

APPLICATION OF ENDOFAST RELIANT™ SYSTEM – A NOVEL SOFT TISSUE FASTENING TECHNIQUE FOR PELVIC ORGAN PROLAPSE REPAIR

Synopsis of Video

This video presents a new surgical technique for Pelvic Organ Prolapse (POP) repair

Hypothesis / aims of study

Mesh reinforcement during prolapse repair is advocated to reduce prolapse failure rate.(1,2) The common technique for mesh placement uses trocars that blindly penetrate the obturator fossa and the ischiorectal fossa, exposing the patient to potential complications such as bleeding and visceral injury.(3)

The EndoFast Reliant™ system offers a new method for reinforcement of the pelvic floor in a minimally-invasive procedure with a system comprised of a mesh and soft tissue fasteners (Endogun Medical Systems, Kibbutz Haogen, Israel). The system was developed to enable direct mesh attachment into connective tissue, therefore potentially reducing intra and post-operative complications and pain.

The fasteners are easily deployed in narrow spaces into soft tissue, and support substantially more weight than needed for Pelvic Organ Prolapse repair. The system requires minimal dissection and enables mesh attachment by palpation directly through the dissection space, as shown in the video.

The study was conducted in order to evaluate the efficacy of EndoFast Reliant™ system.

Study design, materials and methods

A prospective multicenter study was carried out in 15 women with anterior and/or posterior POP, who underwent vaginal repairs with mesh reinforcement. Eleven patients (79%) underwent double compartment corrections out of 26 corrections performed.

We excluded patients who needed hysterectomy or correction of stress urinary incontinence. All patients had preoperative evaluation including physical examination (using the 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 with the system was documented, and the patients were followed at 2 weeks, 3 and 6 months post operatively, using the same measures that were evaluated at the preoperative visit. To follow any potential migration of the fasteners, the patients had an X-ray examination of the bony pelvis immediately after the procedure and 3 months postoperatively.

One of the patients was a 61 year old, otherwise healthy female patient with cystocele POP-Q stage 3, who was treated for cystocele repair using the EndoFast Reliant™ system.

The patient was placed in a modified dorsal lithotomic position. Longitudinal midline incision was made at the anterior vaginal wall. Deep dissection was performed between the vaginal epithelium and the bladder base. Following dissection, the mesh was inserted via the incision, and the fasteners were anchored the mesh into the soft tissue adjacent to the ischial spines and posterior symphysis in the anterior compartment.

This video contains an animation demonstrating the use of the EndoFast Reliant™ system, followed by clips from an actual cystocele repair performed on the patient described above, and detailing the steps involved in the procedure. In addition, it displays the patient's pelvic x-ray following the procedure

Results

This video highlights the use of the EndoFast Reliant™ system in prolapse repair surgery. To date, this surgical procedure has been performed on 15 patients with 6-month follow up data for 12 patients.

In the case presented, there were no intra-operative complications and to date no major complications were observed. During follow up of this case, no detachment or migration of fasteners has been observed and no mesh erosions have been noted. .

Detailed clinical data is presented in another abstract submitted to this conference.

Interpretation of results

Application of mesh for POP repair using the EndoFast Reliant™ System shows promising results. The procedure appears safe and up to 6 months there is maintenance of the anatomical correction with constant improvement of pelvic floor symptoms .

Concluding message

The EndoFast Reliant™ system is a minimally invasive procedure for mesh placement, avoiding the use of trocars. This video demonstrates the ease of use of the system. This procedure is a simple procedure for treatment of prolapse which makes it an attractive option for mesh use during prolapse repair.

References

1. Fattouh B, Amblard J, Debonance P, Cosson M, Jacquelin B (2007) Transvaginal repair of genital prolapse: preliminary results of a new tension-free vaginal mesh (Prolift technique)-a case series multicentric study. *Int Urogynecol J Pelvic Floor Dysfunct* 18:743-752.
2. Altman D, Väyrynen T, Engh ME, Axelsen S, Falconer C; For the Nordic Transvaginal Mesh Group. Short-term outcome after transvaginal mesh repair of pelvic organ prolapse. *Int Urogynecol J Pelvic Floor Dysfunct*. 2007 Dec 12 .
3. Abdel-Fattah M, Ramsay I; West of Scotland Study Group. Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapse. *BJOG*. 2008 Jan;115(1):22-30.

Specify source of funding or grant

Endogun Medical Systems LTD.

Is this a clinical trial?

Yes

Is this study registered in a public clinical trials registry?

Yes

Specify Name of Public Registry, Registration Number

ClinicalTrials.gov Identifier:NCT00446693

<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	This study was approved by the: COMITE DE PROTECTION DES PERSONNES NORD-OUEST I 1, rue de Germont – 76031 ROUEN , FRANCE on 22 January 2007 and by the Ethics Committee of the Chaim Sheba Medical Center ,Israel.
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes