

ADHESIVE SEALANT BIOMATERIALS

Technical Bulletin

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Burst pressure comparison of TissuePatchThoracic™ with three different surgical sealants used in Thoracic Surgery

Introduction

The aim of this study was to compare the burst pressure performance of TissuePatchThoracic (TPT) with three commercially available 'surgical sealants' available to thoracic surgeons, including: a PEG based sealant, an impregnated collagen fleece and a fibrin sealant.

Methods

Burst pressure testing was conducted in accordance with an internationally recognised procedure, ASTM F 2392-04 Standard Test Method for Burst Pressure Strength of Surgical Sealants.

Collagen films (4 mm diameter) were prepared as per the ASTM method, with a 3 mm diameter hole punched in the centre of each film.

For application of the fibrin and PEG based sealants, an ≈1 mm thick mould was placed over the collagen film, so that the 15 mm hole of the mould was centrally placed over the hole within the collagen film. The sealants were prepared according to the manufacturer's instructions, and applied so that the hole of the mould was filled. The fibrin sealant and the PEG based sealant were left for 30 seconds before the mould was carefully removed.

A 15 mm diameter disc of TissuePatchThoracic or the impregnated collagen fleece was applied over the 3 mm diameter hole within the collagen film, with pressure being applied for 30 seconds.

The collagen film was placed on the base of the test rig (see figure 1). The top of the rig was fixed in position, and secured using o-rings and wing nuts. Saline was delivered at a rate of 2ml/minute via a peristaltic pump and a digital pressure gauge was used to monitor the pressure to the point of failure.



Figure 1 – Burst Pressure Test Rig

Results

Table 1 and Figure 2 illustrate the comparative performance of the products tested.

Table 1 – Mean Burst Pressure of TissuePatchThoracic and Commercially Available Comparator Products

| Product | Mean Burst Pressure (mm Hg) |
|---------------------|-----------------------------|
| TissuePatchThoracic | 163 |
| PEG based sealant | 57.3 |
| Collagen fleece | 40.8 |
| Fibrin sealant | 6.0 |

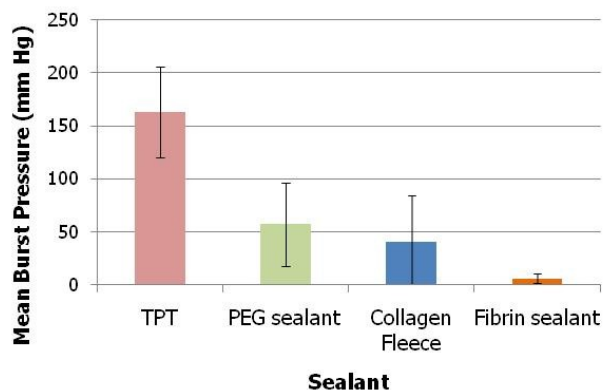


Figure 2 – Mean Burst Pressure of TissuePatchThoracic and Commercially Available sealant products used by thoracic surgeons.

The average burst pressure of TissuePatchThoracic was in excess of twice that of the competitor products. The mean burst pressure of the fibrin sealant was statistically lower (t-test, $p=0.01$) than that of TissuePatchThoracic. Due to the variability of the test results, there were no statistical differences in the performance of the other surgical sealants.

Conclusion

This *in vitro* study has revealed that defects treated with TissuePatchThoracic have a mean pressure to failure that is higher than the three other surgical sealants tested.

References

Data on file at Tissuemed.

ASTM method F 2392-04 Standard Test Method for Burst Strength of Surgical Sealants

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