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Safety and efficacy of spider anchoring device for apical repair in laparoscopic sacrocolpopexy: Retrospective cohort study

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ABSTRACT

Objective: The aim of the study was to assess safety and efficacy of apical support when using the soft-tissue metal fasteners of EndoFast Reliant™ SCP during laparoscopic sacrocolpopexy (LSCP).

Study design: This is a single-center, retrospective cohort study including all patients which underwent LSCP between 2015 and 2017. Safety outcome included the procedure and the device related complications. Effectiveness outcomes included the anatomical success of apical repair and the functional results as were obtained from the clinic and from a Quality of life questionnaire (PFDI-20).

Results: Eighty-four patients, 54% with grade III and IV prolapse were included in the study. Uterus was preserved in 68% of patients with uterus. Mean follow-up period for the clinic visit was 4.5 ± 4 months. Short term anatomical success was achieved for 98.8% of the patients. Marked improvement was observed in the related symptoms including urinary incontinence. Three intra-operative complications occurred: 1 case of bladder injury, 1 case of intra-abdominal bleeding, and 1 case of post-operative vaginal bleeding. Later complications included only two patients (2.3%) complained of chronic abdominal pain. There were no cases of mesh erosion or de-novo dyspareunia. The mean follow-up period for the PFDI-20 questionnaire was 15.6 months. 75% of patients had no bulge symptoms at all. Quarter of the patients had some bulge symptoms, bothers them between somewhat to moderately according to the questionnaire grading.

Conclusions: The use of Endofast SCP fasteners for laparoscopic promonto-fixation is a safe and effective surgery. Longer follow-up and larger studies should be performed to establish the results.

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Introduction

Pelvic Organ Prolapse (POP) is one of the most common indications for surgery in women, with approximately 200,000 inpatient surgical procedures performed for this indication in the United States annually. A woman's risk of requiring surgery for prolapse is approximately 7% by the age of 80 years [1]. Of those who underwent surgery, an estimated 13% will require a repeat operation within 5 years and as many as 29% will undergo another surgery for prolapse or a related condition at some point during their life [1,2].

Given the rates of prolapse recurrence after surgery, many pelvic reconstructive surgeons have incorporated the use of

synthetic or biologic graft materials into their repairs in an attempt to improve long-term outcomes. The use of synthetic mesh during sacral colpopexy, from abdominal or laparoscopic approach, in order to suspend the vaginal apex is a well-established technique supported by level I evidence [3]. Sacrocolpopexy (SCP) is the most appropriate procedure for young and sexually active woman with symptomatic POP. This procedure provides anatomic pelvic restoration, durable results, and less dyspareunia by maintaining vaginal length and axis [4].

Abdominal and laparoscopic sacrocolpopexy (LSCP) are considered to have high success rates of over 90% with low recurrence rates. The laparoscopic sacrocolpopexy (LSCP) has an additional advantage of less blood loss, reduced morbidity, and shorter hospital stay [3]. Nevertheless, complications such as new onset bowel, voiding, and sexual dysfunction, de-novo stress incontinence, obstructed defecation syndrome, intraoperative bladder injury, need for reoperation for POP, pelvic/abdominal abscess formation, osteomyelitis, dorso-lumbar pain and mesh erosion after LSCP have been reported and may have a negative effect on patient's satisfaction [4–6].

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Various mesh fixation techniques that are in use in general surgery for laparoscopic ventral and incisional hernia repair were adapted to urogynecology, specifically for mesh promonto-fixation in LSCP. These fixation techniques include absorbable and non-absorbable tackers, non-absorbable sutures and titanium bone anchor fixations [7–10]. These methods were developed in order to reduce suture related complications, especially major bleeding from great vessels and to reduce the recurrence rate of the POP.

The EndoFast Reliant™ SCP (IBI Medical Systems Ltd. Caesarea Industrial Park, Israel) is a device that includes novel soft-tissue metal fasteners which was designed for LSCP mesh fixation to the promontory and a pre-cut polypropylene type 1 mesh. The fasteners are easily deployed through narrow spaces into soft tissues and can support an average weight of 1.5 kg each, far more than required in a typical POP repair procedure [11].

