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## **NEW SINGLE-INCISION TROCAR-LESS SYSTEM FOR THE TREATMENT OF PELVIC ORGAN PROLAPSE: SHORT AND LONG TERM RESULTS OF FIRST 29 PATIENTS**

### Hypothesis / aims of study

Most of the transvaginal mesh kits available today to treat Pelvic Organ Prolapse (POP) are trocar-guided. The trocars which pass blindly through the pelvis walls can cause intra and post-operative complications i.e. damage to visceral organs, especially when the anatomical knowledge of the pelvic structures and the correct passage of the trocars is lacking. Up to date, few trocar-less kits are available in the market but publications regarding their safety, efficacy and outcomes are lacking.

The EndoFast Reliant system (Endogun Medical Systems Ltd., Israel) is a minimally invasive system which employs a novel technology for reinforcement of the vaginal wall using Endogun's Spider Fastener and consists of a polypropylene monofilaments mesh and soft-tissue fasteners. The aims of the study were to evaluate the short and long term outcomes of all patients treated in our institution with the EndoFast Reliant system with regards to anatomical and functional results, intra and post-operative complications.

### Study design, materials and methods

We conducted a retrospective study, including all patients treated for the treatment of POP with the EndoFast Reliant System between Mars 2007 and January 2010. Data included: pre-operative and post-operative evaluation including POP-Q, functional symptoms and results. All patients were asked systematically pre- and post-operatively about urinary, defecation and pain symptoms. Data concerning the procedure included intra and post-operative complications, post-operative pain which was assessed by VAS at 6, 12 and 24 hours and the use of pain killers. Patients were followed 6 weeks, 6 months and 1 year following the procedure and were advised to return with any problem.

### Results

29 patients were treated in our department with the EndoFast Reliant system. Six patients went through anterior repair, 4 had posterior repair and 19 had simultaneous anterior and posterior repair. Up to date, 10 patients reached 24-30 months follow-up and 9 patients reached between 12-18 months follow-up. Mean operation time was 47 min. There were no intra-operative complications, neither mesh-related post-operative complications. One fastener was removed 8 weeks post-operatively. Mean VAS for the 1<sup>st</sup> post-operative day was 1.1, for the 2<sup>nd</sup> 1.6 and 1.25 for the 3<sup>rd</sup>. Most patients needed one analgesic drug or less for the management of pain. Anatomical results are demonstrated in Figure 1 and functional results are summarized in Table 1.

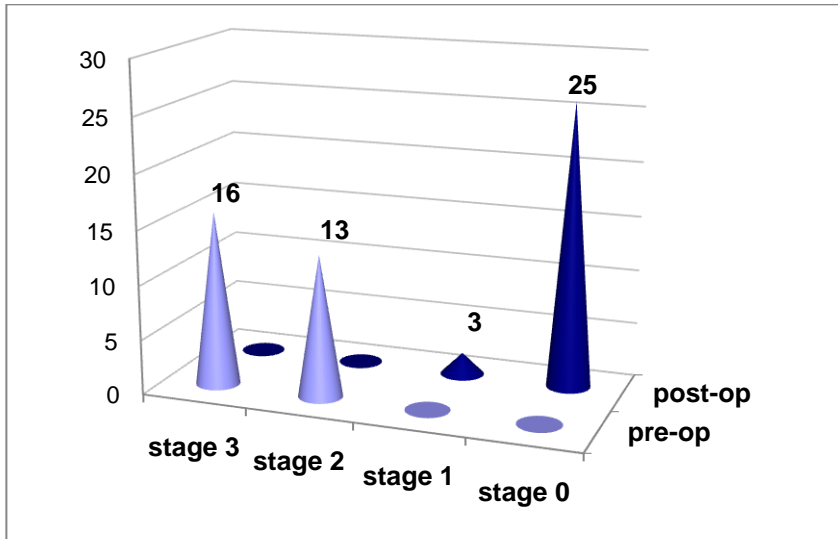
### Interpretation of results

With mean follow-up of more than 1 year for the majority of the patients, anatomical results are very satisfactory and considered perfect for 25 patients. 3 patients presented non symptomatic stage 1 prolapse, 2 with Ba at -1 and one with cervical elongation, point C at -1. Few cases of de novo Stress urinary Incontinence and urgency were diagnosed however post-operative voiding difficulties, dyspareunia and perineal pain were not observed. The procedures were of short duration with no intra or post operative complications and almost no post-operative pain. One patient, which was asymptomatic required the removal of 1 fastener due to too superficial placement. Removal was carried out under local anesthesia and POP-Q stage at 1 year follow up was 0.

### Concluding message

The advantages of the trocar-less systems are gained mainly by bypassing the need of blind trocar insertion. While reducing the probability for complications, the trocar-less system also provides a quicker and less invasive operation. The procedure with the EndoFast Reliant system was found to be safe, easy to learn and to implement with very satisfactory long-term functional and anatomical results. Further larger comparative studies are required before final conclusions.

**Figure 1:** pre and post operative prolapse stage\*



\* Prolapse stage was determined by using the ICS POP quantification and staging system

\*\* Post-operative stage was available only for 28 patients, one was lost for follow-up

**Table 1:** Pre-operative functional symptoms and post-operative functional results

Pre-operative symptoms (n)	Post-operative			Treatment
	Cure	ongoing	de novo	
Stress Urinary Incontinence (7)*	6	1	6	re-op with sub-urethral sling (3) no treatment, symptoms were not severe (4)
Urgency (15)	10	5	2	no treatment, symptoms were not severe (3) Anticholinergic trx. (4)
Incomplete voiding (6)	5	1	0	Resolved spontaneously
Defecations problems (5)	2	3	0	Symptoms improved after the operation
Pain and dyspareunia (2) **	2			

\* 6 patients were operated with additional sub-urethral sling

\*\* 10 patients were not sexually active

<b>Specify source of funding or grant</b>	none
<b>Is this a clinical trial?</b>	No
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	Yes
<b>Specify Name of Ethics Committee</b>	CNGOF (Collège National des Gynécologues et Obstétriciens Français)
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	No