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Does pelvic mesh treated with phosphorylcholine improve outcomes? An early experience

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ABSTRACT

Objectives: Implantable devices treated with phosphorylcholine (PC) have been successfully used in cardiac, ophthalmic, and other applications. This surface modification has resulted in a reduction in the host inflammatory responses. This pilot study tested the safety and efficacy of PC treated polypropylene mesh grafts implanted for the treatment of pelvic organ prolapse.
Study design: Surgeons from five U.S. sites collected data on subjects implanted with Perigee IntePro Lite + PC. Pre-procedure data collected included demographics and prolapse severity. At follow-up, subjects were assessed for anatomical outcomes (success $\leq$ stage I POPQ or Baden Walker), symptomatic improvement, and complications, particularly mesh exposure.
Results: A total of 40 subjects were enrolled with 80% (32/40) of them completing at least 5–7 months of follow-up. Mean patient age was 60 years (range 36–78 years) and the mean BMI was 28 (range 20–40). There were no cases of mesh exposure/extrusion or granuloma formation. The anatomical success rate was 100% at 5–7 months (32/32).
Conclusions: This is the first publication on pelvic mesh treated with PC. There were no adverse events attributed to this surface modification. However, as the numbers are small, the results are not statistically significant. PC surface modification of pelvic mesh shows promise in its application for the reduction of mesh related complications.

1. Introduction

Synthetic meshes are frequently used in the surgical treatment of vaginal prolapse to improve the outcome of traditional surgical treatment [1]. Although the success rates with synthetic materials are good, the risk of vaginal extrusion has been concerning [2,3]. Several modifications have been made over the years to reduce some of the adverse events related to mesh. These modifications include surface coatings intended to minimize foreign body response. Despite the advantages of the newer polypropylene meshes, capsular fibrosis remains a common complication resulting from foreign body reaction to the mesh [4]. This reaction is theoretically linked to the hydrophobic surface properties of polypropylene, which enable deposition of non-specific proteins and cells. Excessive inflammatory responses to implants can lead to consequent adverse events, such as fibrosis and scarring of the vagina, with subsequent deformity that might be a cause of dyspareunia or pain.

The biomimetic nature of phosphorylcholine (PC) polymers improves the biocompatibility of implanted medical devices. Polymers containing PC have been used with various implanted medical devices, including coronary stents, intraocular lenses, and contact lenses (Fig. 1) [5]. None of devices involved pelvic organ prolapse (POP) repair. Because tissue interaction with mesh may differ across body regions, this study was undertaken to assess the safety of PC-surface modification of an existing mesh used in the treatment of POP repair.

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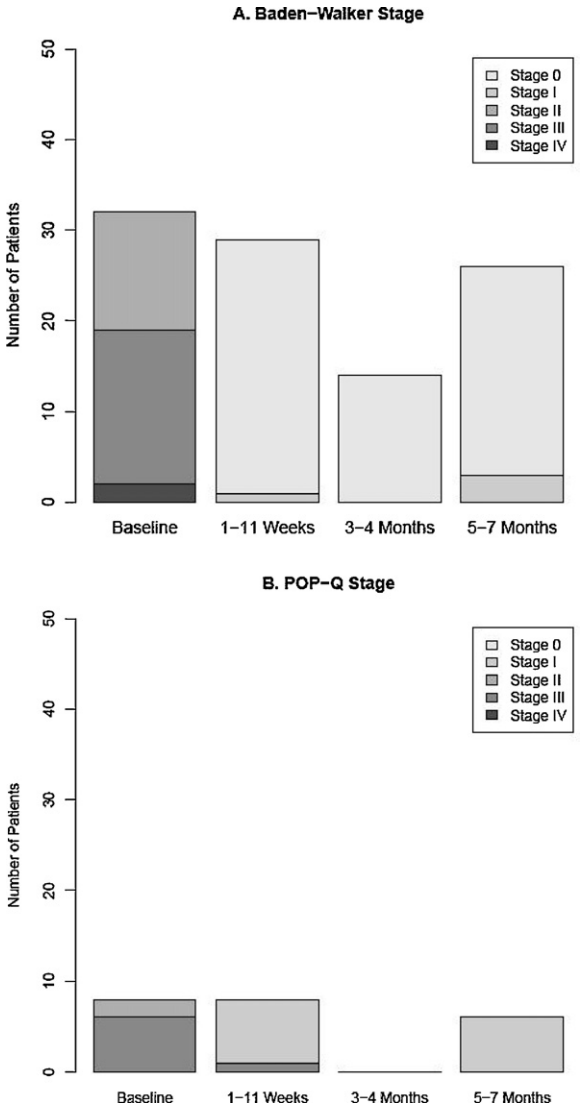

Fig. 1. Anterior prolapse stage at baseline and post-implant follow-up.