The aim of this study was to assess the safety and the anatomical results of apical support in women undergoing POP repair with the EndoFast Reliant™ SCP.

Materials and methods

This is a single arm, single-center, retrospective cohort study. The study objectives were to evaluate the safety and anatomical results of the EndoFast Reliant SCP for apical support in women undergoing Laparoscopic POP repair procedure. Local IRB approval was obtained prior the collection of the data.

The Safety outcome included the procedure and device related complications and device malfunction. The Effectiveness outcomes included the anatomical success of apical repair measured by the change in Pelvic Organ Prolapse Quantification System (POP-Q), the measured functional data and Quality of life questionnaire, the PFDI-20.

The study population included all female subjects, 18 years and older that underwent LSCP repair utilizing the EndoFast Reliant SCP in the Gynecology department at the Germany Catholic Hospital Hoxter, Germany during the years 2015–2017. Patients without follow-up were excluded.

The baseline data collected include: demographics (BMI, Previous hysterectomy, Previous POP and incontinence surgery), pre-procedure POP-Q (Ba, C, D, Bp, TLV) and stage of prolapse.

Pre-procedure symptoms included: urinary incontinence, voiding dysfunction, urge, nocturia, dyspareunia and constipation.

Intra operative data collected include: surgery duration (min), estimated blood loss (ml), bowel or bladder injury, any other complication and hospital stay.

Patients were seen at the clinic up to 12 months post-operative. Follow-up data included POP-Q, symptoms and specific procedure related complications such as pain, mesh erosion, and infection.

Success was defined as no bulge symptoms and prolapse < stage 2.

A PFDI quality of life questionnaire was sent to all patients. The PFDI is both a symptom inventory and a measure of the level of bother and distress caused by pelvic floor symptoms. The symptom inventory requires Yes/No answer while the degree of bother and distress require grading from 1 to 4 (1 not at all and 4 quite a bit). The questionnaire includes 20 questions and 3 scales. The 3 scales include questions taken from the following widely used outcome measures: Pelvic Organ Prolapse Distress Inventory (questions 1–6), Colorectal-Anal Distress Inventory (questions 7–14) and Urinary Distress Inventory (questions 15–20).

Surgical technique

All patients underwent laparoscopic sacrocolpopexy or sacrohysteropexy with preservation of the uterus. The mesh was attached to the cervix or vaginal cuff with non-absorbable sutures,

passing under the peritoneum and attached to the promontory with the Endofast SCP, 1 or 2 fasteners. In cases of accompanied cystocele, a vaginal colporrhaphy without mesh was added. In cases of Stress urinary incontinence (SUI), the 2 steps approach was taken. A routine mid urethral sling was not added during the LSCP procedure, and only added if consistent after surgery in separated procedure.

Investigational device

EndoFast Reliant™ SCP enables a minimally invasive technique for reinforcement of the vaginal wall using IBI's Spider Fastener™ device shown in Fig. 1. The device is indicated for treating female POP through a laparoscopic approach by fixation of a surgical mesh to the promontory as shown in Fig. 2. The EndoFast Reliant™ SCP consists of monofilament polypropylene pre-cut mesh and soft-tissue metal fasteners. The fasteners are easily deployed through narrow spaces into soft tissue and can support an average weight of 1.5 kg each. The device is introduced through a 5 mm trocar via a laparoscopic approach. The mesh is attached to the vaginal vault and the vagina is pulled towards the posterior pelvic bony part. The other end of the mesh is attached to the promontory, using the EndoFast Reliant™ SCP fasteners, at one or two fixation points.

Statistical analysis

The incidence of all study parameters, including individual components, is presented descriptively as frequencies and percentages. Baseline data were summarized in tabular format. Continuous variables were presented as means with standard deviations or as medians with interquartile ranges if not normally distributed. Dichotomous variables were presented as frequencies in percentages with binary confidence intervals.

Results

Data was collected from 84 patients who underwent a POP repair procedure with the EndoFast Reliant SCP system during the years of 2015–2017. The demographics and baseline characteristics are summarized in Table 1.

