A Novel, Meshless Method of Vaginal Colpopexy by Sacrospinous Ligament Fixation to Treat Pelvic Organ Prolapse

PRESENTER: Elad Leron, M.D., Gynecology and Obstetrics Department, Soroka Medical Center, Ben Gurion University of the Negev, Beer Sheva, Israel, **Vincent Lucente, M.D.**, The Institute for Female Pelvic Medicine, Allentown, PA, **Alan D. Garely, M.D.**, South Nassau Communities Hospital, Rye, NY, **John Bertrand, M.D.**, Walnut Hill Obstetrics and Gynecology Associates, Dallas, TX, **S. Abbas Shobeiri, M.D.**, MBA, Professor, Obstetrics and Gynecology, Inova Health System, Falls Church, VA, **Eric A. Hurtado, M.D.**, Cleveland Clinic Florida, Davie, FL, **Baeßler Kaven, PD Dr. med** - St. Joseph Krankenhaus, Berlin, Germany, Tuscher **Michal, Dr. med.** Krankenhaus Waldfriede, Berlin, Germany , Peschers Ursula, **Prof. Dr. Isar Kliniken** GmbH, Munich, Germany, **Davila Willy, MD**, Urogynecology/Reconstructive Pelvic Surgery Medical Director, Women and Chlldren's Services at Holy Cross Medical Group Ft. Lauderdale, FL, **Andrew I. Sokol, M.D.**, and **Cheryl B. Iglesia, M.D.**, Female Pelvic Medicine and Reconstructive Surgery, MedStar Washington Hospital Center/ Georgetown University, Washington, DC, **Stephanie Molden, M.D.**, Medical Director The Female Pelvic Health Center (Newtown, PA), **Allison Polland, M.D.**, Maimonides Medical Center, Brooklyn, NY, **Menahem Neuman, M.D.**, Bar Ilan University, Israel.

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Objective: The objective of the NeuGuide Post-Market Study (PMS) is to assess the safety and durability the NeuGuide™ system when used for vaginal colpopexy to treat uterine prolapse.

Methods: Prospective, observational, multi-center study. Setting: Academic and community hospitals. Patients: Women > 40 years of age with symptomatic pelvic organ prolapse (POP).

Interventions: The NeuGuide™ System (now, branded EnPlace™) is a minimally invasive guided anchor/suture system that provides durable suspension of the vaginal apex.

Results: Fifty-three women have been enrolled from 13 sites. The average age was 71 years. All patients were post-menopausal, and all complained of a sensation of vaginal bulging. None of the patients complained of stress incontinence necessitating surgical treatment. The sacrospinous ligament fixation (SSLF) procedure was conducted under general anesthesia. A NeuGuide (EnPlace) device was inserted through a small, transvaginal puncture on either side of the vaginal apex. The NeuGuide Finger Guide, which directs the NeuGuide anchor, was positioned over the midpoint (in the lower third) of the right and left sacrospinous ligaments, and the anchor (2mm) was pushed through the ligament so the anchor's fixation-wings could open and deploy, positioned behind the ligament, and the anchor's pre-attached sutures pass through the ligament to the apex of the vagina and are fixed into the cervix to suspend the prolapsed uterus. The study is being conducted in two stages: the first stage includes ~30 women with isolated apical prolapse treated with only the NeuGuide System for repair of the POP. The second stage of the study includes ~30 patients with any form of prolapse associated with a POP-Q C-point value greater than -1 cm in whom the NeuGuide (EnPlace) device was used along with concomitant native tissue repairs of cystoceles and/or rectoceles, shortening of an elongated cervix, perineorrhaphy and/or anti-incontinence tape procedures. With the first patient group, anterior and posterior average pre-operative Ba and Bp POP Q scores were between -0.2 and -2.0 cm and C = 2.0 cm. At 6 months (n = 16 patients) following the NeuGuide procedure, the average Ba, Bp and C point POP Q scores were significantly more negative ($p < 0.01$), and in most of the patients, the C-point was < - 6.5 cm. Not all patients responded with a complete remission of prolapse when the NeuGuide device was used in isolation, and symptoms recurred by 6 months in 4 patients, who opted for further surgery within a year of the NeuGuide procedure. Follow-up has been shorter for the patients in the second stage of the study, but none of the patients have required further surgery to date.

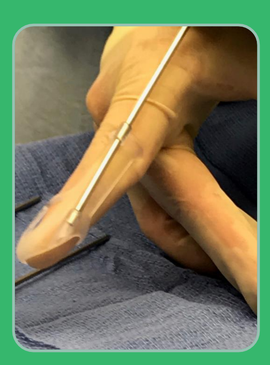
Conclusions: The NeuGuide System (EnPlace) is efficacious and safe. The procedure is minimally invasive, requires no deep pelvic dissection or mesh implants, and provides simple and easily confirmed guidance to the sacrospinous ligament. The NeuGuide System can be used for non-invasive repair of pelvic organ prolapse and does not preclude more extensive repair. As the study progresses, the NeuGuide (EnPlace) will be used in a group of patients in whom other native tissue transvaginal surgical procedures may be used as a comprehensive surgical approach to treatment of pelvic organ prolapse

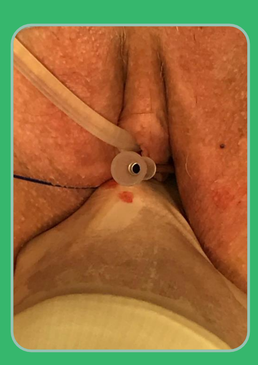
Objective: The objective of the NeuGuide Post-Market Study (PMS) is to assess the safety and durability the NeuGuide™ system when used for vaginal colpopexy to treat uterine prolapse.

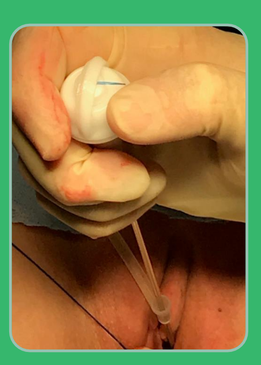
The NeuGuide™ Post-Market Study is a prospective, observational, multi-center study in women > 40 years of age with symptomatic pelvic organ prolapse (POP-Q Ba, Bp or C point > 0 cm).

The first group of patients has been treated using the NeuGuide™ System to treat POP without any other intervention.

We report the results after 6 months from a consistent cohort of 14 women in whom the NeuGuide™ System was used alone to treat POP.







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*** POP Medical Solutions NeuGuide™ formally changed to FEMSelect EnPlace™ in 2019*

Results: POP-Q points measured at baseline (BL), post-sacrospinous ligament fixation with the NeuGuide™ device (P-P), one month follow-up (1-M) and 6 month follow-up (6-M) in a consistent cohort of 16 women (all past the 6-month evaluation date). * indicates $p < 0.001$ compared to baseline value.