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The Small Intestinal Submucosa (SIS) as a Suburethral Sling for Correction of Stress Urinary Incontinence: Preliminary Experience

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ABSTRACT

INTRODUCTION: The purpose of the present investigation was to demonstrate the authors' preliminary experience with the use of small intestine submucosa (SIS) as a suburethral sling in the treatment of stress urinary incontinence (SUI) in females.

METHODS: The participants were a carefully selected cohort of 17 women (mean age = 55 years; range, 44-63 years) with SUI based on clinical and urodynamic evidence. Patients with mixed incontinence, prior anti-incontinence, or transvaginal surgery were excluded. The SIS sling was placed as a midurethral sling via a transvaginal retropubic approach. Patients were followed up at 1 week and 3, 6, and 12 months after the procedure. Urodynamic evaluation was repeated at the last postoperative visit.

RESULTS: No adverse inflammatory reactions to the implanted sling or evidence of sling erosion or extrusion were noted in any patients throughout the follow-up period. No major complications were reported; however, minor complications were reported in 3 patients (17.6%). One year after the procedure, 14 patients (82.3%) were completely dry and 2 patients reported occasional episodes of leakage on more than usual daily exercise. The procedure failed to cure SUI in 1 patient, and 1 patient had persistent de novo urinary urgency requiring anticholinergic medication.

CONCLUSION: The preliminary results strongly support the feasibility of the use of SIS as a suburethral sling for treatment of SUI. However, long-term follow up is needed to confirm the durability of these encouraging initial observations.

KEYWORDS: Stress urinary incontinence; Suburethral slings; Small intestine submucosa (SIS).

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INTRODUCTION

Female stress urinary incontinence (SUI) is a major health and social problem affecting 26% to 57% of women. Stress urinary incontinence is diagnosed in more than half of these cases; another 40% have both stress and urge urinary incontinence (mixed incontinence) [1,2].

There has been a dramatic shift in anti-incontinence surgery from the older empirically based colposuspension and traditional pubovaginal slings toward the more pathophysiologically oriented midurethral slings. According to a meta-analysis review, tension-free vaginal tape (TVT) is now considered by many surgeons as the gold standard surgery for female SUI [3,4].

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TVT via the retropubic approach was described first by Ulmsten in 1995. The transobturator route was described later [5] in an attempt to avoid the blind passage into the retropubic space, which could be associated with higher risk of inadvertent bladder injury or pelvic hematoma [6].

A wide array of biological (eg, autologous, cadaveric, xenografts) and synthetic sling graft materials are available. However, synthetic sling materials have been used in most of the retropubic and transobturator approaches. These materials are abundantly available, durable, and easy to use without the need for another incision. However, they carry the risk of local infection and subsequent erosion or extrusion as they remain in situ [7].

The small intestine submucosa (SIS) is a processed acellular collagen matrix xenograft. The surgically implanted SIS graft is infiltrated by the host fibroblast and inflammatory cells of the host. Within 90 - 120 days, the implanted graft becomes remodeled and replaced by the autologous host tissue. A particular advantage of the SIS graft is its biocompatibility and resistance to infection [8]. Currently, SIS grafts have a well established role in clinical urological application (eg, substitution urethroplasty, tunica grafting in penile operations, bladder augmentation, and ureteral replacement) [9,10,11].

Despite the advantages of the SIS graft, there are several practical issues that might be debated. Examples include the biocompatibility and how the tissue would react to the implanted graft, and the suitability of the SIS to serve as a suburethral sling to correct the biomechanical capabilities of stress incontinence. The purpose of the present study was to attempt to resolve this controversy by reporting the authors' experience with the SIS xenograft as a suburethral sling for correction of SUI in women.

METHODS

Preoperative Evaluation

The participants were 17 women with SUI. Their mean age was 55 years (range, 44-63 years).

All patients received a preoperative evaluation that consisted of a thorough case history report and physical examination (abdominal, pelvic, and neurological). Diagnosis of stress incontinence was based on objective demonstration of involuntary leakage upon stress (cough stress test with at least 250 mL urine inside the bladder as assured during ultrasound examination) and documentation of urethral hypermobility by the Q-tip test. Assessment of the status of the pelvic organs, bladder and postvoid residual volume were completed by ultrasound.

