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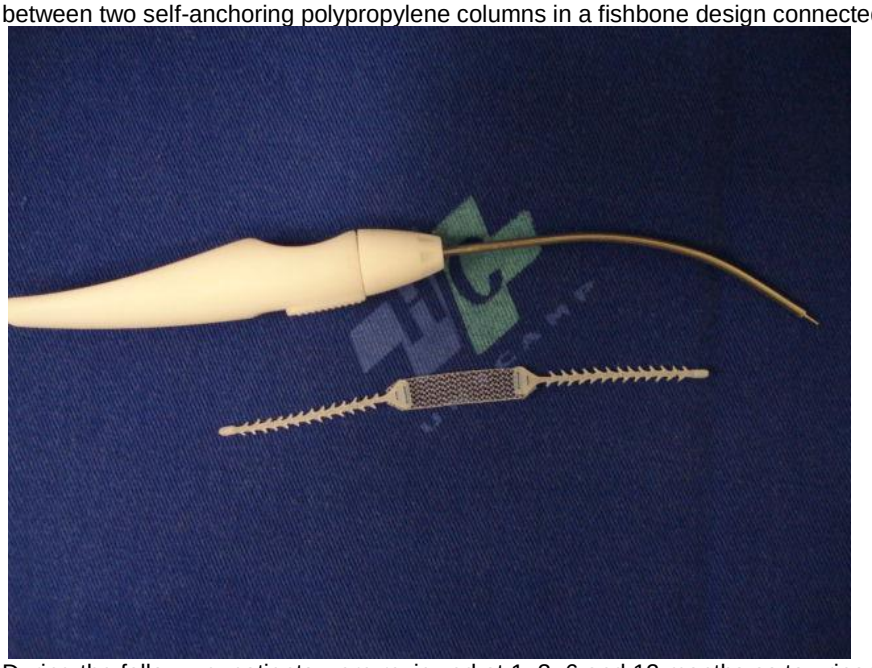
OPHIRA MINI SLING SYSTEM: TECHNIQUE AND RESULTS OF A MULTICENTRE INTERNATIONAL CLINICAL TRIAL

Hypothesis / aims of study:

Study the efficacy and complications of a mini sling used for the treatment of female stress incontinence.
The material used is Mini Sling Ophira, tha is an anatomical approach that involves placing a midurethral low-tension tape anchored to the obturator internus muscles bilaterally at the level of tendineous arc.

Study design, materials and methods

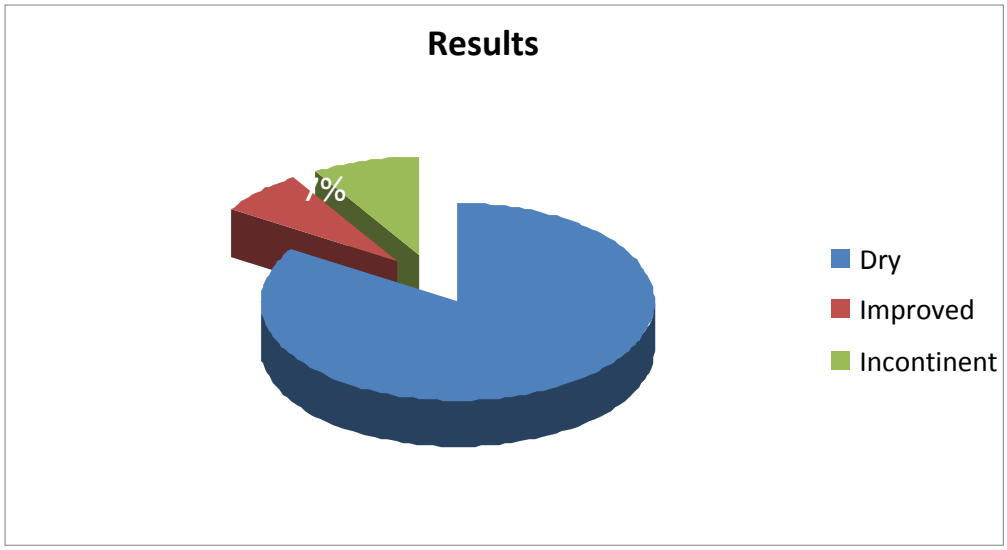
From February 2008 to March 2009, 109 female patients (mean age: 53 years old) with stress urinary incontinence underwent outpatient management using the Ophira Mini Sling System. This Mini sling System has a polypropylene monofilament mesh, held between two self-anchoring polypropylene columns in a fishbone design connected to a delivering mini trocar.



During the follow-up, patients were reviewed at 1, 3, 6 and 12 months as to urinary incontinence, lower urinary tract symptoms and dyspareunia. The pad test was used in the objective evaluation of urine loss. The procedure was carried under local anesthesia, using 10 ml of 2% lydocaine solution, injected at the midurethra towards the vaginal fornix, advancing 2 cm in the internus muscles. A vertical 1-cm long vaginal incision was performed at 1 cm from the urethral meatus. Minimal vaginal dissection was performed laterally towards the ascending ramus of the ischiopubic bone, preserving the endopelvic fascia. The delivery trocar was introduced through the small vaginal incision, guided by the surgeon's index finger previously introduced at the vaginal fornix to avoid vaginal wall perforation. Once the needle was felt at the fornix, the tip was introduced towards the obturator internus muscle, 1 cm above the vaginal fornix. When half of the mesh was within the incision, the deploying bottom at the handle of the mini trocar was retracted, deploying the sling was in place, allowing for the self-anchoring fishbone columns to provide strong primary fixation. The same maneuvers were repeated on the other side.

Results

The mean operative time was 17,5 minutes, ranging from 7 to 60 minutes, and the mean hospital stay was one day. Complications, such as infection, bleeding or dyspareunia, were not observed in this series. Mesh exposure was observed in 12 (11%) patients and was managed conservatively in all cases. Using the pad weight test to objectively evaluate the patients after 6 months, 93 (85,3%) women were completely dry, 8 (7,4%) had improved and 8 (7,3%) were incontinent.



Interpretation of results

This results are comparable to the literature[2], showing that this technique have the same rate of common slings with less time of procedure, less rate of complications and no further issues[1,3].

Concluding message

Ophira Mini sling system is a safe and effective option for the management of SUI. Further studies are ongoing to define the role of this new alternative in the surgeon's armamentarium.

References

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2. "Microsling: Towards the office Procedure" - Palma P and Co - Internacional Uroginecology Journal – volume 18, Supplement 1 / Jun 2007
3. Cardozo L, Bidmead J. Sling techniques in the treatment of genuine stress incontinence. Br J Obstet Gynecol 2000, 107:147-56

Specify source of funding or grant	**The material used is from Promedon.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Comitê de Ética em Pesquisa (UNICAMP)**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**