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CLINICAL ARTICLE

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Minimally invasive meshless and minimal dissection ligament fixation system for apical organ prolapse procedures: A 4-year prospective follow up study

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Abstract

Objective: EnPlace™ (formerly named NeuGuide™) is a minimally invasive meshless anchoring system for pelvic organ prolapse (POP) repair designed to provide centro-apical pelvic floor support. We present a 4-year prospective follow up evaluation of this repair system.

Methods: This was a single-center longitudinal prospective study of women with advanced POP who underwent pelvic floor apical repair using EnPlace™ with at least 4 years of follow-up. The primary outcome was surgical success defined as anatomical success, no symptoms of vaginal bulging and no need for re-treatment. A standardized validated questionnaire to assess symptom burden was used.

Results: Fifteen women were enrolled in the study. Two patients were lost to follow-up. The median follow-up was 51 months (range 42–57) with a surgical success rate of 92.3%. One patient (7.7%) reported symptoms of vaginal vault prolapse and underwent a repeated prolapse surgery. Using the UDI-6 questionnaire, an improvement in all domains was seen.

Conclusion: The 4-year prospective follow up suggests that apical repair using the EnPlace™ device may be considered safe and effective for sacrospinous ligament fixation with a sustainable long-term success. This procedure is a minimally invasive meshless addition to pelvic surgeon's armamentarium.

KEYWORDS

anchor, meshless, minimally invasive, pelvic organ prolapse, sacrospinous fixation

1 | INTRODUCTION

Pelvic organ prolapse (POP) is a common condition associated with a significant impairment in overall quality of life (QoL) that often necessitates surgical repair.[1] Many women will undergo a surgical repair to treat POP, some studies show the odds of a women to undergo surgery for POP during her life are between 11%–19%.[1-3]

Centro apical prolapse is the descent of the uterus, cervix or vaginal vault into the lower vagina either above or below the hymeneal ring. Loss of apical support is typically found in women with symptomatic Stage II prolapse or greater, according to the Pelvic Organ Prolapse Quantification system (POP-Q).[4-6]

Women may present with single compartment compromise (anterior, posterior or apical prolapse) or with a combination of

symptoms and compromise of multiple compartments simultaneously. Good vaginal apical support plays an important role in a long-lasting treatment for advance prolapse.[7] More so, repair of the anterior and posterior walls may fail unless the apex is supported appropriately.[8]

There is a plethora of repair procedures for POP; suggesting that no one procedure has proven itself above the others.[9,10] Sacrospinous ligament fixation (SSLF), first described by Richter,[11] is among the most common surgical techniques to support the apex. In this procedure, the sacrospinous ligament (SSL) is used as an anchoring site for vaginal vault suspension. Transvaginal SSLF has a shorter procedural time, fewer complications, faster return to daily routines and is less expensive than sacrocolpopexy.[12] Moreover, the vaginal approach facilitates the repair of coexistent defects, such as cystocele, rectocele or urinary incontinence. Because uterosacral ligament (USL) fixation requires advanced surgical training and an intimate understanding of pelvic anatomy, SSLF is usually preferred over USL anchoring.[13] That said, anchoring or placement of the fixation sutures to the SSL transvaginally deep within the pelvis in the restricted target area of SSL fixation is technically challenging and potentially dangerous.

In fact, many surgical tools for SSL anchoring or suture placement have been tested and marketed, but none has proved to be better than the others.[14-20] These methods all require wide dissection of the vaginal wall in order to access the SSL safely. Several SSLF techniques may include mesh implants, though recent FDA guidance recommends restricting use of mesh, since prolapse repair surgeries involving mesh may have an increased risk of severe adverse events.[20] We previously published evidence demonstrating the biomechanical properties, feasibility and potential advantages of a new fixation system- EnPlace™ (previously named NeuGuide™) - as well as safety and short-term outcomes when the EnPlace™ device was used for minimally invasive SSLF of the apex of the vagina.[21,22] The EnPlace device permits the surgeon to perform a centro-apical support procedure without the need for deep pelvic dissection, reduced risk of bleeding and no mesh implants using just anchors and suturing materials. We reported encouraging short-term anatomical and functional results. This anchoring device provides a truly minimally invasive, minimal dissection approach to pelvic floor procedures. The durability and patient satisfaction of a new approach to pelvic floor repair must be proven. This study examines the impact on anatomical and quality of life outcomes of the EnPlace™ device for centro-apical support of the vagina in the setting of Stage II POP or greater prolapse.

