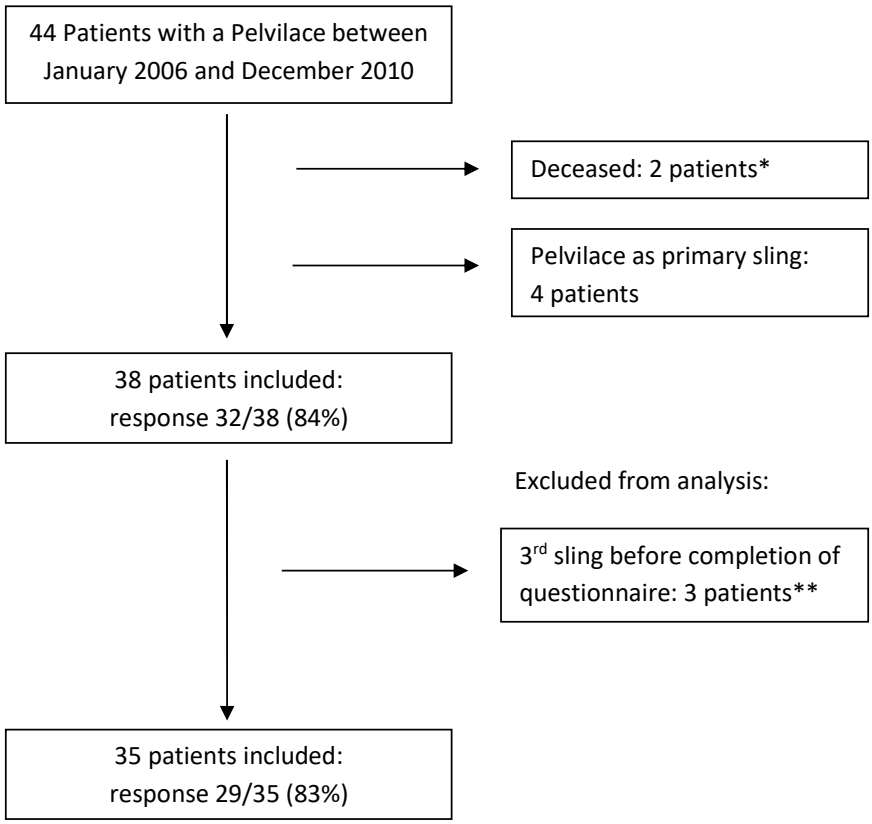

Figure 1 Flow of patients through the study
*Death not due to Pelvilace placement
**These patients were included in the failure/success analysis as failures

Table 2 Types of primary slings and complications[a]

Type of primary sling	All patients	Complications after primary sling placement		
		Erosion (n=15	Displacement (n=13)	Both (n=10)
Tension-free Vaginal Tape	12/38 (32)	8/12 (67)	2/12 (17)	2/12 (17)
Uretex-TO	9/38 (24)	1/9 (11)	5/9 (56)	3/9 (33)
TOT Intramesh Softlift	7 (18)	1/7 (14)	3/7 (43)	3/7 (43)
Intravaginal Sling	4 (11)	2/4 (50)	1/4 (25)	1/4 (25)
TVT-Secur	4 (11)	3/4 (75)	0/4	1/4 (25)
Tension-free Vaginal Tape-Obturator	2 (5)	0/2	2/2 (100)	0/2

Values are given as number (percentage)

More than one-quarter of the 32 women included in analysis of success and failure reported being cured on the UDI (Table 3). Among the 29 women eligible for further analysis, the PGI-I showed a postoperative improvement in approximately half (Table 3). The remaining 15 (52%) patients rated their postoperative status as little improved, unchanged, or deteriorated.

