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CLINICAL ARTICLE

Results of collagen sling placement following the partial removal of a synthetic midurethral sling

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ABSTRACT

Objective: To assess results of placement of the Pelvilace collagen sling following partial removal of a primary synthetic sling because of late complications. *Methods:* A retrospective study was undertaken of patients with late complications after midurethral sling surgery who underwent placement of a Pelvilace sling at a center in the Netherlands between January 2006 and January 2011. A postoperative questionnaire was used to evaluate the continence status and continence-related quality of life. Patients scoring 0 in the Urogenital Distress Inventory stress symptoms section were considered cured. The subjective improvement or deterioration in symptoms was scored using the Patient Global Impression of Improvement (PGI-I). *Results:* The questionnaire was completed and returned by 32 (84%) of 38 patients after a mean follow-up of 54.3 months. Nine (28%) patients were deemed cured. Among 29 patients who had not undergone a third surgery, the PGI-I showed a postoperative improvement in 14 (48%). The other 15 patients rated their postoperative situation as little improved, unchanged, or deteriorated. Further subanalysis showed clear differences in postoperative results between the different types of late complications (erosion and/or displacement). *Conclusion:* The concomitant placement of a collagen sling following partial removal of a primary polypropylene sling shows reasonable results for specific complications.

1. 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 transobturator 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 midurethral 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

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Pelvilace collagen sling placement directly following partial removal of a primary sling because of late complications.

2. 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 Centre, 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 Centre. 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 transobturator 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 nonvalidated questionnaires. It consisted of 44 questions divided into six 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 nonvalidated 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.

3. Results

Between January 2006 and January 2011, 38 patients received the Pelvilace collagen sling after partial sling removal and were included in the study (Fig. 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.

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 (Fig. 1). These patients were included in the success/failure rates as failures to avoid bias.

More than one-quarter of the 32 women included in analyses 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. Postoperative improvement according to the PGI-I was most often observed among the 12 women who underwent

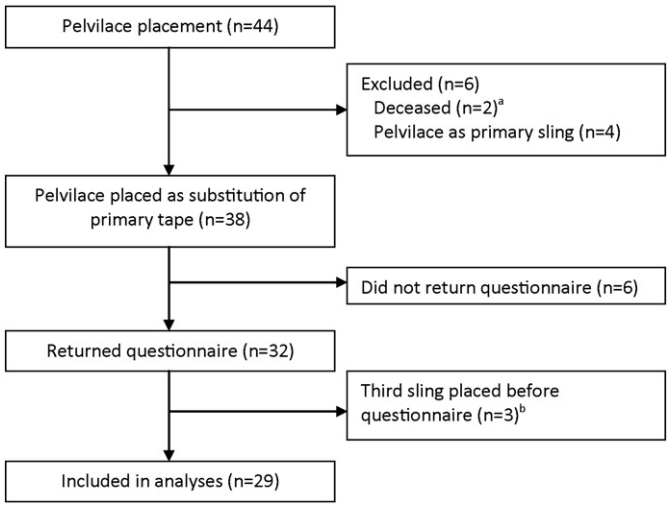

Fig. 1. Flow of patients through the study. [a] Death not due to Pelvilace placement. [b] These patients were included in the failure/success analysis as failures.

Table 1
Baseline characteristics (n = 38).

Characteristic	Mean ± SD (range)
Age, y	54.7 ± 10.5 (27–81)
Body mass index [a]	27.5 ± 4.3 (18.2–37.4)
Mean follow-up, mo [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).