The Ibero-American experience with a re-adjustable minimally invasive sling

PAULO C.R. PALMA, MIRIAM DAMBROS, CÁSSIO Z. RICCETTO, MARCELO THIEL and NELSON R. NETTO Jr
Division of Urology, Universidade Estadual de Campinas, UNICAMP, Cidade Universitária 'Zeferino Vaz', Campinas, SP, Brazil

Accepted for publication 3 September 2004

OBJECTIVE

To report our experience with the Safyre™ (Promedon, Córdoba, Argentina), a new re-adjustable and minimally invasive sling for treating stress urinary incontinence (SUI), which combines the efficacy of slings with re-adjustability.

PATIENTS AND METHODS

In all, 126 consecutive patients with a clinical and urodynamic diagnosis of SUI had a Safyre sling procedure (mean age 63 years, range 40–71). Seventy-six patients (60%) presented after previous failed anti-incontinence procedures; all had a physical and clinical examination, a stress test, urodynamic study and assessment of pad use before the surgery. All the patients presented with symptoms of SUI and 37 (29%) also reported mild urgency.

RESULTS

The mean (range) follow-up was 18 (12–36) months, and the mean operative duration 25 min. Dystopia was repaired whenever necessary during the same procedure. The mean hospital stay was 24 h. In three implants (2%) the bladder was perforated. After surgery 26 patients (21%) developed urgency symptoms; during the follow-up 116 (92%) were continent, three (2%) reported an improvement and seven (6%) were dissatisfied.

CONCLUSION

The Safyre is a safe and quick procedure that allows for postoperative readjustment; this technique may be an attractive alternative if the good results obtained so far prove to be durable.

KEYWORDS

stress urinary incontinence, sling, female, failure, Safyre

INTRODUCTION

Pubovaginal slings date back to the beginning of the last century [1] and currently the sling technique has been considered to be the most effective for treating stress urinary incontinence (SUI) in patients with lesions of the intrinsic urethral mechanism [2]. However, morbidity and convalescence issues have stimulated the search for less-invasive procedures, e.g. minimally invasive slings and periurethral injections.

Synthetic tapes have been used and are very successful, giving strength to damaged tissues. An added benefit of synthetic slings is that they are placed using minimally invasive procedures, and thus reduce operative time, hospital stay and postoperative discomfort [3].

Since the marketing and success of the tension-free vaginal tape (TVT) technique, other products have been developed for suburethral slings. The self-anchoring Safyre™ (Promedon, Córdoba, Argentina) sling has recently been added to the existing systems. This is a tension-free, synthetic sling, placed at the mid urethra so that urethral erosion is unlikely. It is a re-adjustable, self-anchoring synthetic sling that allows the tension to be re-adjusted after surgery should there be urinary leakage or retention [4]. According to the integral continence theory, the medial and distal thirds of the urethra are the most important. The Safyre system is based on this theory and on experimental studies of the female urethral closure mechanism [5].

Slings are now being used more frequently and the Safyre, which has incorporates new concepts, is an attractive alternative for the surgical treatment of SUI. We present our experience with this re-adjustable sling, focusing on the safety during and after surgery, and on efficacy in the medium-term of this procedure.

PATIENTS AND METHODS

In a prospective, multicentre, single-arm, unrandomized clinical study (approved by the Hospital Ethics Committee), from February 2001 to July 2002, 126 patients with SUI had a Safyre implant; in all there were 140 procedures (126 implants, six slings later tightened, four loosened and four removed). The mean (range) age of the patients was 63 (40–71) years.

All patients had a routine diagnosis for incontinence, including a history, an assessment of the effect on quality of life (QoL, based on the International Consultation on Incontinence Questionnaire, short form, ICIQ-SF) [6], a gynaecological examination, a stress test, an assessment of pad use, and a urodynamic investigation. The last assessment used two urethral catheters (10 F for filling and 4 F for measuring bladder pressure), and a rectal 4 F catheter-balloon placed above the anal sphincter to measure abdominal pressure. The test included water cystometry, an assessment of Valsalva leak-point pressure with an intravesical volume of 200 mL and Valsalva manoeuvres, and a pressure-flow study.