2. Materials and methods

2.1. Study device

Perigee® with IntePro® Lite + PC (American Medical Systems (AMS), Minnetonka, MN), which is an anterior POP repair mesh kit that provides level 2 support through a transobturator approach.

2.2. IntePro Lite PC Mesh (test article)

Samples (2 cm × 7 cm) were cut from IntePro® Lite™ polypropylene monofilament mesh. Mesh strips were ultrasonically cleaned with sequential washes in detergent followed by ethanol/hexane (2/1), then dried at 70 °C for 4 h. PC1036 polymer (2 mg/ml in ethanol) was applied by dipping and curing at 70 °C for 4 h [6]. Mass of PC-polymer surface treatment was measured with a micro-balance (Mettler-Toledo XP56). All samples were ethylene oxide sterilized.

2.3. Pre-clinical studies

PC-treated Perigee IntePro Lite was tested against control in rabbits as per protocol (AMS TR6520) and maintaining the good laboratory practice guidelines. Based on gross and histo-pathological evaluations the test material was deemed non-irritant (AMS data on file)

2.4. Study design

Surgeons from five U.S. clinical sites entered data into a secure, password-protected, on-line, self-reported registry that collected data on patients implanted with a range of AMS POP repair products. All surgeons were either gynecologists or urologists; each had done at least 50 mesh-based pelvic floor procedures prior to study commencement. All surgeons complied with the informed consent requirements of their Institutional Review Board. All patients implanted with Perigee IntePro Lite + PC at baseline from June 2009 to April 2010 were included in this study. Data collected included demographics and prolapse severity assessed by the pelvic organ prolapse quantification system (POP-Q) or Baden–Walker (B–W) scale. Inclusion criteria were female patients who were at least 21 years of age with anterior compartment prolapse of POP-Q or B–W stage II or more, and were candidates for surgical repair. Exclusion criteria included patients who were pregnant or had evidence of active/latent infection or tissue necrosis. Intra-operative data, including concomitant procedures and complications, were recorded. At follow-up, patients were interviewed for symptomatic improvement and assessed for anatomical outcomes, and complications, particularly mesh exposure/extrusion. Anatomical success was defined as POP-Q or B–W stage 0 or I. Patients were followed according to each physician's standard of care.

3. Results

A total of 40 Perigee with IntePro Lite + PC patients met the inclusion criteria and 80% (32/40) of patients completed 5–7 months or more of follow-up. Baseline characteristics are summarized in Table 1. Mean age was 60 years (range 36–78 years) and mean body mass index (BMI) was 28 (range 20–40). A total of 80% (32/40) of patients were post-menopausal. Previous pelvic surgery included: hysterectomy (55%, 22/40), anterior compartment repair (10%, 4/40), posterior compartment repair (5%, 2/40), and incontinence procedures (12.5%, 5/40). Eighty percent (32/40) were evaluated with B–W and 20% (8/40) were evaluated with the POP-Q scale. Preoperatively 5% (2/40) had stage IV, 57.5% stage III (23/40), and 37.5% (15/40) stage II anterior compartment prolapse.

Concomitant surgery included hysterectomy (32.5%, 13/40), incontinence repair (85%, 34/40), rectocele repair (50%, 20/40), enterocele repair (30%, 12/40), and vault suspension (40%, 16/40). All patients received general anesthesia. The mean estimated blood loss was 107 ml (range 5–300 ml). The mean operating time, including concomitant repairs, was 97 min. Fifty-five percent (22/40) of patients had mesh trimming as part of the procedure and 17.5% (7/40) had trimming of the anterior vaginal mucosa. No intra-operative complications were noted.

The anatomical success rate was 97% at 1–11 weeks (36/37), 100% at 3–4 months (14/14) and 100% at 5–7 months (32/32). Prolapse stages by visit are detailed in Fig. 1

There were no reported mesh exposures/extrusions. A total of 19 patients were sexually active at baseline. Dyspareunia rates decreased from 26% (5/19) at baseline to 8% (1/12) at 5–7 months follow-up.

Simultaneously, 618 patients were implanted with non-PC mesh by the same surgeons, and had similar characteristics including age, BMI, menopause status, hysterectomy status, and surgeons as PC patients (Table 1). Of note with respect to follow-up, 80% of PC patients completed a 5-month or later visit.