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CLINICAL ARTICLE

Gynecology

The EnPlace® sacrospinous ligament fixation—A novel minimally invasive transvaginal procedure for apical pelvic organ prolapse repair: Safety and short-term outcome results

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Abstract

Objective: The EnPlace® device is a novel minimally invasive tool allowing transvaginal sacrospinous ligament (SSL) fixation of apical pelvic organ prolapse (POP). The study aimed to investigate the safety and short–term efficacy of the EnPlace® SSL fixation for significant apical POP repair.

Methods: A retrospective cohort study of 123 consecutive patients (mean age 64.4 ± 11.1 years) with stage III or IV apical POP who underwent SSL fixation by the EnPlace® device. Safety and 6-month outcome results were analyzed and compared between 91 (74%) patients with uterine prolapse versus 32 (26%) patients with vaginal vault prolapse.

Results: There were no intraoperative or early postoperative complications. The mean (± standard deviation) duration of surgery was 30 ± 6.9 min and mean blood loss was 30.5 ± 18.5 mL. The average position of point C by POP-Quantification measurements before surgery and at 6 months postoperatively was 4.5 ± 2.8 cm and −3.1 ± 3.3 cm, respectively. Of 91 patients with preoperative uterine prolapse, eight (8.8%) patients developed a recurrent uterine prolapse within 6 months postoperatively. Of 32 patients with preoperative vault prolapse, two patients (6.3%) had recurrent vault prolapse.

Conclusion: Short-term outcome results of EnPlace® SSL fixation suggest that it is a safe and effective minimally invasive transvaginal procedure for significant apical POP repair.

KEYWORDS
apical suspension, EnPlace, pelvic organ prolapse, sacrospinous ligament fixation, surgical outcomes, vaginal surgical approach

1 | INTRODUCTION

Pelvic organ prolapse (POP) is a common condition associated with a significant impairment in quality of life. Women have an 11%–19% likelihood of undergoing POP surgery during their lifetime.[1–4] POP can affect the anterior compartment (bladder, urethra), the apical compartment (uterus, vaginal vault), or the posterior compartment (rectum, intestines). In about 20% of cases, apical prolapse is the dominant component.[5–7]

A significant apical POP presents a surgical challenge. Transabdominal sacrocolpopexy, either laparoscopic or robotic, is currently considered the reference standard for apical POP repair. Although the transabdominal approach is very effective, it requires laparoscopic or robotic skills, is more expensive, is not suitable for

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every patient, and may be associated with some abdominal and mesh complications. Transvaginal apical repair is an alternative to the transabdominal approach in cases where the abdominal surgical procedure is less desirable, mainly in women unsuitable for laparoscopic surgery. The most popular transvaginal procedures are utero-sacral ligament suspension (USLS) and sacrospinous ligament (SSL) fixation. Neither of these transvaginal techniques has proven to be more effective than the other.[5–7] Various surgical tools have been developed to manipulate the SSL; none have been proven safer than others.[5–9] Further, all transvaginal approaches require extensive dissection to access the SSL, and some include mesh implants. Following the US Food and Drug Administration warnings regarding vaginal mesh for POP surgery, vaginal mesh has been mostly abandoned.[10,13]

The EnPlace® (FEMSelect, Tel Aviv, Israel) is a novel, minimally invasive device for transvaginal SSL fixation of apical POP. This technique allows SSL fixation with no need for extensive dissection or mesh. The aim of the present study was to investigate the safety and short-term efficacy of EnPlace® SSL fixation for significant (stage III–IV) apical POP repair.

2 | MATERIALS AND METHODS

A retrospective cohort study was conducted in two university-affiliated medical centers from May 2019 to May 2022. The medical charts of 123 consecutive patients who underwent transvaginal SSL fixation by the EnPlace® device for significant (stage III–IV) apical POP were retrospectively reviewed. Demographic, clinical, intraoperative, and postoperative data were retrieved from a computerized database. Exclusion criteria for transvaginal SSL fixation by the EnPlace® device included reproductive tract anomalies, previous pelvic radiation therapy, malignancy, previous pelvic inflammatory disease, or a known allergy to nickel or nitinol. The study was approved by the Institutional Review Board.

The severity of the POP was assessed by a certified urogynecologist using the POP-Quantification (POP-Q) measurements and according to the standardized scoring system.[11] The POP-Q measurements comprise six distinct vaginal locations and three anatomical markers. The position of the six locations is measured in centimeters during a maximum Valsalva maneuver with regard to the hymen. Apical prolapse is represented by point C, the lowest part of the uterine cervix or the vaginal vault. The severity of the prolapse is classified as stage I–IV. Stage III–IV are considered as significant POP.