Exclusion of other causes of incontinence were based on the voiding diary and urodynamic evaluation in the form of cystometrogram (CMG), abdominal leak point pressure (ALPP), and uroflowmetery. Investigations were completed by urine analysis (and culture if necessary) and routine preoperative workup.

Women with urge or mixed incontinence, pelvic organ prolapse, detrusor instability, and prior anti-incontinence procedures were excluded. Only women with at least 12 months of follow-up data were included. The procedures and materials used were explained and informed consent was obtained.

Surgical Technique

The authors used the Surgisis® Biodesign™ (Cook Medical) Tension-Free Urethral Sling Kit. The sling is made from a biological scaffold material composed of extracellular matrix (ECM) derived from porcine small intestinal submucosa, which accommodates either an antegrade or retrograde placement. Each kit contains 1 Surgisis Biodesign sling (2 x 40 cm), 2 ligature carriers (3.2 mm diameter; 19 cm long) with removable handles, and a special sling cutter which allows cutting of the SIS sling about ½ cm away from the abdominal skin (Figure 1).

The sling was prepared by immersion into saline solution for at least 10 minutes for hydration. The principles of the TVT outside-in technique were used for tape placement. Entry to the retropubic space was achieved via a small midline vaginal

Figure 1. Tension-Free Urethral Sling Kit (Surgisis® Biodesign™)

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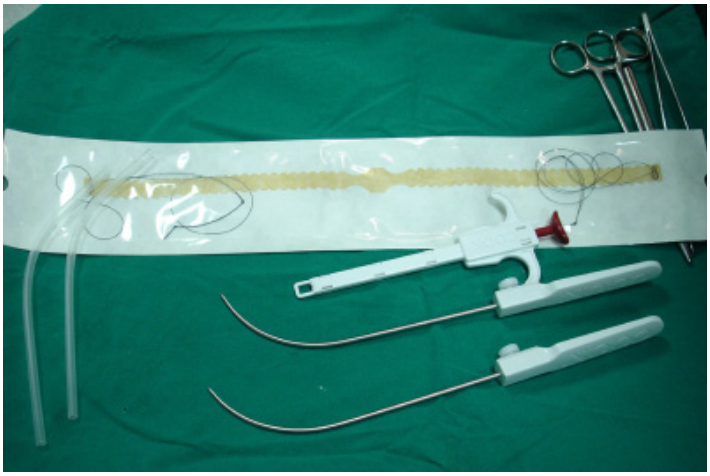

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Figure 2. Eyelets of the Needles at the Vaginal Incision after Passage From the Abdominal Stab Wounds Through the Retropubic Space

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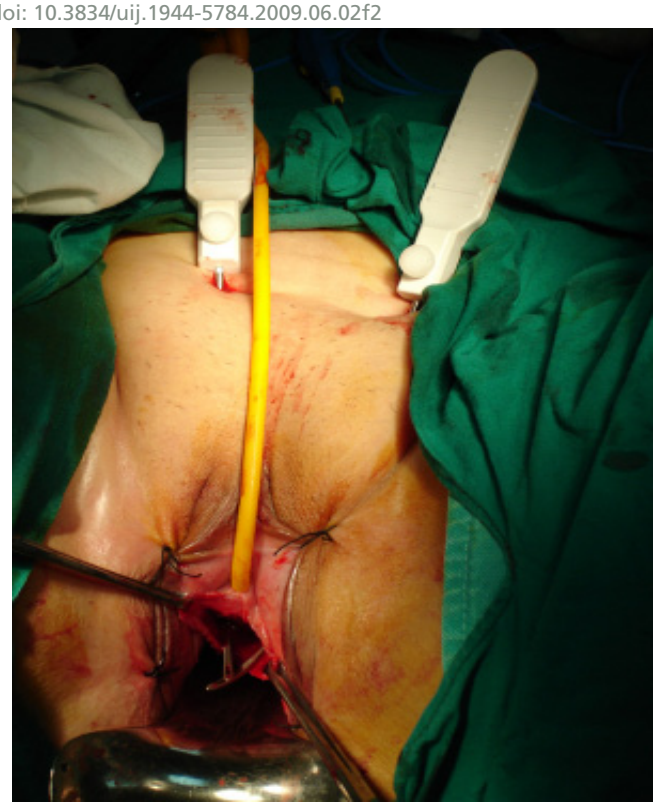

