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SAFYRE™: A READJUSTABLE MINIMALLY INVASIVE SLING FOR FEMALE URINARY STRESS INCONTINENCE

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ABSTRACT

Introduction: SAFYRE™ is a readjustable and minimally invasive sling for the treatment of stress urinary incontinence (SUI). It is as a pubovaginal sling placed in the medial third of the urethra. The initial experience is described.

Materials and Methods: Forty-five patients (mean age = 59 years) underwent a SAFYRE™ implant to treat SUI. Physical examination and urodynamic study were performed before surgery. All patients presented symptoms of SUI and 20% also reported mild urgency. Approximately 60% of this group had a previously failed anti-incontinence procedure. Urethral hypermobility was diagnosed in 40% of the patients and intrinsic sphincter deficiency (ISD) in 60% of the cases.

Results: The average follow up period was 10 months. The mean operative time was 20 minutes. Dystopia repair was performed whenever necessary, during the same procedure. The average hospital stay was 24 hours. In 11% of the implants, bladder perforation occurred. During the postoperative period, 9 patients (20%) developed transient urgency symptoms. During the initial follow up period, 90% were found to be continent, 3% reported an improvement and 7% were unchanged.

Conclusion: SAFYRE™ is a safe and quick procedure that allows postoperative readjustment. This technique may be an attractive alternative in the management of SUI, should the good result obtained so far prove to be long lasting.

Key words: urinary incontinence, stress; prostheses and implants; reconstructive surgical procedures
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INTRODUCTION

Autologous pubovaginal sling is the choosen treatment for complex cases of stress urinary incontinence (SUI) (1). Preference for autologous material was largely due to 2 basic concerns: implant infection and urethral erosion (2).

On the other hand, the use of synthetic slings transforms major surgeries into minimally invasive procedures and also reduces operative time and hospital stay as well as postoperative discomfort and the recovery period (1).

The readjustable and self-anchoring SAFYRE™ sling has recently been added to the existing therapeutic arsenal. It is a tension-free, synthetic sling, placed at the mid urethra that makes urethral erosion unlikely.

According to the integral continence theory (3), the medial and distal third regions of the urethra are the most important regions in urinary continence because of the insertion of the pubourethral ligament and the pelvic muscle floor (4). Should postoperative urinary leakage or retention occurs, this innovative device allows for tension readjustment (3).

Slings are now being used more often and the SAFYRE™ system, which has imbibed these new concepts, is an attractive alternative for the surgical treatment of SUI. The authors present their first experience with this readjustable sling.

MATERIALS AND METHODS

Patients

An open prospective non-randomized clinical study involving SUI patients was conducted after receiving the approval of the Hospital Ethics Committee.

From February 2001 to July 2002, 45 patients with SUI diagnosis underwent the SAFYRE™ implant. The patient's ages ranged from 42 to 72 years (mean age 59 years). The work-up for incontinence included clinical examination and urodynamic study.

After the surgery, the recall was monthly for clinical assessments. At these monthly recalls, the patients were questioned about presence of spontaneous micturition, involuntary urinary leakage, bladder irritative symptoms, vaginal or suprapubic pain and questions related to the degree of satisfaction with the procedure.

Besides history, a physical examination was performed during follow-up to access continence and to verify signs of infection or erosion of the vaginal wall.

The surgical results were classified according to Blaivas & Jacobs (5) into 3 categories: a) cured - absence of incontinence; b) improved - frequency of incontinence episodes less than once every 2 weeks; c) failure - frequency of incontinence episodes more than once a week.

During preoperative evaluation, all patients showed urinary leakage during repeated Valsalva maneuvers. None of them presented significant degree of atrophic vaginitis, even among post-menopausal patients. The gynecological examination revealed the presence of mild cystocele in 13 patients (30%), 90% of the cases was grade I and the rest grade II. Rectocele was diagnosed in 4 patients (9%) and only cases of grade II cystocele were repaired. The dystopias were corrected during the SAFYRE™ implant surgery.

