How I Do It: EnPlace sacrospinous ligament fixation

Bilal Chughtai, MD,[1] Alia Codelia-Anjum, BA,[1] Dean S. Elterman, MD,[2] Nirmala Pillalamarri, MD,[1] Vincent Lucente, MD[3]

[1]Department of Urology, Northwell Health, Manhasset, New York, USA
[2]Division of Urology, University of Toronto, Toronto, Ontario, Canada
[3]Institute for Female Pelvic Medicine and Reconstructive Surgery, Axia Women's Health, Allentown, Pennsylvania, USA

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Pelvic organ prolapse (POP) is a common condition that significantly impairs a woman's quality of life. Currently a range of interventions from non-surgical to surgical options exist, all with their unique advantages and disadvantages. Among these, the EnPlace system stands out as a truly minimally invasive transvaginal percutaneous device designed to repair apical POP by bilaterally anchoring sutures to the sacrospinous ligaments. Readers will familiarize themselves with the EnPlace, relevant historical studies, and the technique for EnPlace transvaginal percutaneous sacrospinous ligament fixation for hysteropexy or colposuspension.

Key Words: pelvic organ prolapse, EnPlace system, minimally invasive transvaginal device

Introduction

Overview of procedure/technology

EnPlace (FEMSelect, Tel Aviv, Israel) is a minimally invasive transvaginal device CE marked for the repair of apical pelvic organ prolapse (POP) and FDA 510(k) cleared for attaching sutures to ligaments of the pelvic floor.[1] The device allows for a meshless and dissection-less approach for sacrospinous ligament (SSL) fixation. It is made up of three parts: a delivery system, a pre-loaded anchor-suture unit, and a finger guide. The delivery system, or applicator, features a single-hand-operated, cylindrical stainless-steel shaft. This shaft, upon alignment and subsequent insertion within the sacrospinous ligament complex, allows for the deployment and securement of a pre-loaded anchor-suture unit within the targeted safe zone (middle third, lower half) of the muscle ligament complex. The anchor is made from nitinol, a shape memory alloy composed of nickel and titanium. Upon ejection from the applicator tip (by depressing the anchor deployment button), the anchor's "spurs" spring open on both sides, securely fastening it to the ligament and preventing dislodgement or "pull-out". The anchor is connected to a polypropylene-monofilament suture, which becomes accessible upon retrieval of the applicator. The system allows for precise suturing and fixation of the prolapsed cervix or vaginal vault apex. The device also incorporates a finger guide, which is worn on the surgeon's index finger, coupled with a working channel. The guide

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Address correspondence to Dr. Bilal Chughtai, Department of Urology, Northwell Health, 8 Greenfield Road, Syosset, NY 11791 USA

facilitates the guidance of the applicator tip based on palpation of the desired target location with the index finger, enhancing precision and control during the procedure. The guide is ergonomically tailored for both right and left placement.

Relevant historical studies

In an initial 2016 study aimed to assess the EnPlace (previously NeuGuide) device's efficacy and safety in SSL fixation,[2] pull-out forces of the anchors were tested in both porcine and cadaveric SSL, with mean forces exceeding 20 N. Functionality tests confirmed device reliability without malfunctions. In cadaveric trials, real-time palpation ensured safe deployment and fixation of anchors without damaging adjacent structures. Results indicated comparable performance between porcine and cadaveric ligaments and between different cadaver specimens, validating device feasibility and safety for potential clinical use. The study demonstrated successful deployment and fixation of anchors into sacrospinous ligaments, with no observed device malfunctions, and ensured safe percutaneous access to the ligaments without causing damage to surrounding structures.

In a prospective pilot study utilizing the EnPlace device for pelvic floor apical repair, Weintraub et al reported significant improvements in all UDI-6 domains at 6-month follow up, particularly in urge and overflow incontinence, which were statistically significant.[3] The study included 10 patients (average age 63.8 ± 12.0 years), all with prior prolapse surgery, and concurrent procedures were performed in six patients. No intraoperative complications or significant postoperative adverse events occurred, and there were no observed recurrences of prolapse or reported subjective related symptoms. The patients themselves expressed satisfaction with the procedure. The device demonstrated procedural efficacy in safely and effectively facilitating SSL fixation, thereby minimizing complications associated with traditional dissection and/or transvaginal mesh use.