Prolapse stage and symptoms at baseline are presented in Table 2. Forty-Five patients (54%) had sever prolapse (22 patients had prolapse grade III and 23 patients had prolapse grade IV). Pre-operative Mean Ba was 2.3 ((-2)-(+5)), mean Bp was 1.4 ((-2)-(+5)), Mean point C was 2.3 ((-6)-(+8)) and mean point D was 0.4 ((-8)-(+5)). Most of the patients (Table 2) suffered from some kind of urinary problem (incontinence, voiding dysfunction or urge).

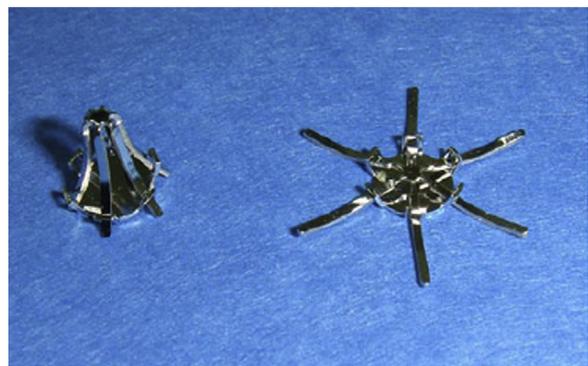


Fig. 1. The Spider technology platform enables minimally-invasive optimal mesh fixation to any soft tissue.



Fig. 2. Soft tissue fixation of a mesh with Spider Fasteners by Laparoscopic SacroColpoPlexy (SCP).

Table 1
Patients demographics and baseline characteristics.

Patient Parameters	Population
Age	64.8 ± 13.5 [66] ^a
BMI	26.1 ± 3.7 [25.3] ^a
Previous hysterectomy	22 (26.2%)
Previous POP ^b surgery	14 (16.7%)
Previous incontinence surgery	(4.8%)

^a Median.

^b Pelvic Organ Prolapse (POP).

Table 2
Prolapse stage and related symptoms.

Patient characteristic	Population
Average POP stage	2.7 ± 0.96
Urinary incontinence	22 (26.2%)
Voiding dysfunction	72 (85.7%)
Urge	71 (84.5%)
Dyspareunia	11 (13.1%)
Constipation	12 (14.3)
Nocturia (≥1)	45 (53.6%)

The implantation of the IBI EndoFast Reliant SCP was successful in all patients with no device malfunction. From the 62 patients with uterus, 20 patients (32%) had supra-cervical hysterectomy during the procedure (Patient request, Menorrhagia, Uterine myomas) and the rest (42 patients) had uterus preservation procedure. Ten patients (11%) had additional vaginal native tissue cystocele repair and one patient had addition rectocele vaginal repair. The mean surgical time was 78 ± 21 min (median 73 min). The mean hospitalization duration was 4 days for patient undergoing POP repair alone (5.9 days for all patients, including patients that underwent additional procedures).

Three intra-operative complications occurred, related to the LPCP procedure: One case of bladder injury, that required a placing of a catheter for 5 days and the patient was hospitalized for 10 days. One case of intra-abdominal bleeding, required revision and blood transfusion, patient was hospitalized for 7 days. One patient with post-operative vaginal bleeding treated with tamponade compression and was hospitalized for 7 days. All patients recovered well.

Three patients developed post-operative fever treated successfully by antibiotics. Marked stress urinary incontinence was still ongoing in one patient and she had a mid-urethral sling procedure 3 weeks after the surgery. All other urinary incontinence patients were improved in the short-term follow-up.

Mean follow up period for the clinic visits was 4.5 ± 4 months. Short term (less than 1 year) anatomical success defined as no

bulge symptoms and prolapse < stage 2 was achieved for 98.8% of the patients (83/84 patients) with no prolapse at all as shown in Table 3. One patient had prolapse stage II, completely asymptomatic. Marked improvement was also observed in the related symptoms including urinary incontinence, voiding dysfunction, urge, dyspareunia, and nocturia as shown in Table 4. Later complications included two patients which developed Cystitis 6 and 4 months following the procedure, treated successfully with antibiotics. Two patients (2.3%) complained of chronic abdominal pain. There were no cases of mesh erosion during follow-up and no cases of de novo dyspareunia.