Figure 3. The SIS Sling Adjusted at the Level of the Mid Urethra Without Tension

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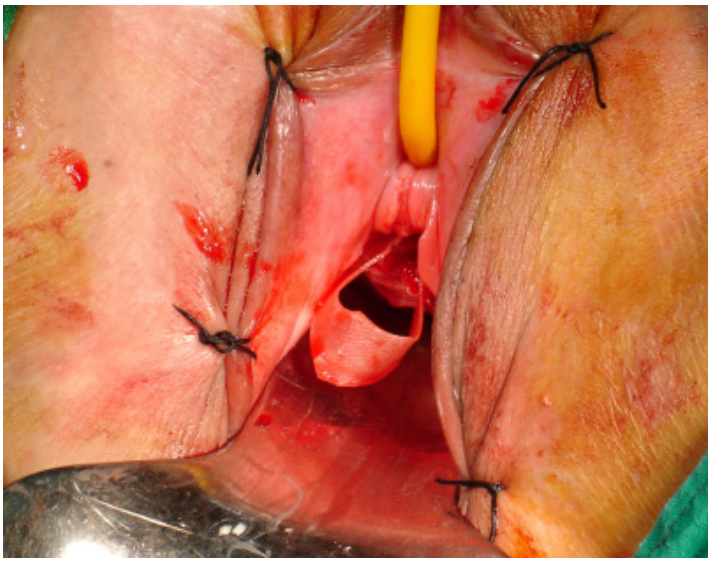

incision to help guide the needles, introduced through small abdominal stabs. The SIS sling was then tied to the needle tips and adjusted without tension at the level of the midurethra (Figure 2 and Figure 3). The abdominal stabs and the vaginal incision were closed after confirmation of absence of bladder injury by cystoscopy.

Postoperative Care and Followup

The urethral catheter was removed 24 hours after the procedure. Patients were discharged after evidence of successful spontaneous voiding. Follow-up visits were scheduled at 1 week and 3, 6, and 12 months. At each visit, patients were given a cough test at supine position and a bedside ultrasound measurement of postvoid residual. Urodynamic testing was performed at the last 12-month postoperative visit.

Results of overall complication rates and treatment outcome at the last postoperative visit are presented. *Cure* was defined by absence of urinary leakage both on subjective (as perceived by the patients) and objective (cough test and urodynamic testing) bases. Patients were also asked about their satisfaction with the procedure.

RESULTS

The SIS sling was placed behind the mid-urethra through a retropubic approach using a preset Surgisis Tension-Free Urethral Sling Kit, with both ends of the sling fixed to the abdominal wall. The mean operative time was 32 minutes (range, 25-40 minutes) including time required for sling placement and confirmatory visualizing cystoscopy to exclude bladder injury. The authors did not encounter any intraoperative complications (eg, bladder perforation, urethral injury, severe bleeding or pelvic hematoma) during dissection and sling placement.

All patients were discharged on the day after surgery, following proof of the ability to void without a catheter. Fifteen of the 17 patients were able to void immediately after catheter removal. All patients were able to return to full preoperative daily and sexual activity within a mean period of 4 weeks (range, 3-6 weeks).

In the *immediate postoperative period*, 3 patients (17.6%) had minor complications. A Foley catheter was reinserted in 2 patients who developed acute urine retention after initial catheter removal. Both patients were discharged with a catheter and instructed to return after 4 days, after which both voided successfully without further need of dilatation or sling

release. An additional patient had a culture-proven urinary tract infection and was treated with the appropriate culture-based antibiotic.