In a retrospective cohort study of 123 patients (mean age 64.4 ± 11.1 years) with stage III or IV apical POP, Gold et al assessed the safety and short term efficacy of SSL fixation using the EnPlace device.[4] Among the cohort, 91 (74%) had uterine prolapse and 32 (26%) had vaginal vault prolapse. The procedure had no intraoperative or early postoperative complications, with mean surgery duration of 30 ± 6.9 min and mean blood loss of 30.5 ± 18.5 mL. Preoperative and 6-month postoperative POP-Q measurements of point C showed improvements from 4.5 ± 2.8 cm to −3.1 ± 3.3 cm, respectively. Recurrence rates within 6 months postoperatively were 8.8% for uterine prolapse (8 out of 91 patients) and 6.3% for vault prolapse (2 out of 32 patients). Only 10 patients required surgical reintervention within 6 months postoperatively.

In a single-center longitudinal prospective study, women underwent apical POP repair, with a minimum 4-year follow up.[5] The primary outcome, surgical success defined as anatomical success without symptoms of vaginal bulging or need for re-treatment, was achieved in 92.3% of patients. One patient (7.7%) required repeat prolapse surgery due to symptoms of vaginal vault prolapse. Symptom burden, assessed using the validated UDI-6 questionnaire, showed improvement across all domains. Results at the 4-year follow up visits demonstrated sustained success, with no de novo pelvic pain or bowel symptoms noted, affirming the EnPlace device as a safe, effective, and durable meshless option for SSL fixation in pelvic floor surgery.

Method and technique

Patient assessment

Prior to surgical intervention, a thorough evaluation of POP is to be performed. This is typically assessed through medical history, physical examination, and patient symptom assessment questionnaires. A careful focused pelvic examination follows, where the provider will inspect the vaginal support in the anterior apical and posterior segments and assess the degree of apical prolapse. This most often involves the patient bearing down and/or coughing to demonstrate the full extent of the prolapse. Vaginal prolapse is assessed using the POP-Q system, where specific points and segments on the vaginal wall are measured while the patient is in the semi-lithotomy position.

Patient preparation

Intravenous antibiotics are given prior to the start of the procedure. More often general anesthesia is not required. In the operating room, after the induction of adequate anesthesia, the patient is placed in the dorsal lithotomy position, prepped and draped in standard surgical fashion in the operating room after the induction of adequate anesthesia. All patients undergo mechanical prophylaxis for DVT.

Device use/procedural steps

Step 1: First, clearly identify the three referenced landmarks: ischial spine, sacrospinous ligament, and sacral edge with just the index finger (single glove). Then with the index finger within the guide determine the anchor target zone (middle third lower half of the

muscle ligament complex). Deployment of anchors should ideally be with the delivery applicator held at an angle of 45 degrees to achieve optimal penetration into the ligament.

Step 2: Using the device, insert the anchor delivery system into the finger guide. Apply force to compress (finger pressure within guide), penetrate (advance stainless-steel shaft to stop point), and deploy (finger depress deployment button) anchors into the sacrospinous muscle ligament complex. Apply traction to suture to ensure anchor is firmly within SSL complex. Place an allis clamp on the anterior cervical lip and expose the cervix to determine where to make the cervical incision (1 cm proximal to the allis clamp).

Step 3: At the determined demarcation, infiltrate a local anesthetic to create a full thickness hydro dissection into the vesical-cervical space. Make a cervical incision (2-3 cm) mimicking the "hood of a car" using a Bovie cautery on a cut modem to minimize bleeding.

Step 4: Using Metzenbaum scissors, press flatly along the anterior aspect of the cervical stroma with a push and spread technique to identify the pericervical ring of the cervix. A total of four suture passes, two on each side is performed by using a ½ circle taper point mayo needle, re-enter the suture puncture site on each side of the cervix. Individually thread each suspension suture onto the needle, then pass back through the vaginal wall via the puncture hole, then traversing behind the vagina pierce up through the full thickness of the cervical stroma, creating a 4-point fixation.