All 123 patients underwent SSL fixation of significant apical POP using the EnPlace® device. The device includes a finger guide built-in working channel (Figure 1), which enables transvaginal insertion and deployment of anchor and sutures into the SSL. A detailed description of the surgical technique and instrumentation was previously presented in 2016.[12] In patients with concomitant anterior and posterior POP and stress urinary incontinence, a native-tissue prolapse repair and mid-urethral sling

FIGURE 1 The EnPlace® device (with permission from FEMSelect).

were performed. The patients were divided into two sub-groups: 91 (74%) patients with stage III–IV uterine prolapse and 32 (26%) patients with stage III–IV vault prolapse. A comparison was made between the two sub-groups.

Follow-up assessment was carried out at 6 weeks, 3 months, and 6 months postoperatively. The postoperative evaluation included anatomical and functional cure rates, pain, dyspareunia, lower urinary tract symptoms, or other complications. Surgical success was defined as a combination of no POP symptoms, no observed apical POP beyond stage I, and no need for recurrent apical POP surgery or a vaginal pessary during the follow-up period.

Statistical analysis was performed using Student *t* test for continuous data, or Fisher's exact test for categorical data. Data are summarized as mean ± standard deviation (SD), or percentage, according to the variables. All statistical tests were two-sided, and a *P* value of less than 0.05 was considered statistically significant. SPSS

software, version 27 (IBM Corporation, Armonk, NY, USA) was used for the statistical analysis.

3 | RESULTS

One hundred and twenty-three consecutive patients (mean ± SD age 64.4 ± 11.1 years; range 42–84 years) with significant (stage III–IV) apical POP were investigated. Demographic and clinical characteristics of the patients were similar. Preoperatively, 91 (74%) patients had stage III or IV uterine prolapse, and 32 (26%) had stage III or IV vaginal vault prolapse. All patients underwent EnPlace® apical SSL fixation. Patients characteristics and surgical outcomes are presented in Table 1.

Of the 123 patients, 121 (98.4%) underwent concomitant colporrhaphies for cystocele and rectocele repair, 13 (10.6%) of whom also underwent mid-urethral sling. The mean duration of surgery was 30 ± 6.9 min (range 25–50 min), and the mean blood loss was 30.5 ± 18.5 mL (range 10–100 mL). There were no intraoperative or early postoperative complications. All patients were discharged on the day of surgery or the day after.

The average position of point C by POP-Q measurements before surgery was +4.5 ± 2.8 cm. The average position of point C at the end of surgery was −5.4 ± 0.7 cm. The average position of point C at 6 months postoperatively was −3.1 ± 3.3 cm.

Of 91 patients with preoperative uterine prolapse, eight (8.8%) patients developed a recurrent uterine prolapse during the 6 months of follow up, four of whom underwent a repeat surgical intervention, and four others had stage II asymptomatic uterine prolapse that did not require any intervention, neither conservative nor surgical. Of the 32 patients with preoperative vault prolapse, two (6.3%) patients had a recurrent vault prolapse and chose to be treated with a vaginal pessary. Seven patients (5.7%) developed recurrent stage II cystocele and/or rectocele within the 6-month follow-up period. No significant risk factors for failure of the procedure were identified.

Postoperatively, there were no de novo significant lower urinary tract symptoms, bowel symptoms, or dyspareunia. Five patients (4%) had a single episode of urinary tract infection during the follow-up period, none of whom had recurrent urinary tract infections. One patient (3.1%) underwent unilateral removal of an EnPlace® suture because of persistent pain. A median score of 87.3 was obtained on a scale from 0 to 100 when patients were asked at the last follow up whether their preoperative symptoms were improved.

4 | DISCUSSION

Transabdominal sacrocolpopexy, either laparoscopic or robotic, is considered as the reference standard for apical POP repair. However, this approach requires advanced laparoscopic skills and is more expensive and time-consuming. Furthermore, this approach requires general anesthesia and is, therefore, not suitable for every patient. Alternatively, transvaginal surgical approach can be used to repair apical POP; however, available procedures are associated with extensive dissection to expose pelvic structures.[5–9]

Until a few years ago, apical POP was frequently repaired by using synthetic transvaginal vaginal mesh implants. In 2019, the FDA reclassified transvaginal mesh as class III and banned the use of these products in the USA.[13] Moreover, the existing data do not confirm superior subjective outcomes with transvaginal mesh implants for POP treatment.[8] Transvaginal native tissue repair of apical POP is an attractive alternative to synthetic mesh implants. The two main transvaginal techniques are the USLS and the SSL fixation. The USLS procedure, compared with SSL fixation, carries a higher risk of ureteral kinking, especially in

TABLE 1 Patients characteristics and surgical outcomes.[a]