Table 3 Cure/failure according to the UDI and improvement acoording to the PGI-I., by complications after primary sling placement[a]

	All women	Erosion (12)	Displacement (9)	Both (11)
UDI[b]				
Cure	9 (28)	4 (33)	0	5 (45)
Failure	23 (72)[a]	8 (67)	9 (100)	6 (55))
PGI-I[c]				
Very much better	8 (28)	4 (33)	1 (13)	3 (33)
Much better	6 (21)	4 (33)	1 (13)	1 (11)
A little better	4 (14)	2 (17)	2 (25)	0
No difference	6 (21)	2 (17)	3 (38)	1 (11)
A little worse	2 (7)	0	1 (13)	1 (11)
Much worse	0	0	0	0
Very much worse	3 (10)	0	0	3 (33)
Improvement [d]	14 (48)	8 (67)	2 (25)	4 (44)
No improvement[e]	15 (52)	4 (33)	6 (75)	5 (56)

Abbreviations: UDI, Urinary Distress Inventory; PGI-I, Patient Global Impression of Improvement.
a Values are given as number (percentage).
b n=32 (12 with erosion, 9 with displacement, 11 with both). Includes the 3 patients who had a third sling placed before the time of the postoperative questionnaire as failures.
c n=29 (12 with erosion, 8 with displacement, 9 with both),
d Very much better or much better.
e A little better, no difference, a little worse, much worse, or very much worse.

Postoperative improvement according to the PGI-I was most often observed among the 12 women who underwent Pelvilace placement as a result of erosion (Table 3). Scores on the UDI, IIQ, QoL scale, and VAS are shown in Table 4. In terms of postoperative sexual functioning, 16 (55%) of the 29 patients stated being completely sexually inactive at the time of follow-up. One of these patients (6%) blamed urinary incontinence during intercourse as the direct cause of her sexual inactivity, whereas 3 (19%) indicated pain as the main reason.

Table 4 Postoperative scores for the UDI, IIQ, quality of life scale and visual analogue scale (n=29)

Questionnaire	Postoperative scores
UDI	
Total	25.2 ± 20.2
Discomfort/pain	21.4 ± 30.4
Urinary incontinence	38.5 ± 30.9
Overactive bladder	32.8 ± 32.3
Obstructive micturition	29.2 ± 31.6
Genital prolapse	3.6 ± 9.5
IIQ	
Total	20.5 ± 23.2
Mobility	32.2 ± 29.0
Emotional	23.4 ± 30.5
Physical	19.05 ± 24.3
Social	13.9 ± 26.1
Embarrassment	20.7 ± 32.6
Quality of life scale	4.4 ± 1.2
Visual analogue scale	6.8 ± 1.9

Abbreviations: UDI,Urinary Distress Inventory; IIQ, Incontinence Impact Questionnaire.
a Values are given as mean ±SD.
b Scaled from 1 (no complaints) to 100 (severe complaints).
c Scaled from 1 (very bad) to 6 (excellent).
d Scaled from 1 (very bad) to 10 (excellent).

When asked whether they would recommend this intervention to other patients under similar circumstances, 19 (66%) of 29 patients answered "yes". The 10 (34%) patients advising against the treatment indicated persistent urinary incontinence as their main reason for doing so.

Table 5 Urodynamics [a]

	Preoperative	Postoperative [b]	P-value [c]
Maximal urethral closing pressure (cmH2O)	42.1 ± 13.4	55.2 ± 17.9	0.001
Maximum flow (ml/s)	25.4 ± 10.8	18.2 ± 8.4	<0.001
Bladder capacity (ml)	411 ± 129	318 ± 72	0.001

a Values are given as mean ± SD unless indicated otherwise
b Conducted at a minimum of 6 months post-surgery
c Paired samples *t*-test.

In 19 (66%) of the 29 patients, a presurgical urodynamic analysis was conducted when urethral instability was suspected and repeated at least 6 months after the placement of the Pelvilace sling. Analysis showed that the MUCP increased significantly after surgery (P=0.001) (Table 5). The maximum flow showed a significant decrease (P <0.001) (Table 5). The postoperative bladder capacity also showed a significant decrease (P=0.001) (Table 5). No significant differences were found in MUCP, maximum flow, and bladder capacity between the patients with success and failure, or with and without improvement (data not shown).