A quality-of-life questionnaire, the PFDI-20 was sent to all study patients. Fifty-eight (69%) of patients have completed the questionnaire and all completed questionnaires were analyzed (Appendix A). The mean follow-up period according to the dates of completing the questionnaires was 15.6 months. Twenty patients had more than 2 years follow up (average of 30 months). Seventy-eight percent of patients had no bulge symptoms at all. Quarter of the patients answered that they had some POP symptoms, bothers them between somewhat to moderately according to the questionnaire grading. When reviewing the Colorectal-Anal Distress questions, more than third of the patients suffers from constipation, feeling of non-complete emptying, gas and a strong sense of urgency. Those parameters bother the patients at a rate which is between somewhat to moderately. Regarding the urinary distress questions, almost half of the patients experienced frequent urination and urine leakage mainly during coughing, laughing or sneezing that bothers them moderately. When comparing the answers of the 20 patients which completed the questionnaire more than 2 years after the surgery to those with the short follow up period, no significant differences in the questionnaire answers both in the occurrence of the symptoms and in the rating were noted showing that the effect of the procedure maintain with time.

Comment

The Endofast Reliant SCP was design for the fixation of a mesh to the promontory during laparoscopic SCP. The fixation is achieved with a unique metal fastener having a spider shape (Figs. 1 and 2) allowing a shallow but strong fixation [11] and therefore avoids the risks associated with deep penetration to the promontory such as back pain, infection or hemorrhage from the sacral plexus. Although proven to have strong fixation in the laboratory [11], this study was design to clinically demonstrate its safety and efficacy. The same Endofast Reliant fasteners were used in vaginal approach procedures, and were shown to be safe and effective in treating POP [12–14].

The procedure was successful in all patients with no device malfunction and without major intra-operative complication. Post-operative complication rate was low, including only chronic pain (2.3%) with no cases of mesh erosion in this cohort study. Mesh erosion after vaginal mesh surgery can reach up to 12% according to the literature [15–19]. The rate of mesh erosion after abdominal or laparoscopic SCP is lower during short follow-up, but can reach up to 10% in long-term (up to 3 years) follow-up [20–22].

Table 3
Change in POP stage according to POP-Q before and after the procedure.

POP stage	Before procedure N = 85	At follow up visit N = 84
0	0	82
I	7	1
II	32	1
III	22	0
IV	24	0

Table 4

Improvement in prolapse related symptoms at follow up.

Symptom	Before procedure	At follow up (after procedure)	% of patients improved
Urinary incontinence	22 (26.2%)	6 (7.1%)	72%
Voiding dysfunction	72 (85.7%)	19 (22.6%)	73.6%
Urge	71 (84.5%)	19 (22.6%)	73.2%
Dyspareunia	11 (13.1%)	2 (2.3%)	81.8%
Nocturia (>1)	21 (25%)	7 (8.3%)	66.6%
Constipation	12 (14.3%)	11 (13%)	8.3%

The short-term anatomical results expressed as the improvement in POP-Q were excellent and marked improvement was achieved for 98.8% of the patient following the procedure. It is important to mention that 54% had severe POP with 27% of the patients having grade IV prolapse prior to surgery.

Improvement in all functional results was also obtained; dyspareunia was improved by 81.8% of the patients following the procedure to a level of 2.3%.

A symptomatic urinary incontinence was observed in 22 patients (26.2%) prior to surgery, 19 had mixed incontinence and 3 pure SUI. Only one patient needed mid-urethral sling procedure following the surgery and overall urinary incontinence after the surgery, dropped from 22 (26.2%) to 7 patients (7.1%), an improvement of 72%.

The PFDI questionnaire with 15 months follow-up on average showed that more than 75% of the patients were free of any bulge symptoms. Some bothering symptoms still occur in many patients even when the anatomy is perfect however, most symptoms were graded low, mild to moderate (scale 1–2).

This study has some limitations which are connected to its retrospective nature. The study clinical evaluation is short-term evaluation and cannot be extrapolate for long-term results. However, the data from the questionnaire are long-term data of average 15 months post-operatively. These data demonstrate good subjective results as the patients experienced them. The patient feeling is the “true” result regardless the objective parameters since the patient’s reason for performing a POP repair procedure is the bothering symptoms that are not necessarily relate to the objective parameters thus it is quite common in large series to evaluate the long-term results by questionnaire [23]. The study is strength by its large series of patients, most of them with severe prolapse, all operated by one surgeon in one center and therefore reduces the different between protocols and surgical techniques.

We conclude that the use of Endofast SCP mesh and fasteners for LSCP promonto-fixation is a safe and efficient surgery. Longer follow-up and larger studies should be performed to establish the results.

Conflict of interest

Dr. Naama Marcus and Dr. Stefan Bettin are consultants of IBI company.

Appendix A. Pelvic Floor Questionnaire (PFDI-20) answers completed for 58 patients with mean follow-up of 15.6 months

Question (If yes, how much does this bother you?)	Yes N (%)	Average rate (scale 1-4)
1 Do you usually experience pressure in the lower abdomen?	14 (24)	2.44
2 Do you usually experience heaviness or dullness in the pelvic area?	13 (22)	2.32
3 Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?	11 (19)	2.38

(Continued)

Question (If yes, how much does this bother you?)	Yes N (%)	Average rate (scale 1-4)
4 Do you usually have to push on the vagina or around the rectum to have or complete bowel movement?	17 (29)	2.55
5 Do you usually experience a feeling of incomplete bladder emptying?	47 (81)	2.75
6 Do you ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?	2 (3)	1.50
7 Do you feel you need to strain too hard to have a bowel movement?	25 (43)	3.09
8 Do you feel you have not completely emptied your bowels at the end of a bowel movement?	22 (38)	2.78
9 Do you usually lose stool beyond your control if your stool is well formed?	5 (8.6)	1.88
10 Do you usually lose stool beyond your control if your stool is loose or liquid?	9 (15)	2.17
11 Do you usually lose gas from the rectum beyond your control?	25 (43)	2.75
12 Do you usually have pain when you pass your stool?	11 (19)	2.27
13 Do you experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?	21 (36)	2.30
14 Does a part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?	1 (1.7)	1.25
15 Do you usually experience frequent urination?	28 (48)	3.17
16 Do you usually experience urine leakage associated with a feeling of urgency that is a strong sensation of needing to go to the bathroom?	24 (43)	2.63
17 Do you usually experience urine leakage related to coughing, sneezing, or laughing?	30 (52)	2.38
18 Do you usually experience small amounts of urine leakage (that is, drops)?	20 (34)	2.60
19 Do you usually experience difficulty emptying your bladder?	11 (19)	2.75
20 Do you usually experience pain or discomfort in the lower abdomen or genital region?	18 (31)	2.67

References

- [1] Olsen AL, Smith VJ, Bergstrom JO, et al. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol* 1997;89:501–6.
- [2] Clark AL, Gregory T, Smith VJ, et al. Epidemiologic evaluation of reoperation for surgically treated pelvic organ prolapsed and urinary incontinence. *Am J Obstet Gynecol* 2003;189:1261–7.
- [3] Maher CM, Feiner B, Baessler K, Glazener CM. Surgical management of pelvic organ prolapse in women: the updated summary version Cochrane review. *Int Urogynecol J* 2011;22:1445–57.
- [4] Ganatra AM, Rozet F, Salas RS, Barret E, Galiano M, Cathelineau X, et al. The current status of laparoscopic sacrocolpopexy: a review. *J Urol* 2009;55:1089–105.
- [5] Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. *Cochrane Database Syst Rev* 2013;30(April 4)CD004014 Review.
- [6] Unger CA, Paraiso MF, Jelovsek JE, Barber MD, Ridgeway B. Perioperative adverse events after minimally invasive abdominal sacrocolpopexy. *Am J Obstet Gynecol* 2014;211(547):e1–8.
- [7] Muysoms F, Vander Mijnsbrugge G, et al. Randomized clinical trial of mesh fixation with “double crown” versus “sutures and tackers” in laparoscopic ventral hernia repair. *Hernia* 2013;17:603–12.