Urodynamic evaluation disclosed urethral hypermobility in patients with Valsalva leak point pressure (VLPP) above 90 cm H_2O and intrinsic sphincter deficiency when VLPP was less than 60 cm H_2O. Intermediate VLPP values were analyzed along with clinical information to establish the diagnosis (6,7). Using these criteria, 18 patients (40%) were diagnosed as intrinsic sphincteric deficiency and in 27 patients (60%) urethral hpermobility. Patients who presented involuntary detrusor contractions during bladder filling or infravesical obstruction were excluded from the study but those with irritative symptoms without urodynamically proven involuntary contractions were included. Although urodynamically proven detrusor instability does not have a significant effect on surgical outcome, this decision was based on the concept regarding the postoperative improvement of sensory urgency, as described previously (8). Patients with involuntary detrusor contractions were excluded from this initial study due to the less favorable prognosis regarding post-operative irritative symptoms (9).

Urgency in association with urinary leakage symptoms was reported by 20% of the patients while 60% of the patients reported a history of previous surgical treatment for incontinence; the one most commonly performed was the anterior vaginal repair (Table-1).

Material

SAFYRE™ consists of a polypropylene mesh that acts as a urethral support, held between 2 self-anchoring tails made of polydimethylsiloxane polymer. These tails are the basis of the readjust able self-anchoring system. In order to minimize the surgical damage to pelvic floor natural support structures, a special 3.5 mm in diameter needle, allows for both suprapubic and transvaginal approaches, according to the surgeon best skills. The versatile needle is assembled for trans-

Table 1 – *Previous surgical procedures for stress urinary incontinence.*

Technique	N	(%)
None	18	40.0
Anterior repair (Kelly plication)	13	28.9
Retropubic colpossuspension	5	11.1
Pubovaginal sling	5	11.1
Periurethral injection	3	6.7
Needle suspension	1	2.2
Total	45	100.0

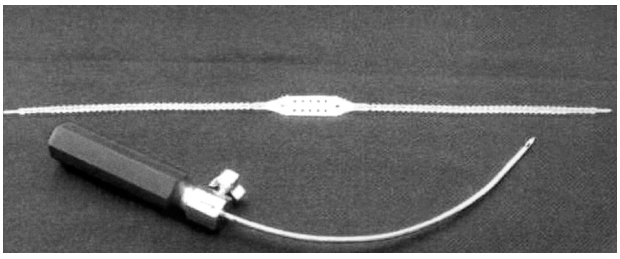

Figure 1 - *SAFYRE™* sling set.

vaginal approach when the hooked extremity is introduced inside the needle holder, and for supra pubic approach when assembled the other way (Figure-1).

Surgical Technique

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 in length is made, starting 1 cm from the urethral meatus. Notice that this incision is not allowed encroaching on the bladder neck. Dissection is done to create a 1 cm tunnel lateral to the urethra for the introduction of the needle. First, the needle is advanced through the vaginal tunnel until the perforation of pelvic floor at the level of the mid-urethra. Then, it is redirected against the back of pubic bone and advanced continuously to the previously made landmarks in the suprapubic area (Figure-2). Cystoscopy is performed to rule out bladder perforation. After the removal of the holder, SAFYRE™ is attached to the needle and pulled out to the suprapubic area (Figure-3). The same maneuvers are repeated on the other side. The proper tension of the sling is adjusted maintaining a Metzenbaum scissors between the urethra and the sling, to prevent undue tension (Figure-4). The extremities of the sling are cut and the Metzenbaum scissors removed (Figure-5). No further fixation is needed and the incisions are closed in the usual manner. An indwelling catheter is left in place overnight.

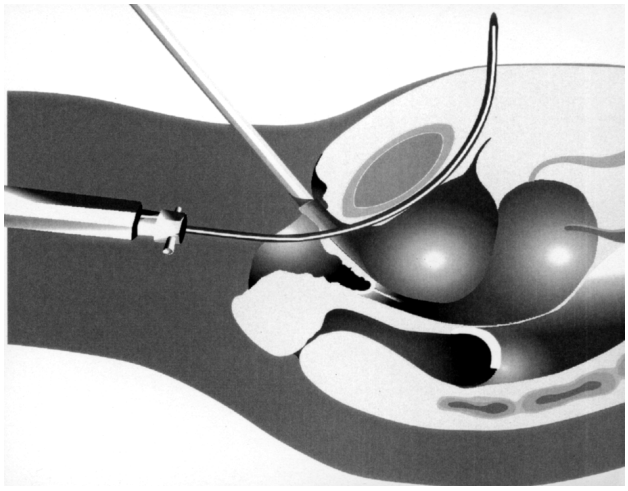

Figure 2 - *After perforation of the endopelvic fascia, the needle is directed through the retropubic space close to the pubic bone.*

