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# ANCHORLESS IMPLANT FOR THE TREATMENT OF ANTERIOR AND APICAL PELVIC FLOOR COMPARTMENT PROLAPSE

Hypothesis / aims of study

The aim of this study was to evaluate a new surgical technique that has the potential to provide the benefits of mesh implants while eliminating complications of current techniques. The treatment involves anchorless placement of an implant which comprises polypropylene mesh stretched within a solid frame, for the treatment of anterior and apical vaginal prolapse.

Study design, materials and methods

This is a multicenter, international study for the evaluation of a new vaginal implant which was approved by the relevant health ministries and local ethical committees. A detailed explanation of the risks involved in vaginal implants and an informed consent was signed by all participants.

The implant is comprised of polypropylene (PP) mesh stretched within a solid flexible frame. It is surgically placed for the treatment of advanced prolapse of both anterior and apical vaginal compartments. An ultra-light PP mesh (16 gr/m$^2$) is stretched and retained in place by a U-shaped structure. The surgical technique includes central dissection of the bladder from the vagina, which extends to the paravesical space for direct bilateral palpation of the ischial spines. The device is inserted between the bladder and the vaginal mucosa with the lateral arms following the anatomy of the arcus-tendineus-fascia-pelvis (ATFP) and the connecting bridge positioned under the pubic symphysis. Appropriate location is confirmed by visualization of a symmetrically positioned device and a fully stretched mesh under the bladder. In case of uterine preservation, the inner aspect of the upper cervical lip is sutured to the middle of the proximal edge of the mesh. No other anchoring techniques are used. The vaginal incision is closed with no tension and vaginal packing is used for 24 hours.

Exclusion criteria included: previous vaginal mesh surgery, > 75 years old, POP-Q less than 2nd degree prolapse or asymptomatic POP. Demographic data, pre-surgical POP-Q scoring and QoL questionnaires (PFDI) were collected. Surgical data included intra and post-operative complications, surgery duration and estimated blood loss. Patients were followed at 2 weeks, 2, 6 and 12 months post- surgery.

Results

Twenty (20) women were recruited for the study. Average age was 62.1 (50-75 years old), average parity was 4.0 (1-16 deliveries), 4 patients had previous vaginal surgery and 3 had previous hysterectomy. The average BMI was 28.0, eight patients had hypertension and two were smokers. Nineteen (95%) patients suffered from both anterior and apical compartments prolapse, while one (5%) patient had only anterior prolapse. All patients underwent transvaginal repair of anterior and apical compartment prolapse using the self-retaining support (SRS) device. Five patients underwent concomitant vaginal hysterectomy and five had repair of the posterior compartment as well. Duration of surgery for the device implantation averaged 31.2 min (21-50 min). Estimated blood loss averaged 205 ml (150-500 ml). Estimated blood loss for patients who underwent implant-only procedure averaged 165 ml. No intra-operative complications were observed.

Two intra-operative cystoscopies were performed for minimal hematuria with no bladder injury documented. Post-operatively, one patient received one unit of packed cells and no events of urinary retention were recorded.

One case (5%) of frame erosion into the anterior vaginal wall was documented 8 months post-procedure. The eroded part of the frame was resected under local anesthesia in an ambulatory setting. Patient's symptoms were relieved immediately after the resection. This was the only case where a large sized frame was used and may have caused excessive pressure on the vaginal mucosa that lead to the erosion.

At one year follow up, all women had complete anatomical cure with POP-Q measurements of the anterior and apical compartment at normal values (table 1). No mesh erosions or chronic pelvic pain were documented at follow up. PFDI scores showed significant improvement of the prolapse and urinary domains. No deterioration was noted in the colorectal domain of the questionnaire.

**Table 1 POP-Q measurements at baseline vs. follow-up**

| Variable | Pre-Operative | Post-Operative |
|---|---|---|
| POP-Q: | | |
| Stage 0 | 0 | 17 (85%) |
| Stage 1 | 0 | 3 (15 %) |
| Stage 2 | 7 (35%) | 0 |
| Stage 3 | 5 (25%) | 0 |
| Stage 4 | 8 (40%) | 0 |
| Mean point Aa (cm)* | 1.4 ((-1)-3) | -2.95 ((-3)-(-2)) |
| Mean point Ba (cm)* | 2.3 ((-1)-6) | -2.8 ((-3)-(-2)) |
| Mean point C (cm)* | 0.4 ((-7)-6) | -6.9 ((-10)-(-3)) |

*Values given as mean (range)

Interpretation of results

The solid frame allows an anchorless surgical technique, retains the mesh at the desired location and provides the required long-term mechanical support. The study results suggest that eliminating the need for mesh fixation can potentially reduce both intra and post-operative complications. The sole case of frame erosion was secondary to an oversized implant and therefore can be prevented.

Concluding message

Results of the clinical use of this anchorless implant for the treatment of anterior and apical vaginal wall prolapse are promising, with no intra-operative or immediate post-operative complications and complete anatomical and subjective cure at one-year follow-up.

Results suggest that the safety profile and clinical outcome of this anchorless implant is potentially better than that reported for traditional trans-vaginal surgical meshes.

These results need to be confirmed with a larger sample size and a longer follow-up in order to clinically evaluate this new anchorless support concept to treat POP.

Disclosures

**Funding:** Study sponsored by industry **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov: NCT02209337 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Israeli Ministry of Health Hungarian Ministry of Health Szeged University Hospital Ethics Committee Ma'ayanei Hayeshua Medical Center Ethics Committee Asaf HaRofeh Medical Center Ethics Committee **Helsinki:** Yes **Informed Consent:** Yes