2 | MATERIALS AND METHODS

A prospective longitudinal study of women with advanced POP was conducted. The study was approved by the local ethics committee and institutional review board approval, and informed consent was obtained from all patients. Surgeries were carried out between November 2014 and August 2015 by two experienced surgeons specializing in Urogynecology in Wolfson Medical Center.

Ten patients were enrolled in a previous pilot study,[22] additional five patients were enrolled later (total study population = 15). The EnPlace device was implanted in all 15 patients.

A total of 15 patients who were diagnosed with recurrent Stage III centro-apical prolapse (according to POP-Q) and suffered from significant symptoms were enrolled in the study. Age range was 40–85 years. Office examination and pelvic examination were performed, which involved site-specific vaginal examination in the lithotomy position with a Sim's speculum during a maximal Valsalva maneuver. POP-Q measurements and staging were performed according to the standardized International Continence Society (ICS) scoring system.[6] Inclusion criteria included: centro-apical prolapse grading of POP-Q Stage III with planned POP surgery and consent to the POP surgery using the EnPlace™ device. Surgical discretion was used regarding concomitant repairs of additional pelvic floor disorders, namely - colporrhaphies. Patients agreed to return for follow-up exam and to complete questionnaires according to the study protocol. Women with a diagnosis of reproductive tract anomalies, prior radiation therapy to the pelvis, any malignancy, or a significant history of previous pelvic inflammatory disease, a known allergy to nickel or nitinol were excluded, as were women unable to complete written questionnaires.

Follow-up assessment was carried out at 4–6 weeks, 3 months and 6 months. The UDI-6 score and PISQ-12 were completed at all follow-up visits. All women who underwent an EnPlace™ system procedure, at least 42 months prior, were invited to attend a follow-up visit. These occurred between 02/19 and 08/19 (study period). The postoperative evaluation protocol was similar to the preoperative evaluation.

Outcome measures included anatomical and functional cure rates, post-operative pain and dyspareunia levels, urinary symptoms and post-operative complication rates. Data were collected prospectively and included demographic features and validated PFD related quality of life (QoL) questionnaires (Urogenital Distress Inventory UDI-6 and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire PISQ-12). Modified POP-Q scores (Ba, Bp, C and D) were measured pre-operatively and at each follow-up visit. Stage of prolapse was defined according to the compartment with most severe prolapse. Success of the procedure was defined as a combination of no central compartment bulge symptoms, no prolapse beyond Stage I (1 cm proximal to the hymenal ring), and no need for additional surgery.

2.1 | Device description and surgical technique

EnPlace™ (previously named NeuGuide) was described in detail in previously published preclinical and pilot studies.[20,21] EnPlace™ device comprises two main elements: an anchor inserter connected to a Prolene suture and a finger guide delivery system (Figure 1). Since its introduction, The EnPlace device has received both FDA clearance

