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EnPlace®: A truly minimally invasive vaginal pelvic organ prolapse suspension with no deep dissection and no mesh, personal 581 operations experience

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ABSTRACT

Objectives: The aim of this study was to assess the clinical outcomes of safety and efficacy of a minimally invasive, meshless anchoring system-the EnPlace® SSL fixation for apical POP repair in 581 patients.

Materials and Methods: The patients follow-up exams and questionnaires were performed and completed first day after surgery, one and four months after. Anatomical and functional cure rates, post-operative complication rate and severity, as well as urine and bowel symptoms, post-operative pain and dyspareunia levels, were all used as outcome measures.

Results: The mean age of the study population (n=581) was 63.5±10.7 years. Fifty-two (9.9%) patients had a previous hysterectomy and 117 (22.3%) patients had urinary stress incontinence (USI) symptoms. All women had a prolapse in a minimum of two compartments and at least one compartment was at stage III. Preoperative C point pelvic organ prolapse (POP)-quantification showed a mean of 1.44 (-2-12). 99.2% of patients had concomitant anterior and posterior colporrhaphy. 20% of patients had an addition of a midurethral sling due to USI symptoms. POPs, USI and overactive bladder symptoms were all found to be reduced significantly. However, the prevalence of *de novo* dyspareunia among sexually active women was 1.7% (0.7% increase). The patient's satisfaction rates at the 4 months follow-up was 92.1%.

Conclusions: SSL fixation is made simple to execute with the EnPlace® device, which prevents mesh and dissection-related issues by allowing quick and a suspending suture being safely inserted through the SSL. The EnPlace® operation, done weather with or without concomitant colporrhaphy, produced positive objective and subjective results and low recurrence.

Keywords: Anchor; meshless; minimally invasive surgical procedure; pelvic floor disorders; prolapse; sacrospinous fixation

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INTRODUCTION

Pelvic organ prolapse (POP) is the term used to describe the descent of one or more pelvic structures, such as the uterus (including the cervix), the vaginal walls, or the vaginal apex (cuff scar or vaginal vault after hysterectomy). Mild POP would usually be asymptomatic, but if the bulge exceeds the vaginal entrance, it might significantly lower a woman's quality of life. The patients usually feel or palpate the vaginal bulge toward or through the vaginal introitus and suffer decline in body image, as well as impairment with urinary, defecatory, and sexual functions. Both non-surgical and surgical options should be provided to a woman who is troubled by the prolapse.[1] Up to 50% of women will experience POP in their lifetime.[2] Apical prolapse is the primary factor in 20% of instances,[3,4] and exists to some degree with up to 50% of POPs. A large apical POP makes surgery difficult. The current gold standard for apical POP repair is transabdominal sacrocolpopexy, whether open, laparoscopic, or robotic. Although the transabdominal method is very successful, it is more expensive, necessitates laparoscopic or robotic expertise, is not appropriate for all patients, because it requires general anesthesia and may result in certain abdominal and mesh-associated complications. In general, and especially in situations where the abdominal surgical method is less desirable, typically in women who are not candidates for laparoscopic surgery, transvaginal apical correction offers an excellent alternative to the transabdominal approach. Another surgical challenge is that the anatomic recurrence rates in women who have POP surgery are predicted to be between 8 to 27% within 2 to 7 years,[5] where vaginal reconstruction might be considered. The most important outcomes of POP treatment is now thought to be patient satisfaction, health-related quality of life and lower recurrence rate. These aspects prompted the development the minimally invasive surgical device for sacrospinous ligament (SSL) fixation of apical prolapse -the EnPlace® (FEMSelect, Modi'in, Israel), which allows SSL fixation with no need for deep pelvic dissection nor mesh implants. Due to recent FDA guidance recommendations restricting the use of mesh, which may increase the risk of severe adverse events in prolapse repair surgeries involving mesh, the EnPlace® device allows the surgeon to perform a centro-apical support procedure with reduced bleeding, no need for mesh implants, and only using anchors and suturing materials.[6] The aim of this study was to assess the clinical outcomes of safety and efficacy of the EnPlace® SSL fixation for apical POP repair in a large cohort of patients (581).

