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Assessment of collagen versus non collagen coated anterior vaginal mesh in pelvic reconstructive surgery: prospective study

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ABSTRACT

Objective: To evaluate the sonologic and clinical outcome of collagen coated (CC) versus non-collagen coated (NC) anterior vaginal mesh (AVM) for pelvic organ prolapse (POP) surgery.
Study design: The study is a prospective observational study which included 122 patients who had symptomatic POP stage III and IV. AvaultaPlus™ (collagen coated, CC group) was compared to Perigee™ (non collagen coated, NC group). Introital ultrasound morphology, measure of neovascularization by color Doppler and clinical outcomes were assessed. Student t test was used for comparison of pre- and post-operation continuous data (p value of <0.05).
Results: A total of 110 (CC group = 50, NC group = 60) women completed the study. A woman in the CC group developed ureteral injury. Both groups had comparable morphologic and clinical outcomes however, the onset of changes in mesh thickness and neovascularization occurred earlier in the NC group (1 month) compared to the CC group (6 months to 1 year).
Conclusion: CC group was comparable to the NC group in terms of erosion rate, ultrasound and clinical assessment. Collagen coating may induce delayed inflammatory response however may also delay tissue integration.

The onset of changes in mesh thickness and neovascularization may give us an insight toward utilization of collagen coated mesh for host-tissue integration.

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Introduction

Managementfor recurrent pelvic organ prolapse (POP) continues to be challenging, especially at the anterior compartment where 70% of recurrences are noted [1]. In 2011, a public health notification by the United States Food and Drug Administration (FDA) highlighted the increase in cases of mesh erosion associated with the use of commercial mesh [2]. The direct contact between the vaginal tissue on the uncoated propylene mesh was hypothesized to be a factor causing mesh erosion [3]. The industry has developed a collagen coated mesh which is hypothesized to be a more superior mesh that acts as a barrier [4] to prevent mesh erosion.

Commercially available Avaulta Plus™ Anterior system (Avaulta Plus™Biosynthetic Support System, C.R. Bard, Inc., USA) is an acellular, propylene, porous, anterior vaginal mesh with ultra-thin sheet of cross-linked collagen on the central portion that functions as a barrier that contains apertures enabling ingrowth of tissue and capillary vessels [5]. AvaultaPlus™ is no longer available in the United States since 2012. However, manufacturing and marketing of AvaultaPlus™ is allowed by the FDA and European Union regulations, enabling them to sell the product to other countries including China, Europe and Taiwan.

The dynamics of pelvic floor ultrasonography has enhanced our understanding about the effects of new synthetic materials for

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prolapse surgery [6]. The role of 2D and 4D ultrasound studies have documented the morphology and mesh folding [7] while Doppler studies enabled us to evaluate vascular ingrowth and tissue integration within and around the mesh [8]. Doppler evaluation of neovascularization has never been validated for use in post-operative mesh. Yet, it is a current practice especially in the field of Plastic surgery that color Doppler signals is performed to assess ingrowth of tissue and capillary vessels [9]. The term neovascularization was used in the study to describe ingrowth of tissue and capillary vessels.

From our previous study, a single arm prospective assessment of women who underwent the AvaultaPlus™ system was done [8]. The study utilized introital ultrasound as well as Doppler studies and revealed a subjective and objective cure rate of 90.8% and 89.2%, respectively [8]. This was a continuation from our previous study to evaluate the morphology through sonologic and clinical outcome of collagen compared to non-collagen coated anterior polypropylene vaginal mesh for the treatment of POP.

Materials and methods

All experimental protocols and procedures were approved by the Chang Gung Memorial Hospital institutional review board (No.: 100-0592A3). From April 2010 till October 2012, women who had symptomatic POP stage III and IV were assessed for eligibility in this prospective study. Women, who refused synthetic mesh implantation, required mid-urethral sling surgery for incontinence and those who were medically unfit for the surgery after cardiopulmonary clearance were excluded from the study. Mesh kit selection was based on the informed decision of the patient. Patient selection was based on the hospital where the surgery was carried out. The women were stratified into 2 groups based on the 2 centers included in the study: Chang Gung Memorial Hospital Taipei provided women in the collagen coated mesh group (CC group) while Chang Gung Memorial Hospital Linkou provided women for the non-collagen coated group (NC group).

