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ORIGINAL ARTICLE

Does the design of mini slings anchoring systems really matter? A biomechanical comparison between Mini Arc™ and Ophira™☆

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Abstract

Introduction and hypothesis: Currently, a sling implant is the standard treatment for stress urinary incontinence in women. To be effective, they require an adequate anchoring system. The aim of this study is compare biomechanical features of fixation systems of two mini slings models available on the market (Ophira™ and Mini Arc™) through a tensile test.

Materials and methods: Anchoring devices of each sling were surgically implanted in abdominal wall of 15 rats divided into three groups of five animals which were arranged according to the date of post implant euthanasia on 7, 14 and 30 days. Abdominal walls of rats were extracted on bloc containing the anchoring system and were submitted to a tensile strength test to measure the maximum load and elongation until device avulsion from the tissue. The results were compared using Student's test *t* and a 5% cut off was considered significant.

Results: The Ophira™ mini sling fixation system demanded a greater maximum load and developed a longer stretch for avulsion from the implanted site at all moments evaluated (*p* value less than 0.05).

Conclusion: There were significant differences in fixation patterns of the anchoring systems, which were exclusively related to their designs. The Ophira™ mini sling fixation device provided better fixation to the abdominal wall of rats compared to the Mini Arc™ device, even in the late post-implant period.

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Abbreviations: SUI, stress urinary incontinence; TVT, tension-free vaginal tape; TOT, transobturator tape; SIMS, single incision mini sling; ML, maximum load; SD, standard deviation.

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PALABRAS CLAVE
Mini cabestrillo;
Incontinencia urinaria de esfuerzo;
Sistema de anclaje;
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Alargamiento;
Fijación;
Ensayo de tracción

¿El diseño de sistemas de anclaje mini cabestrillo realmente importa? Una comparación biomecánica entre Mini Arc™ y Ophira™

Resumen

Introducción e hipótesis: En la actualidad un implante de cabestrillo es el tratamiento estándar para la incontinencia urinaria de esfuerzo en mujeres. Para ser eficaces requieren un sistema de anclaje adecuado. El objetivo de este estudio es comparar las características biomecánicas de los sistemas de fijación de 2 modelos de mini cabestrillos disponibles en el mercado (Ophira™ y Mini Arc™) a través de un ensayo de tracción.

Materiales y métodos: Los dispositivos de anclaje de cada cabestrillo se implantaron quirúrgicamente en la pared abdominal de 15 ratas divididas en 3 grupos de 5 animales que se organizaron de acuerdo a la fecha de la eutanasia después del implante en los días 7, 14 y 30. Las paredes abdominales de las ratas fueron extraídas en bloque, conteniendo el sistema de anclaje, y se sometieron a una prueba de resistencia tensil para medir la carga máxima y el alargamiento hasta la avulsión del dispositivo desde el tejido. Los resultados se compararon mediante la prueba «t» de Student y un punto de corte del 5% fue considerado significativo.

Resultados: El sistema de fijación mini cabestrillo Ophira™ requirió una mayor carga máxima y desarrolló un tramo más largo de la avulsión del sitio implantado en todos los momentos evaluados (valor de p inferior a 0,05).

Conclusión: Hubo diferencias significativas en los patrones de fijación de los sistemas de anclaje, que fueron exclusivamente relacionadas con sus diseños. El dispositivo de fijación de mini cabestrillo Ophira™ proporcionó una mejor fijación a la pared abdominal de ratas en comparación con el dispositivo Mini Arc™, incluso en el período posterior al implante tardío.

Introduction

One-third of women will present involuntary urinary leakage during their lifetime[1] and 1 in 1000 will require surgery due to stress urinary incontinence (SUI).[2] The standard treatment of SUI is based on the implant of synthetic midurethral slings, which became popular after the Integral Theory by Petros and Ulmstem.[3] Tension-free vaginal tape (TVT)[4] and transobturator tapes (TOT)[5,6] have obtained long-lasting results with cure rates above 80%.

The single incision mini sling (SIMS) is an innovative anatomical approach that is anchored in the obturator internus muscles bilaterally at the level of the tendinous arch through a unique vaginal incision. The purpose of SIMS is to offer a minimally invasive treatment for SUI with shorter surgical time plus less bleeding and a rapid patient recovery. They are shorter than former midurethral slings (fewer synthetic material) and avoid percutaneous passage, preventing a blind path by insertion guides through the crural area.

