

Polyform[™]

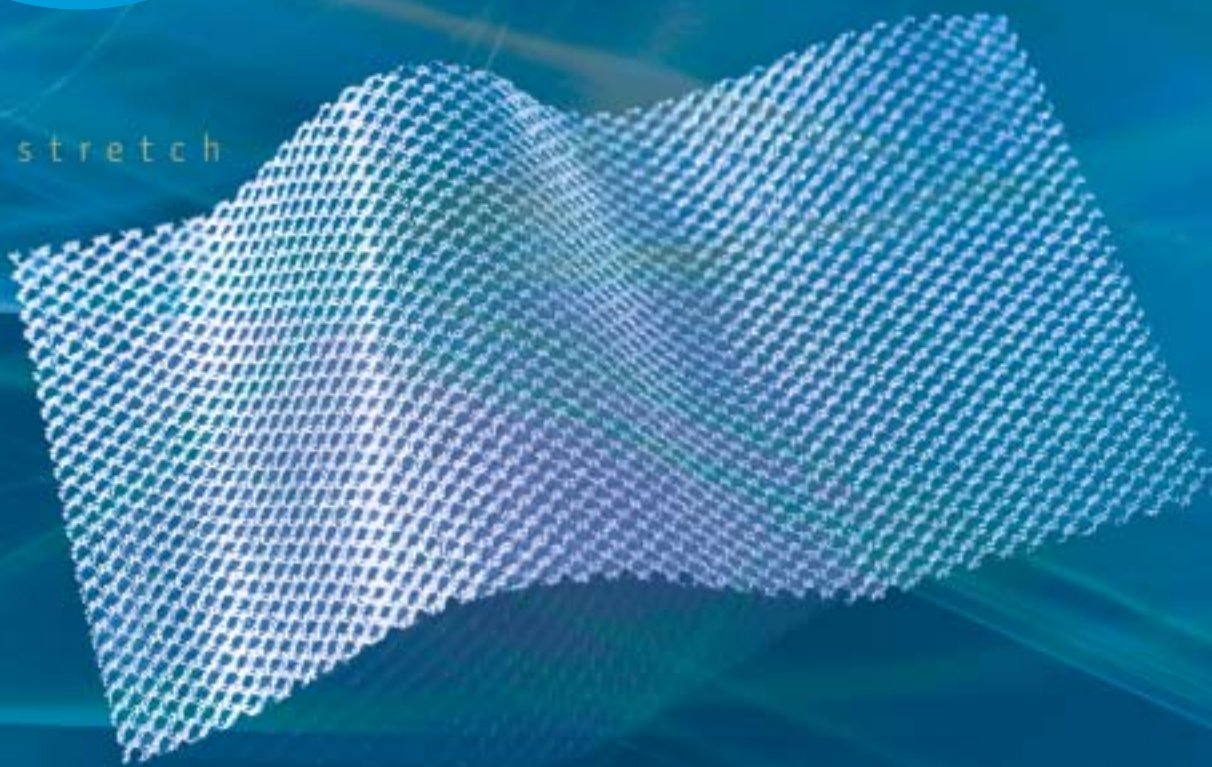
Synthetic Mesh

Boston
Scientific

**Soft, Smooth,
Thin, Light**

less rigid

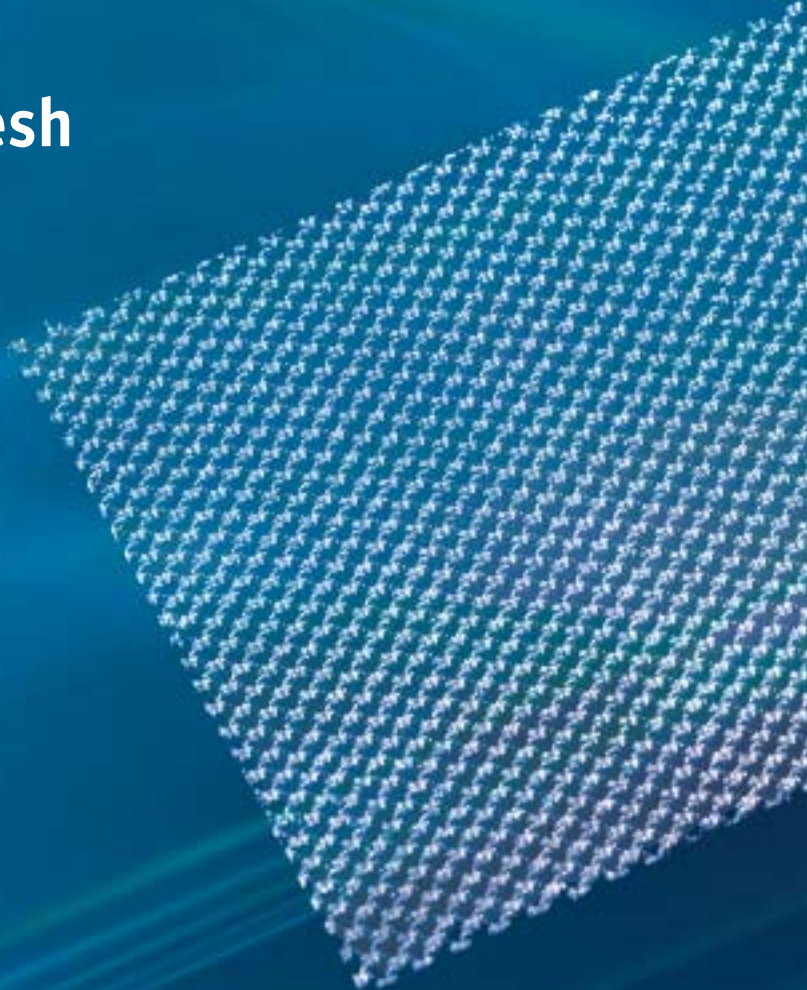
more stretch



reduced friction

Polyform™ Synthetic Mesh

Polyform Mesh is made from uncoated monofilament macroporous Polypropylene. This material has the greatest history of success and has been implanted throughout the body for over 30 years¹. The goal was to improve upon this well known material and make it softer, smoother, thinner, and lighter with increased stretch compared to the leading synthetic mesh for pelvic organ prolapse². Polyform Mesh has arrived!



PRODUCT COMPARISON^{1,2}

LEADING POLYPROPYLENE MESH

POLYFORM MESH

Polypropylene Mesh	✓
Monofilament Material	✓
Macroporous (>100 microns)	✓
Consistent large pieces	✓
Strong and readily available	✓
Rough, coarse to touch	Smoother to the touch
Thick and heavy	Thinner and lighter
Not enough stretch	Increased stretch in both directions
Lacks softness	Decreased rigidity

1 – Independent bench testing at Proxy Biomedical Limited – data on file

2 – Physician advisory board and marketing research – 2004

Bench testing may not be indicative of clinical results

SMOOTH WITH MORE STRETCH

Having a smooth surface is important in a synthetic material to reduce the irritation on adjacent tissues^{1,2}. In addition, stretch is a feature that physicians commented would be beneficial to move with the anatomy and reduce possible suture pullout. Polyform Mesh is both smooth and provides stretch.

THIN AND LIGHT

It is accepted among physician experts, the less mesh implanted, the better. Polyform Mesh is both lighter and thinner than Gynemesh® PS Mesh³.

SOFTNESS AND STRENGTH

Softness and conformity are important attributes when performing a graft-aided repair². The ability to stay soft while not compromising strength was the goal. Polyform Mesh has been successful in providing both: softness and strength³.