Characteristics	Total no. of patients (*N* = 123)	Uterine prolapse (*N* = 91; 74%)	Vault prolapse (*N* = 32; 26%)	*P* value
Age, years	64.4 ± 11.1	62.8 ± 12.6	66.8 ± 8.7	0.146
Parity	3.6 ± 1.9	3.3 ± 1.8	3.6 ± 2.2	0.301
Body mass index[b]	26.47 ± 2.99	26.85 ± 3.09	25.96 ± 3.28	0.148
Smoking	8 (6.5%)	4 (4.39%)	4 (12.5%)	0.149
Duration of surgery, min	32.8 ± 7.2	32.4 ± 7	33.7 ± 7.6	0.884
Blood loss, mL	30.5 ± 16.2	28.3 ± 15.6	35 ± 16.9	0.424
Point C, cm[c]				
Preoperative	+3. 9 ± 1.8	+4.1 ± 1.8	+3.4 ± 1.7	0.513
Postoperative	−5.4 ± 0.7	−5 ± 0.5	−5.5 ± 0.8	0.174
6-month follow up	−3.1 ± 3.3	−2.6 ± 0.6	−4.7 ± 2.9	0.029
Recurrent apical POP	10 (8.1%)	8 (8.8%)	2 (6.3%)	0.643

Abbreviation: POP, pelvic organ prolapse.

[a]Data are presented as mean ± standard deviation or as number (percentage).

[b]Body mass index is calculated as weight in kilograms divided by the square of height in meters.

[c]Point C (cm) is taken from POP-Quantification measurements.

patients with a concomitant significant cystocele.[14] Moreover, USLS is less effective in patients with vaginal vault prolapse. On the other hand, a significant disadvantage of transvaginal SSL fixation is the need for extensive dissection to approach the SSL. Both surgical techniques are associated with an increased risk of intraoperative bleeding and pelvic organ injury and require advanced surgical skills.[15]

The EnPlace® device was developed to optimize the technique and outcome results of SSL fixation for apical POP repair. It consists of two components: a nitinol anchor unit with a surgical suture and a delivery system. The delivery system facilitates the transvaginal insertion and deployment of the anchor into the SSL. Following the deployment of the anchor, the attached surgical suture enables the fixation of the uterine cervix, or vaginal vault, into the SSL. The insertion of the nitinol anchor into the ligament is precise and does not require extensive vaginal dissection.

In 2016, Tsivian et al.[12] demonstrated the feasibility of the EnPlace® device in animal and cadaver models. In 2017 Weintraub et al.[16] reported short-term outcome results of 10 patients who underwent EnPlace® SSL fixation for significant apical POP. Six months postoperatively, no cases of recurrent apical POP were noted, and there were no intraoperative or postoperative complications. The investigators concluded that EnPlace® SSL fixation is safe and effective. In 2021 Ben Zvi et al.[17] reported the long-term (42–57 months) outcome results of 13 patients who underwent EnPlace® SSL fixation for significant apical POP. A recurrent apical POP was noted among 7.7% of the patients during the follow-up period.

The present study investigated the short-term outcome results of 123 patients with significant apical POP who underwent EnPlace® SSL fixation. This is the largest series of patients published to date. Results of the study show that EnPlace® SSL fixation is safe and effective in patients with significant apical POP, either uterine prolapse or vaginal vault prolapse. Of 91 patients with preoperative uterine prolapse, eight (8.8%) patients developed a recurrent uterine prolapse during the 6-month follow up. Of 32 patients with preoperative vault prolapse, two (6.3%) had a recurrent vault prolapse. These rates are similar to the previously published long-term failure rates and are identical to failure rates associated with other SSL fixation techniques.[5–7] The postoperative position of point C by POP-Q measurements was significantly lower among patients with preoperative uterine prolapse versus patients with vaginal vault prolapse (−2.6 ± 0.6 vs. −4.7 ± 2.9 cm). This difference has no clinical implication, as evidenced by the same recurrent stage III or IV apical POP rate in both groups. The main disadvantages of the study include retrospective data assessment, lack of valid questionnaires and relatively short follow up. In addition, the women included in the study constitute a homogeneous group of patients who were operated on by experienced surgeons. It is possible that results may be different in other populations and/or with less skilled surgeons. The advantages of the study include a relatively large number of patients who underwent the procedure, strict follow up after the surgery, the absence of patients lost to follow up, and professional urogynecologic evaluation, including using the POP-Q measurements. Furthermore, in terms of cost-effectiveness, there is no doubt that a vaginal approach is more economical than a laparoscopic or robotic abdominal approach. Among the available vaginal approaches, EnPlace® SSL fixation does not require any mesh or deep dissection, so the surgery time is short and the rate of complications is low.

