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AN ANCHORLESS IMPLANT FOR THE TREATMENT OF ANTERIOR AND APICAL COMPARTMENT PROLAPSE – REPORT OF 59 PATIENTS

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 the complications of current techniques. The root cause of complications associated with current trans-vaginal mesh (TVM) kits' was questioned as part of a search for an improved trans-vaginal treatment. The literature suggests that mesh fixation could be a main reason for complications rather than the implant itself or graft material. Following this assumption, a new treatment was developed involving the anchorless placement of a vaginal implant for the treatment of anterior and apical prolapse, which comprises a polypropylene mesh stretched within a solid frame.

Study design, materials and methods

Two multicenter, international studies for the evaluation of a new vaginal implant were approved by the relevant health ministries and local ethical committees. Informed consents including a detailed explanation of the risks involved in mesh implants were signed by all participants.

The implant is comprised of an ultra-light (16 g/m^2) polypropylene (PP) mesh stretched within a U-shaped solid flexible frame. The device is surgically placed for the treatment of advanced prolapse of both anterior and apical vaginal compartments. The surgical technique includes central dissection of the bladder from the vaginal wall extending bilaterally to the paravesical space to allow 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 midline 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, POP-Q less than stage 2 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, 12, 24 months after surgery and further follow-up is planned until the completion of 36 months after the procedure.

Results

Fifty nine (59) women were recruited. Average age was 63.0 (43-79) years old, average parity was 4.4 (1-16) deliveries, 7 patients had previous vaginal surgery and 5 had prior hysterectomy. Average BMI was 27.0 (20.3-36.6) Kg/m^2, 25 patients had hypertension, 10 were diabetic and 6 were smokers. Pre-operative POP-Q was Aa = 2.0 (-1 to 3) cm, Ba =3.1 (-1 to 6) cm and C=0.7 (-7 to 8) cm. Fifty-seven (97%) patients suffered from both anterior and apical compartments prolapse, while two (3%) patients had only anterior prolapse. Surgical time for device implantation averaged 27 (11-50) min. Estimated blood loss averaged 150 ml (25-500 ml). No intra-operative complications were observed. One case (1.7%) of frame erosion into the anterior vaginal wall was documented 8 months after the procedure. The eroded part of the frame was resected under local anesthesia in an ambulatory setting. The patient's symptoms were relieved immediately after the resection. This was the only case where a large sized frame was used and may have exerted excessive pressure on the vaginal mucosa, which possibly caused the erosion. Mean follow-up was 12.8 (range 0.7-30.8) months. Twenty patients (34%) completed their 24 months FU, 2 patients (3%) completed their 12 months FU, 14 patients (24%) completed their 6 months FU, 17 patients (29%) completed their 2 months FU. At follow-up the mean POP-Q measurements were: Aa= -3.0 (-3 to -2) cm, Ba= -2.9 (-3 to -2) cm and C = -7.2 (-10 to -1) cm. Fifty three (89.8%) patients with leading edge at stage 0 and 5 patients (8.5%) at stage 1. One patient (1.7%) had an asymptomatic apical descent with C at -1 cm. No cases of mesh erosion or chronic pelvic pain were documented at follow up. PFDI scores showed significant improvement of both the prolapse and urinary domains as well as total scores. No deterioration was noted in the colorectal symptom domain of the questionnaire.

Variable	Pre-Operative	Post-Operative
POP-Q:		
Stage 0	0	53 (89.8%)
Stage 1	0	5 (8.5 %)
Stage 2	6 (10%)	1 (1.7%)
Stage 3	43 (73%)	0
Stage 4	10 (17%)	0
Mean point Aa (cm)*	2.0 (-1 to 3)	-3.0 (-3 to -2)
Mean point Ba (cm)*	3.1 (-1 to 6)	-2.9 (-3 to -2)
Mean point C (cm)*	0.7 (-7 to 8)	-7.2 (-10 to -3)

Table 1 POP-Q measurements at baseline vs. follow-up. *Values given as mean (range)

Interpretation of results

In this novel implant for vaginal POP repair, the solid frame allows an anchorless surgical technique, retains the mesh at the desired location and provides the required long-term mechanical support. Our 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 seems therefore preventable.

Concluding message

Our outcome data on the clinical use of the SRS implant for the treatment of anterior vaginal wall prolapse with or without apical prolapse showed no intra-operative or immediate post-operative complications. The sole case of frame erosion was secondary to an oversized implant and can therefore be prevented. All patients had complete subjective cure. Fifty eight (98.3%) patients had complete anatomical cure, including 20 patients who completed 24 months follow up.

Our results suggest that an anchorless implant which retains the mesh in a flat and tension-free configuration can potentially reduce the complication rate reported with current mesh kits. It was demonstrated that accurately mimicking the physiologic support mechanism, provides firm mechanical support and as a result long-term subjective and anatomical cure are achieved. The safety profile and performance of the SRS implant showed better outcome compared to previous and current vaginal implants. These results need to be confirmed with a larger sample size and longer follow-up.

Disclosures

Funding: Both studies were funded by industry **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov: NCT02209337 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Israeli MOH, Hungarian MOH, Maayanei HaYeshua Medical Center, Assaf Harofeh Medical Center, Szeged University, Ziv Medical Center **Helsinki:** Yes **Informed Consent:** Yes