FIGURE 1 The EnPlace™ system

and CE marking (appendix). The delivery system enables the guidance, insertion, and deployment of the anchor element. The sharp point of the Nitinol anchor (permanent material) enables piercing of the vaginal wall and the ligament. The anchor is implanted using the inserter as a guide and depth gauge. The system has separate right and left finger guides and is designed to be used bilaterally. Each finger guide is used to introduce and place the anchor. The anchor penetration diameter is 2.0 mm. Once deployed, the flexible wings open to 4.0 mm. The finger guide inserter length is 120 mm (this way the anchor penetration depth beyond the ligament is limited to avoid injury). The inserter shaft diameter is 2.5 mm and its length 285 mm. The suture length is 70 cm and the finger guide is designed to fit all sizes (self-adjusting). The inserter includes two concentric hollow shafts. The outer shaft constrains the anchor wings from being deployed. Once the deployment button is pressed, the inner shaft pushes the anchor distally to exit the inserter allowing the wings to be opened. The inserter is equipped with a trigger latch that prevents the button deployment until it is engaged. The steps of the procedure are described in Table 1. Following deployment of anchors into the midpoints of the right and left SSL, the distal, free ends of the sutures on the right and left sides of the vagina are used to anchor the apex of the vagina bilaterally by a permanent stitch into the adnexal tissue of the cervix. With patients having their uteri in situ – the apical suspensory fixation point for the EnPlace™ system is the anterior distal area aspect of the uterine cervical cervix. With hysterectomized patients, the apical suspensory fixation point for the EnPlace™ system is the remnants of the uterosacral ligaments, at the attachment to the vaginal apex. Figure 2 is X-ray showing the anchors and their relations in the pelvis.

TABLE 1 Preoperative demographic and clinical characteristics of 15 patients who underwent EnPlace™ surgery

Characteristics	N = 15
Age	65.4 (48–82)
BMI	25.2 (23–30)
Previous hysterectomy	6
SUI	2
POP stage 3	15
Point C/D POPQ median (range)	3 (2–4)
Central compartment prolapse stage ≥3	15
Cystocele stage ≥2	11
Rectocele stage ≥2	10
Enterocele stage ≥2	0
Concomitant procedures	
Anterior colporrhaphy	11
Posterior colporrhaphy	10
MUS	0

Abbreviations: MUS, Midurethral sling; POP, Pelvic organ prolapse; POPQ, Pelvic organ prolapse quantification system; SUI, Stress urinary incontinence.

Values are presented as mean ± SD, median and range or number of women.

2.2 | Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS, software version 22.0; IBM Corp., Armonk, NY, USA). Continuous variables with normal distribution were presented as mean ± SD. Ordinal variables were presented as median and range. Categorical data were shown in counts. Statistical analyses were completed using the Wilcoxon test, and a two-sided *P*-value of <0.05 was considered significant.

3 | RESULTS

Fifteen women were enrolled in the study upon implantation with EnPlace between November 2014 and August 2015. Two patients

were lost to follow-up. Baseline pre-operative patient characteristics who were implanted with EnPlace™ are presented in Table 1. The mean age of the study population at the time of the procedure was 65.4 years (range 42–82). Six patients had a previous hysterectomy, and two had stress urinary incontinence (SUI) symptoms. All women had prolapse in a minimum of two compartments and at least in one compartment was Stage III. Pre-operative C point (when the uterus was intact)/D point POP-Q showed a median (range) of 3 (2–4). Eleven patients had a concomitant colporrhaphy performed and no injuries to the bladder, rectum, pudendal nerves or major pelvic vessels were noted (Table 1). At 4 year follow-up, only one of the 13 patients had had further colposacropexy for recurrence of apical prolapse giving a surgical success rate of 92.3% (Table 2).