The gynaecological examination showed mild cystocele in 62 patients (49%); 43 of the 62 (69%) were grade I and the rest grade II. A rectocele grade I was diagnosed in 13 of the 126 patients (10%) and only symptomatic grade II cystoceles were repaired (three patients).

The stress test was positive in all patients, with a mean (range) leak-point pressure of 71 (38–90) cmH_2O in 54 (43%) and of 99 (91–125) cmH_2O in 72 (57%). Patients who had involuntary detrusor contractions during bladder filling or a maximum urinary flow rate of <15 mL/s and/or a postvoid residual urine (PVR) of >20% of the volume voided were excluded from the study, but those with irritative symptoms with no urodynamically confirmed involuntary contractions were included. Although urodynamically confirmed detrusor instability has no significant effect on surgical outcome, this decision was based on the concept of a postoperative improvement in sensory urgency, as described previously [7]. Patients with involuntary detrusor contractions were excluded from this initial study because of their less favourable prognosis for postoperative irritative symptoms [8]. Most patients (76, 60%) in the trial had had at least one previously failed anti-incontinence procedure, the most common being anterior vaginal repair (Table 1).

Variable	Mean (range) or N (%)
Previous procedure	
None	50/126 (39.7)
Anterior repair (Kelly plication)	37/76 (49)
Retropubic colposuspension	12/76 (16)
Pubovaginal sling	12/76 (16)
Periurethral injection	8/76 (11)
Needle suspension	7/76 (9)
Age, years	63 (40–71)
Parity	2 (0–8)
Concomitant disease (diabetes, etc.)	73 (58)
Previous anti incontinence operation	76 (60)
Menopausal status:	
Premenopausal	25 (20)
Menopausal, with oestrogen use	25 (20)
Menopausal, without oestrogen use	76 (60)
Urge symptoms before surgery	38 (30)

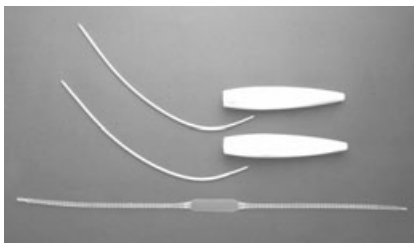
TABLE 1
Previous surgical procedures for SUI and demographic data on the 126 patients

Patients were followed at 1 month and then every 6 months, when the patients were questioned about the presence of spontaneous voiding, involuntary urinary leakage, bladder irritant symptoms and vaginal and suprapubic pain, followed by an assessment of QoL, a stress test and pad use.

The surgical results were classified according to Blaivas and Jacobs [9] into three categories: (a) cured, no incontinence; (b) improved, frequency of incontinence episodes less than once every 2 weeks; and (c) failure, frequency of incontinence episodes more than once a week.

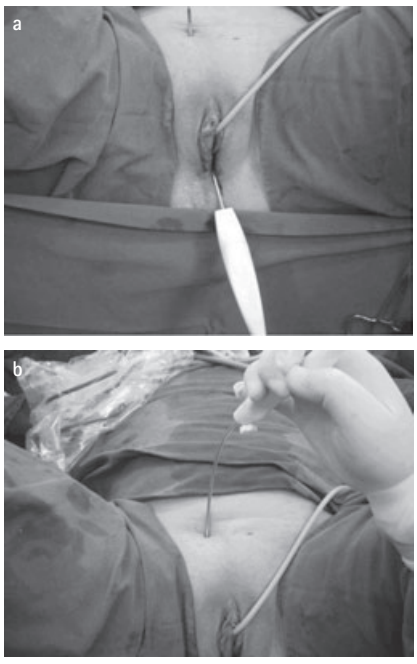
The Safyre consists of a polypropylene mesh that acts as a urethral support, held between self-anchoring columns made of implant-grade polydimethylsiloxane polymer. These columns are the basis of the self-fixing system. To minimize surgical damage to the natural support structures of the pelvic floor a special 3.5 mm diameter needle allows both suprapubic and transvaginal approaches, according to the surgeon's skills (Fig. 1). The versatile needle is assembled for the transvaginal approach when the hooked extremity is introduced inside the needle holder, and for suprapubic approach when assembled the other way.

