

MICRO SLING: TOWARDS ZERO COMPLICATION?

Hypothesis / aims of study

Although synthetic slings are the gold standard for the management of Urinary Stress incontinence, complications are the main concern. The Micro Sling System is an innovative anatomical approach that involves placing a midurethral micro tape anchored to the endopelvic fascia and vaginal fornix, using a single vaginal incision.

Its rationale have evolved from the mini sling tape, which has proved to be as efficient as retropubic sling for the restoration of the pubourethral ligaments and urethropelvic fascia support. It was developed in order to keep the optimal results of the Ophira mini sling System that uses a multipoint fixation arm, which confers a stable primary fixation to the tissue, adding safety-and minimizing the surgical and recovery time.

The aim of this presentation is to report the preliminary results with the Micro sling System

Study design, materials and methods

This is a prospective non-randomized clinical trial. There were 15 female patients (mean age: 53.9 ± 9.5 years old) with stress urinary incontinence (SUI) underwent treatment with Micro Sling System, as a proof of concept.

The Micro Sling System has a Type 1 polypropylene monofilament mesh held between two self-anchoring polypropylene arms with a multi-point fixation design, which is connected to disposable retractable insertion guide during the procedure (Figure 1).

The rationale behind this procedure is that the vaginal plays a major role as a supporting element of the urethra.

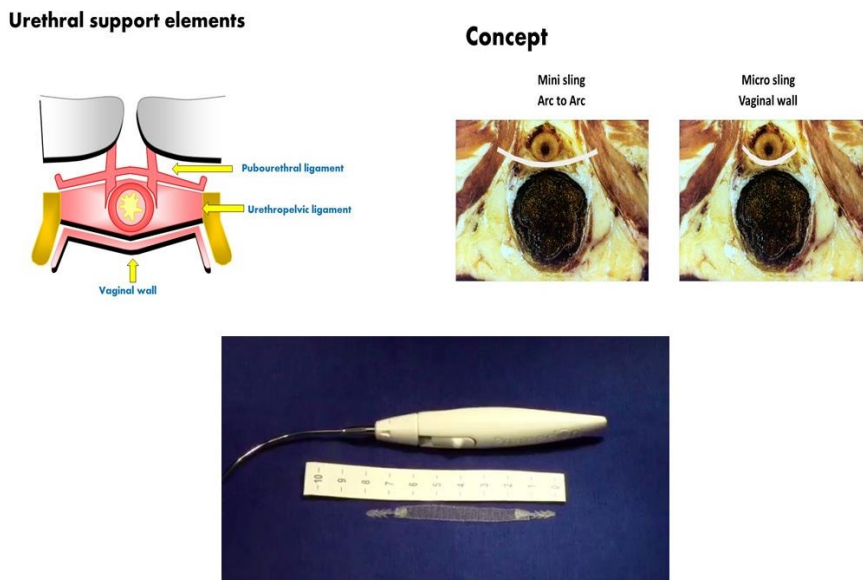


Figure 1. Rationale of Micro Sling.

The work-up included history, physical examination, stress test, standardized 1-h pad test, and pre-operative urodynamic study. The procedure was carried under local anesthesia in all but one patient, using 10 ml of 2% lidocaine solution, injected at the midurethra towards the vaginal fornix. A vertical 1-cm length vaginal incision was performed at 1 cm from the urethral meatus. Minimal dissection was performed laterally towards the ascending ramus of the ischiopubic bone, preserving the endopelvic fascia. For insertion of the implant, first, the retractable insertion guide is connected to the multipoint fixation arm and is introduced one centimeter above the vaginal fornix, guided by surgeon's index finger. When the centering mark of the implant is slightly underneath the right flap of the vaginal incision, the trigger at the handle is deployed to release in place the fixation arm. The multipoint fixation arms design provides strong and stable primary fixation. The same maneuvers were repeated on the other side.

Cystoscopy was not necessary. No Foley catheter was left in place. The patients were discharged immediately after spontaneous voiding.

Results

The mean operative time was 5 minutes. There were no bleeding and technical problems of the device. Complications such as infection, pain, sexual dysfunction, no tape exposure and urgency were observed. At 12 months follow-up, 14 patients were dry and one patient with Intrinsic Sphincter Deficiency (IDD), improved.

Interpretation of results

Our results suggest that reinforcing the vaginal wall underneath the midurethra provides surgical cure of SUI, moreover using less synthetic material allows for less trauma of insertion and less complications.

Concluding message

The Micro Sling System may be an effective option for the treatment of SUI, offering reliable fixation and stability of the device and represents a real advance towards an in office procedure and zero complication.

References

1. Int Urogynecol J. 2014 May;25(5):637-43. doi: 10.1007/s00192-013-2242-4. Epub 2013 Oct 30. What is the best indication for single-incision Ophira Mini Sling? Insights from a 2-year follow-up international multicentric study. Palma P1, Riccetto C, Bronzatto E, Castro R, Altuna S.
2. Int Braz J Urol. 2012 Mar-Apr;38(2):258-65; discussion 265-6. Primary fixation of mini slings: a comparative biomechanical study in vivo. Palma P1, Siniscalchi RT, Maciel LC, Bigozzi MA, Dal Fabbro I, Riccetto C.
3. Int Braz J Urol. 2011 Mar-Apr;37(2):252-6; discussion 257-8. Arc-to-Arc mini-sling 1999: a critical analysis of concept and technology. Palma P1.

Disclosures

Funding: None **Clinical Trial:** Yes **Registration Number:** FCM 2013-69 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Comite ética HC-UNICAMP **Helsinki:** Yes **Informed Consent:** Yes