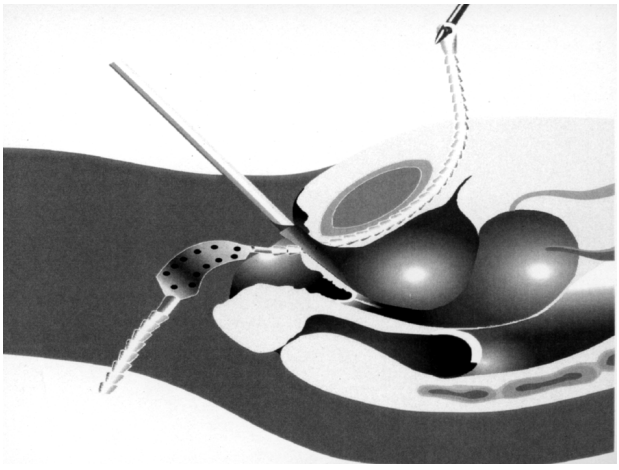

Figure 3 - *SAFYRE™ is attached to the needle and pulled out to the suprapubic area.*

Readjustment Technique

The procedure to tight the SAFYRE™ can be performed under local or spinal anesthesia. As the extremities of the polydimethylsiloxane tails can be easily palpable in the subcutaneous tissue, local anesthesia with lidocaine 1% solution seems to be the method of choice. Usually, the readjustment of only one tail is enough, without 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 it is gentle dissected and grasped using a haemostatic clamp. Then, it is pulled carefully, until the proper tension is achieved. During this maneuver, a cystoscope sheath should be maintained inside the urethra, to prevent over correction. The bladder is filled with saline solution before the procedure, so the patient can be asked to cough

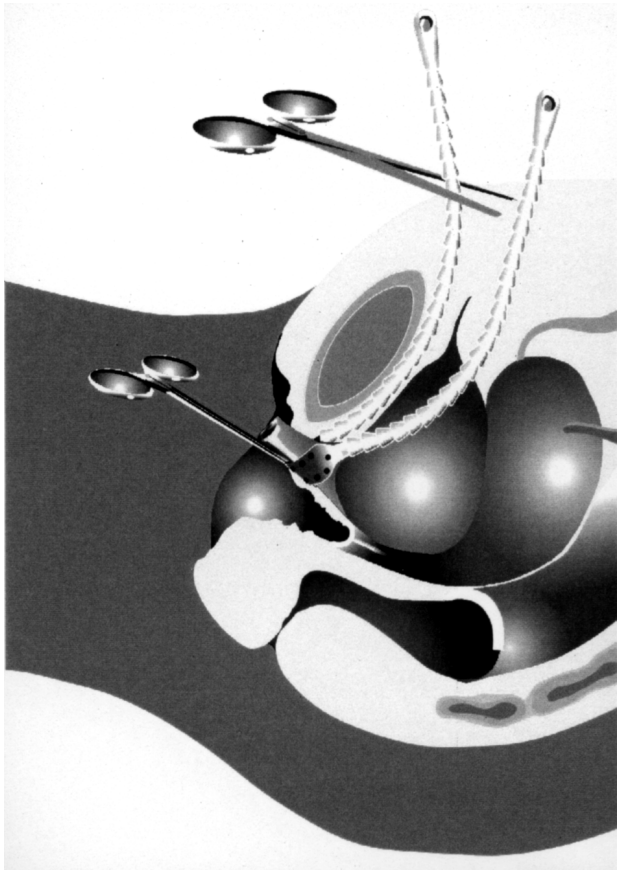

Figure 4 *- A Metzenbaum scissors is placed between the tape and the urethra for proper tension adjustment.*