MATERIALS AND METHODS

The study was performed on a prospective cohort of females who had advanced POP. Informed consent was obtained from all patients. All ethics committee requirements were fulfilled.

Between January 2019 and April 2023, EnPlace® surgeries were performed by an experienced urogynecological surgeon (MN). A total of 581 patients who were diagnosed with advanced POP (according to POP-Q) and suffered from significant symptoms were enrolled in the study. The EnPlace® surgical device, designed for pelvic floor apical suspension has a working channel integrated into finger guide the that allows transvaginal anchor and suture placement into the SSL. This novel product is designed to provide apical central support for the vaginal vault or uterine cervix in patients with a central compartment defect who require suspension, without requiring mesh implants or transvaginal deep dissection. An anchor and a delivery system are the two primary components of the Enplace® device. The anchor element can be guided, inserted, and deployed through the delivery system. The anchor is composed of a nitinol harpoon with a sharp edge point that can be pierce through the vaginal and the SSL. The anchor is inserted and deployed beyond the medial segment of the SSL with the use of an applicator. The anchor includes two surgical stitches at its proximal end, allowing fixation of the uterine cervix or vaginal apex to carry out the intended goal of suspending the pelvic floor apex. The Finger Guide is an accessory to the device that enables precise placement of the introducer against the mid-SSL for better positioning of the Enplace®.

The diameter of the anchor penetration is 2.0 mm. Its wings spread to 4.0 mm once it is launched and passes through the SSL. In order to prevent damage, the working channel's rear stop, which is set at 17 mm, limits the anchor's penetration depth below the ligament. The gadget shaft measures 285 mm in length and 2.5 mm in diameter. The polypropylene suture has a length of 70 cm, and the self-adjusting work channel can accommodate a wide range of surgeon finger sizes. There are two hollow, concentric shafts in the applicator. The anchor wings can only be deployed to the extent allowed by the outer shaft. The inner shaft moves the anchor out of the way when the deployment button is depressed, enabling the wings to extend. The applicator is equipped with a safety latch that protects the button, to avoid undesired deployment.After deploying anchors into the midpoints of the right and left SSL, the distal, free ends of the sutures on both sides of the vagina are used to anchor the apex of the vagina bilaterally by making

a permanent stitch into the tissue of the cervix or vaginal apex. The anterior distal region aspect of the uterine cervix serves as the apical suspensory attachment point for the EnPlace® system in patients with their uteri *in situ*. The remaining uterosacral ligaments at the connection to the vaginal apex serve as the apical suspensory fixation point for the EnPlace® system in hysterectomized patients. A comprehensive description of the tools and surgical technique was released earlier in 2016.[7] Preoperative, site-specific vaginal examination using a Sim's speculum in the lithotomy position was carried out as part of the office pelvic examination while performing a maximal Valsalva maneuver. We staged and measured POP-Q in accordance with the International Continence Society (ICS) standard scoring methodology. Centroapical pelvic prolapse grade of POP-Q Stage II-IV, scheduled POP reconstructive surgery, and agreement to the POP operation with the EnPlace® device were the inclusion criteria for this study. Women who had been diagnosed with reproductive tract anomalies, had undergone pelvic radiation therapy in the past, had a history of pelvic inflammatory illness or pelvic cancer, or who were unable to give their informed consent or complete questionnaires were not enrolled in this study.

Native-tissue vaginal wall prolapse repair and sub midurethral sling were applied to individuals who had concurrent anterior and posterior pelvic floor compartment POP and/or urinary stress incontinence, accordingly.

The patients follow-up exam were performed immediately after surgery, one month and 4 months after. Questionnaires according to the study protocol were completed one and four months after surgery.

Postoperative pain and dyspareunia levels and duration, anatomical and functional cure rates, postoperative complication nature, severity and rates, and urinary and defecatory symptoms were all used as outcome measures.

Preoperative and postoperative detailed patient interviews were documented, focusing on pain, urinary and defecatory symptoms, dyspareunia, satisfaction, and adverse events. Preoperative and postoperative modified POP-Q scores (Ba, Bp, and C) were assessed and determined according to the compartment with the most advanced prolapse.

The absence of central compartment bulging subjective symptoms, together with the absence of objective anatomical prolapse beyond Stage I (1 cm proximal to the hymenal ring), and the necessity for subsequent surgery were considered as successful procedures.