In the *first 3 postoperative months*, no evidence of severe inflammatory reaction to the implanted graft was noted at either the vaginal incision or the abdominal stabs. Five patients (30%) reported changes in the voiding pattern (3 patients complained of de novo urinary urgency, and an additional 2 patients complained of increased urinary frequency). Anticholinergic medications were given to all 5 patients. At the *6-month follow up*, only 2 of the 5 patients that reported changes in the voiding pattern required further continuation of anticholinergic medication.

At the last *12-month follow-up* visit, 14 patients (82.3 %) were completely dry according to subjective and objective assessments. Two patients still had occasional episodes of involuntary leakage on strenuous exercise (more than usual daily exercise). However, both women reported improvement in quality of life and needed no further treatment. Finally, the procedure failed to correct incontinence in 1 patient. No cases of erosion or extrusion were observed throughout the follow-up period.

Table 1 contains the pre and postoperative means and ranges for Q-max, postvoid residual volume, and number of pads. None of the patients complained of voiding difficulty. However, an insignificant decrease in the mean Q-max and another insignificant increase in the mean postvoid residual volume were recorded in comparison with their preoperative values. Accordingly, none of the patients required tape release or urethrolysis. Nine patients had preoperative ALPP values above 120 cm H_2O; 6 had ALPP of 60-120 cm H_2O; 2 had ALPP < 60 cm H_2O. Postoperatively, patients who were not completely cured with the procedure (2 improved; 1 failed) had ALPP values above 120 cm H_2O and 80 cm H_2O, respectively.

Despite anticholinergic therapy, 1 patient still complained of persistent urinary urgency. Urodynamic evaluation confirmed the presence of detrusor overactivity.

DISCUSSION

Advantages and Disadvantages of Various Types of Slings

Despite the lack of prospective randomized trials in the last decade, there has been a dramatic shift in anti-incontinence surgery from the older empirically based suspension or traditional pubovaginal sling procedures toward the pathophysiologically-oriented suburethral slings. The latter procedures have a technical advantage, because they provide a tension-free dynamic support rather than the high fixed retropubic support (as in the case of pubovaginal slings). Midurethral slings offer several technical advantages in addition to high success rates and few complications. Midurethral slings are simpler and less invasive than pubovaginal slings. They are also associated with short operative time, short learning curve, brief hospitalization, and rapid convalescence and return to daily physical and sexual activity [3,4,12,13].

Although various sling materials have been used in the traditional pubovaginal sling, most midurethral slings are made of synthetic materials. Synthetic materials are well known for high erosion or extrusion rates. According to the literature, vaginal extrusion has been observed in 0 to 2.4% with retropubic slings, and 0 to 6.2 with transobturator slings. Erosion or extrusion may be caused by excessive tension leading to ischemic tissue necrosis or by poor tissue vasculature (eg, cases of postmenopausal atrophy, scars from prior anti-incontinence surgery, or from pelvic irradiation). Finally, other causes of erosion or extrusion might be related to the manufacturer's criteria for the synthetic slings (eg, mono vs polyfilament and pore size) [4,12].

Biologic materials, on the other hand, provide the promise of a tolerable local tissue reaction with minimal adverse effect. However, biological autologous grafts require a second incision and longer operative time to obtain. Meanwhile, biological cadaveric allografts are difficult to prepare and carry the risk of transmission of diseases [7].

Table 1. Pre and Postoperative Means and Ranges for Q-Max (mL/s), Postvoid Residual Volume (mL), and Number of Pads.
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Variable	Preoperative Values		Postoperative Values	
	Mean	Range	Mean	Range
Q-Max (mL/s)	25.4	17-35	23.5	15-32
Postvoid Residual Volume (mL)	11.7	7-15	13.5	8-20
Number of Pads	4	2-8	0.5	0-4

SIS Xenograft

The SIS xenograft is a processed acellular biocompatible collagen matrix of porcine origin. SIS is now a well established tool in several reconstructive urologic procedures [9,10,11]. In the field of urinary incontinence, SIS has been used with encouraging results in treatment of postprostatectomy incontinence [14], neuropathic incontinence [15], and stress urinary incontinence [16,17,18].

Practical concerns regarding the use of the SIS implant in clinical practice mainly revolve around its biocompatibility and biomechanical suitability to serve as a suburethral sling for the correction of stress incontinence in women. These concerns are addressed in the present study.

