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MECHANICAL PROPERTIES OF MINI SLING FIXATION DEVICES: OPHIRA® VERSUS MINI ARC ®

Hypothesis / aims of study

The mini sling concept for stress urinary incontinence (SUI) is an anatomical approach that involves placing a midurethral low-tension tape anchored to the obturator internus muscles bilaterally, which overcome the blind passage of long needles and its related complications. The rationale of mini slings is based on its primary fixation capacity, which plays an important role in the final outcome. The aim of study was to compare two types of commercially used mini-sling for management of stress urinary incontinence in order to identify which fixation device promotes higher tissue adherence on the implant area and for how long such adherence is more significant.

Study design, materials and methods

A total of 15 Wistar rats were submitted to subcutaneous implantation (in the interface between the hypoderm and the anterior fascia of the abdominal muscles) of 2 different mini slings fixation devices: Ophira® (Promedon – Argentine) and Mini Arc® (American Medicals Systems – USA) (Fig. 1A). They were randomly divided in 03 groups of 05 rats each, according to the time of sacrifice (7, 14 and 30 days). The abdominal wall was removed en bloc and each anchoring system underwent uniaxial evaluations using a precision tensiomenter. Force was applied to the extremity of the fixation system or mesh, until it was completely removed from the tissue (Fig. 1B). Resistance to extraction of both fixation devices was determined based on the maximum load (ML), defletion to ML and work to ML. ANOVA test was used for statistical analysis. The significant level adopted for the statistical test was 5%.
5%.

A B

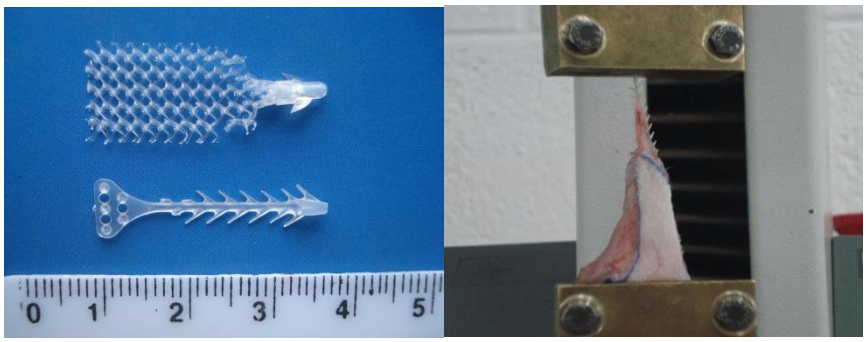
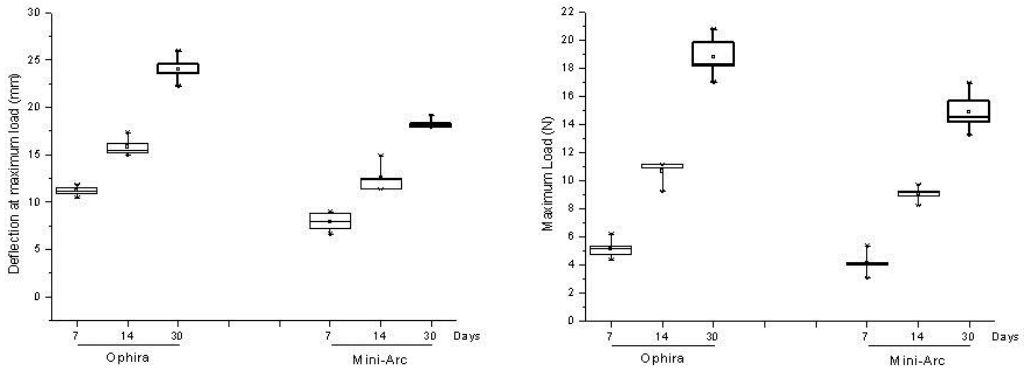


Figure 1. (A) Mini Arc and Ophira's fixation devices. (B) Biomechanical evaluation.

Results

There were significant differences in the resistance to extraction between the different fixation systems. In the three periods, Ophira® presented better fixation when compared with Mini Arc® (p<0,001) (Fig. 2)

(A) (B)



(C)

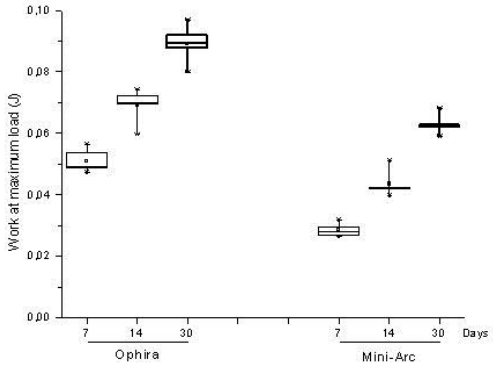


Figure 2. Box plot showing: (A) resistence to extraction; (B) deflection to maximum load; and (C) Work to maximum load for Mini Arc and Ophira at 3, 14 and 30 days post implant.

Interpretation of results

Self-anchoring polypropylene columns with immediate fixation to the obturator internus muscles are essential for avoiding blind passage of long needles and its related complications. So it is true that mini-sling fail has been attributed to poor fixation in the obturator muscle or membrane by excessive exertion in the postoperative period, leading to a reduction in continence rates (1). This fact may be more important mainly for outpatient surgeries, as it has been proposed for the mini slings, in which the patients are discharged from the hospital to their homes and activities in the same day of the procedure. Previously studies with bench testing, indicates that the average pull-out force to remove the Mini Arc from the obturator muscle is 5.5 lbs of force (4 times the normal pelvic floor pressures of 1.3 lbs) (2). Ophira has not been studied yet. Despite the fact that in the present model, Ophira® presented better fixation when compared with Mini Arc®, we don´t know yet if it has got any clinical relevance or impact on continence outcome.

Concluding message

Ophira® mini sling system presented better primary fixation in experimental study when compared with Mini Arc®. Further studies are necessary to confirm if these findings may have implication in the clinical setting for outpatient procedures.

References

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Is this a clinical trial?	**No**
What were the subjects in the study?	**ANIMAL**
Were guidelines for care and use of laboratory animals followed or ethical committee approval obtained?	**Yes**
Name of ethics committee	**Ethics Committee for Animal Trials(In portuguese: Comissão de Ética na Experimentação Animal - CEEA)**