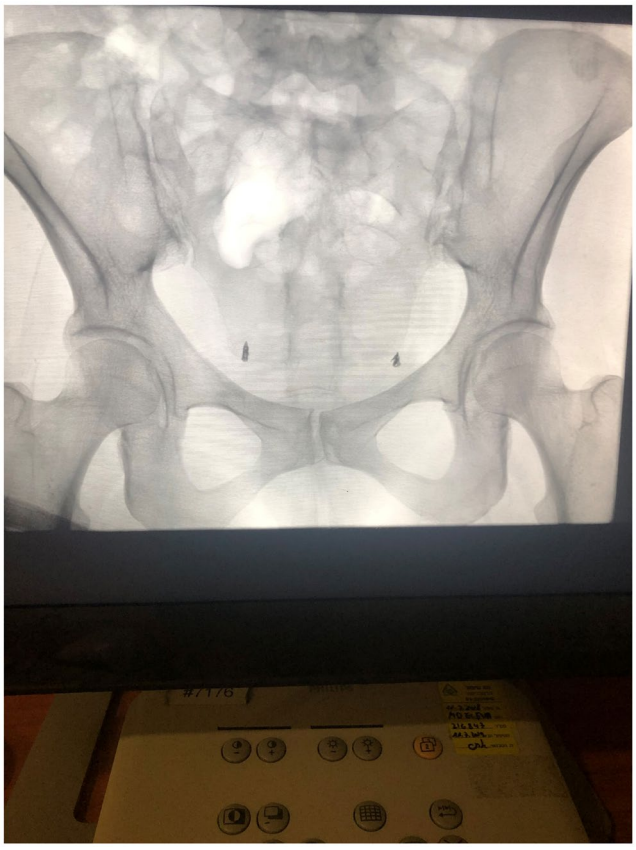

FIGURE 2 X-ray of the anchors and their relations in the pelvis

This occurred during the early post-operative period and was reported previously.[22] Three patients required subsequent prolapse surgery for cystocele (Table 3). An improvement in the apical defect was evident during the gynecological examination for all of the women (median point C/D POP-Q score was −6 post-procedure). Two additional patients had a mild cystocele, and one had mild uterine prolapse, all suffered mild symptoms, and thus refused further interventions.

Patients were satisfied with the procedure. When asked whether the symptoms improved compared to presurgical symptoms, a favorable score of median 88.75 was obtained (on a scale of 0 = not at all to 100 = very much) (Table 3). Quality of life improved for the women as shown by the improvement in the urogenital distress scores of the UDI-6 standardized questionnaire ($P = 0.002$).

We were not able to adequately assess the rate of dyspareunia among the patients due to an overall low number of sexually active patients. However, no cases of de novo pelvic pain were reported. In addition, no new onset of bowel symptoms was noted.

4 | DISCUSSION

While there are many options for treatment of apical prolapse surgically, there has yet to be conclusive evidence on a specific repair that surpasses others in its benefit/risk profile (8,10). Until several years ago, mesh was frequently used for apical prolapse repair. In January 2016, the FDA completed its reclassification of surgical mesh for transvaginal repair of POP to the highest risk class of devices (class III), followed by FDA ordering the manufacturers of all remaining surgical mesh products indicated for the transvaginal repair of pelvic organ prolapse (POP) to stop selling and distributing their products in the U.S. in April 2019.[15,20] The current recommendations of the American College of Obstetricians and Gynecologists and the American Urogynecologic Society are for judicious use of mesh implants, i.e., reserved for high-risk and

TABLE 2 The steps of the EnPlace™ device surgical procedure

1	The EnPlace™ finger guide is mounted on the right index finger, and introduced into the vaginal cavity
2	The right ischial spine and the SSL are palpated through the vaginal wall
3	The index finger is stabilized intimately to the mid SSL
4	The anchor is deployed, and adequate pull-out force is proven
5	A 1 cm longitudinal shallow and high mucosal incision is made at the posterior vaginal wall
6	The anchor's suture is mounted on a virgin needle
7	The suture is passed backwards through the vaginal wall at its entering point, under the vaginal wall, then through the cervical istmus and out to the vaginal cavity again through the posterior colpotomy
8	The previous steps are repeated on the left side and the suture is tied appropriately
9	The small posterior vaginal incision is closed

Abbreviation: SSL, Sacro-spinous ligament.

TABLE 3 Postoperative outcomes of patients who underwent EnPlace™ surgery

Characteristics	*N* = 13 (2 lost to F/U)
Point C/D POPQ	−6 range (1/−7)
De Novo chronic pelvic pain	0
De Novo SUI	0
De Novo urge incontinence	1
Bowel symptoms	0
Recurrent apical prolapse – repaired with CSP	1
Cystocele repair	3
TVT	1
Patient's Satisfaction	88.75% (1 = low 100 = excellent)

Abbreviations: POP, Pelvic organ prolapse; POPQ, Pelvic organ prolapse quantification system; SCP, Sacrocolpopexy; SUI, Stress urinary incontinence; TVT, Tension free vaginal tape insertion.
Values are presented as median and range or number of women.

selected patients only.[15,20] The FDA recommendations reinforce concerns regarding potentially serious complications when mesh is used during POP repair surgeries. Moreover, there are no data confirming superior subjective outcomes with mesh implants as treatment for POP. Therefore, other solutions such as the EnPlace™ system are in order.

