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A LIGHT-WEIGHT, PARTIALLY RESORBABLE MESH FOR SEVERE PELVIC ORGAN PROLAPSE: 1 YEAR ANATOMICAL AND FUNCTIONAL RESULTS

Hypothesis / aims of study

In an effort to minimize mesh complications, a lighter-weight alternative mesh replaced the original polypropylene mesh used in the trans-vaginal mesh repair. The new mesh material is composed of approximately a fifty-fifty blend of monofilament non-absorbable polypropylene and resorbable polyglecaprone 25. After absorption, the mesh weighs approximately 31 g/m², as opposed to the 45g/m^2 of the original polypropylene mesh. The mesh is warp knitted by a process which provides for increased elasticity in the longitudinal direction compared to the original polypropylene mesh. The reduced surface area and supplement of polypropylene with polyglecaprone 25 also leads to significantly decreased foreign body reaction.[1] This leads to formation of a scar net rather than a scar plate.[1] This study aims to assess whether these new mesh characteristics provide adequate anatomic support and whether these characteristics would have a beneficial effect on subsequent functional outcomes and complications.

Study design, materials and methods

Inclusion criteria were POP stage III or IV, according to the ICS criteria. Exclusion criteria were additional surgical repair of prolapse concurrent to the study procedure and previous prolapse repair using mesh. Depending on the site of prolapse, the mesh repair could be anterior, posterior or total (Gynecare Prolift+M^{TM} Pelvic Floor Repair System, Ethicon, Somerville, NJ). Concurrent hysterectomies and/or mid urethral sling procedures were allowed.

The primary outcome was defined as anatomic success at one year, being a POP-Q Stage ≤ I, in the treated compartment, without further surgical re-intervention for POP in that compartment. An alternate outcome measure was added; leading edge of prolapse proximal to the hymen (i.e. <0 cm) in the treated compartment at one year, without further re-operation.

Secondary outcomes were Patients Global Impression of Improvement (PGI-C), the short form versions of the Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7). For sexually active women dyspareunia was assessed and the short-form of Pelvic Organ Prolapse/Urinary Incontinence Sexual Function (PISQ-12) questionnaire was administered. In addition, surgeons were asked to specifically examine patients during follow-up visits to detect any clinically significant vaginal wall stiffness and / or pelvic pain.

Results

One hundred and twenty-eight women consented to participate in the study. Surgery was completed in 127. Forty-one patients (32.3%) underwent an anterior mesh repair; 16 (12.6%) a posterior repair and 70 women (55.1%) a total pelvic floor repair (total uncut: 32 and total cut meshes: 38). Anatomic success (POP Stage ≤ I) in the treated compartments at 12 months was 77.4% (95% CI 69.0%-84.4%). Three re-interventions in the treated compartment were reported within 1 year following surgery. One further patient who had undergone an anterior mesh repair, required re-intervention in a previously untreated compartment. A summary of the primary and secondary anatomic endpoints, after 12 months of follow up, are presented in tables 1 and 2. Based on the PGI-C, 96.0% of patients indicated their prolapse situation was better following the procedure, of which 86.2% indicated “much better”. Thirteen cases of mesh exposure were reported over a period of 12 months (10.2%). Eleven of these underwent a total mesh repair (4 cut, 7 uncut), two had an anterior repair; 7 were excised, 6 were treated conservatively with the use of topical estrogens. Seven patients (5.5%) reported pelvic pain at baseline, and by 12 months, there was resolution of this pre-existing pelvic pain in all 7. At 1 year, in 5 (3.9%) patients de novo pelvic pain was reported: 2 during routine daily life, and in 3 patients, pain was only elicited during pelvic examination. At 1 year, in 2 (1.6%) of the patients the investigator considered that there was evidence of vaginal wall stiffness.

At baseline, dyspareunia was reported in 18/61 (29.5%) sexually active patients. At 12 months, 13 of these 18 patients reported resolution of dyspareunia; 4 had ongoing dyspareunia and 1 patient had not returned to sexual activity for unrelated reasons. There was one report of de novo dyspareunia out of 66 (1.5%) patients who reported sexual activity at 1 year. Of these 66 sexually active patients, 9 (13.6%) were patients who had not been sexually active at baseline, and had resumed sexual intercourse without reporting de novo dyspareunia following surgery.

Interpretation of results

The overall anatomic success (Stage 0 or I) in the treated compartments at 12 months was 77.4%. These results are consistent with similar multicentre studies with the original polypropylene mesh in the Prolift system.[2,3] Improvements in the leading edge definition of success (89.5%) were consistent with the patient’s report of “much better” on the PGI-C (86.2%). The discrepancy between this and the primary definition of success highlights the ongoing debate on the appropriateness of POP-Q stage ≤ I as the ultimate anatomic goal to be achieved when defining success in studies evaluating POP repairs. The improvements observed in symptoms and QoL, measured using the PFDI-20 and PFIQ-7 questionnaires highlight large and statistically functional improvements which were sustained over time.

One of the key rationales for adopting a lighter-weight mesh, with improved directional elastic properties was to minimize tissue shrinkage, which may lead to dyspareunia. In this study, the rate of de novo dyspareunia was 1.5%, which was encouragingly low.

Concluding message

These results are suggestive of good anatomic support consistent with those reported with the original mesh, and high global patient impression and functional improvements. The low rate of de novo and preexisting dyspareunia together with the low rate of de novo pelvic pain is encouraging. Longer-term follow up continues.

Table 1: Anatomical outcome measures

POP stage	Baseline (n=127)	12 Months (n=124)
Stage 0	-	51 (41.1%)
Stage I	-	45 (36.3%)
Stage II	4 (3.1%)	24 (19.4%)
Stage III	104 (81.9%)	1 (0.8%)
Stage IV	10 (15.0%)	-
Re-intervention	-	3 (2.4%)
Success: ≤Stage 1, % (95% CI)		77.4% (69.0%- 84.4%)
Success: Leading edge <0cm, % (95% CI)		89.5% (82.7% - 94.3%)

Table 2: Functional results

All patients n: 127	Baseline	12 months
PFDI-20	98.9 (52.0)	25.9 (28.1)*
PFIQ-7	74.5 (70.5)	9.3 (23.1)*
PISQ-12 (n=58)	33.4 (7.8)	39.0 (4.4)*

*denotes p<0.001

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Was the Declaration of Helsinki followed?	**Yes**
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