Statistical Analysis

Preoperative and operative numerical data were presented with a combination of the following: Mean, median, range, standard deviation (SD). This included both discrete (parity), and continuous (patient age, POP-Q points, duration of surgery, and blood loss) data. Concomitant nominal categorical data was displayed via counts and percentages (concomitant procedures). Postoperative data included both categorical (ordinal and nominal) and numerical (continuous) data. Postoperative ordinal (patient satisfaction rating) and continuous (POP-Q points) data were represented with all of the following: Mean, median, range, SD, while the nominal data was shown with counts and percentages as well. Paired data was analyzed with paired t-tests for continuous variables, while McNemar's test was used for nominal variables; a two-sided *p*-value of 0.05 was regarded as significant.

Statistical analysis rendered the following paired, nominal data "extremely" significant by the McNemar test: USI and OAB, with both *p*-values <0.0001. The preoperative to postoperative number of patients with the symptom went from 117 to 12 and 152 to 32, respectively. Whereas the difference in the number of patients before and after with dyspareunia, bowel symptoms, and pelvic pain, were rendered not statistically significant.

Paired, continuous data analyzed with the paired t-test all resulted to be "extremely" significant, with the *p*-values for the POP-Q points of Ba, C, and Bp being less than 0.0001.

RESULTS

Between January 2019 and April 2023, 581 women underwent the EnPlace® procedure and were enrolled in the study. Fifty patients were lost to follow-up. Table 1. lists the initial preoperative patient characteristics of those who received an EnPlace® implant. The mean age of the study population at the time of the procedure was 63.5 SD ±10,7 years (range 32-92). Fifty-two (9.9%) patients had a previous hysterectomy and 117 (22.3%) patients had urinary stress incontinence (USI) symptoms. All women had a prolapse in a minimum of two compartments and at least one compartment was at a Stage III. The mean prolapse duration was 2.9 years. Preoperative C point POP-Q showed a mean (range) of 1,44 (-2-12). 99.2% of patients had concomitant anterior and posterior colporrhaphy. No injuries to the bladder, rectum, pudendal nerves, or major pelvic vessels were noted. 20% of patients had an addition of a midurethral sling due to USI symptoms, proven at preoperative site-specific vaginal examinations (Table 1).

The second, and third postoperative follow-up records were satisfactory in terms of subjective and objective success and adverse effects occurrence. Table 2 displays data on the POP-Q points C, Ba, and Bp at the follow-ups. The secondary outcome measures, including urinary, sexual, bowel, and pain

symptoms, and the subjective and objective success rates are shown in Tables 3 and 4. Urinary stress incontinence and bladder overactivity symptoms (namely urgency, frequency, and nocturia), were all found to be reduced significantly. Fecal incontinence, constipation, and pelvic pain rates were reduced as well. However, the prevalence of *de novo* dyspareunia among sexually active women was 1.7%, which is a 0.7% increase. Although bowel symptoms and pelvic pain frequency decreased overall, there were still 13 (2.5%) and 25 (4.8%) *de novo* cases, respectively (Figure 1).

An improvement in the apical defect was evident at the postoperative pelvic examination; the average POP-Q Ba point was -3 cm, Bp point was -3 cm, and C point was -5 cm, four months after the procedure (Figure 2).

There was a significant positive correlation between anatomical success and functional success, because the correlation

Table 1. Preoperative patient characteristics and concomitant procedures

Preoperative patient characteristics	**Mean**	**SD**	**Range**
Age (years)	63.5	±10.7	(32-92)
Parity (n)	3.3	±1.9	(0-17)
Point C (cm)	1.44	±2.52	(-2-12)
Point Ba (cm)	2.84	±1.67	(-3-6)
Point Bp (cm)	0.54	±1.32	(-2-12)
	Time	**Range**	
Prolapse duration (years, months)	2 years, 11 months	39 months, 11 months	
	Number	**Percentage**	**Total***
Previous hysterectomy (n)	52	(9.9%)	527
Prior TVT (n)	24	(4.6%)	526
Prior colporrhaphy (n)	22	(4.2%)	527
Prior POP reconstruction (n)	19	(3.6%)	527
USI (n)	117	(22.3%)	525
Dyspareunia (n)	5	(1.0%)	523
OAB (n)	152	(28.6%)	531
Bowel symptoms (n)	18	(3.4%)	525
Concomitant procedures			
Anterior colporrhaphy (n)	526	(99.2%)	530
Posterior colporrhaphy (n)	526	(99.2%)	530
Midurethral sling (n)	106	(20.0%)	530
	Mean	**SD**	**Range**
Duration of surgery (min)	23.94	±6.26	(15-60)
Blood loss (mL)	24.11	±6.34	(15-45)