POP is common and frequently necessitates surgical repair. The appropriate surgical method of POP treatment should be tailored to the individual patient. If a vaginal approach is preferred by the patient or by the surgeon, and the patient is sexually active, then correction of the vaginal defect should be a goal of the surgical treatment of prolapse.[23,24]

Vaginal preservation has traditionally been accomplished with SSLF or other vaginal procedures such as uterosacral ligament suspension (USLS). USLS may be easier to perform than SSLF with less risk of hemorrhage or infection, but it also carries a higher risk of ureteral injury especially in patients with concomitant anterior colporrhaphy.[25] Moreover, USLS is less efficient in patients with post-hysterectomy vault prolapse.

For many surgeons, the vagina is the natural orifice for POP reconstruction, and this approach is commonly used for apical prolapse repair surgery using SSLF to anchor support of the vaginal apex. One major disadvantage of open, transvaginal SSLF is the wide and deep dissection needed to approach the SSL. Such surgical steps increase the risk of intra-operative bleeding and pelvic organ injury.[23]

In this study, we report our four-year post-operative outcomes of apical prolapse repair using a novel device – the EnPlace™ system – a pelvic floor ligament fixation system designed to provide a minimally invasive and minimal dissection approach to SSLF. The results reflect a high success rate and safety and effectiveness of this centro-apical POP repair procedure after 4 years.

Only one of the patients had recurrent apical prolapse at the 4 year-follow-up, however three others needed reoperation for prolapse in other compartments. Patient satisfaction and QoL scores as well as the anatomical results were favorable.

With regard to safety, it was previously shown that there were no intraoperative complications thus the procedure was found to be safe and feasible.[22] In addition, safety and efficacy of the EnPlace system were previously demonstrated in a methodologically meticulous cadaver and animal study.[21]

The EnPlace™ approach to the surgical treatment of apical POP by vaginal SSLF is safe, feasible and efficient. Safety and feasibility of a device are particularly important given the complexities involved in the repair of the apical compartment during POP reconstruction.

The EnPlace™ system allows rapid and safe introduction of a suspending suture through the sacrospinous ligament and makes SSLF easy and fast to perform without the need for dissection or mesh implant.

The primary limitations of the study include that it is a small, single-arm evaluation with no control group. Another limitation is the fact that all 15 procedures were completed by two surgeons (MN and AT) who are experts in pelvic floor surgery. However, since the procedure was new at the time, and therefore new to both MN and AT, it is unlikely that the surgeon's experience impacted the results.

The strengths of the study include medium to long term follow-up and the prospective design allowing comprehensive data collection. The evaluation of self-reported patient-centered outcomes and validated QoL questionnaires is another advantage of the current study.

In summary, the EnPlace™ device, which allows rapid and safe insertion of a suspending suture through the SSL, makes SSLF easy to perform, while avoiding dissection and mesh complications. In the medium to long-term, the EnPlace procedure performed in concert with colporrhaphy demonstrated low recurrence rates and favorable objective and subjective outcomes.

The EnPlace procedure may be appropriate for patients who need to undergo apical suspension and wish to avoid complications from mesh augmentation, deep surgical dissection, and more invasive transvaginal or abdominal surgeries for POP repair.

CONFLICTS OF INTEREST

Menahem Neuman is Founder and Medical Director of FEMselect. Other Authors: The authors have no conflicts of interest to declare that are relevant to the content of this article.

AUTHOR CONTRIBUTIONS

M. Ben Zvi, MD- Project development, Manuscript writing/editing. A.Y. Weintraub- Data analysis and project development. T. Friedman - Project development and Data collection. M. Neuman- Data collection or management, Data analysis, Project development. A. Tsivian- Data analysis, Manuscript writing/editing.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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