FIG. 1. The Safyre sling set; the mesh is made of polypropylene and the two self-anchoring columns of polydimethylsiloxane polymer; the needle allows a vaginal or suprapubic approach.



The sling was placed with the patient in the lithotomy position under spinal anaesthesia; 2 g of cephalosporin were administered intravenously at the time of anaesthesia induction, followed by 1 g at 6, 12 and 18 h after the procedure. Two 0.5 cm transverse incisions are made close to the superior aspect of the pubic bone, 5 cm apart. A longitudinal vaginal incision 1.5 cm long is made, starting 0.5 cm from the urethral meatus. This incision is not allowed to encroach on the bladder neck. Dissection is used to create a 1-cm tunnel lateral to the urethra for introducing the Safyre insertion needle. First the needle is advanced through the vaginal tunnel until perforating the pelvic floor at the level of the mid-urethra. Then it is redirected against the back of pubic bone and advanced continuously to the benchmarks in the suprapubic area (transvaginal approach) (Fig. 2a). In the suprapubic approach the needle is advanced through one of the suprapubic incisions, down the posterior side

*FIG. 2. In the transvaginal approach **(a)** the needle is directed through the retropubic space along the inner surface of the pubic bone; in the suprapubic approach **(b)**, the needle is passed through the suprapubic incision towards the vaginal incision.*



of the pubic bone towards the vaginal incision (Fig. 2b). The needle tip remains in contact with the posterior pubic bone until it passes through the endopelvic fascia. Using the index finger of the other hand, the surgeon locates the tip of the needle and then guides it through the vaginal incision. Cystoscopy is

FIG. 3. With long, heavy Mayo scissors spaced between the tape and the urethra, gentle tension is applied to each end of the tape sling in contact with the scissors for proper placement.

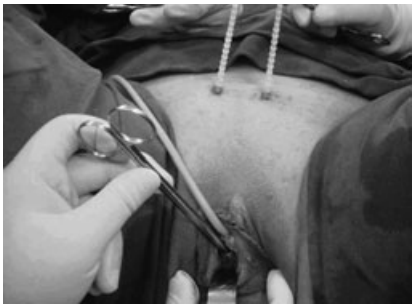
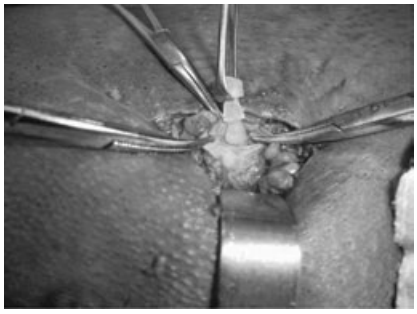


FIG. 4. The fibroblastic pseudocapsule surrounding the polydimethylsiloxane tail of the Safyre. The pseudocapsule should be dissected to mobilize the tail and readjust the tape.



used to exclude bladder perforation. After removing the holder, the Safyre is attached to the needle and pulled out to the suprapubic area. The same manoeuvres are repeated on the other side. The proper tension of the sling is adjusted, maintaining Metzenbaum scissors between the urethra and the sling, to prevent undue tension (Fig. 3). The extremities of the sling are cut and the Metzembaum scissors removed. No further fixation is needed and the incisions are closed in the usual manner. An indwelling catheter is left in place overnight.

