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A new reusable suturing device for vaginal sacrospinous fixation: feasibility and safety study

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ABSTRACT

Objective: We sought to evaluate the feasibility and safety of SeraPro® (Serag-Wiessner, Germany), an innovative reusable suturing device for vaginal sacrospinous ligament fixation.
Study design: We reviewed the electronic files of all women who underwent vaginal sacrospinous ligament fixation with SeraPro® for apical pelvic floor prolapse, with or without mesh implant, performed between April 2013 and September 2013. Preoperative demographic, clinical, operative and postoperative data were analyzed. The women were interviewed and examined before the procedure, at one month postoperatively and tele-interviewed again after three months.
Results: Overall, 88 women were included in the study. Fifty-three patients (60.2%) had additional anterior mesh placement, 42 (47.7%) had posterior mesh, and 16 (18.2%) had both anterior and posterior mesh insertion. Five patients (5.7%) had no mesh implant. Sixteen patients (18.2%) had an additional mid-urethral sling for the treatment of stress urinary incontinence. No significant technical difficulty was recorded at the procedures. None of the patients had significant long-term morbidity. The mean 3-month follow-up demonstrated significant anatomical and functional improvement.
Conclusions: The SeraPro® reusable suturing device is a feasible and safe tool for sacrospinous ligament fixation during vaginal pelvic floor reconstruction.

Introduction

Pelvic organ prolapse (POP) is a common condition negatively affecting the quality of life of millions of women worldwide with a lifetime prevalence of 3–6% when defined by symptoms and up to 50% when based upon vaginal examination [1]. However, treatment is generally indicated only for women with symptoms of prolapse or associated debilitating conditions (urinary/bowel incontinence, or sexual dysfunction) [2]. The definitive treatment for POP is surgery. Population-based studies report an 11–19% lifetime risk in women to undergo surgery for prolapse or incontinence [3].

Choice of surgical route is the main concern in women who require repair of apical pelvic floor (uterine or vaginal vault prolapse), while isolated repair of anterior or posterior vaginal wall prolapse is typically performed trans-vaginally. Many abdominal (open, laparoscopic and robotic) as well as vaginal techniques have been described to correct apical prolapse [4–8]. Abdominal repair by sacral colpopexy results in a lower rate of recurrence. However, the vaginal approach is related a faster and less painful recovery [9].

One of the most common vaginal techniques is the sacrospinous ligament fixation (SSLF), first described by Richter [10], who used the sacrospinous ligament (SSL) as an anchoring site for vaginal vault suspension. During this procedure, the prolapsed apex is anchored with precisely inserted sutures to the sacrospinous ligament. Prolapse of the anterior or posterior walls of the vagina are repaired at the same time. The main technical obstacles in this technique are the wide and deep trans-vaginal pelvic dissection necessary for proper approach to the SSL and the manipulations for needle passage through the SSL. Some operative facilitating

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Fig. 1. The SERAPRO® RSD-Ney suturing device.

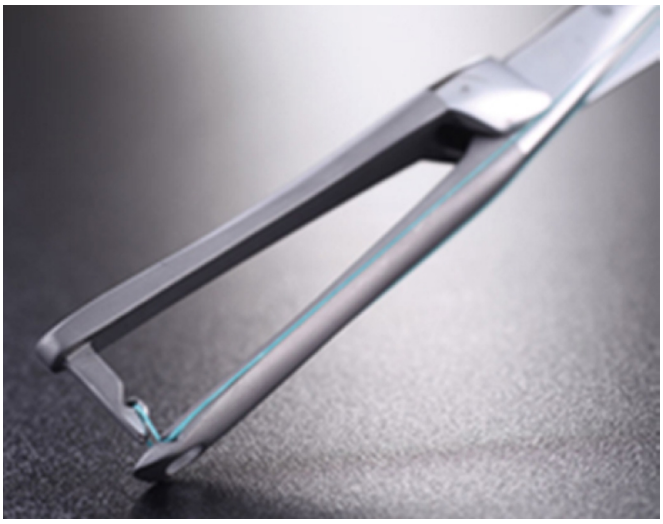

Fig. 2. Tip of the SERAPRO® RSD-Ney suturing device.

techniques have been suggested over the years to overcome these problems [11]. Some surgeons elected to implant meshes for the reinforcement of the weakened and herniated pelvic floor. Owing to the recent USA Food and Drug Administration communication about vaginally implanted mesh-related complications [12], many surgeons are reluctant to adopt this method.