Discussion

The present study showed that 28% of women who underwent placement of a Pelvilace after partial removal of a primary sling reported postoperative success after a mean follow-up of 54.3 months. Almost half of the questionnaire respondents reported improvement. Success and improvement showed no significant differences between women who experienced erosion, displacement, or both after primary sling placement. However, significant differences were observed in urodynamic analysis (maximum flow, MUCP, bladder capacity) before and at least 6 months after surgery. Overall, two-thirds of respondents would recommend this intervention to other patients under similar circumstances. The patients who would not recommend surgery indicated persistent urinary incontinence as their main reason to advise against the treatment.

To correlate the present results with those found in previous studies, a literature search was performed using the MeSH terms "urinary incontinence," "suburethral sling," and "complications". This search produced 939 results, of which none had a design similar to that of the present study. Several studies did discuss partial or complete sling removal, but did not include the subsequent placement of a second tape of porcine dermis (16-18). One paper did approach the present study design by describing 21 patients in whom a primary synthetic sling was removed and replaced by a concomitant sling of

autologous rectus fascia (19); the study achieved continence in 71.5% of the patients with urethral perforation and in 100% of patients with a bladder perforation.
The main outcome variable in the present study was the subjective cure of urinary incontinence after surgery. The results showed an overall postoperative continence rate of 28%, with a maximum cure rate of 45% in the group with both erosion and displacement of the primary sling. A review of the current literature on the management of mesh complications after SUI and pelvic organ prolapse surgery describes a 20% recurrence of SUI after transvaginal MUS excision (20). Although the concomitant placement of a second sling should theoretically enhance continence after primary sling removal, this was not observed in the present study. One explanation for these disappointing results could be the fact that the collagen sling used seems to be less effective in curing SUI in the long term by comparison with conventional polypropylene tapes (21). However, when considering that the present study population involved patients who experienced postoperative complications, the results should not be compared with those of studies in which the Pelvilace collagen sling was used as a primary sling. The second explanation could be the strict definition of success/failure measured solely by the UDI stress symptoms section and the lack of objective measurements. Nevertheless, the UDI represents a patient's experience over an extended period of time and should therefore be relied upon to produce trustworthy information. Moreover, because no comparable studies are currently available, no viable statements can and should be made on whether the success rates found are actually lower than expected.
The most important limitation of the present study is the fact that the patient group was not homogenous. In a tertiary referral center, all complications following MUS surgery are treated, including erosion and displacement. Further, the concomitant placement of the same collagen sling in all patients and their evaluation through the use of the same questionnaire makes it difficult to interpret the results. In an attempt to further clarify the results, the study population was divided into separate groups; nevertheless, the numbers needed to draw viable conclusions are lacking. Finally, the study included 6 different types of primary slings, with small patient numbers for each type. Although a lack of sufficient patient numbers is a common problem when describing rare complications, it does inevitably lead to difficulties in the processing of results.
In conclusion, despite nearly half of patients experiencing an improvement after surgery, only 28% of patients were cured of their SUI after partial sling removal with concomitant placement of a Pelvilace collagen sling. The divergence in the failure rates between different types of complications (erosion and displacement) shows that there is no general approach in the treatment of these complications. Further, as evidenced by an evaluation of the current literature, no consensus has yet been reached on the proper treatment of late postoperative complications following MUS surgery. Although the current study presents reasonable results for specific complications, the solution to

this ever-growing problem remains to be elucidated. More research on the individual approach of specific complications will be needed in the future to provide optimal patient care.