*The total refers to the number of patients that had value at all in that category. E.g., 527 patients (out of 581 population) had a recorded value for the question of "previous hysterectomy". Fifty-two out of the 527 patients did indeed have a previous hysterectomy. SD: Standard deviation, TVT: Transmissible venereal tumor, USI: Urinary stress incontinence

Table 2. POP-Q points C, Ba, and Bp data at follow-ups

(Median, SD, range)	**1st follow-up**	**2nd follow-up**	**3rd follow-up**
C (Cm)	median -6, SD ±0.5 range -6-(-4)	median -6, SD ±1.1 range -7-4	median -5, SD ±1.5 range -6-3
Ba (Cm)	median -3, SD ±0.4 range -4-(-2)	median -3, SD ±0.6 range -4-1	median -3, SD ±1.0 range -6-4
Bp (Cm)	median -3, SD ±0.3 range -3-(-2)	median -3, SD ±0.4 range -4-0	median -3, SD ±0.8 range -6-3

SD: Standard deviation, POP-Q: Pelvic organ prolapse-quantification

coefficient is significantly different from zero (rpb=0.482, $p<0.05$). Anatomical successes have higher ratings, thereby functional successes do too.

The overall subjective and objective outcome results of this study are promising (average success rate after 1 Mo - 94.6% and 4 Mo - 92.1%). When asked if the patients' symptoms improved over their presurgical symptoms, the majority of patients expressed

Table 3. Postoperative functional outcomes of patients who underwent EnPlace surgery

Symptom	Number	Percentage	Total
De novo USI	12	(2.3%)	520
De novo OAB	32	(6.2%)	519
De novo dyspareunia	9	(1.7%)	519
De novo bowel symptoms	13	(2.5%)	520
De novo pelvic pain	25	(4.8%)	521

USI: Urinary stress incontinence, OAB: Overactive bladder

Table 4. Postoperative outcomes of patients who underwent EnPlace surgery

	Preoperative data			Postoperative outcomes			Calculations	
Symptom/POP-Q	Before (n)	Total	%	After (n)	Total	%	Δ (%)	Δ (n)
USI	117	525	22.3%	12	520	2.3%	20%	105
OAB	152	531	28.6%	32	519	6.2%	22%	120
Dyspareunia	5	523	1.0%	9	519	1.7%	-1%	-4
Bowel symptoms	18	525	3.4%	13	520	2.5%	1%	5
Pelvic pain	38	526	7.2%	25	521	4.8%	2%	13
Ba	426	525	81.1%	1	523	0.2%	81%	425
C	237	526	45.1%	3	523	0.6%	44%	234
Bp	110	526	20.9%	0	523	0.0%	21%	110

POP-Q: Pelvic organ prolapse-quantification, USI: Urinary stress incontinence, OAB: Overactive bladder