The procedure to tighten the Safyre can be done with the patient under local or spinal anaesthesia. As the extremities of the polydimethylsiloxane tails are easily palpable in the subcutaneous tissue, local anaesthesia with lidocaine 1% solution seems to be the method of choice. The sling arms are palpable and the patients can feel it for at least a year after surgery. However, in our experience, patients have not complained about this, even though they are asked. Usually, the readjustment of only one tail is enough, with no risk of significant deviation of the urethral axis. A small incision is made over the palpable tail extremity (close to the superior aspect of the pubic bone), and is gently dissected and pulled carefully until the proper tension is achieved (Fig. 4). Only the top incision need be opened to tighten the Safyre. During this manoeuvre Metzenbaum scissors should be maintained between the mesh and the urethra, to prevent over-correction. The bladder is filled with saline solution before the procedure, so the patient can be asked to cough and to repeat Valsalva manoeuvres to check for leakage. Generally, any readjustment is proposed within 30 days of the original surgery, but theoretically it can be done at any time after surgery because of the formation of a fibroblastic pseudocapsule surrounding the polydimethylsiloxane tail of the Safyre that permits easy dissection and mobilization of the tails inside this pseudocapsule whenever necessary.

The procedure to loosen the Safyre is best done under spinal, intravenous or local anaesthesia. When local anaesthesia is used, both the suprapubic area (including the urethropelvic fascia) and anterior vaginal wall (including the rectus muscle and fascia) must be anaesthetized with lidocaine 1% solution. It is not necessary to make a suprapubic incision to reach the sling; only the bottom incision should be opened. However, it is necessary to anaesthetise the urethropelvic fascia to avoid pain while mobilizing the tails. A longitudinal vaginal incision 1.5 cm long is made, starting 1 cm from the urethral meatus, and the polypropylene mesh dissected from the urethropelvic fascia. The tails are dissected bilaterally, grasped with haemostatic clamps and pulled back, until Metzenbaum scissors or a right-angle clamp can be interposed between the mesh and the urethra, to prevent undue tension and to check whether the space between the mesh and the urethra is enough to avoid urethral obstruction. A Foley catheter is left in place overnight. The procedures to tighten or loosen the Safyre are easy and take ≈20 min. No complications were identified during either procedure.

RESULTS

The basic characteristics and the demographic data of all patients are shown in Table 1. The mean (range) follow-up period was 18 (12–36) months, the duration of surgery 25 min and the hospitalization 24 (12–36) h. All patients went home the day after the surgery. The overall complication rate was 33% (42 patients); most of these women had more than one complication. Peroperative complications occurred in three women (2%), with perforation of the upper lateral wall of the bladder in all three. All three patients had had at least one previous surgical procedure for SUI; the Foley catheter was kept for 48 h in these patients and they developed no further complications. There was no bleeding, blood transfusion, urethral or vaginal perforation during the procedure in any patient.

Urinary retention was diagnosed when the residual volume, obtained by urethral catheterization after voiding, was >100 mL. Patients who could not void spontaneously immediately after surgery were maintained on clean intermittent catheterization for 4 weeks, when the Safyre was loosened if the retention persisted. All patients voiding spontaneously soon after surgery had a PVR of <100 mL and were thus considered to have no retention. Following these criteria there was urinary retention in four of the 126 patients (3%) who could not void spontaneously 4 weeks after surgery. All had the sling tension loosened under local anaesthesia and voided spontaneously, with completed relief of irritative symptoms and with a mean PVR of 60 mL afterward. The tape did not need to be sectioned in any patient.

The main complication after surgery was 'de novo' urgency, which occurred in 26 patients (21%); this symptom occurred immediately after surgery and no specific treatment was used. The symptoms resolved in all patients within 4 weeks. Of the 37 women (29%) with urgency before surgery, none, seven (19%) and 30 (81%) reported being worse, unchanged or improved, and of the 89 who reported no urgency before surgery, 70 (79%) remained the same and 19 (21%) reported de novo urgency.

Six patients (5%) presented with vaginal erosion of the tape. They had vaginal pain, discharge and bleeding, dyspareunia, and dysuria, and one had recurrent UTIs. On physical examination the erosion of Safyre was clearly visible. They were unsuccessfully treated with topical ointments and oral antibiotics. All of them underwent

transvaginal tissue debridement. The protruding part of the tape was removed in four women and the tape was covered by an advanced vaginal flap in the others. These patients were then followed; all remained continent and a vaginal examination showed no visible or palpable abnormality.

