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## A LIGHT-WEIGHT MESH SYSTEM FOR TRANS-VAGINAL MESH REPAIR: INTERIM 3-MONTH RESULTS

### Hypothesis / aims of study:

There is increasing evidence suggesting that trans-vaginal placement of prosthetic mesh may reduce recurrence rates<sup>1</sup>. However, the use of mesh has introduced new morbidities: specifically mesh exposure, contraction and possibly related symptoms of pain and dyspareunia. In an attempt to reduce these complications, existing polypropylene mesh (45g/m<sup>2</sup>) was replaced by a composite mesh, comprising equal parts of absorbable Polyglecaprone-25 monofilament fiber and non-absorbable polypropylene monofilament fiber (GYNECARE PROLIFT+M™ Pelvic Floor Repair System, Ethicon, Somerville, NJ). Following resorption of the absorbable component by around 90 days, the remaining mesh weighs approximately 28g/m<sup>2</sup>. The objectives of this study are to evaluate anatomic, functional and safety outcomes of this lighter-weight mesh.

### Study design, materials and methods:

Women from 11 sites in Europe (8) and United States (3) with symptomatic prolapse (ICS POP-Q Stage III-IV) were invited to participate in this prospective, single-arm study. The study was to include approximately 125 subjects to allow for approximately 118 evaluable subjects at 1 year.

All patients were to undergo pelvic organ prolapse repair utilizing the Prolift+M system. Concurrent hysterectomies and/or mid urethral sling procedures were allowed at surgeon discretion. Evaluations were at baseline, peri-operatively and 3 months, with planned follow up at 1, 2 and 3 years post procedure. Anatomic outcomes were assessed using the POP-Q scale, with the primary outcome defined as anatomic success (POP-Q Stage ≤ I) at 1 year in the treated compartment. Symptoms were assessed by completion of the Pelvic Floor Distress Inventory (PFDI-20), the Pelvic Floor Impact Questionnaire (PFIQ-7) and a Patient Global Impression of Change (PGI-C). Patients were asked specific questions regarding sexual activity and dyspareunia. Here we report interim results at 3 months.

### Results:

In total, 128 women were enrolled with a mean age of 63.9 years (SD 10.0) and mean BMI of 27.5 (SD 3.8). 21.1% had undergone prior prolapse surgery and 40.6% prior hysterectomy. Pre-operatively, 82.0% were Stage III, 14.8% Stage IV and 4 women were Stage II. 70 women (55.1%) had total Prolift+M repairs, with the mesh divided in 38 of these cases; 41 (32.3%) had anterior Prolift+M repairs, and 16 (12.6%) had posterior Prolift+M repairs. 16.4% had concurrent hysterectomy; 28.1% a mid-urethral sling and 10.9% perineal repair.

At 3 months, 118 patients had available data. 93.2% had treated compartment POP-Q Stage ≤ I; 57.0% had Stage 0 and 36.8% had Stage I; 6.0% had Stage II prolapse (see Table 1 for POP-Q measurements). Based on the PGI-C scale, 85.0% of patients reported being "much better"; 9.7% "a little better"; 2.7% "about the same" and 2.7% "a little worse" at 3 months after surgery. There were significant improvements in all overall scores and sub-scales of the PFDI-20 and PFIQ-7 (see Table 2). 17 patients reported dyspareunia at baseline, and by 3 months, 11 reported resolution, 3 were unresolved, and 3 had yet to return to sex by 3 months. There were no reports of *de novo* dyspareunia. Two patients who had not been sexually active at baseline, resumed sexual intercourse following surgery without dyspareunia.

There was a total mesh expulsion in one patient during the immediate post-operative phase; she was returned to the operating room and a further Prolift+M mesh was placed without further sequelae. Bladder perforation occurred in two patients during dissection; in one case, the mesh was placed, and in the other, the procedure was abandoned. Mesh exposure occurred in 6 patients (4.7%): 3 required partial excision of the mesh; 2 were treated with local oestrogen and 1 remained untreated.

### Interpretation of results:

These results are suggestive of good anatomic support consistent with those reported with the original mesh<sup>2</sup>, and high global patient and functional improvements. No apparent safety concerns were seen from the change in mesh. The lack of *de novo* dyspareunia and resolution of pre-existing dyspareunia is encouraging. Longer-term evaluation of this light-weight mesh continues.

### Concluding message:

These preliminary results indicate that Prolift+M is safe, with good short-term outcomes.

	Baseline	3 Month	Mean change
N=118			

Table 1: Mean (SD) in cm				POP-Q Measurements
Ba	2.5 (2.0)	-2.6 (0.7)	-5.0 (2.2)*	
Bp	0.2 (2.5)	-2.6 (0.8)	-2.8 (2.8)*	
C	-2.0 (4.4)	-6.7 (1.7)	-4.7 (4.5)*	
Gh	4.3 (1.0)	3.4 (0.8)	-0.8 (1.1)*	
Pb	2.9 (0.9)	3.4 (0.8)	0.4 (0.8)*	
TVL	8.7 (1.3)	8.4 (1.2)	-0.4 (1.3)	

\*p<0.001

Table 2: Mean Total Scores (SD) in Functional Outcomes

References	Baseline	3 months	Change from baseline
N=118			
PFDI-20*	99.3 (53.0)	31.2 (26.4)	-68.1 (51.1)^
POPDI-6**	40.9 (22.1)	5.9 (8.2)	-35.1 (22.1)^
CRADI-8**	21.9 (17.4)	11.5 (12.3)	-10.6 (16.4)^
UDI-6**	36.5 (25.3)	13.8 (17.1)	-22.4 (26.3)^
PFIQ-7*	72.4 (71.4)	17.6 (36.5)	-54.6 (76.0)^
POPIQ**	24.1 (28.2)	3.8 (12.0)	-20.3 (29.5)^
CRAIQ**	17.1 (24.4)	4.7 (13.5)	-12.3 (25.7)^
UIQ**	31.2 (28.3)	9.1 (16.6)	-22.2 (31.9)^

\*0 = best score to 300 = worst score; \*\*0 = best score to 100 = worst score, ^ = p<0.001

1. Feiner B, et al. BJOG 2009; 116:15-24
2. Altman D, et al. Int Urogynecol J 2008; 19:787-793

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Is this a clinical trial?	Yes
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Is this study registered in a public clinical trials registry?	Yes
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Specify Name of Public Registry, Registration Number	ClinicalTrials.gov Registration Number: NCT00833001
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What were the subjects in the study?	HUMAN
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Was this study approved by an ethics committee?	Yes
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<b>Specify Name of Ethics Committee</b>	Vorsitzender der Ethik-Kommission der Medizinischen Fakultät (Chair of the Medical Faculty Ethics Commission) Universitätsklinikum Tübingen (Tübingen University Clinic) Oakwood Hospital IRB, Dearborn, MI Spectrum Health IRB, Grand Rapids, MI St. Luke's Hospital IRB, Allentown, PA Ethics Committee, Martin-Luther University, Halle, Germany Ethics Committee Southeast 6, France
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	Yes