The SeraPro® stainless steel forceps has a reusable-suturing device designed to facilitate suture placement through the SSL. It necessitates a relatively narrow trans-vaginal dissection toward the SSL, thus potentially reducing the dissection-related complication rate. An added advantage is that the fixation is made by suture only or with a small mesh implant, thus further reducing negative adverse effects as pain and exposure. The instrument has no lumen, or screw-off parts or cavities (Fig. 1), which makes it easy to sterilize. Furthermore, the device can only be dismantled at an angle or twist of more than 90°, which prevents unwanted dismantling during surgery. The tooth and nose proportions prevent excessive deep tissue penetration (Fig. 2). The aim of this study was to assess the surgical feasibility and safety of the SeraPro® at trans-vaginal SSLF for apical POP repair.

Materials and methods

This descriptive, retrospective study was based on the experience of a single surgeon (M.N.) who performed a vaginal SSLF procedure using SeraPro® in 88 women planned to undergo SSLF for apical prolapse repair between April 2013 and September 2013 in our center.

The study was approved by the local international review board.

Preoperatively, all patients completed a comprehensive questionnaire which included prolapse, urinary, bowel, and sexual symptoms. Office examination and detailed pelvic examination was performed, which involved site-specific vaginal examination in the lithotomy position with a Sim's speculum during a maximal valsalva maneuver. All POP quantification measurements and staging were performed according to the standardized International Continence Society (ICS) scoring system [13]. Each compartment (apical, anterior and posterior) was evaluated for defects in pelvic support. In cases where the vaginal defect was combined with stress incontinence, additional continence surgery was performed, as needed. All patients were interviewed and had a pelvic examination at the end of the first postoperative month and were tele-interviewed again 3 months after surgery.

The surgical procedure

All patients received preoperative prophylactic antibiotics (cefazolin 1 g). Surgery was performed under general anesthesia with the patients in the dorsal lithotomy position. Urethral catheters were not routinely placed at operation. A single longitudinal anterior or posterior vaginal wall incision was made according to the most damaged compartment, followed by an infra-fascial para-vesical or para-rectal sharp dissection toward the lateral pelvic side-wall, aiming at the ischial spine (IS). This served as a landmark for identifying the SSL. Digital palpation of the IS and SSL guided the device and introduced a No. 0 non-absorbable monofilament suture preferably into the mid-SSL. Once the suture was secured, it was passed through the vaginal wall at the vault without penetrating the vaginal mucosa or through the cervical fibrotic ring if the patient was not hysterectomized before, for suspension. The use of a mesh implant for apical POP reinforcement was performed according to the supportive tissue conditions. This procedure was repeated on the other side. A posterior or anterior vaginal wall repair, if required, was then performed with or without mesh according to the surgeon's impression of the quality of the fascial tissue. After closure of the posterior vaginal wall, the sacrospinous ligament sutures were tied on either side to elevate the vault. In patients with urinary stress incontinence, a mid-urethral sling procedure was performed after the prolapse surgery. All patients were advised to avoid strenuous activities for two months after the procedure.

Outcome measures included the feasibility and safety of the procedure, intraoperative and postoperative complications, prolapse-associated symptoms and POP quantification.

Statistical analysis

A computerized database was created and all clinical data were collected and evaluated. Data analysis was performed with the SPSS software, version 20.0. Student's test was used to compare continuous variables between the groups, and χ^2 test of Fisher's exact test were used for categorical variables. Differences were considered significant when p value was less than 0.05.

Results

Overall, 88 women were included in the study. Patient characteristics are described in Table 1. Mean age of patients was 62.8 ± 9.4 years. Fifteen women (17.0%) had undergone previous hysterectomy and 12 (13.6%) had previous POP surgery. During our surgery hysterectomy was not performed in any patient. Anterior mesh was implanted in 53 patients (60.2%), and in 42 (47.7%), posterior mesh. Sixteen patients (18.2%) had both anterior and posterior mesh implants, and 5 patients (5.7%) had no mesh