Step 5: The 4-point fixation should ideally have a high suture and a low suture on each side to evenly distribute the biomechanical load of the sutures throughout the cervical stroma.

Step 6: Begin closure of incision using 2-0 Vicryl (2-3 throws is sufficient). It is important to start bilateral vaginal incision closure before tying suspension sutures to avoid any closure difficulties once the cervix has been reduced.

Step 7: Place the allis clamp on the posterior cervical lip and reduce cervix to a normal anatomical position -5.5 cm/ -6.5 cm. Pull on suspension sutures to get rid of any hidden slack. Begin tying sutures with 8 half-hitch knots on each side switching right and left strands after 4 ties. After the completion of eight knots on each side, tie four knots across the middle. When tying and tensioning it is important to make sure there are no air knots or hidden slack. Care should be taken to avoid excessive tension which could restrict the capacity of the rectum.

Step 8: Finish closure of the vaginal incision using 2-0 Vicryl. Of note, a transverse anterior colporrhaphy can be incorporated prior to vaginal closure to address any cystocele formation from longitudinal distension of the vaginal wall. A transverse defect with separation of the pubocervical fascia from the pericervical ring is a leading cause of anterior vaginal elongation contributing to the distension cystocele often seen along with apical detachment.

Post-Op management

Complications associated with this procedure are infrequent but include urge incontinence (7.7%) and recurrence of apical prolapse (7.7%).[5] Additional complications were urinary tract infection (4%) and removal of an EnPlace suture (3.1%).[4] Following the operation, the vagina is packed with gauze, which is removed prior to discharge. A voiding trial should be administered prior to discharge. Patients may experience mild to moderate discomfort in the immediate postoperative period, which is managed with non-narcotic pain medication.

Adherence to specific postoperative guidelines is recommended for optimal recovery. Patients are advised to initiate a walking regimen, beginning with short, frequent walks of five minutes, at least 3-4 times daily, gradually increasing the duration over time. It is important to avoid lifting heavy objects or anything exceeding the weight of 10 pounds for six weeks post-surgery, as such activities can increase abdominal pressure and stress on the surgical site. Additionally, a stool softener can be prescribed for 10 to 14 days post-procedure to prevent constipation, which can delay healing and increase stress on the surgical site. Topical estrogens may be continued as per surgeon's discretion. Sexual activity, as well as the use of tampons and douches, should be avoided for at least one-month post-surgery to allow healing.

Discussion and conclusion

The EnPlace system has emerged as a notable advancement in addressing apical POP through its minimally invasive approach to SSL fixation. This device is distinguished by its meshless design, percutaneous approach and precise deployment capabilities. The EnPlace procedure has demonstrated promising outcomes in clinical studies, including improved anatomical support and symptomatic relief. Historical developmental research underscores its feasibility and safety, providing a foundation for its adoption in surgical practice.

The EnPlace system's evolution from initial feasibility studies to comprehensive clinical evaluations highlights its reliability and effectiveness in treating POP. Studies have consistently reported favorable outcomes with

minimal complications, supporting its role as a viable alternative to traditional surgical approaches. As research continues to refine techniques and expand patient outcomes data, ongoing advancements promise further enhancements in surgical precision and patient recovery. Moving forward, continued collaboration between clinicians, researchers, and device developers will be essential in optimizing outcomes and expanding access to this innovative treatment option for women worldwide affected by pelvic organ prolapse.

Disclosures

Bilal Chughtai is a consultant for Olympus, Boston Scientific, FEMSelect, ARMs, Prodeon Medical, Sumitomo, Zenflow, and Teleflex. He is an advisor for Promaxo, Bright Uro, COSM, and Soundable. Dean Elterman is a consultant for Olympus, Boston Scientific, and Procept BioRobotics. Vincent Lucente is an advisor for FEMSelect.The other authors declare that they have no known competing interests. □

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