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ONE YEAR FOLLOW UP WITH ENDOFAST RELIANT™ SYSTEM – A NOVEL TECHNIQUE FOR PELVIC ORGAN PROLAPSE REPAIR

Hypothesis / aims of study

The use of mesh reinforcement in repair of pelvic organ prolapse (POP) with various surgical kits has become popular in the last few years, and its efficacy has been mainly proven to reduce recurrent cytocele (1). The current used kits are based on trocar assisted mesh positioning, inserting the trocars blindly through the obturator membrane or ischial fossa. The most severe complications that had been reported of those kits were due to visceral injury (2). In order to overcome those serious complications, and to avoid blind trocar passage, Endofast Reliant system was developed for mesh attachment into soft tissue, using four soft-tissue stainless steel fasteners (Fig. 1).
The aim of this study was to evaluate prospectively 1 year follow up of patients who underwent prolapse repair with EndoFast Reliant™ system.

Figure 1: Endofast fastener

Study design, materials and methods

From March 2007 an ongoing prospective multicenter study is carried out in 20 women with anterior and/or posterior POP, who underwent vaginal mesh reinforcement with Endofast Reliant System. The mesh anchored by fasteners to soft tissues, generates at least 1 Kg of holding force per fastener.
We excluded patients who needed hysterectomy or correction of stress urinary incontinence. All patients had preoperative evaluation including physical examination (POP-Q system), pelvic floor symptom evaluation using the PFDI questionnaire, and sexual function assessment using the FSFI questionnaire. Following surgery the physician's satisfaction was documented, and the patients were followed at 2 weeks, 3, 6 and 12 months post operatively, using the above mentioned measures. To follow possible anchor migration, X-ray of the bony pelvis was performed immediately after the procedure and following 3 months. For statistical analysis we used SAS software.

Results

The surgical procedure was performed under general or regional anesthesia. At the conference time 20 patients will reach 1 year follow up. Mean age was 61.2 years (range 34.2-79.2) and the mean BMI was 25.9 (range: 21.6 – 29). There were no intra-operative complications and up to discharge, no major complications were observed. During follow up period, no mesh erosion was noted. No detachment or migration of fasteners was observed. One case of misplacement of a single fastener was observed due to dyspareunia, which was removed under local anesthesia. Two cases of de – novo SUI occurred (10%), of whom one was treated surgically
Prolapse resolved in 100 % of our patients at 3 months (Grade 0 or 1) and in 90% at 6 months (2 patients of 18 had asymptomatic grade 2 prolapse). To date, prolapse correction has been maintained in 88.2% of patients that have reached 1 year (15/17 patients). Updated data will be present at the conference. Significant improvements in pelvic floor symptoms that are related to bulging and bladder but not to rectum were observed (Table 1).

Table 1: Pelvic floor symptoms derived from PFDI

	Bladder symptoms	Anorectal symptoms	Bulging symptoms
Baseline	1.4±1.6	0.3 ± 0.6	4.1±1.5
3 months FU	0.6 ±1.0	0.2 ±0.5	0.6±1.2
6 months FU	0.5±0.8	0.2 ±0.5	0.8±2.1
12 months FU	0.2±0.4 p=0.067	0.3 ±0.9 (p=NS)	0.1± 0.3 p < 0.001

Interpretation of results

The initial results are very promising - EndoFast Reliant™ system was proven to be safe and efficacious procedure for one year following its use in mesh overlay during vaginal POP repair.

Concluding message

This novel technique is an attractive option for prolapse repair with potential to minimize complications. Additional comparative studies are needed to validate its advantages over current available techniques.

References

References

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Specify source of funding or grant	**Dr Alcalay is consultant in Endogun Medical systems. Dr. Livne is employed in Endogun Medical system.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Clinical Trial Gov NCT00446693**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Sheba Medical Center IRB**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**