Six patients (5%) had the tape re-adjusted later to tighten the Safyre; they presented with urinary incontinence after the initial surgery and the tape was re-adjusted so they could be continent. The results were good in four patients (cure of preoperative complaints) and improved in two.

According to the Blaivas and Jacobs criteria [9] after the 18-month mean follow-up, 116 of the 126 patients (92%) were continent, three (2%) reported a significant improvement and seven (6%) were dissatisfied with the procedure and considered as failures. The ICQ-SF showed significantly better scores on all questions than before surgery (90% of patients reported that they had fewer urinary symptoms after surgery). At the end of the follow-up the stress test was negative in all the continent and incontinent patients, and the incontinent group was using, at most, one perineal pad daily.

DISCUSSION

Recent studies agree that pubovaginal slings and retropubic urethrocystopexy are the best techniques for resolving SUI during a long-term follow-up [10]. However, sling procedures require a considerable period of surgical training, the inconvenience of needing a donor site to obtain the fascia to be used in the surgery, and risks of infravesical obstruction and other bladder dysfunctions [9]. Retropubic urethrocystopexy requires an abdominal incision, with increased morbidity and hospitalization, high costs when performed using laparoscopic access, and considerable training and experience [5]. Therefore, all efforts in developing minimally invasive techniques are justifiable.

Conceptually the Safyre corresponds to a sling but creating a suburethral support zone increases urethral resistance, and consequently the rotational and descending movement of the urethra is avoided when abdominal pressure increases. Additionally, it facilitates the coaptation of the urethral lumen at rest and under stress. However, contrary to the classical pubovaginal slings, the Safyre is applied to the medial third of the urethra, where the pubourethral ligaments responsible for the natural stability of the urethra are inserted [11]. Maintaining the sling in the appropriate position is explained by the salients and re-entries, creating a hook-like effect on the pelvic fascia and the abdominal smooth muscle, as well as by local inflammatory reactions.

The Safyre insertion is tension-free and not restricted by the size of the bladder neck, as in conventional slings. Although 3% of the present patients had urinary retention after surgery, the Safyre allowed the tension to be readjusted with no difficulties, and under local anaesthesia; the patients voided spontaneously with complete relief of irritative symptoms and a mean PVR of 60 mL. Although there was no urodynamic evaluation after surgery we assume that this technique does not alter voiding pressure, as happens with periurethral injections. Both the Safyre and TVT are applied with no tension and do not limit bladder neck opening, as do conventional slings.

The present results confirm the feasibility and safety of the Safyre for SUI. Since the first report by Ulmsten *et al.* [12], the TVT has become a popular method for genuine SUI. A recent review of 11 studies with objective endpoints gave a cure rate of 87% at a mean of 17 months after surgery [13]. Our group has experience with TVT in 110 patients [14]; the mean follow-up was 18 months and the main complication was irritative voiding symptoms, reported by 29% of patients soon after surgery (up to 4 weeks). These patients had a new urodynamic evaluation, which showed detrusor instability in 35%, urinary incontinence in 30% and no significant changes in the remainder. The frequency of these symptoms was similar to those with the Safyre method. De novo urge symptoms may be related to changes in para-urethral collagen metabolism and fibrosis around the tape. Interestingly, in the Safyre group urge symptom rates did not differ with menopausal status. The safety is comparable with TVT and Safyre in our experience, but the Safyre was more effective than TVT (92% vs 81%), possibly because the Safyre can be readjusted if there is urinary leakage. The infection and erosion rates were similar for TVT and Safyre in our experience. The present study was conducted in a public academic centre where there are urologists in training, and thus the higher rates of tape erosion might be a result of excessive manipulation of the tape and longer operation times. All tape infections were early in the experience with the Safyre (the first 20 cases). Currently care is taken to ensure that there is adequate vaginal-incision suturing, a quicker operation and that manipulating the tape is minimized.