In conclusion, short-term outcome results of EnPlace® SSL fixation suggest that it is a safe and effective minimally invasive procedure for significant apical POP repair. By employing the EnPlace® device, SSL fixation can be performed easily and without extensive vaginal dissection or mesh. This approach is particularly valuable in high-risk patients, such as patients with contraindications to general anesthesia, patients with a high probability of adhesions in the abdominal cavity or pelvis, and patients for whom a transabdominal approach may pose technical difficulties. More studies are required to investigate the long-term outcome results of this procedure and to determine whether there are any predictive factors for postoperative success or failure.

AUTHOR CONTRIBUTIONS

Ronen S. Gold, Yoav Baruch, and Asnat Groutz contributed to the conception and design of the work, the acquisition, analysis, and interpretation of data for the work, and manuscript writing and editing. Menahem Neuman and Natalia Sumerov contributed to project development, data acquisition, and manuscript editing.

CONFLICT OF INTEREST STATEMENT

RSG, YB, NS, and AG have no conflict of interest. MN is the founder and Medical Director of FEMSelect.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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REFERENCES

1. Fritel X, Varnoux N, Zins M, Breart G, Ringa V. Symptomatic pelvic organ prolapse at midlife, quality of life, and risk factors. *Obstet Gynecol*. 2009;113(3):609-616.
2. Smith FJ, Holman CD, Moorin RE, Tsokos N. Lifetime risk of undergoing surgery for pelvic organ prolapse. *Obstet Gynecol*. 2010;116(5):1096-1100.
3. Boyles SH, Weber AM, Meyn L. Procedures for pelvic organ prolapse in the United States, 1979–1997. *Am J Obstet Gynecol*. 2003;188(1):108-115.
4. Jelovsek JE, Maher C, Barber MD. Pelvic organ prolapse. *Lancet*. 2007;369:1027-1038.
5. Geoffrion R, Larouche M. Guideline No. 413: surgical management of apical pelvic organ prolapse in women. *J Obstet Gynaecol Can*. 2021;43(4):511-523.e1.
6. Larouche M, Belzile E, Geoffrion R. Surgical management of symptomatic apical pelvic organ prolapse: a systematic review and meta-analysis. *Obstet Gynecol*. 2021;137(6):1061-1073.
7. Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Brown J. Surgery for women with apical vaginal prolapse. *Cochrane Database Syst Rev*. 2016;10(10):CD012376 Published 2016 Oct 1.
8. Maher C, Feiner B, Baessler K, Glazener CM. Surgical management of pelvic organ prolapse in women. *Cochrane Database Syst Rev*. 2010;4:CD004014. doi:10.1002/14651858.CD004014.pub4

9. Maher CF, Qatawneh AM, Dwyer PL, Carey MP, Cornish A, Schluter PJ. Abdominal sacral colpopexy or vaginal sacrospinous colpopexy for vaginal vault prolapse: a prospective randomized study. *Am J Obstet Gynecol*. 2004;190(1):20-26.
10. Reclassification of Urogynecologic Surgical Mesh Instrumentation Food and Drug Administration Executive Summary Gastroenterology-Urology Medical Devices Advisory Committee Panel February 26, 2016.
11. Bump RC, Mattiasson A, Bø K, et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *Am J Obstet Gynecol*. 1996;175(1):10-17.
12. Tsivian M, Weintraub AY, Neuman M, Tsivian A. Introducing a true minimally invasive meshless and dissection-less anchoring system for pelvic organ prolapse repair. *Int Urogynecol J*. 2016;27(4):601-606.
13. U.S. Food and Drug Administration. FDA takes action to protect women's health and orders manufacturers of surgical mesh intended for transvaginal repair of pelvic organ prolapse to stop selling all devices. Silver Spring, MD: FDA. 2019 Accessed July 17, 2019. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm636114.htm
14. Jackson E, Bilbao JA, Vera RW, Mulla ZD, Mallett VT, Montoya TI. Risk factors for ureteral occlusion during transvaginal uterosacral ligament suspension. *Int Urogynecol J*. 2015;26(12):1809-1814.
15. Pollak J, Takacs P, Medina C. Complications of three sacrospinous ligament fixation techniques. *Int J Gynaecol Obstet*. 2007;99(1):18-22.
16. Weintraub AY, Ben Zvi M, Yohay D, et al. Safety and short-term outcomes of a new truly minimally invasive mesh-less and dissection-less anchoring system for pelvic organ prolapse apical repair. *Int Braz J Urol*. 2017;43(3):533-539.
17. Ben Zvi M, Weintraub AY, Friedman T, Neuman M, Tsivian A. Minimally invasive meshless and minimal dissection ligament fixation system for apical organ prolapse procedures: a 4-year prospective follow up study. *Int J Gynaecol Obstet*. 2022;158(3):657-662.

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