Reference list

1. Cooper J, Annappa M, Quigley A, Dracocardos D, Bondili A, Mallen C. Prevalence of female urinary incontinence and its impact on quality of life in a cluster population in the United Kingdom (UK): a community survey. Prim Health Care Res Dev 1-6, 2014.
2. unskaar S, Lose G, Sykes D, Voss S. The prevalence of urinary incontinence in women in four European countries. BJU Int 93: 324-30, 2004.
3. Farage MA, Miller KW, Berardesca E, Maibach HI. Psychosocial and societal burden of incontinence in the aged population: a review. Arch Gynecol Obstet 277: 285-90, 2008.
4. Handa VL, Harvey L, Cundiff GW, Siddique SA, Kjerulff KH. Sexual function among women with urinary incontinence and pelvic organ prolapse. Am J Obstet Gynecol 191: 751-6, 2004.
5. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 7: 81-5, 1996.
6. de Leval, J. Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. Eur Urol 44: 724-30, 2003.
7. Delorme E. [Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women]. Prog Urol 11: 1306-13, 2001.
8. Schimpf MO, Rahn DD, Wheeler TL, Patel M, White AB, Orejuela FJ, El-Nashar SA, Marqulies RU, Gleason JL, Aschkenazi SO, Mamik MM, Ward RM, Balk EM, Sung VW, Society of Gynecologic Surgeons Systematic Review Group. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol 211: 71, 2014.
9. Wu JM, Matthews CA, Conover MM, Pate V, Jonsson FM. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. Obstet Gynecol 123: 1201-6, 2014.
10. Abrams P, Andersson KE, Birder L, Brubaker L, Cardozo L, Chapple C, Cottenden A, Davila W, de Ridder D, Dmochowski R, Drake M, Dubeau C, Fry C,Hanno P, Smith JH, Herschorn S, Hosker G, Kelleher C, Koelbl H, Khoury S, Madoff R, Milsom I, Moore K, Newman D, Nitti V, Norton C, Nygaard I, Payne C,Smith A, Staskin D, Tekgul S, Thuroff J, Tubaro A, Vodusek D, Wein A, Wyndaele JJ; Members of Committees. Fourth International Consultation on Incontinence Recommendations of the International Scientific Committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. Neurourol Urodyn 29: 213-40, 2010.
11. Comiter CV, Colegrove PM. High rate of vaginal extrusion of silicone-coated polyester sling. Urology 63: 1066-70, 2004.
12. Shumaker SA, Wyman JF, Uebersax JS, McClish D, Fantl JA. Health-related quality of life measures for women with urinary incontinence: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program in Women (CPW) Research Group. Qual Life Res 3: 291-306, 1994.
13. Utomo E, Korfage IJ, Wildhagen MF, Steensma AB, Bangma CH, Blok BF. Validation of the urogenital distress inventory (UDI-6) and incontinence impact questionnaire (IIQ-7) in a Dutch population. Neurourol Urodyn 2013.
14. Utomo E, Blok BF, Steensma AB, Korfage IJ. Validation of the Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7) in a Dutch population. Int Urogynecol J 25: 531-44, 2014.

15. van der Vaart CH, de Leeuw JR, Roovers JP, Heintz AP. Measuring health-related quality of life in women with urogenital dysfunction: the urogenital distress inventory and incontinence impact questionnaire revisited. Neurourol Urodyn 22: 97-104, 2003.
16. Forzini T, Viart L, Alezra E, Saint F. [Erosive complications of mid urethral slings (MUS): 10 years of surgical experience.]. Prog Urol 2015.
17. Misrai V, Roupret M, Xylinas E, Cour F, Vaessen C, Haertig A, Richard F, Chartier-Kastler E. Surgical resection for suburethral sling complications after treatment for stress urinary incontinence. J Urol 181: 2198-202, 2009.
18. Sweat SD, Itano NB, Clemens JQ, Bushman W, Gruenenfelder J, McGuire EJ, Lightner DJ. Polypropylene mesh tape for stress urinary incontinence: complications of urethral erosion and outlet obstruction. J Urol 168: 144-6, 2002.
19. Shah K, Nikolavsky D, Gilsdorf D, Flynn BJ. Surgical management of lower urinary mesh perforation after mid-urethral polypropylene mesh sling: mesh excision, urinary tract reconstruction and concomitant pubovaginal sling with autologous rectus fascia. Int Urogynecol J 24: 2111-7, 2013.
20. D.Barski, D.Y.Deng. Management of Mesh Complications after SUI and POP Repair: Review and Analysis of the Current Literature. BioMed Research International Article ID 831285: 2014.
21. Broussard AP, Reddy TG, Frilot CF, Kubricht WS, III, Gomelsky A. Long-term follow-up of porcine dermis pubovaginal slings. Int Urogynecol J 24: 583-7, 2013.