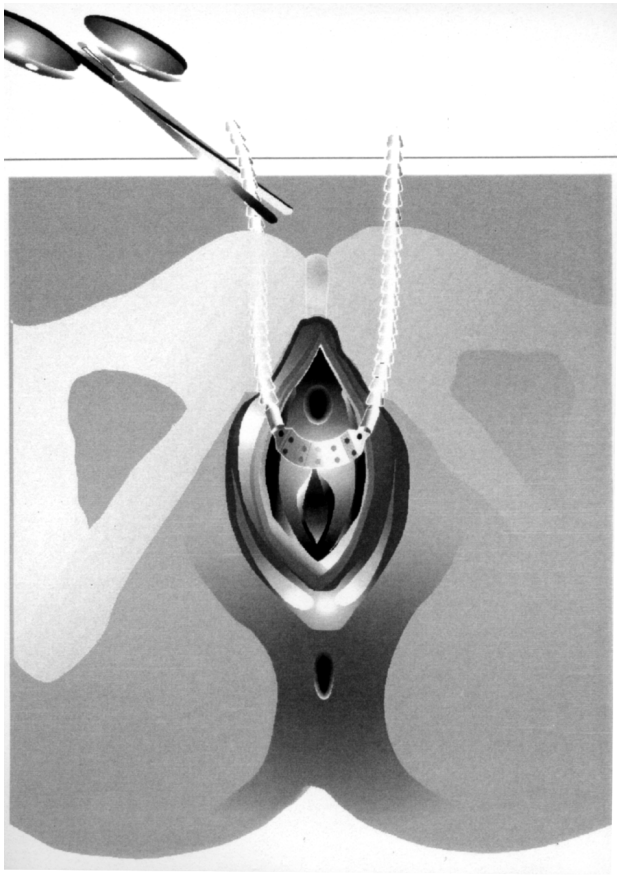

Figure 5 *- The final aspect of the sling in place.*

and to do repeated Valsalva maneuvers to check if leakage occurs. Prophylactics antibiotics are used for 3 days. Generally, the readjustment is proposed before 30 days postoperative, but theoretically it can be done at any time after the procedure, because of the formation of a fibroblastic pseudocapsule surrounding the polydimethylsiloxane tails of SAFYRE™, that permits easy dissection and mobilization of the tails inside this pseudocapsule, whenever it became necessary.

The procedure to loosen the SAFYRE™ can be performed under spinal, intravenous or local anesthesia. When local anesthesia is used, both suprapubic area (including rectus muscle and fascia) and anterior vaginal wall (including urethropelvic fascia) have to be anesthetized with lydocaine 1% solution. A longitudinal vaginal incision, 1.5 cm in length is made, starting 1 cm from the urethral meatus, and the polypropylene mesh is dissected from the urethropelvic fascia. The tails are dissected bilaterally, grasped with haemostatic clamps and pulled back, until a Metzenbaum scissors or a right-angle clamp can be interposed between the mesh and the urethra. A Foley catheter is left in place overnight and prophylactics antibiotics are used for 3 days.

RESULTS

The follow up period ranged from 2 to 17 months, the mean follow up period was 10 months. The mean duration of the procedure was 20 minutes (15 to 35 minutes) and the mean hospital stay was 24 hours (from 12 to 36 hours). All procedures were performed under spinal anesthesia. Perforation of the upper lateral wall of the bladder occurred in 5 patients

(11%), including, 2 patients that have been previously submitted to a retropubic colpossuspension and to an anterior repair as well. A Foley catheter was left in place for 48 hours and the patients presented no complications.

The diagnosis of urinary retention was done when the residual volume, obtained by post micturition urethral catheterization, was higher than 100 ml. Patients which could not present spontaneous micturition in the immediate post-operative period were maintained in a clear intermittent catheterization program until 4 weeks post-operatively when a loosening procedure was performed if retention had persisted. All of the patients that presented spontaneous micturition in early post-operative period showed post-void residual less than 100 ml and were considered without retention. Following the above criteria, postoperative urinary retention occurred in 3 patients (6.7%) that had not presented spontaneous micturition after 4 weeks post-operatively. All underwent sling tension loosening under local anesthesia and voided spontaneously, with completed relief of irritative symptoms and with a mean post void residual volume of 60 ml after the procedure.