1 – Podium presentations at AUGS and AAGL – 2004
2 – Boston Scientific advisory board meeting – 2005

TECHNICAL COMPARISON^{1,2:}

Within key criteria, compared to Gynemesh PS Mesh, Polyform Mesh is:

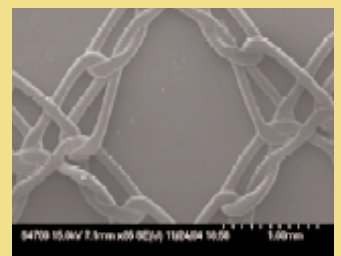
- 40% softer (reduction in rigidity/stiffness)
- 55% thinner (reduction in thickness)
- 35% smoother (reduction in coefficient of friction)
- 20% lighter (reduction in basis weight)
- 3x greater stretch (blended reduction in force v displacement)

CHARACTERISTIC	POLYFORM MESH	GYNEMESH PS
Composition	Monofilament Polypropylene	Monofilament Polypropylene
Pore Size (microns)	Macroporous - 1450	Macroporous - 2500
Fiber Diameter (microns)	100	100
Basis Weight (g/m ²)	40	50
Thickness (microns)	205	457
Coefficient of Friction (μ^2)	.67	1.03
Flexural Rigidity/Stiffness (F _{max} N)	2.6	4.3
Ball Burst (F _{max} N)	263	280
Elongation Machine (F _{max} N)	4.0	20
Elongation Transverse (F _{max} N)	6.0	14
Size	10cm x 15cm	10cm x 15cm

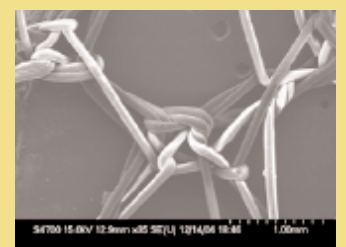
3 – Independent bench testing at Proxy Biomedical Limited by or on behalf of Boston Scientific – all comparisons completed on Zwick material testing machine, July 2005
Bench testing may not be indicative of clinical results

KNIT COMPARISON

Polyform Mesh:



Gynemesh PS Mesh:



Photographs by Proxy Biomedical Limited.

Polyform™

Synthetic Mesh

PRE-CLINICAL REVIEW¹:

TITLE:

In vivo tolerance of Polyform Mesh and Gynemesh® PS Mesh in a rodent model

ANALYSIS:

To compare the in vivo repair process induced by Polyform Mesh to that elicited by Gynemesh PS Mesh with respect to collagen deposition and assessment of wound healing

LAYOUT:

Animal model, rat, subcutaneous tissue. Time points 1, 3, 6, and 12 weeks

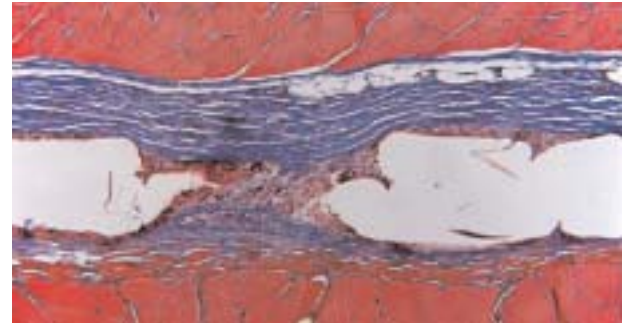
CONCLUSIONS:

The subcutaneous implantation of Polyform Mesh and Gynemesh PS Mesh did not lead to an actual fibrous capsule for either material. The inter-nodal wound healing was characterized by collagen deposition, but not actual generation of a fibrous capsule extending over the surface of the materials. Thus, the open mesh design of both materials led to tissue-material integration rather than fibrous capsule isolation.

Both materials behaved similarly at all time points with respect to the inflammatory and wound healing response and collagen deposition characteristics.

¹ – Testing conducted at Case Western Reserve University independent lab setting, and histopathy performed by James M. Anderson, MD, PhD, Professor of Medicine, Biomedical Engineering and Macromolecular Science, April 2005.

12-weeks post implantation:



Polyform™ Mesh



Gynemesh PS Mesh

ORDERING INFORMATION

POLYFORM SYNTHETIC MESH

Order Number	Description	Size (cm)
M0068402400	Polyform Synthetic Mesh	10 x 15

Gynemesh is a trademark of Johnson & Johnson Corporation. Polyform Synthetic Mesh is manufactured by Proxy Biomedical and distributed by Boston Scientific.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Refer to package insert provided with the product for complete Instructions for Use, Contraindications, Potential Adverse Effects, Warnings and Precautions prior to using this product.

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