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ORIGINAL ARTICLE

Clinical effects of transobturator tape procedure with porcine small intestine submucosa for female stress urinary incontinence



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Transobturator tape

Abstract The aim of this study was to evaluate the efficacy of the transobturator tape (TOT) procedure using porcine small intestine submucosa (SIS) for the treatment of female stress urinary incontinence (SUI). Forty-two consecutive patients with SUI who underwent the TOT procedure with porcine SIS were enrolled. The surgical outcomes, and data of urodynamic study and a questionnaire prior to and after surgery were collected and analyzed retrospectively. SUI was reported subjectively cured in 34 of the 42 patients (81.0%) 1 year after surgery, and declined to the rate of 66.7% at 5 years postoperatively. The subjective symptoms of frequency and nocturia also improved significantly ($p < 0.01$). Graft-versus-host disease (GVHD) developed in four patients, but without major complications. Despite the bladder volume at first desire to void increased significantly after surgery ($p < 0.01$), the remaining urodynamic parameters did not differ in a significant manner. In conclusion, the long-term cure rate of the TOT procedure with SIS is lower than with synthetic materials, but with relatively lower morbidity.

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Conflicts of interest: All authors declare no conflicts of interest.

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Introduction

Stress urinary incontinence (SUI), affecting approximately 4% to 35% of women [1,2], is a common disorder which can greatly impact the quality of life of affected individuals. Management of SUI includes conservative and surgical treatments. Over 100 types of anti-incontinence surgeries were invented since the introduction of Kelly's plication in 1915 [3]. Different kinds of surgical approach were developed, including abdominal, vaginal, laparoscopic, and combined procedures. In the past 2 decades, minimally invasive midurethral slings have become the procedure of choice for female SUI, since its introduction in 1995 [4]. The two main categories are tension-free vaginal tape (TVT) and transobturator tape (TOT). TVT was introduced in 1995 with a high success rate [5], but it has been associated with various complications, such as bladder perforation, urinary retention, and vascular and bowel injuries [6,7]. TOT was then introduced in 2001 [8] with the goal of avoiding some of the complications of TVT.

Apart from the different approaches of midurethral slings, four types of reconstructive materials differ by the sources which are available, including allografts, autografts, synthetic grafts, and xenografts. Each graft has its advantages and drawbacks, however limited data is available to determine which materials are superior to the others.

Autografts are harvested from the patients themselves. Host reaction seldom occurs with autografts, however, its use is limited by its morbidity associated with harvesting, such as longer operative time, causing greater post-operative pain and a longer time for recovery [9]. Allografts harvested from cadaveric human donors eliminate the morbidity associated with autologous graft harvest. However, supply shortage is a main problem of allografts. Synthetic grafts have the advantages of not requiring harvesting and being cost-effective, but increased complications of infection and extrusion were noted. Allman et al. [10] demonstrated implanted small intestine submucosa (SIS) may induce a vigorous response of tissue acceptance rather than rejection. As a result, xenografts were developed to lower these complications.

Stratasis TF (Cook Urological Incorporated, Spencer, IN, USA) is derived from the extracellular matrix of porcine SIS. It is an acellular, nonimmunogenic, xenogenic, and collagen-based biomaterial. Studies concerning the efficacy of porcine dermis (Pelvicol) with a pubovaginal approach have been reported [6–8], but little information was obtained about the porcine SIS with a midurethral tape approach. The purpose of this paper was to evaluate the efficacy, safety, and morbidity of porcine SIS used for TOT surgery in women with SUI. To our knowledge, this is the first study investigating the results of the TOT procedure using porcine SIS for the treatment of SUI.

Material and methods

This retrospective study included 69 women who underwent a TOT procedure with Stratasis TF for SUI between July 2002 and July 2005, and who were diagnosed both clinically and urologically. All women had proven

urodynamic stress incontinence without detrusor overactivity. Twenty-seven women were excluded from this study due to the following reasons: (1) incomplete medical records ($n = 18$); and (2) loss of follow up ($n = 9$). Data pertaining to 42 women were therefore assessed for the present study. Basic demographic data were obtained at their first visits. In addition, all patients underwent physical examination, urodynamic assessment, and an interview to identify urinary symptoms using the standardized questionnaire taking into account the 2010 International Continence Society definitions [1]. The diagnosis of overactive bladder (OAB) was made when the patient answered "somewhat" or more to any one of the three urge questions in the OAB V8 questionnaire (Question 2. An uncomfortable urge to urinate? Question 3. A sudden urge to urinate with little or no warning? Question 7. An uncontrollable urge to urinate?) [11], once we had excluded any obvious etiology. The same assessments were repeated again 6 months after surgery.

Urodynamic studies were performed using a six channel urodynamic monitor (MMS UD2000; Medical Measurements Systems, Enschede, The Netherlands) according to the recommendations by the International Continence Society [1]. The studies included spontaneous uroflowmetry, both filling (at a rate of 50 mL/min with a 10F Foley catheter) and voiding cystometry with infusion of normal saline at room temperature, and urethral pressure profilometry. Any uninhibited detrusor contraction during filling cystometry was deemed positive for idiopathic detrusor overactivity. Intrinsic sphincter deficiency was defined as Valsalva leak-point pressure < 60 cmH₂O during filling cystometry.

After inducing laryngeal mask general anesthesia, the patient was placed in a standard lithotomy position, legs in stirrups, and thighs in hyperflexion. A single dose of prophylactic antibiotics with 1 g of cefazolin (Cefamezin; Fujisawa, Tokyo, Japan) was given 30 minutes prior to the operation. A midline vertical incision over the anterior vaginal wall was made 1 cm below the urethral meatus. The vaginal wall was then dissected laterally using Metzenbaum scissors (Prima, Tuttlingen, Germany) to the undersurface of the bilateral obturator foramina. Another incision was made on the perineum 2 cm lateral to the clitoris on both

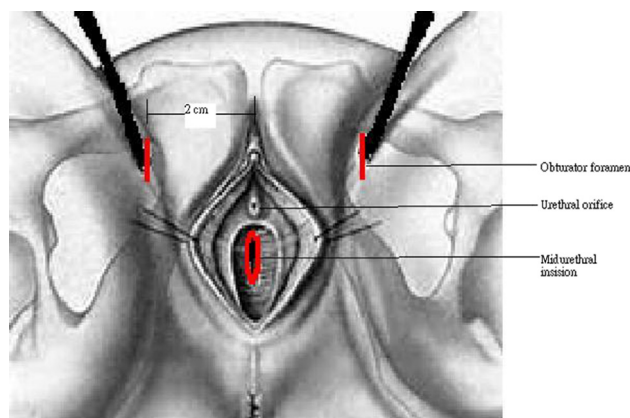


Figure 1. Transobturator tape (TOT) procedure with small intestine submucosa (SIS), the position of the mesh placed, and the incision wounds.

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