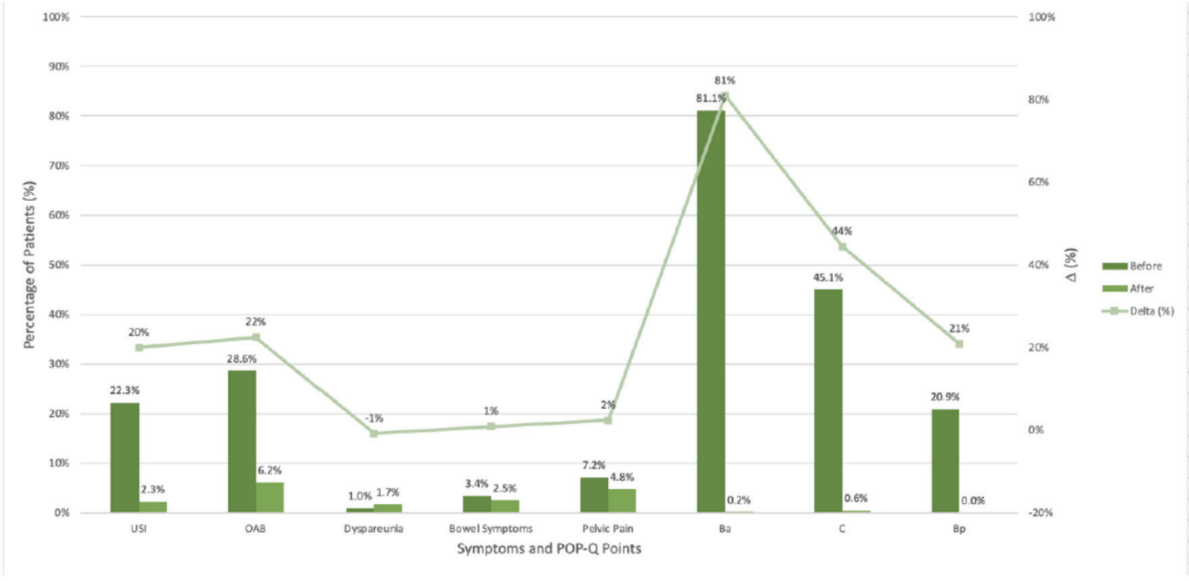

Figure 1. Postoperative functional results

POP-Q: Pelvic organ prolapse-quantification

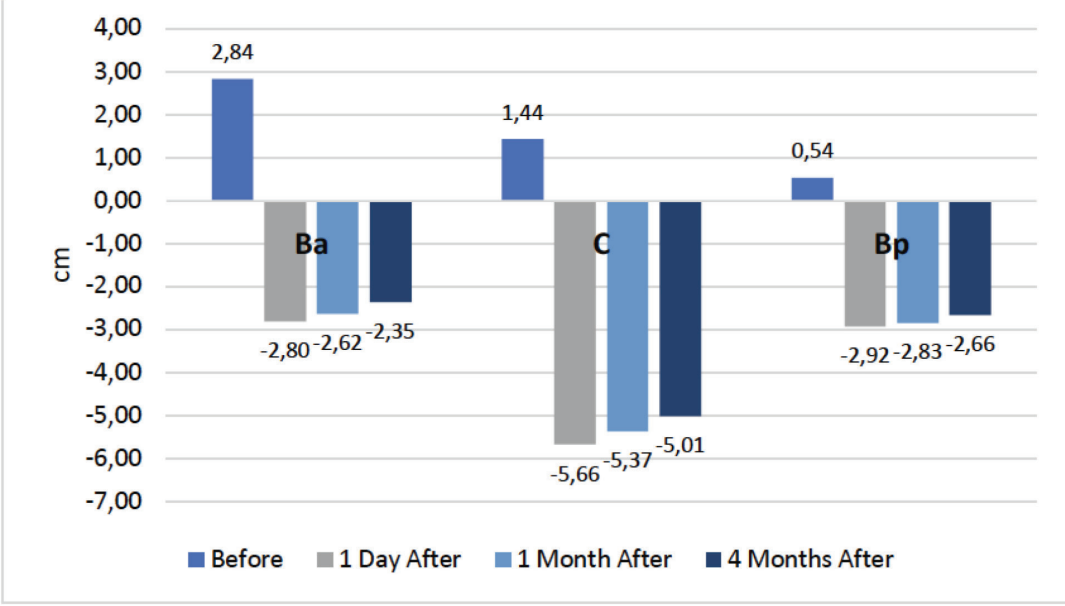

Figure 2. Postoperative anatomical outcomes of patients who underwent EnPlace surgery

Table 5. Patient satisfaction rates

Patient satisfaction	Mean	Range	SD
1 mo follow-up	94.6%	50-100%	±8.9%
4 mo follow-up	92.1%	50-100%	±11.6%

SD: Standard deviation

satisfaction with the surgery (on a scale of 50% = not at all to 100% = very much). Table 5 indicates that the women's quality of life increased.