Primary fixation is an important feature needed for the effectiveness of SIMS. Accordingly, the purpose of this research is to compare if the design of mini slings anchoring systems can influence their biomechanical properties. We evaluated Ophira™ (Promedon – Argentina) versus Mini Arc™ (American Medical Systems, AMS – USA, United States of America) through in ex vivo animal tensile experiment.

Materials and methods

This work was performed in ex vivo experimental model using Wistar rats. This research was approved by the institutional Committee for Ethics in Animal Research (State University of Campinas – Unicamp – Brazil).

Experimental protocol

The experiment was conducted in 15 female Wistar (150–200 g weight, 8 weeks old and considered young adults)[11] as ex vivo model. Fixation devices of Ophira™ and Mini Arc™ mini slings were originally made of polypropylene and samples were prepared and conditioned in the laboratory to have the same length, i.e. 2.7 cm (Fig. 1). They were implanted in the rat's abdominal wall between hypodermis and abdominal fascia. For this procedure, the

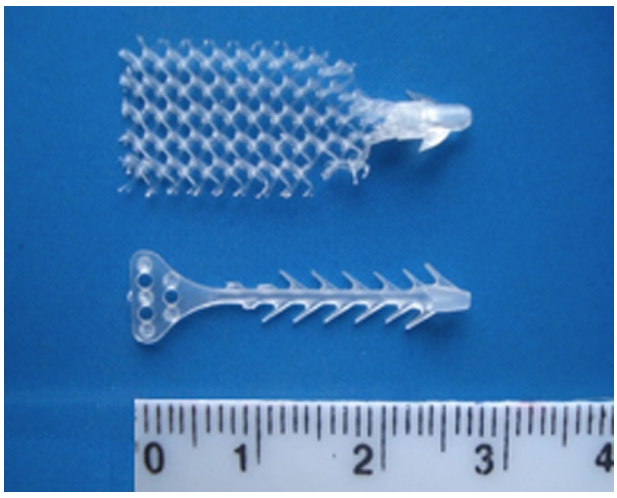

Figure 1 This figure shows the fixation devices of Mini Arc™ (top) and Ophira™ (bottom) presenting the same length of 2.7 cm after being prepared. Note that Mini Arc™ has a single pair of claws, while Ophira™ has a multipoint anchoring device.

