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Long-term Outcome of the Readjustable Sling Procedure for Female Stress Urinary Incontinence With Intrinsic Sphincter Deficiency or Recurrence

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Purpose: We evaluated the long-term outcome of a readjustable midurethral sling system (Remeex) in the treatment of recurrence of stress urinary incontinence (SUI) after surgical treatment or SUI with intrinsic sphincter deficiency (ISD).

Materials and Methods: This study included 19 patients who underwent the Remeex procedure with a mean of 45.6 months of follow-up. The patients had responded to a telephone questionnaire. Thirteen patients had ISD, four patients had SUI recurrence, and two patients had both. The questionnaire included subjective cure and satisfaction surveys and also recommended surgery to some patients.

Results: The mean patient age was 69.1 years (range, 50–85 years), the mean parity was 2.79 times (range, 2–5 times), and the mean follow-up period was 45.6 months (range, 21–72 months). The long-term follow-up cure rate was 79%, the improvement rate was 21%, and the fail rate was 0%. The long-term follow-up "very satisfactory" rate was 26.3%, the "satisfactory" rate was 73.7%, and the "usual" and "unsatisfactory" rates were both 0%. In addition to these results, 16 patients (84.2%) would recommend the Remeex procedure to other patients with SUI recurrence or ISD. After the procedure, four patients had urinary retention, three patients had difficulty emptying, and one patient had SUI recurrence. Furthermore, all of the patients subsequently endured sling readjustments.

Conclusions: After long-term follow-up, the Remeex system showed good cure rates and subjective satisfaction rates that were similar to the results found at the 1-year follow-up, and minimal complications were reported. Therefore, the Remeex system is effective in treating patients with SUI recurrence or ISD.

Keywords: *Intrinsic sphincter deficiency; Stress; Urinary incontinence*

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INTRODUCTION

Stress urinary incontinence (SUI) is defined as a disorder that presents with involuntary urine loss during effort, exertion, or coughing [1]. In recent years, owing to the high efficiency and reliability of the procedures, tension-free vaginal tape (TVT) and transobturator tape (TOT) have been mainly used to surgically treat SUI. Compared with treating simple SUI, TVT and TOT have been shown to be less effective in treating patients who have recurrent SUI after undergoing a surgical procedure or who have intrinsic sphincter deficiency (ISD) [2-6].

Remeex (Neomedic International, Terrassa, Spain), a readjustable midurethral sling system for the surgical treatment of SUI, allows the surgeon to recover continence through adjustment of the sling tension in a hospitalized patient and also permits the surgeon to regain continence in a patient who has recurrent SUI with a previous Remeex history by readjusting the sling tension under local anesthesia. Because of this advantage, the Remeex system

is an effective approach for treating recurrent SUI or ISD.

Many short-term follow-up results for the Remeex procedure have been published, including our urology department's 1-year follow-up results [7], which showed high cure (100%) and satisfaction (100%) rates. Some long-term follow-up results, mostly Western data, are available, which showed that the cure rate of the readjustable sling procedure was between 87% and 92.2% [8-10]. However, there are no long-term follow-up results of the Remeex procedure in Korea. The previous 1-year follow-up results from our urology department were short-term follow-up results [7]. In the present study, therefore, we studied the results related to the readjustable sling procedure performed on patients with recurrent SUI or ISD at a mean follow-up of 45.6 months and compared these results with the those from the 1-year follow-up.

