

Safety and Efficacy of the Ophira Mini-Sling System: One-Year Follow-Up From a Multicenter International Clinical Trial

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ABSTRACT

INTRODUCTION: The Ophira mini-sling system (Promedon; Cordoba, Argentina) uses a minimally invasive, midurethral low-tension tape that is anchored to the obturator internus muscles bilaterally at the level of the tendinous arc by a single vaginal incision. It minimizes surgical trauma and enables an outpatient procedure. First-year follow-up results are reported.

METHODS: The study was a prospective clinical trial conducted from February 2008 to March 2010. Participants were 149 female patients with stress urinary incontinence from Brazil and Argentina. Their mean age was 53.9 years (SD = 9.5; range, 36-71 years). All patients received a medical history, physical examination, stress test, standardized 1-hour pad test, and urodynamic study. Patients also completed the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and Urogenital Distress Inventory (UDI-6). All underwent treatment with the Ophira mini-sling system. The procedure was conducted under local (73%), general (18%), or regional anesthesia (9%). A vertical 1 cm long vaginal incision was performed at 1 cm from the urethral meatus to deliver the prosthesis. Patients repeated the presurgical tests at 1, 3, 6, and 12 months after surgery. Outcome measures were postvoid residual volume, pad and stress test results, ICIQ-SF and UDI-6 scores, and complications. Means and standard deviations were calculated and tabled.

RESULTS: The mean (SD) operative time was 12.6 (7.4) minutes. One patient receiving the procedure under local anesthesia had severe intraoperative pain and needed intravenous sedation. Severe bleeding and technical problems with the device were not observed. The mean follow-up was 9 months; 91 patients had 12 months of follow-up evaluations. Postvoid residual volumes were variable across time. Pad tests showed less urine leakage after surgery. The percentage of patients with a positive stress test dramatically decreased after surgery. ICIQ-SF and UDI-6 scores also decreased. Major complications were not observed. Minor complications were mesh exposure (n = 3), urinary retention (n = 3), urinary tract infection (n = 8), and de novo urge incontinence (n = 7).

CONCLUSIONS: The Ophira mini-sling system appears to be an effective, minimally invasive option for the treatment of stress urinary incontinence.

KEYWORDS: Female urinary incontinence; Treatment; Minimally invasive surgery; Mini-sling

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Abbreviations and Acronyms

ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form
 SUI, stress urinary incontinence
 TOT, transobturator tape
 TVT-S, tension-free vaginal tape-Secur
 UDI-6, Urogenital Distress Inventory
 UTI, urinary tract infection

INTRODUCTION

The Ophira mini-sling system (Promedon; Cordoba, Argentina) is an innovative anatomical approach for the management of female stress urinary incontinence (SUI) [1]. It involves anchoring a midurethral low-tension tape to the obturator internus muscles bilaterally at the level of the tendinous arc by a single vaginal incision.

The rationale for the Ophira mini-sling procedure evolved from transobturator tape (TOT), which has proven to be as effective as the retropubic sling for the restoration of pubourethral ligaments and ureteropelvic fascia support [2]. It was developed in order to keep the optimal results of the transobturator sling through a multipoint fixation arm. This confers a stable primary fixation to the tissue, which adds safety and minimizes surgical and recovery time.

The aim of this presentation is to report the first-year follow-up results of the use of the Ophira mini-sling system from an open international, multicenter prospective trial.

METHODS

The study was a prospective clinical trial that was conducted from February 2008 to March 2010. Participants were obtained from the State University of Campinas and the University of Sao Paulo in Brazil and Austral University Hospital in Argentina. The protocol was approved by a committee at Hospital de Clinicas, State University of Campinas. All participants provided

informed consent.

Participants

The participants were 149 female patients with SUI. Their mean age was 53.9 years (SD = 9.5; range, 36-71 years); 94 patients (63%) were postmenopausal. The mean (SD) number of previous gestations was 2.9 (2.2). A total of 48 patients (32%) had previous anti-incontinence surgery. Their mean body mass index was 27.9 (4.4). The mean (SD) preoperative Valsalva leak point pressure was 78.2 cm H₂O (27.1).

Procedure

Prior to surgery, all patients received a medical history, physical examination, stress test, standardized 1-hour pad test, and urodynamic study. Patients also completed the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and Urogenital Distress Inventory (UDI-6).

All patients underwent treatment with the Ophira mini-sling system. This system has a Type 1 polypropylene monofilament mesh that is held between 2 self-anchoring polypropylene arms with a multi-point fixation design (Figure 1). The device is connected to disposable retractable insertion guide during the procedure (Figure 2).

The procedure was conducted under local anesthesia in 73% of the patients, using 10 mL of 2% lidocaine solution that was injected at the midurethra toward the vaginal fornix and

Figure 1. Ophira mini-sling mesh (Promedon; Argentina) with anchoring fish-spine-like arms.