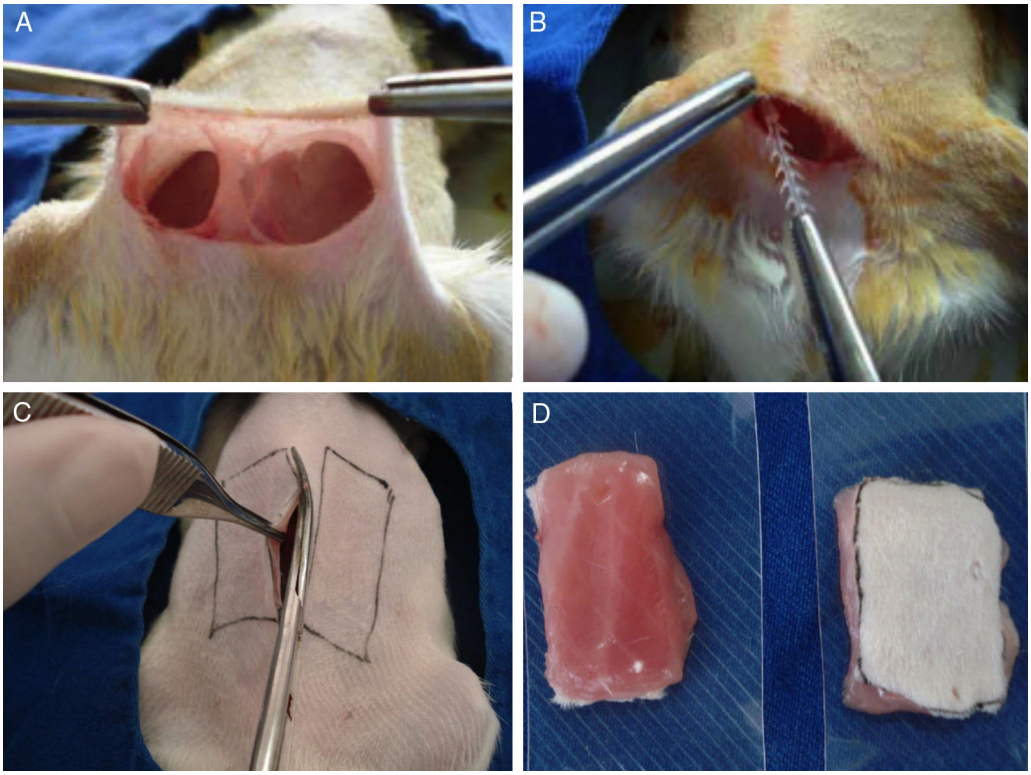

Figure 2 (A) Dissection between hypodermis and anterior abdominal fascia. Note that the linea alba was not violated to isolate two non-communicated cavities. (B) Detail of insertion of Ophira™ anchoring device in the right space. (C) Incision standardized and removal of abdominal wall blocs. (D) Total thickness blocs with anchoring systems within its layers.

animals were anesthetized with intravenous 6% sodium barbital (30 mg/kg), maintained in horizontal supine position, submitted to abdominal trichotomy followed by antisepsis with iodopovidone PVP-I (10%) and placed on sterile surgical fields. A 2 cm transverse suprapubic incision was made followed by subcutaneous dissection preserving the mid tissue fiber – linea alba (Fig. 2A). This step creates two separate cavities where anchoring systems were placed allowing for no contact with each other. The Ophira™ device was inserted on the right side according to the standards adopted (Fig. 2B), while the Mini Arc™ device was systematically inserted on the left side (they were just put above anterior muscular fascia freely without any stitch). The incision was closed with Dexon II™ 2–0 (synthetic absorbable sutures made of the homopolymer of glycolic acid and coated with polycaprolate, the copolymer of caprolactone and glycolide) avoiding contact between the suture and the implanted material. Post-operative analgesia was made with oral paracetamol 100 mg/kg every four hours for the first 12 post-operative hours (3 doses).

Rats were divided into three groups of five animals according to the date of devices recovery performed on 7, 14 and 30 days following implantation. These animals were sacrificed by induced hypoxia with a lethal dose of same anesthetic drug applied intravenously, placed in supine position and trichotomized. Then, contour abdominal lines were made with a standard model marking the areas to be removed separately (Fig. 2C). Finally, two sagittal halves of abdominal blocs containing the mini sling anchoring systems and tissue were extracted from each animal (Fig. 2D).

Biomechanics test

The biomechanical stretch test was performed on the 7, 14 and 30 days after the implant. The abdominal bloc was immediately submitted to a tensile test after it had been harvested. The fresh blocs were prepared on a back-table maintaining 2 mm of the mesh exposed. This portion was anchored to the upper strap of a tensiometer (Universal Test Machine TA 500, LLOYD Instruments – United Kingdom) able to perform a load of 500 N with 0.01 N resolution.[12] The opposite side (mesh free – containing only tissue) was affixed to the lower strap of the equipment. The upper strap moved upward at a constant speed (2 mm/s) with increasing load until the mesh device was completely removed from the bloc (Fig. 3). Two variables were analyzed: maximum load (expressed in Newton – N units) representing the force until the mesh was entirely released and elongated (mm).

Statistical analysis

Exploratory data analysis was performed using descriptive measures of position, dispersion and graphing. Student's ''*t*''-test was used to compare the slings in each time. The ANOVA followed by Turkey's test was used to compare the times of each sling. The 5% level of significance was adopted. Minitab 16 software was used for data record and analysis.

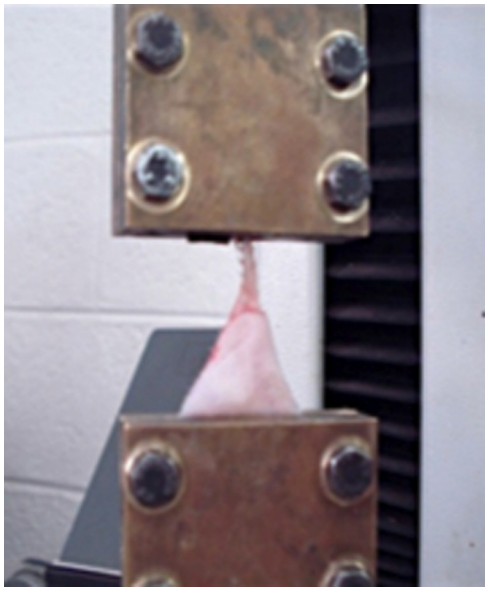

Figure 3 This figure shows a tensile test applied on abdominal bloc. Note the anchoring system being pulled upward unidirectionally with increasing load.