The two groups of AVM used in the study were had the similar type I polypropylene mesh with large pore size, deployed at the anterior vaginal wall and was four armed wherein the arm and body of the mesh were made from one piece. The major difference relied on the material at the central area of the AvaultaPlus™ mesh which was collagen coated whereas Perigee™ had not collagen coating [10]. AvaultaPlus™ Anterior system (Avaulta Plus™Bio-synthetic Support System, C.R. Bard, Inc., USA), represented the CC group, it is thicker, heavier and with increased flexural rigidity compared to the NC group represented by the Perigee transobturator mesh repair system (Perigee™ system, American Medical Systems, Minnetonka, MN, USA).

Pre and Post-OP evaluation were described from our previous study [8]. All women were asked to complete a 72-h bladder diary and validated questionnaires, namely: the Urogenital Distress Inventory (UDI-6) [11], Incontinence Impact Questionnaire (IIQ-7) [12], Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6) [13] and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) [14,15]. Follow-up was arranged at 1 week, 1 month, 3 months, 6 months, and annually thereafter. Urodynamic study and answering validated questionnaires were done at baseline and 12 months after the operation. Introital ultrasound evaluation was performed on the 1st month, and a year after the surgery.

The primary clinical outcome measured was the morphology of the mesh implanted, the difference in length and thickness of the mesh complex assessed by ultrasonography and neovascularization evaluated by color Doppler flow at 1 month and 1 year of then operation. Secondary outcome were POP recurrence, subjective cure was based on the validated questionnaires and major and minor complications were also noted. Results from UDI-6 and IIQ-7 reported on lower urinary tract symptoms; POPDI-6 assessed prolapse symptoms and PISQ-12 assessed prolapse symptoms, stress incontinence and sexual problems. POP recurrence was defined as POP-Q > 1 at the anterior vaginal wall and/or all of its compartments. Patients' negative responses to questions 2 and 3 of the (POPDI-6) were considered subjective success. Patients' sexual function was assessed using the PISQ-12 questionnaire. Data was compared at 1 month and 1 year of then operation.

Surgical operation

All surgeries were done by the principal author, who had prior experience with the use of synthetic mesh in POP surgery [16,17]. The surgeries were performed in sequence of: vaginal hysterectomy (if indicated), AVM, sacrospinous ligament fixation (SSF) and posterior colporrhaphy. Hydro-dissection with normal saline was done prior to full thickness midline dissection of the vagina from the neck of bladder to the apex. The paravesical fossa was opened only up to the level of the ischiopubic ramus. The paravesical space was entered and the AVM was placed with the use of 4 needle passages, outside-in trans-obturator technique. Avaulta Plus™ and Perigee™ were placed according to their respective procedural guidelines [16,17]. No vaginal trimming was performed. The AVM was inserted between the bladder and the vagina and was secured bilaterally by the two arms at each side passing through the obturator foramen at the level of arcus tendineous fascia. In both procedures the mesh was positioned in a tension-free manner under the bladder. Vaginal sacrospinous ligament fixation using the Miya hook technique was adopted for apical prolapse [18]. Cystoscopy was performed at the end of every surgery. A Foley catheter and a vaginal pack (gauze soaked with Povidone Iodine) were placed for 24 h.

Ultrasound assessment

Morphology of the implanted mesh in the sagittal and transverse planes was acquired through a 3.5-MHz curved linear array transducer (Philips HD11XE; Philips Ltd., Netherlands). The AVM was the hyperechoic area located underneath the bladder neck and the bladder base within the vesicovaginal space (Figs. 1–3). The transducer was positioned adjacent to the vaginal introitus for investigating the morphology of the implanted mesh in sagittal and transverse planes. The length and thickness of the mesh complex, vaginal mucosa thickness between outer vaginal wall and mesh margin were all measured at rest as described by Tunn in 2005 [19] (Figs. 1–3). The techniques for scanning of the mesh have been utilized from our previous study [8]. The method on neovascularization scanning has been reported previously. In brief, Doppler studies facilitated assessment of neovascularization on the implanted vaginal mesh scanned in the transverse plane using color Doppler scanners. After the color signals were located, both color and simultaneous Doppler waveforms were obtained [8].

Statistical methods

Methods, definitions and units conform to the standards of International Urogynecological Association (IUGA) and the International Continence Society (ICS), except where specifically noted [20]. Descriptive statistics was used for the demographics and pre-operative data. Paired Student's t-test was applied for comparison of pre- and post-operation continuous data. Inter and intra group difference was also analyzed in the two groups. The sample size of 45–50 patients were required for each arm to detect a 25% difference in postoperative vaginal mesh thickness with 95%

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