

In Vitro and In Vivo Degradation of a Fully-Absorbable Poly(glycolide-co-lactide) Mesh

Meng Deng, Sandy Savidge, Wei Kong, and Timothy Muench
R&D, Ethicon, Johnson & Johnson, P.O.Box 151, Somerville, New Jersey 08876, USA

INTRODUCTION

Understanding the *in vitro* and *in vivo* degradation behaviors and the correlation of the two are among the critical tasks for absorbable polymeric biomaterials and the medical devices manufactured from them. While an *in vitro* test is generally conducted under simulated biological environment, the *in vivo* study needs to implant a test article into animals. This study investigated the *in vitro* and *in vivo* strength retention of a poly(glycolide-co-L-lactide)-based mesh material for a time period of 2 weeks. Effects of experimental conditions on tensile and burst strengths were evaluated.

MATERIALS AND METHODS

The experimental material was a knitted mesh constructed by multifilament yarns that were made from a partially-crystalline copolymer of ~90mol% glycolide and ~10mol% L-lactide (PGL). The meshes were Eto-sterilized. Table 1 lists the mesh properties before degradation. Meshes were cut into specimens of 60mm by 10mm strips along machine direction for tensile testing and 25mm by 25mm for burst testing. For *in vitro* study, the samples were placed into phosphate buffer solution of pH7.3 at 37°C. For *in vivo* tensile tests, samples were implanted subcutaneously over the thorax on the dorsum of rats (female Long Evans) in two ways, (1) in direct contact with tissue and (2) the sample was placed in a dialysis tubing and then implanted. Each rat received two implants, one on either side of the midline. For *in vivo* burst tests, a ventral abdominal midline skin incision (~3cm) was made through the linea alba of rats and closed in two way, (1) using 4-0 PGL sutures only and (2) using both suture and mesh (~5x3cm). Total 12 animals were used. The animals were handled and maintained in accordance with the standards promulgated in the Guide for the Care and Use of Laboratory Animals. At 2-week post-surgery animals were euthanized. Mechanical tests were performed on the samples immediately following their removal at room temperature for tensile (mesh only) and ball burst (abdominal tissue plus mesh) strengths with an Instron mechanical tester with a 500-N load cell. Tensile test was run with gauge length 50mm, and crosshead speed 150mm/min. Ball burst test was performed with test area diameter 12.5mm, probe diameter 6.3mm, and crosshead speed 25mm/min. Tissue reaction was evaluated through histological analysis.

RESULTS AND DISCUSSION

Fig 1 shows how *in vivo* tensile samples looked like at explantation. At 2 weeks the samples could be easily removed from implantation site and the mesh samples should have still a strength retention of ~50% (comparing to the data in Table 1). As can be seen, the sample in direct contact with tissue showed curling. At this time tissues, if any, could be easily separated from the mesh. Fig 2 shows the comparison of tensile strength at 2-week degradation, and the results were not statistically different among 3 treatment groups, indicating the degradation was dominated through hydrolysis and curling did not affect the mesh strength as far as it could be removed from implantation site. Tensile elongation at breaking was also not affected, indicating the stretching ability of the mesh did not change under 3 conditions. Fig 3 shows the comparison of burst strength at 2-week degradation, which clearly indicates that use of the mesh greatly increased the burst strength at incision sites, ie, a better wound closure security when suture and mesh were used together. Compared to sutures alone, using both sutures and mesh led to an increase of burst strength by ~300%, which were mainly due to the

mesh. The burst strength of tissue closed with suture only was similar to the strength of fresh tissue. Histological analysis showed no abnormal reaction of the tissue to the implants in both cases. No significant tissue ingrowth was observed at 2 weeks.

SUMMARY

The *in vitro* and *in vivo* degradation behaviors of a PGL mesh were investigated at 14-day degradation. The results show that the *in vitro* and *in vivo* tensile strengths correlated well. The burst test results showed that using both suture and mesh to close incision would greatly increase the wound closure security if compared to suture alone. The animal tolerated well the mesh.

ACKNOWLEDGEMENTS

The authors want to thank Dr. David Burwell, Dr. Larry Johnson, Dr. Stephen Rothenburger, Dr. Richard Skula, Robert Tannhauser and Liz Vailhe for reviewing the abstract.

Table 1. Initial Mesh Properties

| Density (g/m ²) | Porosity (%) | Tension Strength (N) | Burst Strength (N) | Mw (g/mol) |
|-----------------------------|--------------|----------------------|--------------------|------------|
| 51.1±2.3 | 45.8±0.8 | 92.8±10.2 | 99.09±5.81 | 58300 |

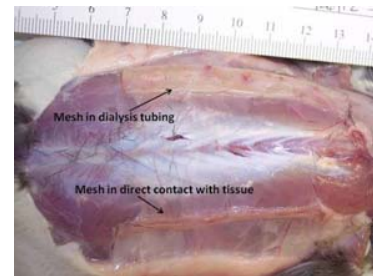


Fig 1. Images of Two Mesh Samples at Explantation

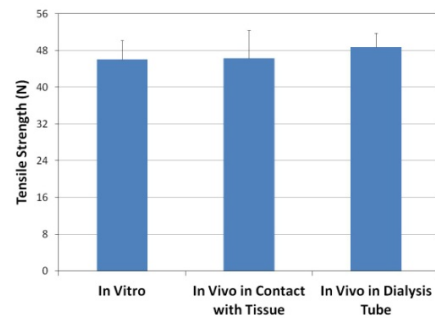


Fig 2. Comparison of In Vitro and In Vivo Tensile Strength

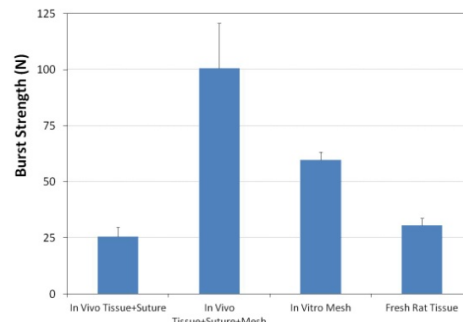


Fig 3. Comparison of In Vitro and In Vivo Burst Strength