ADHESIVE SEALANT BIOMATERIALS

Technical Bulletin

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Burst pressure comparison of TissuePatchDural™ with two different surgical sealants used in Neurosurgery

Introduction

The aim of this study was to compare the burst pressure performance of TissuePatchDural (TD) with two commercially available 'surgical sealants' available to neurosurgeons, including: a PEG based sealant 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 TissuePatchDural 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 TissuePatchDural and two commercially available sealants used in neurosurgery.

Product	Mean Burst Pressure (mm Hg)
TissuePatchDural	163
PEG based sealant	57.3
Fibrin sealant	6.0

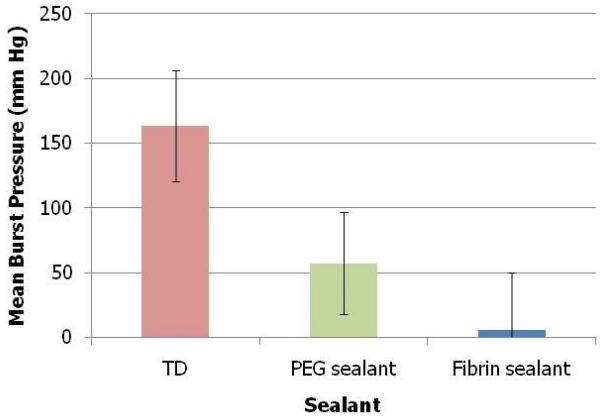

Figure 2 – Mean Burst Pressure of TissuePatchDural and Commercially Available sealant products used by thoracic surgeons.

The average burst pressure of TissuePatchDural was in excess of twice that of the PEG based sealant. The mean burst pressure of the fibrin sealant was statistically lower (t-test, p=0.01) than that of TissuePatchDural. Due to the variability of the test results, there was no statistical difference in the performance of the PEG based sealant.

Conclusion

This *in vitro* study has revealed that defects treated with TissuePatchDural have a mean pressure to failure that is higher than a series of commercially available surgical sealants.

References

Data on file at Tissuemed.

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