Original article

Partially absorbable versus non-absorbable mesh implants for trans-vaginal reconstruction reinforcement of advanced pelvic organ prolapse

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Abstract: *Objectives:* We aimed to compare the efficacy and safety of non-absorbable and partially absorbable meshes for the reinforcement of pelvic floor reconstruction. *Study design:* Patients with advanced pelvic floor prolapse were enrolled to this study and had either non-absorbable or partially absorbable mesh implants for reinforcement of pelvic floor reconstraction. Patients were evaluated at the end of the 1st post-operative months and interviewed at the study conclusion. *Results:* Of the 236 women enrolled to the study, 213 (90.2%) were available for evaluation. Nonabsorbable mesh implants were used in 109 women (51.1%) and partially absorbable mesh implants were used in 104 women (48.9%). Median follow-up for non-absorbable mesh patients was 4.6±1.0 years and for the partially absorbable mesh, 2.3±1.9 years. At the end of the first postoperative month, pain was the only subjective statistically significant parameter: 33.3% in the non-absorbable mesh group versus 10.7% in the partially absorbable mesh group ($p<0.002$). Similarly, the percentage of mesh felt at vaginal palpation was distinctly higher in the nonabsorbable mesh group than the partially absorbable mesh group (100% vs. 29%, respectively) ($p<0.04$). All other findings were similar with the 2 study groups. *Conclusions:* Partially absorbed mesh implant is safe and effective and has less early postoperative complications than the non-absorbable mesh implant with pelvic floor reconstruction reinforcements.

Keywords: Mesh; Pelvic organ prolapse.

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 30%.[1] Women with advanced symptomatic POP experience daily discomfort, as well body image dissatisfaction and impaired sexual function.[2] Treatment for POP requires significant health care resources,[3] with an ever-growing impact in parallel with the growing elderly population.[4,5]

According to recent studies, approximately one in ten women will undergo surgery for POP and/or incontinence during their lifetime.[6] The vagina is widely accepted as the natural orifice for POP reconstruction; hence, many favor the trans-vaginal route over the abdominal approach. Yet, POP repair surgeries have an unacceptably high failure rate with a 10-year reoperation rate of 17% reported by some[7] and 45%, reported by others.[8] This may be attributed to connective tissue weakness, related to genetic factors, reduced collagen content or increased collagen destruction.[9]

Given that POP is a herniation process, one must acknowledge the importance of replacing the weakened fascia that caused the defect with an implant to reinforce the reconstructive procedure. In an attempt to reduce these high failure rates, synthetic meshes were designed and implanted. They provided reinforcement and better support for vaginal surgical repair of prolapse. This led to a significant reduction in anatomical failure and reoperation rates.[10,11] However, mesh implantrelated complications ranged from mild issues of transient pain and small mesh erosions to severe adverse effects such as large vaginal mesh exposures or extrusions, perforations into the bladder or bowel, and chronic pain. Mild mesh complications can be managed conservatively, but bladder or bowel injuries, fistulae, abscess formation, and debilitating pain may require repeat surgery and are not always curable.[12]

One of the recent implant modifications aimed at reducing adverse effects is the partial absorbable mesh,[13,14] which is composed of a blend of monofilament, non-absorbable polypropylene and absorbable polyglecaprone. It reduces stiffness and increases elasticity after implantation.[15] Furthermore, the partial absorbable mesh provides easy handling and reduces implant mass. It is assumed that significant reduction of the implant mass may lead to reduction of the adverse effects and complications of the graft that are thought to be directly related to the mesh mass.

The purpose of this study was to compare the new partially absorbable mesh to the non-absorbable mesh at vaginal reconstructive surgery for POP.

METHODS

We conducted a retrospective, observational study utilizing data obtained from the medical records of women who had undergone reconstructive pelvic surgery for advanced and symptomatic posterior pelvic floor compartment prolapse, using trans-vaginal mesh implants, either nonabsorbable or partially absorbable, between the years 2008 to 2011. The study was approved by the local IRB committee (no. 50611).

All women that presented with symptomatic stage 3 posterior compartment prolapse, and thus had a mesh implant at increased risk for prolapse recurrence, who had been treated with a mesh implant, were included in the study. Risk factors for prolapse recurrence included previous POP reconstructive surgery and clinical assessment of supportive pelvic floor tissue. Exclusion criteria were previous vaginal mesh implantation, pelvic inflammatory disease, and chronic pelvic pain.

Prior to surgery, all patients completed a comprehensive questionnaire on symptoms of prolapse, urinary, bowel, and sexual malfunction. Preoperative evaluation included a detailed pelvic sitespecific vaginal examination at lithotomy position with a Sim's speculum during a maximal Valsalva maneuver and Pelvic Organ Prolapse Quantification (POP-Q) measurements and staging according to the standardized International Continence Society (ICS) scoring system.[16] Each compartment (anterior, apical and posterior) was separately evaluated for detection of defects in pelvic support.

During the years 2008 to 2009, patients underwent transvaginal mesh placement using the nonabsorbable Gynecare

Table 1. Patient characteristics of 236 women who underwent POP reconstruction with nonabsorbable or partially absorbable meshes.

P value	Partially absorbable mesh n=119	Non-absorbable mesh n=117	
0.161	59.4±11.2	61.6±11.8	Age, mean±SD
0.384	3.12±1.3	2.96±1.4	Parity, mean±SD
0.752	77.1%	79.5%	Menopause, %
0.212	93.3%	87.8%	Overactive bladder, %

Prolift kit system (Ethicon, Summerville, USA). From 2010 to 2011, the partially absorbable mesh Gynecare Prolift+M (Ethicon, Summerville, USA) was used. Both kits and operative techniques were identical, except for the difference in absorbance in the partial absorbable mesh.Anti-incontinence surgery was performed when indicated using sub-mid-ureteral synthetic tape, according to the surgeon's preference.