Graft biocompatibility. The first practical concern is related to the graft biocompatibility and how the tissue would react to the implant. Many clinical trials and histopathological studies support the fact that the SIS graft has excellent biocompatibility as evidenced by lack of significant immunological reaction, foreign body reaction, and chronic inflammatory reaction. In addition, the SIS sling is well known for its strength, durability, and resistance to infection [8,13,16,17].

However, unlike most reports confirming the safe use of the SIS graft, Soergel et al [19] reported major complications in 16% of their patients when the SIS graft was used for corporal grafting to correct proximal hypospadias. Although the authors discontinued its use for such application, they speculated that the high complication rate may be related to the use of the 4-ply SIS graft; other surgeons using a single-layer SIS graft did not report a similar complication rate and demonstrated excellent results [16,17,18].

When applied as a suburethral sling, Ho et al [20] reported inflammatory reactions at the abdominal incision (but none at the vaginal incision) in 6 out of 10 patients treated with the 8-ply SIS sling. Most cases resolved with minimal or no intervention. Abscess formation was observed in 2 patients.

John et al [21] used both the Cook 4-ply and the 8-ply Stratasis-TF in 16 women with stress urinary incontinence. They reported intense inflammatory complications in 5 patients (nearly one third). Most of the inflammatory reactions were related to the suprapubic region rather than near the vagina or urethra. Four of the 5 patients with complications had the new 8-ply Stratasis-TF. The remaining patient had the 4-ply SIS; however, this patient had a concomitant extensive pelvic floor reconstruction by a gynecologist prior to placement of the SIS sling. Apparently adding more layers to the SIS graft material may have a contributing role in inflammatory reactions, because these high complication rates were not observed with the older 1-ply and 4-ply formulations [21,22].

The authors of the present study do not know of any study comparing the 1-ply, 4-ply, and 8-ply SIS grafts in humans. Use of SIS in urethroplasty in rabbits shows that complete healing with the use of the single-layer SIS graft may occur as early as 1 month, whereas complete healing with the 4-layer SIS graft may be delayed up to 3 months [23].

The results of the present investigation showed that the SIS sling was accepted nicely by the tissue after 12 months. No erosion, extrusion, or severe inflammatory reactions were noted. Most reactions were mild and usually observed as early as 10 days or as late as 45 days after the procedure. Most reactions were well tolerated and resolved spontaneously.

Biomechanical properties. The second practical concern is related to the biomechanical properties of the SIS sling and its suitability for curing stress incontinence.

The strength of the graft is probably an important factor, especially when a mechanical function is involved. Dora et al [24] compared the changes in the biomechanical properties of 6 different materials that may be used for stress incontinence surgery. They studied tensile strength and stiffness after being implanted on the anterior rectus sheath of rabbits for 12 weeks. A significant, time-dependent decrease in the tensile strength and stiffness of the SIS (60% and 66%, respectively) was noted at 12 weeks. A similar time-dependent decrease in the biomechanical properties of the polypropylene mesh was not noted during a similar time period. Because of this biomechanical study, the authors withdrew support for the use of polypropylene mesh for sling surgery relative to other nonautologous materials. The authors of the present research do not know of any other studies comparing the biomechanical properties of vaginal slings applied directly to the urethra in animals or humans.

It is worth mentioning that the theory of application of suburethral slings mainly depends on tension-free anatomic support, as opposed to the tension and extrinsic compression needed for pubovaginal slings. Hence the task of the SIS sling is mainly to act as a scaffold that allows in-growth and structural organization of the native host tissue.

The implant actively supports connective and epithelial tissue ingrowth and differentiation, as well as deposition, organization, and maturation of extracellular matrix components that characterize site-specific tissue remodeling.

This phenomenon has been called *smart tissue remodeling* [25] and it is important to note that the balance between implant degradation and host incorporation results in a dynamic implant strength response.

The strength of the SIS sling is expected to be the net result between SIS degradation and tissue regeneration. Degradation rates that are too rapid or reconstruction rates that are too slow can result in transient minimum strengths that are below the critical threshold. Supposedly, this carries increased risk of recurrence of incontinence symptoms after an initial successful anti-incontinence surgery [13].