MATERIALS AND METHODS

Clinical data were collected retrospectively from 23 women with recurrent SUI or ISD were treated by use of the Remeex system at the Christian Hospital Urology Department located in Gwangju between January 2007 and March 2011. Among those 23 females, 19 patients were included in this study because 4 patients could not be followed up. Before this study was conducted, a 1-year follow-up study was performed of 17 patients who had been treated with the Remeex procedure between 2007 and 2009. ISD was defined as a leak-point pressure of less than 60 cm H_2O or a maximum urethral closure pressure (MUCP) of less than 20 cm H_2O. Thirteen patients had ISD, four patients had SUI recurrence, and two patients had both. The preoperative work-up consisted of obtaining a detailed medical history, physical examination, urine analysis and culture, stress test, and a urodynamic study (UDS), which included the Valsalva leak-point pressure (VLPP), uroflowmetry, and postvoiding residual measurement. One-year follow-up evaluations included history taking, 1-hour pad test, uroflowmetry, and postvoid residual (PVR) urine measurement. In this study, the Remeex procedure outcome was evaluated by telephone interviews of each patient. The interview consisted of several questions related to subjective cure and satisfaction. The subjective cure of the patients was defined according to Stamey's criteria [11] as follows: a state in which urinary incontinence did not exist at all was defined as "cured," "improvement" was considered to be a state in which urinary incontinence was quite rare and unnoticeable or in which the patient was satisfied with the surgical result, and "failure" was considered to be a state in which severe urinary incontinence had not improved after the surgery or in which patients showed dissatisfaction with the surgery outcome. A patient's subjective satisfaction was investigated by using a questionnaire in which the patient was asked to classify her satisfaction level regarding the outcome of the surgery by selecting one of the four grades listed: very satisfactory, satisfactory, usual, or unsatisfactory.

The Remeex device consists of a suburethral polypropylene prosthesis linked to a pressure adjusting device (varitensor) by two traction threads. The varitensor was implanted permanently in the abdominal rectus muscle fascia, and the postoperative sling tension was adjusted by connecting the manipulator to the varitensor. The manipulator was removed after the patient had reached continence. A 4-cm abdominal transverse incision was made at the midline 2 fingers above the pubic symphysis, the fat was dissected, and the fascia of the anterior rectal abdominal muscles was exposed. Traction threads were implanted in the abdominal site through the anterior vaginal wall at the midurethral level. Subsequently, the bladder integrity was evaluated by cystoscopy.

After determining that the bladder was intact, the threads were connected to the varitensor and the manipulator was turned clockwise until the varitensor was positioned approximately two fingers' distance over the rectus fascia. When the varitensor was positioned at its proper location, the surgeon sutured the opening site, which kept the incision area open where the manipulator was connected. This approach allows the manipulator to remain perpendicular to the skin. Twenty-four hours after surgery, 250 mL of saline was injected into the bladder, the urethral catheter was removed, and the patient was instructed to perform a Valsalva maneuver and cough while standing. If a leak was still observed, two clockwise turns twice a day were performed on the manipulator until continence was reached. The patient was subsequently instructed to void urine in the toilet, and the residual urine volume was determined by using a portable sonar. If the residual urine volume was less than 100 mL, the manipulator could be disconnected from the varitensor and the patient could be discharged. However, if the residual urine volume was more than 100 mL, a counterclockwise turn of the manipulator was performed to decrease the sling support.

RESULTS

The study population included 19 female patients. The mean age of the population was 69.1 years (range, 50–85 years), the mean parity was 2.79 times (range, 2–5 times), and the mean follow-up period was 45.6 months (range, 21–72 months). Five patients underwent a hysterectomy and six received TVT operations. All of the patients were postmenopausal and five had mixed incontinence (Table 1).

Evaluation of the success rate revealed that the overall 1-year cure rate was 82.3%, the improvement rate was 17.6%, and the failure rate was 0%. Similarly, at the long-term follow-up, the overall subjective cure and improvement rates were 79% and 21%, respectively, whereas the failure rate was 0%. When evaluating the satisfaction rate over 1 year, the very satisfactory rate was 23.5%, the satisfactory rate was 76.4%, and the usual and unsatisfactory rates were both 0%. Similarly, at the long-term follow-up, five patients (26.3%) answered that they were

TABLE 1. Characteristics of the 19 patients

Characteristic	Value
Age (y)	69.1 (50–85)
Parity times	2.79 (2–5)
Menopausal women	19 (100)
Urge urinary incontinence	5 (26.3)
Anti-incontinence surgery	6 (31.5)
Hysterectomy (%)	5 (26.3)
1-Hour pad test (g)	53.1 (23–154)
Maximum flow rate (mL/s)	35.2 (20–52)
Postvoid residual (mL)	12.3 (5–27)
VLPP (cm H_2O)	55.7 (25–80)
MUCP (cm H_2O)	28.5 (14–39)

Values are presented as mean (range) or number (%).
VLPP, Valsalva leak point pressure; MUCP, maximum urethral closure pressure.

