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SINGLE INCISION MONOPROSTHESIS FOR THE TREATMENT OF ANTERIOR PROLAPSE, STRESS URINARY INCONTINENCE AND LEVEL ONE APICAL PROLAPSE REPAIR

Hypothesis / aims of study

A new mesh (Calistar A – Promedon, Argentine) was developed to treat concomitantly anterior and apical prolapses even when associated to stress urinary incontinence (SUI). It is made of type I macroporous polypropylene with 6 milimeter diameter orifices in the body to improve tissue in growth and to provide flexibility. The suburethral portion of the mesh is attached to two self-anchoring polypropylene arms with a multi point fixation design, especially developed to be anchored at the internal obturator muscle bilaterally, in order to provide a strong suburethral primary fixation. Each arm is attached to a polypropylene stitch, to move it backwards during the procedure, if necessary, for a fine suburethral adjustment. A new tissue anchoring system was also developed, to fix the mesh's arms to the sacrospinous ligament bilaterally, which represent the other anatomical landmark of the procedure. The set also includes a disposable retractable insertion trocar (Fig. 1).
In this study, it is evaluated the safety, feasibility and the results of this technique in a cohort of patients with stage 3 anterior / apical prolapses.

(A) (B) (C)

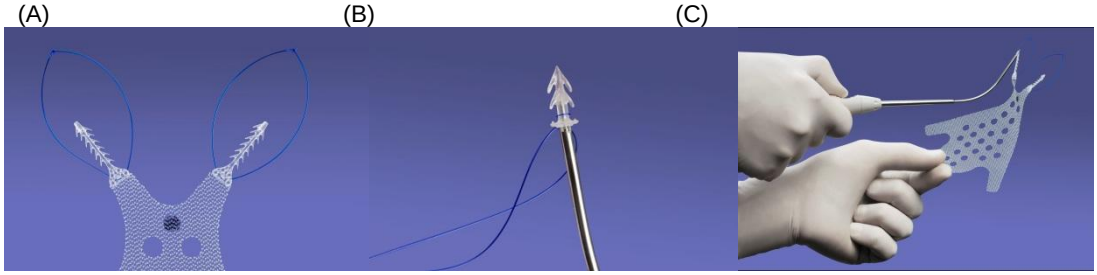

Figure 1. (A) Polypropylene mesh and multipoint fixation arms (B) Tissue anchoring system and trocar. (C) Surgical set.

Study design, materials and methods

From January 2010 to March 2011, 31 patients were enrolled in the study. Only patients with Pelvic Organ Prolapse Quantification System (POP-Q) stage 3 anterior vaginal wall prolapse were included. Concomitant SUI were diagnosed in 19 (61%) patients. The work-up included history, physical examination, stress test, standardized 1-h pad test, POP-Q staging, and validated questionnaires (International Consultation on Incontinence Questionnaire Short Form – ICIQ-SF; International Consultation on Incontinence Questionnaire Vaginal Symptoms – ICIQ-VS). Sexual function was assessed with the Female Sexual Function Index (FSFI). Follow-up was performed at 1, 3, 6 and 12 months post implant.
The procedure was carried on with the patient in lithotomy position. The anterior vaginal wall was incised from midurethra towards the uterine cervix and the pubocervical fascia is carefully dissected. Blunt dissection was performed until identification of the ischial spines and the sacrospinous ligaments. Then, the retractable insertion guide was primed with the tissue anchoring system and was introduced into the sacrospinous ligament 1.5 cm medial from the ischial spine bilaterally. The same retractable guide was connected to the multipoint fixation arm for fixation of the suburethral part of the mesh bilaterally to the internal obturator muscle, one centimeter above the vaginal fornix. Then the polypropylene stitches were attached to the arms of the implant bilaterally. Stitches were placed at the posterior body of the implant and fixed at the remanents of cardinal ligaments or pericervical ring in order to avoid high cystocele reccurence. Finally, the vaginal incision is closed in the usual manner. Cystoscopy was not mandatory (Fig. 2).