- [8] Wassenaar E, Schoenmaeckers E, Raymakers J, van der Palen J, Rakic S. Mesh-fixation method and pain and quality of life after laparoscopic ventral or incisional hernia repair: a randomized trial of three fixation techniques. *Surg Endosc* 2010;24:1296–302.
- [9] van der Weiden RM, Withagen MI, Bergkamp AB, Mannaerts GH. A new device for bone anchor fixation in laparoscopic sacrocolpopexy: the Franciscan laparoscopic bone anchor inserter. *Surg Endosc* 2005;19:594–7.
- [10] Vieillefosse S, Thubert T, Dache A, Hermieu JF, Deffieux X. Satisfaction, quality of life and lumbar pain following laparoscopic sacrocolpopexy: suture vs. tackers. *Eur J Obstet Gynecol Reprod Biol* 2015;187:51–6.
- [11] Alcalay M, Livneh M, Braun NM, Tov YS, Hod E. Mesh pullout force: comparative study of different deployment techniques in a sheep model. *Int Urogynecol J* 2014;25:103–7.
- [12] Alcalay M, Cosson M, Livneh M, Lucot JP, Theobald PV. Trocarless system for mesh attachment in pelvic organ prolapse repair—1-year evaluation. *Int Urogynecol J* 2011;22:551–6.
- [13] Marcus-Braun N, von Theobald P. Cystocele repair with single incision trocarless mesh system. *Int Urogynecol J* 2014;25:285–7.
- [14] Fink K, Ben Shachar I, Marcus Braun N. Uterine preservation for advanced pelvic organ prolapse repair: anatomical results and patient satisfaction. *Int Braz J Urol* 2016;42:773–8.
- [15] Hinoul P, Ombelet WU, Burger MP, Roovers JP. A prospective study to evaluate the anatomic and functional outcome of a transobturator mesh kit (prolifer anterior) for symptomatic cystocele repair. *J Minim Invasive Gynecol* 2008;15:615–20.
- [16] Gerten KA, Wheeler 2nd TL, Holley RL, Varner RE, Richter HE. Synthetic graft use in vaginal prolapse surgery: objective and subjective outcomes. *Int Urogynecol J* 2009;20:1307–12.
- [17] Hurtado EA, Appell RA. Management of complications arising from transvaginal mesh kit procedures: a tertiary referral center's experience. *Int Urogynecol J* 2009;20:11–7.
- [18] Menefee SA, Dyer KY, Lukacz ES, Simsiman AJ, Luber KM, Nguyen JN. Colporrhaphy compared with mesh or graft-reinforced vaginal paravaginal repair for anterior vaginal wall prolapse: a randomized controlled trial. *Obstet Gynecol* 2011;118:1337–44.
- [19] Ridgeway B, Walters MD, Paraiso MF, et al. Early experience with mesh excision for adverse outcomes after transvaginal mesh placement using prolapse kits. *Am J Obstet Gynecol* 2008;199(703):e1–7.
- [20] Nygaard I, Brubaker L, Zyczynski HM, et al. Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse. *JAMA* 2013;309:2016–24.
- [21] Sarlos D, Kots L, Ryu G, Schaer G. Long-term follow-up of laparoscopic sacrocolpopexy. *Int Urogynecol J* 2014;25:1207–12.
- [22] Eisenberg VH, Steinberg M, Weiner Z, Schiff E, Lowenstein L. Long-term follow-up of sacrocolpopexy mesh implants at two time intervals at least 1 year apart using 4D transperineal ultrasound. *Ultrasound Obstet Gynecol* 2017;49:398–403.
- [23] Glazener CM, Breeman S, Elders A, et al. PROSPECT study group. Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT). *Lancet* 2017;389:381–92.