Outcome of the SIS Sling

The suitability of the SIS sling is better reflected by the clinical outcome. In terms of clinical efficacy in correction of stress incontinence, the results of the present study confirm that the SIS sling was able to provide strong suburethral support and durable clinical results. The authors achieved an overall success rate of 94% one year after the procedure, with 82.3 % of the patients completely cured and 11.7% reporting improvement in the degree and number of episodes of leakage in relation to their usual daily activity.

The clinical results of the current study have been supported by prior clinical studies. Rutner et al [17] used the SIS graft as a pubvaginal sling and bone anchoring mechanism for fixation of the sling. They reported an overall success of 93.4%. All patients had minimal local reactions and pelvic pain; no cases of erosion or extrusion were noted. The authors also performed a biopsy for cases which required reoperation for correction of incontinence. They observed absence of the implanted graft on gross examination. Microscopically, only a few remnants of the SIS (< 0.4 mm) could be found. More recently, Jones et al [18] achieved an overall success rate of approximately 80% in 34 cases and none of the patients developed urine retention or erosion.

Voiding difficulty, increased urinary frequency, and urinary urgency are common consequences of all types of anti-incontinence procedures. These symptoms are more frequently observed during the first postoperative month following the application of suburethral slings. The overall incidence of de novo urgency following suburethral slings ranges from 3% to 26%. Urgency may be related to irritation from the sling itself or to the sclerotic and fibrotic process around it, especially in cases where a synthetic sling is used. Urgency may be also related to bladder outlet obstruction secondary to excessive tension exerted by the sling or to excess fibrosis around the sling [4,12,13].

In the present study, voiding dysfunction results were also consistent with the literature. Urgency and increased urinary frequency were more common during the first 3 months after the procedure, approaching 17.6%, and 11.6% respectively. However, by the end of the first year after the procedure, only 1 patient had persistent urinary urgency despite anticholinergic therapy. A cystometrogram confirmed the presence of detrusor over-activity. No women complained of voiding difficulty and a statistically insignificant decrease in the Q-max compared to preoperative level was noted.

Finally, midurethral slings can be placed through either the transobturator or retropubic routes. Complications of the retropubic approach are related to the blind passage of the suprapubic needle with the subsequent risk of visceral injury or pelvic hematoma. With the retropubic approach, the risk of bladder perforation may range from 0 to as high as 15%; the risk of bladder injury is usually dependent upon previous prolapse surgery and experience of the surgeon. Other arguments against the retropubic approach include higher incidence of outlet obstruction by the tape and subsequently higher incidence of acquired postoperative voiding dysfunction [4,12,26]. The authors of most trials have concluded that both approaches are equally comparable in terms of clinical effectiveness, postprocedure voiding dysfunction, and overall complication rate [27,28].

In the present study, the authors were obligated to resort to the retropubic approach rather than the transobturator approach, because the kit used at the time of initiation of the study was prepared to be used through the retropubic route. Additionally, a primary goal was to investigate the biocompatibility and feasibility of use of SIS as a suburethral sling in general, rather than to compare the approaches.

The authors did not encounter any cases of visceral injuries during needle passage in their patients. A helpful technical tip to avoid visceral injuries during needle passage is adequate dissection of the paraurethral space and entry into the retropubic space to help guide the needle to exit from the vaginal incision once is has been introduced into the abdomen. Placement of the urethral catheter to assure continuous bladder emptying throughout the procedure is crucial in avoiding both bladder and urethral injuries. The authors believe that the SIS sling can also be applied according to the principles of transobturator tape, depending on the availability of designated needles.

CONCLUSION

The most ideal material to be used as a suburethral sling for correction of SUI still does not exist. The authors of the present

study found that the SIS graft material was well accepted by the host tissue, and considered safe and effective. The SIS suburethral sling was implanted with the retropubic approach in the present study. However, the authors hypothesize that a transobturator approach would also be successful, according to the surgeon's individual preference.

Longer periods of follow up are still required to support the durability of these preliminary results. Long-term results will be updated in subsequent reports.

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