

MEDTRONIC SUMMARY: PRECLINICAL PAPER

Medtronic provides the following synopsis of a clinical publication involving Symbotex™ composite mesh.

TITLE	“Large pore size and controlled mesh elongation are relevant predictors for mesh integration quality and low shrinkage” - Systematic analysis of key parameters of meshes in a novel minipig hernia model
AUTHORS	Dirk Weyhe, William Cobb, Julie Lecuivre*, Antoine Alves, Sebastien Ladet*, Davide Lomanto, Yves Bayon*
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INTRODUCTION

Until now, the development of mesh implants was mainly influenced by reduction of material amount to improve their biocompatibility. Today it is well known that pore size is a key influencing factor of biocompatibility in term of mesh integration, scar plate formation and chronic inflammation

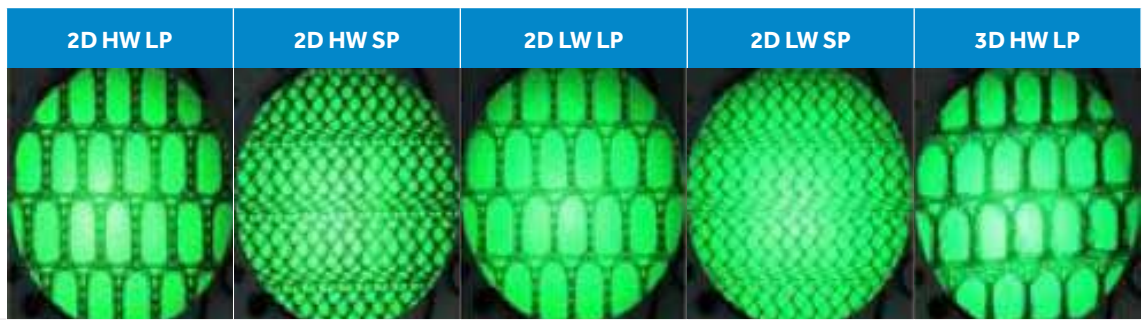
PURPOSE OF THE STUDY

This experimental study aimed to compare a series of two dimensional lightweight and heavyweight mesh prototypes as well as a large pore three dimensional mesh in order to define the optimal range of pore size based on the postoperative assessment of tissue integration and shrinkage behavior in hernia minipig model.

METHODS

- Experiment and analysis were carried out in twenty female Gottingen minipigs, this model was selected because of the high comparability between human and pig anatomy and immunology
- 20 minipigs were each implanted at four implantation sites between the transverse and the internal oblique muscles. Three weeks (10 animals) and 21 weeks (10 animals) post implantation, the minipigs were euthanized. The three-week span was chosen because after this time the mesh typically shows optimal connective tissue development, and the 21-week span was chosen because at this time the mesh is fully remodeled and any scar tissue has completely developed and is healed up
- Five monofilament polyester mesh prototypes were designed and knitted specifically for the study: One 2D lightweight small pore mesh, one 2D heavy weight small pore mesh, one 2D lightweight large pore mesh, one 2D heavyweight large pore, and one 3D heavyweight large pore mesh

- The implanted sites were then macroscopically observed (n=8 sites per article and per time period) and sampled for histopathological analysis and mechanical testing
- The integration of each implanted article into surrounding tissues was systematically recorded on the edges from macroscopic observations at 3 and 21 weeks postoperatively. Integration was considered complete when no void was observed between articles and surrounding tissues, and incomplete when areas of articles were not attached to the surrounding tissues
- The tissue integration of each collected sample was evaluated by measuring the peeling work required to separate the mesh from the transverse muscle using a traction testing machine
- Histopathological analysis: Stained sections were qualitatively evaluated
- Shrinkage measurements: After performing peeling tests of the mesh from the transverse muscles, the length of the mesh attached on the internal oblique muscle was measured in the dorsal-ventral implantation axis. The shrinkage rate was then calculated with the following formula: $\text{shrinkage rate} = \frac{[(\text{initial length} - \text{measured length at explantation}) / (\text{initial length})] * 100}{(\text{Initial length is } 8 \text{ cm})}$



		2D HW LP		2D HW SP		2D LW LP		2D LW SP		3D HW LP	
Basis weight (g/m ²)		90		90		42		42		98	
Pore size (X x Y) mm		1.8 x 3.4		0.9 x 1.0		2.0 x 3.4		1.0 x 1.1		2.0 x 3.3	
Thickness (mm)		0.7		0.5		0.4		0.4		1.3	
Direction		WARP	WEFT	WARP	WEFT	WARP	WEFT	WARP	WEFT	WARP	WEFT
Tensile test	Tensile strength at break (N)	320 ± 10	196 ± 10	385 ± 17	299 ± 6	200 ± 6	114 ± 14	207 ± 16	146 ± 5	215 ± 7	195 ± 10
	Elongation at 50N	19 ± 0	28 ± 0	27 ± 0	23 ± 0	28 ± 0	42 ± 1	39 ± 0	36 ± 1	21 ± 1	26 ± 1

RESULTS

- Integration of the small pore meshes was not complete, even at 21 weeks postoperatively
- On the contrary, integration of the large pore meshes was almost complete at only 3 weeks postoperatively and was statistically different at 21 weeks when compared to the integration of their small pore counterparts ($p < 0.005$; Exact Fisher test)
- The 3D large pore mesh generally promoted better integration of the article (as confirmed by histopathology), particularly at 21 weeks postoperatively
- At 3 weeks postoperatively, the peeling work was the highest for the 2D lightweight large pore mesh (2D LW LP) and for the 3D large pore mesh (3D HW LP). A statistical difference was demonstrated between these two groups and the 2D heavyweight small pore mesh (2D HW SP)
- The highest shrinkage was observed with the 2D lightweight small pore mesh (2D LW SP), displaying a statistically different behavior than each of the other tested meshes. At the other end was the 3D heavyweight large pore mesh (3D HW LP), showing the lowest shrinkage rate, with statistical differences compared to the 2D LW SP mesh and the 2D lightweight large pore mesh (2D LW LP). The 2D heavyweight meshes appeared to shrink at the same level as the 2D LW LP mesh, even though their behavior was not statistically different from the 3D mesh, due to high variability in the shrinkage

observations. These observations were supported by the histopathological analyses, which showed the same ranking in terms of retraction or shrinkage in the same direction of the ventral-dorsal axis

CONCLUSION

- Large pore construct support stronger tissue integration during the early postoperative period, this appeared to be even truer for the 3D large pore construct. This indicates that an improvement in tissue integration is independent of the amount of material but is significantly influenced by the 2D and 3D porosity
- The 3D large pore mesh was also found to offer the best resistance to shrinkage
- New mesh constructions with large porosity (i.e., > 1.5 mm), appropriate stability (elongation at 50 N), an application-oriented texture (i.e., 3D structure), and a tensile strength should promise assistance in selecting more effective medical devices

REFERENCES

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This concludes the clinical synopsis of this publication.wv

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