(A) (B) (C)

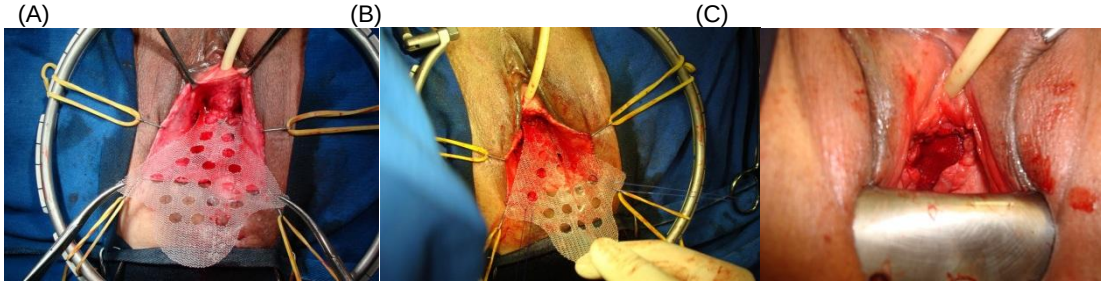

Figure 2. Surgical procedure. (A) Suburethral insertion. (B) Anchoring of mesh to the stitches placed at sacrospine ligaments. (C) Mesh at correct place before vaginal wall suture.

Results

The mean age of patients is 59 ± 8.5 years old. Other demographic data are summarized in Table 1. All surgeries were performed under spinal anesthesia. Severe bleeding and technical or mechanical problems of the device were not observed. Until march 2011, seven patients (22%) completed 12 months follow up but as soon as 11 patients (35%) who completed 6

months follow up showed successful POP-Q staging improvement, as showed in Table 2. Also, all of the patients with concomitant SUI presented negative stress test and improvement of the ICIQ-SF score (Table 2). One patient (3%) presented mesh exposure, diagnosed in the second post-operative day, and were treated with excision and vaginal suture / topical estrogen replacement and antibiotics. This patient presented mesh infection (3%). Urinary retention were observed in one patient (3%), and solved spontaneously at the third day post-operative. One subject who maintained urgency in the post-operative was treated successfully with anticholinergics. The Female Sexual Function Index (FSFI) was 26 ± 1.4 before surgery, 48± 21.5 in six months and 49 ± 12.7 in one year follow up.

Table 1. Demographics

Previous gestation (mean ± SD)	3.0 ± 2.6
Stress urinary incontinence - Stamey (%)	54.1%
Previous anti-incontinence surgery (%)	29.1%
Body Mass Index (mean ± SD)	27.7 ± 4.6

Table 2. Follow up

	Pre	**1 month**	**3 months**	**6 months**	**1 year**
N	31	6	7	11	7
Aa POP-Q point	+2 ± 1.5	-2 ± 0.9	-2 ± 0.7	-2 ± 0.8	-2 ± 0.9
Ba POP-Q point	+4 ± 1.7	-2 ± 1.1	-3 ± 0.6	-3 ± 0.7	-3 ± 0.9
C POP-Q point	+1 ± 3.4	-7 ± 3.1	-7 ± 1.5	-7 ± 1.7	-7 ± 2.1
Positive stress test	37,5%	0.0%	0.0%	9%	0.0%
ICIQ-SF score (0-21)	31	6	7	11	7
FSFI	26 ± 1.4	--	--	48± 21.5	49 ± 12.7

Interpretation of results

In opposite to the transobturator approach, anchoring the mesh to sacrospinous ligaments allows for a D'Lancey level one correction as showed by the optimal POP-Q point C results in the follow-up. Also, the multipoint fixation arms provided primary and stable suburethral support, keeping the mesh in the proper place and allowing for an effective treatment of SUI, if present.

Concluding message

Initial results demonstrate that this technique represents an effective option for the treatment of prolapse and SUI. It introduces the advantages of simultaneous treatment of anterior and apical vaginal prolapses and SUI by a single vaginal incision, building safety and a fully level I correction.

References

1. Haylen B, de Ridder D, Freeman R, Swift S, Berghmans B, Lee J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Neurourol Urodyn. 2010;29(1):4-20
2. Marcus-Braun N, von Theobald P. Mesh removal following transvaginal mesh placement: a case series of 104 operations. Int Urogynecol J Pelvic Floor Dysfunct. 2010 Apr;21(4):423-30
3. Nguyen J. The use of grafts for anterior vaginal prolapse repair: pros and cons. Curr Opin Obstet Gynecol. 2008 Oct;20(5):501-5

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Is this a clinical trial?	**Yes**
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Specify Name of Public Registry, Registration Number	**ACTRN12610000879066**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**CEP - Unicamp**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**