TABLE 2. Surgical outcomes

Variable	1-Year follow-up (n=17)	Long-term follow-up (n=19)
Success		
Cure	14 (82.3)	15 (79.0)
Improvement	3 (17.6)	4 (21.0)
Failure	0 (0)	0 (0)
Satisfaction		
Very satisfactory	4 (23.5)	5 (26.3)
Satisfactory	13 (76.4)	14 (73.7)
Usual	0 (0)	0 (0)
Unsatisfactory	0 (0)	0 (0)

Values are presented as number (%).

very satisfied, and 14 patients (73.7%) answered that they were satisfied (Table 2).

When asked whether the patients would recommend the Remeex procedure to others, 16 patients (84.2%) said yes. However, three patients would not recommend the Remeex procedure because the procedure had some requirements that were stressful; although these patients were satisfied with the surgical results, having a UDS before surgery was uncomfortable and being admitted to the hospital after surgery was a burden.

Four patients (21%) had urinary retention and three (15.7%) had difficulty voiding 1 to 2 months after surgery. All seven of these patients were then managed with manipulator readjustment under local anesthesia. One patient (5.2%) had an abdominal incision because of a wound infection that was easily cured with oral antibiotics. In 36 months, one patient (5.2%) underwent a sling tension readjustment because of SUI recurrence. After surgery, *de novo* urgency and urge incontinence did not develop.

DISCUSSION

For SUI treatment, several forms of retropubic colposuspension, pubovaginal slings, injectable bulking agents, or needle suspensions have been used [12]. The TVT procedure as a treatment for female SUI was initially theorized by Petros and Ulmsten [13] in 1993. After its introduction by Ulmsten et al. [11], the TVT procedure has been widely used owing to its high efficacy and safety. The long-term cure rate of TVT was previously shown to be between 71% and 86% [14-16]. Nilsson et al. [17] performed a follow-up of 80 patients for 7 years and reported an 81.3% cure rate. However, the TVT procedure has associated complications such as bladder injury, bowel perforation, necrotizing fasciitis, and large blood vessel injury [18,19]. In 2001, Delorme [20] described an alternative approach using TOT to avoid these major complications. The cure rates of both procedures are similar, ranging from 90% to 95% [21].

In ISD, the urethral closure mechanism is considered to be ineffective, possibly as a result of aging, previous surgery, or a neurological etiology. Clinically, women with ISD have more severe incontinence and a lower surgical success rate than do women with stress incontinence and normal urethral function [22]. Surgical failure rates increase four- to sixfold when there is evidence of ISD [23]. Paick et al. [2] evaluated 221 patients who underwent TVT for an average of 10.5 months. The success rate was 82% in the group whose VLPP was below 60 cm H_2O but 93.1% in the group whose VLPP was above 60 cm H_2O. In a retrospective, multicenter study, Lee et al. [3] evaluated factors related to long-term (5-year) success rates of the TVT procedure in 155 consecutive SUI patients. Those authors found that 64 patients with a VLPP above 60 cm H_2O had higher cure rates than did 31 patients with a VLPP below 60 cm H_2O (82.8% vs. 51.6%). Conversely, Lee et al. [24] divided the TVT patients into two groups. The first group had a VLPP lower than 60 cm H_2O, and the second group had a VLPP higher than 60 cm H_2O, but the authors did not observe a significant difference in success rates between the two groups (81.1% vs. 86.7%).

For TOT, few studies have been performed on SUI patients with ISD. O'Connor et al. [6] divided patients into either high ($>$60 cm H_2O) or low ($\leq$60 cm H_2O) VLPP groups for 6 months. Based on preoperative VLPP, 77% of patients (24/31) with high VLPP were cured, whereas only 25% of patients (3/12) with low VLPP were cured. Costantini et al. [5] reported that the cure rate of the TOT procedure was 77.3% in women with ISD. Schierlitz et al. [4] observed that at 3 years of follow-up, the risk of repetitive surgery for TOT in SUI with ISD was greater than 15 times that compared with TVT. The median time to failure was 15.6 months for TOT compared with 43.7 months for TVT. Those authors hypothesized that there was a difference in the sling axis, with the TVT sling placed at a more acute angle than the TOT sling. Additionally, on the basis of ultrasonographic imaging findings, the TOT sling location is more distal than that of the TVT sling. As a result, the TVT sling is likely to provide more effective urethral kinking and support, thus improving continence rates.