Although we did not compare the Safyre directly with other minimally invasive techniques, there are specific and significant differences in the biochemical and biomechanical properties of this device. As opposed to TVT or other polypropylene-based minimally invasive slings, the smooth surface of Safyre mesh allows for easy primary adjustment during the implant, and even during eventual readjustment, besides keeping its resistance and shape because of its low deformity rate. Moreover, the elasticity of the polydimethylsiloxane tails allows fine movements according to changes in the patient's abdominal pressure, acting as a dynamic support. Furthermore, the Safyre self-anchoring system is unique in allowing readjustment after surgery. The procedure is minimally invasive and no large abdominal incision is required for harvesting fascia, or to fix the sling to the aponeurosis of the abdominal rectus muscle, as in a classical sling. The sling tension can be re-adjusted in patients with persistent incontinence or urinary retention, avoiding major surgery such as urethrolysis or the need for another sling insertion, thus reducing costs; this procedure is a promising step forward in the surgical treatment of SUI.

CONFLICT OF INTEREST

None declared.

REFERENCES

1 **Goebel R.** Zur operativen Beseitigung der Angeborenen Incontinentia Vesicae. *Z Gynak Urol* 1910; **2**: 187
2 **McGuire EJ, Fitzpatrick CC, Wan J *et al.*** Clinical assessment of urethral sphincter function. *J Urol* 1993; **150**: 1452
3 **Ulmsten U, Henriksson L, Johnson P, Varhos G.** An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J* 1996; **7**: 81
4 **Palma PCR, Riccetto CLZ, Dambros M *et al.*** Pubovaginal Safyre: a new

readjustable minimally invasive sling for female urinary stress incontinence. The Iberoamerican Safyre study group. *Urología Panamericana* 2002; **14**: 22

5 **Petros P, Ulmsten U.** An integral theory and its method for the diagnosis and management of female urinary incontinence. *Scand J Urol Nephrol* 1993; **153**: 1

6 **Avery K, Donovan J, Abrams P.** Validation of a new questionnaire for incontinence: The International Consultation on Incontinence Questionnaire (ICIQ). *Neurourol Urodynamics* 2001; **4**: 510

7 **Schrepferman CG, Griebling TL, Nygaard IE, Kreder KJ.** Resolution of urge symptoms following sling cystourethropexy. *J Urol* 2000; **164**: 1628

8 **Kaplan SA, Te AE, Young GP.** Prospective analysis of 373 consecutive women with stress urinary incontinence treated with a vaginal wall sling the Columbia-Cornell University experience. *J Urol* 2000; **164**: 1623

9 **Blaivas JG, Jacobs BZ.** Pubovaginal fascial sling for the treatment of complicated stress urinary incontinence. *J Urol* 1991; **145**: 1214

10 **Norris JP, Breslin DS, Staskin DR.** Use of synthetic material in sling surgery: a minimally invasive approach. *J Endourol* 1996; **10**: 227

11 **Ulmstem U, Falconer C, Johnson P *et al.*** A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. *Int Urogynecol J* 1998; **9**: 210

12 **Ulmsten U, Henriksson L, Johnson P, Varhos G.** An ambulatory surgical procedure under local anesthesia for treatment o of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunction* 1996; **7**: 81

13 **Perchers UM, Tunn R, Buczkowski M, Perucchini D.** Tension-free vaginal tape for the treatment of Stress Urinary Incontinence. *Clin Obstet Gynecol* 2000; **43**: 670

14 **Palma PCR, Riccetto CLZ, Dambros M *et al.*** Tension-free vaginal tape (TVT): minimally invasive technique for stress urinary incontinence (SUI). *Inter Braz J Urol* 2002; **28**: 458

Correspondence: Paulo C.R. Palma, Rua Tiradentes, 426 apto 51, Vila Itapura, 13023–190 Campinas, SP, Brazil.
e-mail: miriamdambros@yahoo.com.br

Abbreviations: **SUI**, stress urinary incontinence; **TVT**, tension-free vaginal tape; **QoL**, quality of life; **ICIQ-SF**, International Consultation on Incontinence Questionnaire, short form; **PVR**, postvoid residual urine volume.