A SINGLE INCISION MONOPROSTHESIS FOR CONCOMITANT MANAGEMENT OF APICAL, ANTERIOR PROLAPSES AND STRESS URINARY INCONTINENCE.

Introduction

A new monoprostesis for concomitant correction of anterior and apical prolapses and stress urinary incontinence was developed (Calistar A). It consists of an implant made of a type I polypropylene mesh with 6 milimeters diameter orifices to facilitate tissue integration and also provide flexibility.

The suburethral part of the implant is held between 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 be placed underneath the midurethra.

The kit also includes a disposable retractable insertion guide to approach the sacrospinous ligaments bilaterally, which represent the other anatomical landmarks of the procedure.

Design

This video shows the treatment of a patient with anterior and apical prolapses stage 3 according to the POP-Q system.

The procedure is performed with the patient in lithotomy position. After doing a hydrodissection, anterior vaginal wall incision is made from midurethra towards the uterine cervix and the pubocervical fascia is carefully dissected. Blunt dissection is performed towards the ischial spine, and coccigeous muscle, identifying the ischial spines and the sacrospinous ligaments.

Then the retractable insertion guide is primed with the tissue anchoring system and is introduced into the sacrospinous ligament 1.5 cm medial from the ischial spine. The tissue anchoring system is released and the insertion guide is gently retracted. The same maneuvers are repeated on the other side.

For insertion of the implant, first, the retractable insertion guide is connected to the multipoint fixation arm and is introduced towards the internal obturator muscle, one centimeter above the vaginal fornix, guided by surgeon's index finger. When the centering mark of the implant is at the midurethra at a properly position, the trigger at the handle is retracted to release in place the fixation arm. The multipoint fixation arms design provides strong and stable primary fixation. Cystoscopy is not mandatory.

Then, the polypropylene stitches are attached to the arms of the implant bilaterally. Stitches are 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.

Results

This procedure was performed in 12 patients (mean age 57 years-old) with POP-Q stage 3 anterior prolapse. Four of them also presented stage 2 apical prolapse. Six of them had concomitant stress urinary incontinence (mean ICIQ-SF score: 16±4), and four had had recurrence after previous anterior prolapse repair. Mean operative time was 45 min. No intraoperative complications or post-operative significant adverse events were observed. None presented post-operative vaginal mesh exposure, infection or visceral erosion. Mean follow up was 6 months (3 to 9 months). All of the patients were considered cured (POP-Q stage 0 or 1). Five patients showed complete cure of the incontinence (ICIQ-SF score: 0) and one was improved (ICIQ-SF score: 6).

Conclusion

This implant introduces the advantages of simultaneous treatment of apical, anterior vaginal prolapses and stress urinary incontinence by a single incision transvaginal approach building safety and a fully level I correction.

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Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Ethics Committee of the University of Campinas School of
	Medicine - Unicamp - Brazil
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes