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TRANSVAGINAL SINGLE INCISION IMPLANT FOR SEVERE APICAL AND POSTERIOR PROLAPSES: INICIAL RESULTS OF A PROSPECTIVE MUTICENTRE PROSPECTIVE TRIAL.

Hypothesis / aims of study

Although transcoccygeal colpopexy has become a widely used procedure for posterior vaginal repair, the risk of injury of the rectum, as well as pudendal vessels and nerves still represents a major concern. A new mesh (Calistar P – Promedon, Argntine) for transcoccygeal colpopexy was developed for single incision posterior transvaginal level I repair.

This mesh is made of type I polypropylene with of 6 millimeters in diameter helper orifices to facilitate proper integration and provide flexibility.

The kit also includes a disposable retractable insertion guide for insertion of the anchoring system into the sacrospinous ligaments. The multipoint anchoring system is composed of a polypropylene bristly arrowhead attached to polypropylene stitches, which are fixed to the mesh during the procedure. The back of the system has a stop, specially designed to prevent intra-operative damage of pudendal vessels and nerves.

The aim of this study is to present the results of the use of this mesh for the treatment of posterior prolapses.

Study design, materials and methods

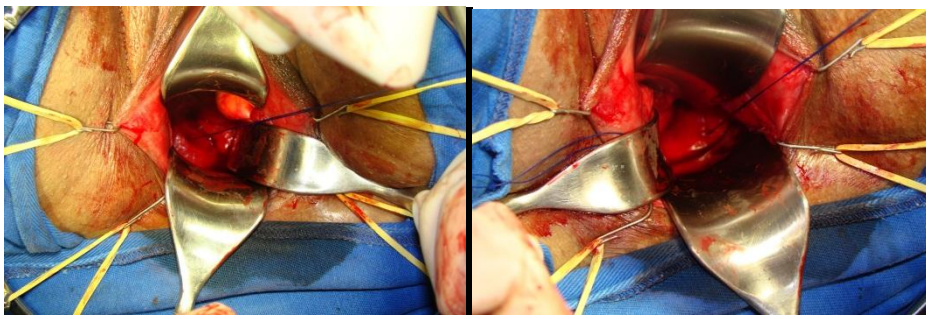
From January 2010 to March 2011, 21 female patients (mean age: 65,3 years old) with a posterior prolapse, underwent treatment with a new mesh for transcoccygeal colpopexy.

The treatment of a patient with a posterior prolapse stage 3 according to the POP-Q system. The procedure begins with hydrodissection of vaginal wall. Then, a vertical incision is done in the posterior vaginal wall towards to the cervix, as long as necessary to ensure proper dissection and identification of rectovaginal fascia defects. In the present patient, rectovaginal fascia is dethatched from the posterior aspect of the pericervical ring, and retracted towards the perineal body.

Blunt dissection is performed towards the ischiatic spine, and coccigeous muscle and sacrospinous ligaments are identified bilaterally. For the restoration of the posterior aspect of the pericervical ring, polypropylene stitches are applied to the sacrouterine ligaments bilaterally or at the posterior aspect of the cervix.

Then, the retractable insertion guide is primed with the multipoint anchoring system and introduced toward the ischiatic spine guided by surgeon's index finger and introduced into the sacrospinous ligament, 1.5 cm medial to ischial spine. The tissue anchoring system is delivered and the retractable insertion guide is gently retracted.

Both arms of the mesh are attached to the polypropylene stitches in order to elevate the mesh to DeLancey's level one. Also, the mesh is sutured to the uterosacrous ligament and posterior aspect of pericervical ring and adjusted in order to correct the posterior defect completely. The exceeding mesh is trimmed off and distal part sutured to levator ani fascia bilaterally. Remanents of rectovaginal fascia are used to cover the distal part of the mesh, allowing for extra protection against vaginal exposure. Finally, the vaginal incision is closed in the usual manner. A Foley catheter is left overnight (Figure 1).



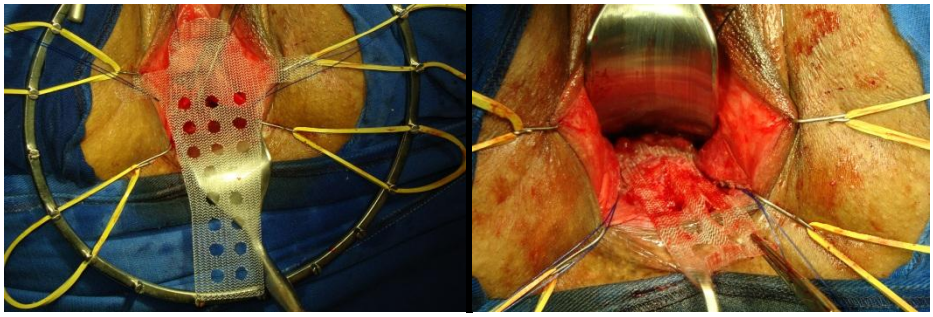


Figure 1. Surgical technique. After placement of multi point anchoring system in the sacrospinous ligament bilaterally, the mesh is delivered, allowing for level one correction.

Results

This procedure was performed in 21 patients (mean age 65,3 years-old) with POP-Q stage 3 posterior/apical prolapses. Ten had recurrence after previous posterior/apical prolapse repair. Mean operative time was 74,2 min. No intra-operative complications or post-operative significant adverse events were observed. One presented post-operative vaginal mesh exposure. Mean follow up was 4,76 months (3 to 8 months). Ninety percent (19/21 patients) of the patients were considered cured (POP-Q posterior/apical stage 0 or 1).

Interpretation of results

This technique prevents de the risks of transgluteal access (pain and bleeding)as demonstrated in this series, in which the was not adverse events related to the sacrospinous puncture with the trocar. The multipoint fixation system allows for the surgeon to choose to use the polypropylene stitches with the mesh, as demonstrated in this series, or alone, to anchor and restore the rectovaginal septum during site specific repair.

Concluding message

Multipoint anchor system adds the advantages of transvaginal approach to a high level of safety and level I correction of apical and posterior vaginal defects. It represents a real evolution of pelvic prolapse surgery.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**cep-fcm-unicamp**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**