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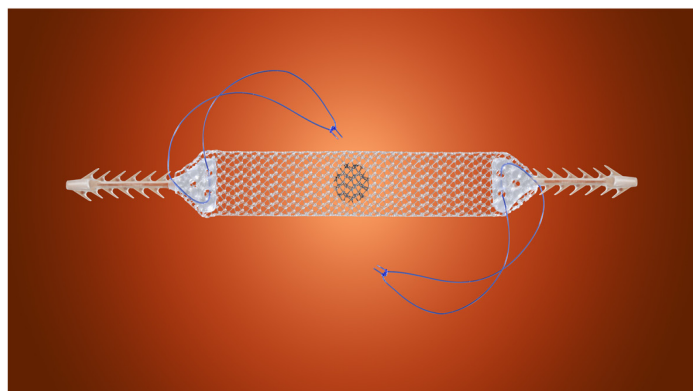


Figure 2. Ophira mini-sling kit (Promedon; Argentina) with suburethral mesh and delivering device.

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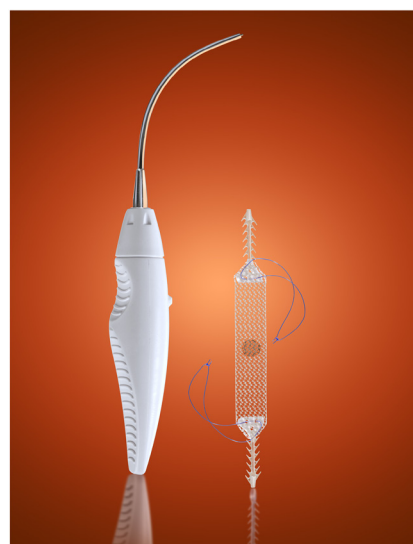


Figure 3. Three-dimensional helical computerized tomography showing the mini-sling in situ (posterior view).

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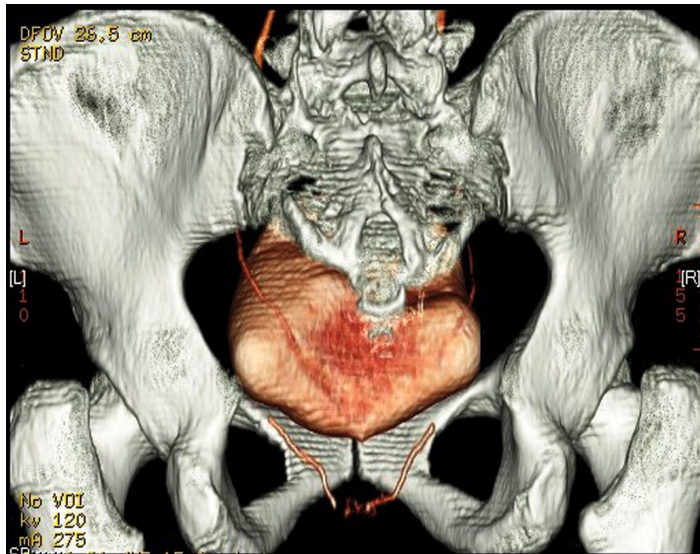
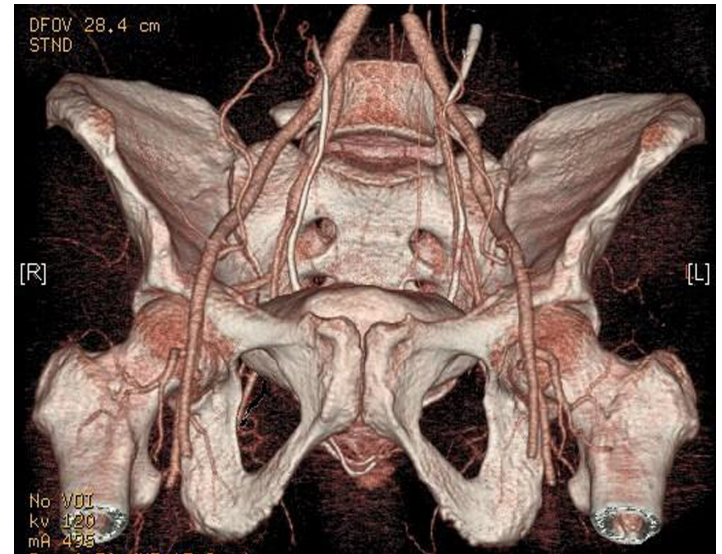


Figure 4. Three-dimensional helical computerized tomography showing the mini-sling in situ (anterior view).

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advanced 2 cm in the obturator internus muscles. The remaining patients had general anesthesia (18%) or regional anesthesia (9%), according to the anesthesiologist's decision.

A vertical vaginal incision that was 1-cm in length was performed at 1 cm from the urethral meatus. Minimal dissection was performed laterally toward the ascending ramus of the ischiopubic bone to preserve the endopelvic fascia. For insertion of the implant, the retractable insertion guide was first connected to the multipoint fixation arm and then introduced toward the obturator internus muscle, 1 cm above the vaginal fornix. Insertion was guided by surgeon's index finger. When the centering mark of the implant was slightly underneath the right flap of the vaginal incision, the trigger at the handle was deployed to release the fixation arm in place (Figure 3; Figure 4). By design, the multipoint fixation arms provide strong and stable primary fixation [3]. The same maneuvers were repeated on the opposite side. After fine adjustments of the mesh, the retractable insertion guide was removed and the vaginal wall was closed in the usual manner. Cystoscopy was not mandatory. No Foley catheter was left in place. The patients were discharged immediately after spontaneous voiding.

Follow-up Examinations and Data Analysis

Patients repeated the presurgical tests at 1, 3, 6, and 12 months after surgery. The outcome measures were postvoid residual volume, pad test and stress test results, and ICIQ-SF and UDI-

6 scores. The means and standard deviations were calculated and tabled. Data were presented for patients at each follow-up test to show patterns of progression across time. Complications were also recorded.

RESULTS

Intraoperative outcomes. The mean (SD) operative time was 12.6 (7.4) minutes. Technical problems with the device were not observed. Three patients presented lidocaine hydrochloride overdose symptoms that were treated conservatively. Among the patients receiving the procedure under local anesthesia, 1 experienced severe intraoperative pain and needed intravenous sedation. None of the patients experienced severe intraoperative bleeding.

Follow-up outcomes. Four patients were lost to follow-up. As of March 2010, the mean follow-up for the remaining 145 participants was 9 months; 91 patients had more than 12 months of follow-up. According to the definition of the Stamey Urinary Incontinence Scale, the dry rate was Grade 0 for 90.2% of the patients at the 1-year follow-up. Results of the presurgical and postsurgical follow-up evaluations are presented in Table 1. The postvoid residual volumes were variable across time. The pad tests showed less urine leakage after surgery. The percentage of patients with a positive stress test dramatically decreased after surgery. ICIQ-SF and UDI-6 scores also decreased.

Table 1. Results of the Presurgical and Postsurgical Follow-up Evaluations.

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Outcome Measure	Presurgery (N = 149) ^a	Postsurgery			
		1 month (n = 8)	3 months (n = 28)	6 months (n = 18)	12 months (n = 91)
Postvoid residual urine, mean (SD), mL	3.0 (7.3)	6.3 (32.9)	1.0 (4.0)	0.9 (7.0)	1.4 (4.2)
Pad test, mean (SD), g	13.1 (16.7)			2.7 (7.9)	2.3 (8.7)
Postive stress test (%N)	96.5	0	7.8	12.5	9.8
ICIQ-SF score, mean (SD), score 0-21	17.0 (2.7)	3.2 (5.9)	2.7 (5.3)	4.3 (6.4)	2.9 (4.8)
UDI-6 score, mean (SD), score 0-18	9.4 (2.9)	2.3 (2.8)	2.0 (2.6)	2.2 (2.7)	2.5 (3.0)

^aFour of these patients were lost to follow-up.

Abbreviations: ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form; UDI-6, Urogenital Distress Inventory

Postoperative complications. Complications such as infection, severe bleeding, or sexual dysfunction were not observed. Mesh exposure occurred in 3 patients (3.2%). It is worth noting that all 3 patients were asymptomatic and mesh exposure of < 0.5 cm was only detected by physical examination. The patients were treated by ambulatory resection of the exposed area (n = 1) and local estrogen (n = 2). Four patients (4%) had urinary retention, which resolved spontaneously (n = 2), was treated with mesh excision (n = 1), and resolved within the first week by sling loosening (n = 1). Urinary tract infection and de novo urge incontinence were present in 8 patients (8.7%) and 7 patients (7.6%), respectively.

DISCUSSION

The concept of the "arc to arc" suburethral sling has been refined since its first description by Palma in 1999 [4]. A better understanding of the female pelvic anatomy and its functionality has allowed researchers to develop more efficacious and minimally invasive ways to correct urinary incontinence.

The mini sling relies on maintaining the efficacy already proven for the traditional tension-free vaginal tape (TVT) and TOT suburethral slings, while trying to improve their side effects. In this sense, our data reinforce the efficacy of the mini slings when compared with data that have been reported with the traditional approaches. The operative time is notably shorter and the surgical procedure is feasible on an outpatient basis. Although we did not perform a detailed cost-effectiveness analysis, it seems obvious that the mini sling saves money because the hospital stay is shortened, fewer analgesics are necessary because patients do not complain of pain at the obturator nerve site that may be experienced with TOT slings, and minor complications are easily managed.