The persistence of incontinence or voiding difficulty is a frequent problem following the midurethral sling procedure because of how loose or tight the tape is set [25]. Urinary retention is resolved with the use of alpha blockers, urethral dilation, or intermittent catheterization. However, excision of the sling tape is required if refractory urethral obstruction occurs [26]. Additionally, patients may require surgical intervention to treat the persistence of SUI after sling surgery or recurrent SUI. Unfortunately, the success rate of this operation is 20% to 40% lower than that of the previous operation [27].

The Remeex system allows the operator to readjust the patient's urethral sling tension with a low complication rate, not only for an immediate adjustment but also for a delayed readjustment in cases of treatment failure. The common postoperative complications are wound infection, vaginal erosion, and *de novo* urgency according to the reported studies. Moreno Sierra et al. [8] reported that 1.7% of patients require detraction of the varitensor owing to persistent abdominal wall seroma, and 0.8% present with vaginal extrusion of the sling. Errando et al reported that no urethral or vaginal erosion occurred after the Remeex procedure, and they found only one patient (0.8%) with a seroma in the subcutaneous tissue around the varitensor. The seroma was subsequently removed. Ten cases (8%) of de novo detrusor overactivity were reported [9].

After long-term follow-up, the Remeex system provided a good cure rate in patients with SUI with ISD or in patients with recurrent SUI. Giberti et al. [10] used the Remeex system on 30 patients who had SUI with ISD for an average of 60.6 months (range, 22–96 months). They reported that 26 (86%) patients were cured, 2 (7.0%) patients had improved, and 2 (7.0%) patients had failed this treatment. Two patients (7%) required sling tension readjustment. Moreno Sierra et al. [8] studied a group of 683 women that consisted of patients with mixed incontinence (30.2%), ISD (73.1%), and recurrent SUI (35.7%); these patients underwent the Remeex treatment with a mean follow-up of 23 months (range, 6–93 months). Those authors reported that the cure rate was 92.2%, with 6.9% reporting improvement and 0.9% reporting failure. Eighty patients (11.7%) underwent readjustment between 6 and 8 months after surgery. Errando et al. [9] performed a follow-up of 125 patients who underwent the Remeex procedure for an average of 38 months (range, 26–72 months) owing to ISD (55%) and recurrent SUI (45%). One hundred and nine patients (87%) were cured of SUI on the basis of pad-tests, 7 patients (6%) were on the waiting list for a readjustment, and 9 patients (7%) refused a sling readjustment because they were satisfied with their improvement in continence. Twenty-one patients (17%) underwent readjustments under local anesthesia for an average of 12 months (range, 1–18 months) after the operation.

After reviewing the results, we concluded that our research results were not significantly different from those of other researchers. Additionally, the outcome of this study and literature reviews related to the readjustable sling procedure suggest that the Remeex system is an effective and simple procedure for treating recurrent SUI or ISD owing to its low complication rate, high success rate, and ability to readjust sling tension.

The limitation of the present study was that only a small number of subjects were examined and the interview was based on subjective data and satisfaction levels of the patient. Therefore, future studies will require more subjects. Additionally, more objective data are needed, such as uroflowmetry, PVR, and pad tests.

CONCLUSIONS

After researching the Remeex system in long-term follow-up for treating recurrent SUI or ISD patients, a good cure rate and subjective satisfaction with minimal complications similar to results found at the 1-year follow-up were observed. This sling system allowed us to adjust the sling tension so that patients could avoid urinary obstruction and incontinence. Therefore, the Remeex procedure could be effective for curing SUI with ISD or for patients who experience SUI after surgery. However, more subjects and objective data are required for future studies.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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