Results

Throughout the tensile test, we obtained the values of maximum load (ML) and the length of elongation for the avulsion of the anchoring systems from the abdominal bloc.

On day 7, the average of Ophira™ ML was 5.14 ± 0.69 N versus 4.11 ± 0.81 N for Mini Arc™ (p 0.037). On day 14, these values were 10.64 ± 0.81 N versus 9.02 ± 0.54 N (p 0.001), while on day 30 they were 18.76 ± 1.48 N and 14.85 ± 1.28 N ($p < 0.001$), respectively (Fig. 4A). At the three times, the differences between the maximum load of both devices were significant.

Concerning elongation, on day 7, the Ophira™ device has developed 11.14 ± 0.53 mm of stretch, while Mini Arc™ 7.89 ± 1.01 mm (p 0.001); on day 14, 15.80 ± 0.95 mm versus 12.49 ± 1.43 mm ($p < 0.001$) and, on day 30, it was 23.95 ± 1.38 mm versus 18.24 ± 0.50 mm ($p < 0.001$), respectively. The Ophira™ anchoring system performed a longer stretch than the Mini Arc™ device at all periods significantly (Fig. 4B). In Table 1 we summarized the results of the biomechanical tests.

Discussion

The understanding of physiopathological concepts related to SUI has consistently improved over the years based on the integral theory. Their authors proposed meshes to be used as neoligaments, functionally replacing the native support elements whose function was compromised in women with SUI.[3,4] These applications have led to the development of innovative surgical techniques and midurethral synthetic slings have shown good results and proven to be technically reproducible.[7] In this context, mini slings appeared in order to minimize complications. Using a single incision, this third generation of slings proposes a safety increase due to the reduction of the blind path performed by insertion guide (trocar), potential reduction of postoperative pain and faster recovery, besides decreasing the amount of synthetic material implanted and being feasible through local anesthesia as a truly outpatient procedure. The first attempt of a SIMS was tissue fixation system (TFS) presented by Petrus et al.[8] TFS was a low-tension midurethral tape fixed in the obturator internus muscles at the level of the tendinous arch bilaterally.

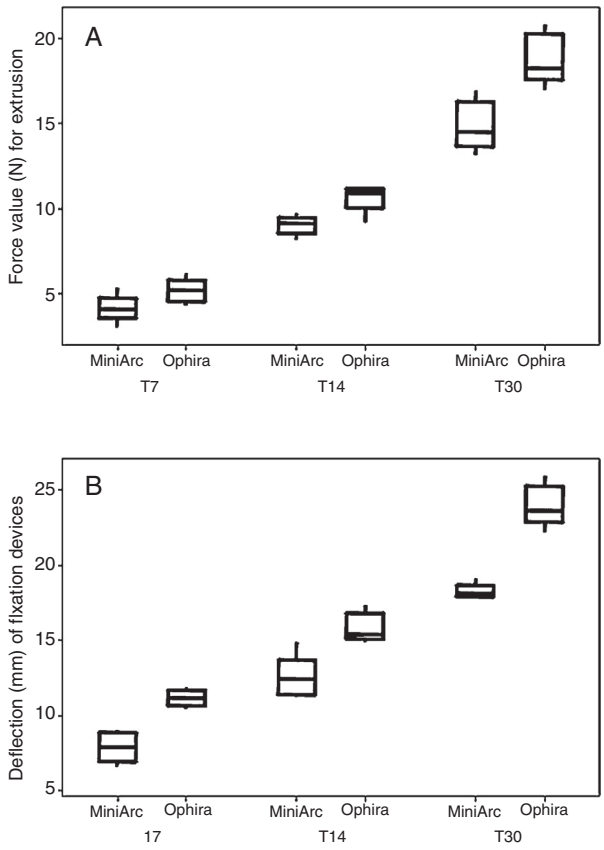

Figure 4 Box plot showing the maximum load (A) and elongation (B) exerted by the clamps over time.

Table 1 Comparisons of maximum load (N) and deflection to maximum load (mm).