Series with more than 12 months follow-up are reported, especially for the TVT-Secur (TVT-S) device (Ethicon; Somerville, NJ, USA). Meschia et al [5] conducted a prospective multicenter study and reported results from 91 patients. The patients had subjective and objective cure rates of 78% and 81%, respectively. Tartaglia and colleagues [6] reviewed 32 patients who underwent TVT-S implant and reported 100% dry rate at 12 months. However, it should be noted that cure rate was only subjectively assessed and patients with intrinsic sphincteric deficiency were excluded from the analysis. In a more recent report, Krofta and colleagues [7] prospectively analyzed 82 patients after TVT-S implant. At the 1-year follow-up, 43 (52.4%) women were objectively cured and 14 (17.1%) women were objectively improved. Subjectively, 49 (59.7%) patients did not experience urine loss and 18 (22.2%) women reported improvement in urine loss. The authors concluded that TVT-S provides inferior cure rates when compared with other tape procedures. In a larger series, Khandwala et al [8] reviewed 141 patients with TVT-S. They found no perioperative complication and had 1 case of urinary retention without the need for mesh release. Eighty five percent of patients were deemed "satisfied" on a subjective evaluation.

The MiniArc single-incision sling (American Medical Systems; Minnetonka, MN, USA) is another prototype of the mini sling that is commercially available. Gauruder-Burmester and Popken [9] analyzed 97 women with either mixed or pure SUI that were treated with this device. Some of the participants (61.7%) had already undergone an initial attempt to correct their urinary incontinence. The cough test was negative in 77.8% of the participants at 12 months; a quality of life measure showed improvement in 69.1% of the participants. One patient had a pelvic hematoma and another had a bladder perforation. The

authors concluded that the mini-sling approach is safe and effective.

The majority of the current data support the idea that mini-sling techniques are able to create cure rates for female SUI that are comparable to the traditional retropubic or transobturator sling procedures, while being less invasive. However, a comparative head-to-head series involving both traditional slings and the more recent mini slings is desired in order to draw a more definitive conclusion. The present study is limited by its lack of a comparison group. In addition, not all of the patients in the present study had completed the 12-month follow-up and no statistical analyses were used to compare the presurgical and postsurgical data.

CONCLUSIONS

The Ophira mini-sling system appears to be an effective option for the treatment of SUI. The device has reliable fixation and stability with the capability of being performed as an outpatient procedure.

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Conflict of Interest: none declared.

REFERENCES

1. Palma P, Riccetto C, Reges R, et al. Arcus to arcus microsling: technique and preliminary results. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008;19(8):1133-1136.
2. Palma P, Riccetto C, Herrmann V, et al. Transobturator SAFYRE sling is as effective as the transvaginal procedure. *Int Urogynecol J Pelvic Floor Dysfunct.* 2005;16(6):487-491.
3. Palma P, Riccetto C, Siniscalchi C, et al. Primary fixation of mini slings: a comparative study in vivo. *Int Urogynecol J Pelvic Floor Dysfunct.* 2009;20(Suppl 2):S73.
4. Palma P. "Sling" tendineovaginal de pericardio bovino (técnica de Palma): Experiência inicial [Tendineovaginal sling of bovine pericardium (Palma's technique): initial experience; Article in Portuguese]. *J Bras Ginecol.* 1999;109:93-97.
5. Meschia M, Barbacini P, Ambrogi V, Pifarotti P, Ricci L, Spreafico L. TVT-secur: a minimally invasive procedure for the treatment of primary stress urinary incontinence. One year data from a multi-centre prospective trial. *Int Urogynecol J Pelvic Floor Dysfunct.* 2009;20(3):313-317.

6. Tartaglia E, Delicato G, Baffigo G, et al. Third-generation tension-free tape for female stress urinary incontinence. *J Urol.* 2009;182(2):612-615.
7. Krofta L, Feyereisl J, Velebil P, Otcenášek M, Kasiková E, Krčmár M. TVT-S for surgical treatment of stress urinary incontinence: prospective trial, 1-year follow-up. *Int Urogynecol J Pelvic Floor Dysfunct.* 2010;21(7):779-785.
8. Khandwala S, Jayachandran C, Sengstock D. Experience with TVT-SECUR sling for stress urinary incontinence: a 141-case analysis. *Int Urogynecol J Pelvic Floor Dysfunct.* 2010;21(7):767-772.
9. Gauruder-Burmester A, Popken G. The MiniArc sling system in the treatment of female stress urinary incontinence. *Int Braz J Urol.* 2009;35(3):334-343; author reply 341-343.