There were 4 cases (9%) of vaginal wall infection but no vaginal or urethral wall erosion. Transient irritative voiding symptoms were reported by 9 patients (20%) during the immediate postoperative period (up to 4 postoperative weeks). None of the patients presented pelvic floor defects that required surgical correction during the follow-up.

According to Blaivas & Jacobs criteria (5) after 10 months mean follow up, 40 patients (90%) were considered cured, 2 (3%) reported significant improvement and 3 patients (7%) were dissatisfied with the procedure and were considered as failures.

DISCUSSION

Pubovaginal slings and the retropubic urethrocystopexies are the procedures that can lead to the best continence results in long-term follow up (1). Autologous pubovaginal slings, however, imply in a considerable period of surgical training and the inconvenient need for a donor site to obtain the fascia to be used in the surgery as well as the risks of infra-vesical obstruction and voiding dysfunction (3). Retropubic urethrocystopexies, on the other hand, imply an abdominal incision with increased morbidity and hospital stay, high costs when performed using a laparoscopic access and a time consuming learning curve (4). Therefore all efforts towards the development of minimally invasive techniques are justifiable.

From a conceptual standpoint, the SAFYRE™ corresponds to a sling. So, the creation of a suburethral support zone increases urethral resistance and diminishes the rotational as well as the descending movement of the urethra when abdominal pressure increases. Additionally, it improves the coaptation of the urethral lumen at rest and under stress. However, contrary to the classical pubovaginal slings, the SAFYRE™ is applied in the middle third of the urethra, where the pubourethral ligaments responsible for natural stability of the urethra are inserted (10). The SAFYRE™ self-anchoring system is created by a sequence of 4 mm cones, creating a hook-like effect on the pelvic fascias and the abdominal rectus muscle as well (11,12).

Although most patients had previously undergone an anti-incontinence procedure, no complications or technical operative difficulties were noticed. Contrary to previous reports, rejection of implanted material was not observed with this synthetic sling (2).

SAFYRE™ insertion is tension-free and is not restricted by the size of the bladder neck as in conventional slings (12,13). Urinary retention occurred in 6.7% of the patients according to the criteria adopted. The diagnosis of post-operative obstruction following anti-incontinence surgeries is a matter of concern. Besides the different urodynamic criteria proposed, the diagnosis is underestimated and most of patients without complete retention were diagnosed in the late post-operative period, usually after they had presented with urinary tract infection. Besides the possibility of retention relief after 4 weeks post-operatively, we advise the loosening procedure by these period in order to avoid the fibrotic reaction around the sling and to allow for the patients to return to their habitual activities as soon as

possible. The unique feature of SAFYRE™ allows for postoperative tension readjustment without difficulties. These patients underwent sling readjustment under local anesthesia and voided spontaneously, with completed relief of irritative symptoms and with a mean post void residual volume of 60 ml.

Although this study have not compared SAFYRE™ to other minimally invasive techniques, such as Tension-free Vaginal Tape (TVT®) or similar, there are specific and significant differences concerning the biochemical and biomechanical properties of this device. As opposed to TVT® or other polypropylene 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 due to its low deformity rate. Moreover, the elasticity of polymetylsyloxane tails can provide fine movements according to the changes of patient's abdominal pressure, acting as a dynamic support. Furthermore SAFYRE™ self-anchoring system is unique as far as postoperative readjustibility is concerned. The procedure is minimally invasive and no large abdominal incision is required for harvesting fascia, neither to fix the sling to the aponeurosis of the abdominal rectus muscle as in classical slings. Its readjustability allows for late adjustments of sling tension in patients presenting persistent incontinence or urinary retention, avoiding major surgeries such as urethrolysis or the need for another sling insertion, reducing costs. The coherence of the physiological principles involved in female urinary incontinence, cure rate over 90% and the uncontestable benefits of postoperative tension readjustments make this procedure a promising step forward in the surgical management of SUI.

CONCLUSION

SAFYRE™ is a safe and quick procedure, easy to perform and to learn, and allows for postoperative readjustment under local anesthesia. This unique and innovative feature is a major advantage for the individual patient and makes SAFYRE™ an attractive alternative in the management of SUI, should the good results prove to be long lasting.

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