All patients were administered first generation Cephalosporin 1 g intravenously, half an hour before surgery. An iodine antiseptic wash was applied to the area prior to the onset of surgery. All procedures were performed under general anesthesia. The detailed surgical technique was as published before.[17]

At the end of the first postoperative month, all patients were asked to complete the same questionnaire they had been given before surgery, and patients were re-evaluated with site-specific vaginal pelvic examination. Postoperative pain was assessed with the visual analogue scale (0-10) where 10 indicate maximal pain.

In 2013, patients were interviewed by telephone for possible mesh-related complicationsand pelvic floor symptoms. The primary outcome measure was the mesh implant adverse effects, and the secondary outcome measure was the subjective cure rate, among the two patient groups.

One-hundred and ten patients were required in each of the two patient groups to detect a 20% increase for the postoperative pain rate, with 80% power and 95% confidence (0.05 significance).

Student's t-test was used for comparison of quantitative variables between groups. Chi-square test was used to compare qualitative variables. The Wilcoxon signed rank test was used to compare the POP-Q measurements before and after surgery. A p value of less than 0.05 was considered statistically significant.

RESULTS

Of the 236 women enrolled in this retrospective study, 117 (49.6%) underwent surgery using the nonabsorbable mesh implants during the years 2008-2009, and 119 women (50.4%) underwent surgery using the partially absorbable mesh implants, afterwards. One surgeon (NM) performed all surgical procedures. At the end of the first postoperative month, 213 women (90.2%) were available for evaluation, of whom, 109 (51.1%) had been implanted with the non-absorbable mesh and 104 (48.9%), with the partially absorbable mesh.

In 2013, of 153 women (64%) interviewed, the non-absorbable mesh was used in 78 women (50.9%), and the non-absorbable mesh, in 75 (49.1%) (Patient flow chart no. 1). The median followup for non-absorbable mesh patients was 4.6±1.0 years and for the partially absorbable mesh, 2.3±1.9 years.

The preoperative patient characteristics, symptoms, and POP-Q examination showed no statistical between-group differences. This was true also for the operative details and length of procedure (Tables 1,2). No major intra- or postoperative significant complication or long term severe morbidity was encountered in any group.

Early postoperative complications occurred in the non-absorbable and partially absorbable mesh groups as follows: pain level (4.35 vs. 4.50, according to VAS scale) urinary tract infections (2 vs. 1), vaginal mesh exposure (3 vs. 1) small pelvic hematoma (1 vs. 0), and bladder outlet obstruction (4 vs. 1), respectively. All these complications resolved spontaneously or with conservative measures and did not necessitate further operative steps. Postoperative bladder over-activity and defecation symptoms were similar in both groups.

The one-month postoperative vaginal examination for the assessment of pelvic floor different compartment prolapse using the POP-Q method showed no statistical differences between the two groups (Table 3).

The one subjective parameter statistically significantly different between the two patient groups was the pain level at the end of the first postoperative month: 33.3% of women in the non-absorbable mesh group still had postoperative pain compared to 10.7% of women in the partially absorbable mesh group ($p<0.002$). Similarly, the mesh could be felt at vaginal palpation distinctly higher in the non-absorbable mesh group than the partially absorbable mesh group, 100% vs. 29%, respectively ($p <0.04$) (Table 4).

Table 2. Preoperative POP-Q by independent t-tes.

P value	Partially absorbable mesh group	Non-absorbable mesh group	POP-Q points
0.502	1.94±1.997	2.02±1.124	Ba
1.620	2.99±1.632	4.25±1.058	Bp
1.856	2.87±2.676	4.14±1.706	C

All values are mean±SD.

Table 3. POP-Q at first postoperative month.

P value	Partially absorbable mesh group	Non-absorbable mesh group	POP-Q points*
0.481	-2.63±0.957	-2.7±0.462	Ba
0.295	-2.85±0.734	-2.74±0.699	Bp
0.332	-6.32±1.579	-6.14±1.098	C

All values are mean±SD.
*By independent t-test.

Table 4. Clinical findings after the first postoperative month measured by chi-square test.

P value	Partially absorbable mesh group	Non-absorbable mesh group	
0.002*	8 (10.7%)	20 (33.5%)	Pelvic pain, n (%)
0.04*	34 (29%)	117 (100%)	Palpable mesh, n (%)

DISCUSSION

The main findings of this study show that at the end of the first postoperative month, the patient's estimation of pelvic pain level was significantly less intense and mesh palpability at vaginal examination was significantly less

prominent in the partially absorbable patient group.These findings are probably attributed to the fact that a substantial fraction of the implant is removed by absorption and hence does not affect the pelvic soft tissue neither regarding pain generation nor regarding tactile sensation.

Pain reduction is crucial when considering mesh implantation. It is especially important in the sexually active patient who might experience dyspareunia after POP reconstruction.

We found no benefit among women who underwent vaginal reconstructive surgery with mesh implants for the posterior pelvic floor compartment, when the non-absorbable mesh was compared with the partially absorbable mesh regarding other intra- and post-operative adverse effects or pelvic floor dysfunction symptoms. The postoperative anatomical and subjective findings were similar as well.

Although the particular mesh used in the present study is no longer available, the principal benefits and drawbacks of the partially absorbed mesh implants are valuable and meaningful.

This study was limited by its nonrandomized nature. We felt that the partially absorbable meshes might cause less pelvic pain, thus implanting the non-absorbable once was not justified.

CONCLUSION

Partial mesh absorbability may offer significant reduction with postoperative implant-related pain with pelvic floor reconstruction reinforcements.

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