DISCUSSION

The FDA's recommendation in January 2016 to reclassify surgical mesh for transvaginal repair of POP to the highest risk class of devices (class III) and the FDA's directive to the makers of all remaining surgical mesh products recommended for the transvaginal repair of POP to stop marketing and distributing their products in the United States by April 2019 were revolutionary in the surgical treatment of genital prolapse.[8,9] These facts served as driving forces to explore surgical methods to treat genital prolapse while refusing to use mesh implants. It is evident that each patient should receive personalized care while selecting the best surgical approach for treating POP. Transabdominal sacrocolpopexy, whether laparoscopic or robotic, is currently the gold standard for apical POP repair. Despite the fact that the transabdominal approach is very effective, it is more expensive, needs laparoscopic or robotic competence, is not suitable for all patients because it necessitates general anesthesia, and may lead to specific abdominal and mesh-related problems.[10]

Transvaginal apical correction offers an alternative to the transabdominal approach in circumstances where the abdominal surgical approach is less acceptable, usually in women who are not candidates for laparoscopic surgery. When treating prolapse surgically, the goal should be to fix the vaginal defect if the patient is sexually active and the surgeon prefers a vaginal approach. The vagina is frequently used for apical prolapse repair surgery using the SSL to anchor support of the vaginal apex, as the vagina is often considered the natural orifice for POP reconstruction. Transvaginal SSL fixation has several drawbacks, among them are the need for mesh implants to reinforce the suspension and the extensive dissection required to reach the SSL. The risk of intraoperative hemorrhage and pelvic organ injury is increased by such surgical procedures.The purpose of this study is to describe our post-operative results and the efficacy of apical prolapse repair utilizing a unique pelvic floor ligament fixation system called the EnPlace® system, which is intended to offer a less invasive and minimal dissection approach to the SSL. The results demonstrate the safety, efficacy, and high success rate of this centro-apical POP repair procedure. The anatomical findings, together with the patient satisfaction and quality of life scores, were all positive.

Since there were no intraoperative difficulties, the procedure was determined to be safe and practicable in terms of safety. Additionally, the EnPlace system's efficacy and safety have already been proven in a meticulously methodical cadaver and animal study. The long-term results of this technique with a four-year follow-up were also published in 2021. It is safe, practical, and effective to use the EnPlace method for vaginal SSL fixation

surgery to treat apical POP. Given the difficulties in repairing the apical compartment during POP reconstruction, a device's safety and viability are especially crucial.

The EnPlace® technology allows for the safe and speedy insertion of a suspending suture via the SSL, therefore simplifying and expediting SSL fixation without the need for dissection or a mesh implant. The study's main drawbacks are that it is a one-arm assessment with no control group and a rather little follow-up time. One of the study's strengths is its sizable cohort of 581 patients. An additional benefit of the current study is the assessment of validated QoL questionnaires and self-reported, patient-centered outcomes.

CONCLUSION

The limitations of this study include its single-arm design, short follow-up period, and lack of use of valid questionnaires. But in conclusion, SSL fixation is made simple to execute with the EnPlace® device, which prevents mesh and dissection-related issues by allowing quick and safe insertion of a suspending suture through the SSL. The EnPlace® operation, done weather with or without concomitantcolporrhaphy, produced positive objective and subjective results and low recurrence. The EnPlace® approach may be a useful option for patients who need apical suspension and wish to avoid complications related to mesh augmentation, deep surgical dissection, or more invasive transvaginal or abdominal surgeries for POP repair.

ETHICS

Ethics Committee Approval: As we mentioned on the cover letter, being a retrospective study, based upon an anonymous data base privately owned by the acting surgeon, the hospital ethics committee approval is not required.

Informed Consent: Informed consent was obtained from all patients.

Peer-review: Internally and externally peer-reviewed.

Contributions

Surgical and Medical Practices: R.F-K.; Concept: N.S., R.F-K., M.N.; Design: N.S.; Data Collection or Processing: J.N., S.F.S.; Analysis or Interpretation: J.N., M.N.; Literature Search: N.S.; Writing: N.S.

DISCLOSURES

Conflict of Interest: M. Neuman is a founder and share holder of FEMSelect.

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