279

Voskerician, PhD G[1], Connor, MS J[2], O'Reilly, MD B[3]
1. *Proxy Biomedical Limited,* ***2.*** *Boston Scientific,* ***3.*** *Department of Urogynaecology, Cork University Maternity Hospital*

EVALUATION OF LOCAL TOLERANCE OF LIGHTWEIGHT MESHES IN AN ANIMAL MODEL

Hypothesis / aims of study
Differences in mesh materials may affect outcomes such as mesh erosion, tissue integration, inflammation, etc. The majority of commercially available meshes are made from monofilament polypropylene with differing morphology and mechanical properties. The objective of this animal study was to assess the local tolerance of the Polyform® Mesh (Boston Scientific) and VitaMesh® Implant PFR (Proxy Biomedical) meshes to other commercially available polypropylene meshes in modulating wound healing response based on their inherent design parameters.

Study design, materials and methods
Meshes of 3cm x 3cm size were implanted in female rats (reciprocation rate of n=5); 1 group served as the control (no mesh, sutures only). The following meshes were used, in order of smallest to largest pore size: Polyform Mesh (Pinnacle® Mesh, Boston Scientific), IntePro® Lite™ Mesh (Perigee® Sling, AMS), VitaMesh Implant PFR (Proxy Biomedical), UltraPro® Mesh (Prolift +M® Mesh, Ethicon). A 3cm skin abdominal incision was made, starting midway between the xyphoid process and the pubic bone and extending to the level of the bladder, and a bilateral subcutaneous pocket was created. The mesh was secured onto the abdominal wall on each of the four corners using 4-0 Prolene® Sutures. The position of the mesh provided a 1.5cm coverage to the left and right of the incision. The skin was closed using 9mm surgical staples. For the sham group, four 4-0 Prolene® Sutures were placed; no mesh was used. The animals were sacrificed at 7, 30, and 90 days. Data collected included parameters on mesh erosion, skin dehiscence, tissue integration, wound contraction, and host tissue response. Parameters were graded on a scale of 0 to 4; mild deviation from sham, to extensive deviation.

Results
All meshes displayed a similar response in histological evaluation and no redness, irritation, mesh extrusion, or skin dehiscence was seen at any time point. For mesh contraction, all meshes showed some contraction or relaxation at 7, 30, and 90 days, yet InteProLite Mesh showed the highest percentage of change in surface area and mesh relaxation at 90 days as compared to the other meshes. Polyform Mesh had the smallest percentage of overall change in surface area, followed by VitaMesh Implant PFR then UltraPro Mesh. The mesh abdominal wall integration presented a common trend with the strength of integration increasing for all mesh groups between 7 and 90 days. At 90 days, Polyform Mesh exhibited the highest strength of separation from the abdominal wall, followed by VitaMesh Implant PFR, InteProLite Mesh, and UltraPro Mesh. Mesh failure was reported in the UltraPro Mesh group when the biodegradable component progressively weakened and the separation of the mesh from the underlying tissue led to mesh failure. No significant differences between mesh types were seen for mesh erosion, skin dehiscence, and host tissue response.

Interpretation of results
Based on the data presented, Polyform Mesh and VitaMesh Implant PFR showed equivalence in most areas reviewed and improvements in specific areas when compared to UltraPro Mesh or InteProLite Mesh. Improvements included enhanced tissue integration with respect to mesh pull-out force when compared to UltraPro Mesh and InteProLite Mesh and less mesh relaxation at 90 days compared to InteProLite Mesh.

Concluding message
The Polyform Mesh structure may have advantages with respect to tissue integration and fixation, while VitaMesh Implant PFR may have advantages as a result of its light weight and reduced surface area; however, additional studies are recommended. In summary, these observations in mesh characteristics may benefit the design of next generation pelvic floor meshes.

Specify source of funding or grant	**Boston Scientific**
Is this a clinical trial?	**No**
What were the subjects in the study?	**ANIMAL**
Were guidelines for care and use of laboratory animals followed or ethical committee approval obtained?	**Yes**
Name of ethics committee	**IACUC protocol # 2006-0147 at Case Western Reserve University, Cleveland, Ohio, USA**