Time (days)	Maximum load (N)			Deflection to maximum load (mm)		
	Ophira™	Mini Arc™	p	Ophira™	Mini Arc™	p
7	5.146 ± 0.697	4.111 ± 0.812	0.037	11.148 ± 0.536	7.982 ± 1.010	0.001
14	10.646 ± 0.817	9.027 ± 0.544	0.001	15.807 ± 0.957	12.494 ± 1.436	<0.001
30	18.762 ± 1.489	14.858 ± 1.432	<0.001	23.958 ± 1.382	18.246 ± 0.501	<0.001

Over the years, several models of mini slings have been created and some authors have questioned their effectiveness. In 2011, a meta-analysis compared mini slings to both retropubic and transobturator standard midurethral slings and concluded that SIMS were associated to inferior patient-reported and objective cure rates.[9] Nonetheless, it is important to note that 71% of the patients in the mini sling group received the TVT Secur™ implant (Gynecare, Bridgewater, NJ, USA). TVT Secur™ was the first SIMS commercially available and it has been withdrawn from the market because of consistently poor results. In 2014, the same researchers updated the 2011 meta-analysis. In this reanalysis, now excluding TVT Secur™, there was no evidence of significant difference in patient-reported cure, objective cure, impact on women's QoL, and sexual function with a mean of 18 months of follow-up.[10] In 2015, Jimenez-Calvo et al. published a retrospective cohort study of 135 women submitted to Mini Arc™ implant. The mean follow-up was 59 months and the authors showed a rate of 86.7% of objective cure and 85.7% of satisfaction by the ICIQ-SF questionnaire (similar result to the retropubic slings and transobturator in the literature).[11]

Overall, a common feature of all slings for proper action is a quick and adequate fixation to the implant site.[12] Their integration by the host depends on some factors already established related to the tape as material and porosity. When a foreign body is implanted, it triggers a cascade of tissue repair reactions. Classically, the healing phenomenon is divided into three phases: inflammatory, proliferative and maturation/remodeling. The separation of the phases is didactic since there is an overlap and continuous transition between them. It is documented that polypropylene has the property of causing a milder and lasting inflammatory reaction by the host compared to biological grafts.[13] However, it is a material that the host is not able to remodel and may lead to an aggressive response mediated by macrophages.[14,15] In certain individuals, an environment will be created with constant inflammation by producing continuous degradative enzymes causing injury to the extracellular matrix around the tape and contributing to the tissue thinning and exposure. On the other hand, a continuous inflammatory response could result in hyper activation of fibroblasts that may conduce to an excessive production of collagen with fibrosis and mesh encapsulation. Between these extremes, a mild fibrosis in a small degree related to the implant of tapes is advantageous for the slings in the repair of SUI as it provides adequate urethral support.[16]

Our study was conceived with the intention of evaluating another factor related to the mesh that can interfere with integration: the design. We tried to simulate the anchoring systems of mini slings in vaginal human tissue. The data obtained in this study show that the longer the euthanasia is postponed, a progressive stretch load increase is required to harvest the mesh from the tissue. This occurs due to the dynamic and evolutionary scarring, which provides resistance and integration of the mesh–host tissue interface. The results showed that Ophira™ fixation device offered higher resistance against removal in all evaluation periods, even in early observations on day 7 following the procedure. As both slings are made of the same material (monofilament polypropylene), it is possible to assume that the pull-out force differences are from the distinct designs. This can be explained by the Ophira™ fixation device having multiple anchoring points while the Mini Arc™ fixation system has only one pair of claws.

The mesh design can also be related to the elongation differences as the maximum load. The Ophira™ device showed greater elongation until the mesh was extracted. One may assume that this feature could lead the mesh to tolerate stretching forces imposed and adjust itself without leaving the implant position until reaching enough load to tear.

Despite the attempts to simulate as accurately as possible the mesh–tissue interface, this experiment presented limitations: 1 – since it was performed in a rat model, the findings indicating Ophira™ better fixation might only be inferred in human vagina; 2 – possibly, if euthanasia had occurred at a later stage of the healing process, perhaps the difference between the maximum load of 2 meshes might be minimized and even equated. 3 – the fixation difference experimentally observed between the devices does not reflect the clinical rate of continence between mesh models: Ophira™ better fixation does not necessarily provide better control of urine loss with regard to that obtained with Mini Arc™, although there are no studies comparing these two mini slings in a prospective and randomized approach.

Conclusion

This study has shown that the design difference between the fixation devices has an impact on the tensile resistance of mini slings. The Ophira™ multipoint anchoring system requires greater load than Mini Arc™ for removal from rat abdominal tissue, which corresponds to a better adherence.

Developments of fixation devices may improve continence control and mini slings results.

Conflict of interest

Paulo Palma: Clinical Consultant at Promedon – Argentina.

The others authors do not have conflict of interest related to the study to declare.

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