ADHESIVE SEALANT BIOMATERIALS

Technical Bulletin

Lesley Shea, Analytical Scientist
Tissuemed Ltd.

Tensile Strength and Burst Pressure Comparison of TissuePatch™3 with other commonly used Surgical Sealants

Summary

The aim of this study was to compare the physical properties (tensile strength and burst pressure) of TissuePatch3 with commercially available comparator products, namely Tisseel™(Baxter), TachoSil®(Nycomed) and PleuraSeal™(Covidien).

The tensile strength of TissuePatch3 was statistically greater than that of TachoSil (t-test, p=0.01), under both wet and dry conditions. The tensile strength of PleuraSeal and Tisseel could not be assessed, due to problems during sample preparation.

The mean burst pressure of Tisseel was significantly lower than that of TissuePatch3 (t-test, p=0.01). There was no significant difference between the mean burst pressures of the other products, probably due to the high standard deviations observed.

Background

The aim of this study was to compare the physical properties of TissuePatch3 with those of the following products: Tisseel, TachoSil, PleuraSeal, these being commonly used products and representative of the categories of product used as surgical sealants.

Methods

Tensile Strength Testing

Tensile strength testing of TissuePatch3 and TachoSil (wet and dry) was conducted according to Tissuemed Standard Operating Procedure 5.12 Tensile Testing of TissuePatch3.

Preparation of PleuraSeal and Tisseel samples involved applying each sealant to a mould and allowing the test strips to set.

Burst Pressure Testing

Burst Pressure testing was conducted in accordance with ASTM F 2392-04 Standard Test Method for Burst Pressure Strength of Surgical Sealants.

Collagen films (4 mm diameter) were washed in distilled water, and then soaked in fresh distilled water for five minutes before being stored in saline solution until use (for a maximum of one hour).

A collagen film was removed from saline and patted dry with blue roll. A 3 mm diameter hole was punched in the centre of the collagen film.

A 15 mm diameter disc of TissuePatch3 or TachoSil was applied over the 3 mm diameter hole within the collagen film, with pressure being applied for 30 seconds.

For applying Tisseel and PleuraSeal, an approximately 1 mm thick mould was placed over the collagen film, so that the 15 mm hole of the mould was centrally placed over the 3 mm 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. Tisseel and PleuraSeal were left to set for 30 seconds before the mould was carefully removed.

The collagen film was placed on the base of the burst pressure test rig. The burst pressure test rig top was put into position before being secured with the o-rings and wing nuts. The pressure gauge was zeroed and the peristaltic pump was switched on at a flow rate of 2 ml/minute. The burst pressure of each sample was recorded.

Results and Discussion

Tensile Strength Testing

When PleuraSeal was applied to the mould, it flowed underneath the top layer. After five minutes, the top part of the mould was removed. The PleuraSeal had not fully set and was observed to be 'jelly-like'. The PleuraSeal was left to fully set in the bottom of the mould but could not be cut into strips. The sealant tore, forming pieces that were not suitable for testing.

Problems were also experienced during the application of PleuraSeal to the mould, with the application mechanism becoming blocked on several occasions.

As a result the tensile strength testing of PleuraSeal (and Tisseel) according to the test protocol was abandoned.

The tensile strength of TachoSil was statistically lower (under both dry and wet conditions), when compared with the tensile strength of TissuePatch3 (t-test, p=0.01).

Table 1 – Tensile Strength of TachoSil and TissuePatch3

	TENSILE STRENGTH (kPa)			
	TachoSil		TissuePatch3 (TP3-015-08)	
	Dry	Wet	Dry	Wet
Mean	62.51 (± 18.66)	16.53 (± 5.90)	24197.42 (± 7814.30)	1294.75 (± 171.24)

Table 2 – Burst Pressure of PleuraSeal, TachoSil, Tisseel and TissuePatch3

Test #	Burst Pressure (cm H_20)			
	PleuraSeal	TachoSil	Tisseel	TissuePatch3
Mean	78.0 ± 53.8	55.4 ± 59.5	8.1 ± 6.2	140.6 ± 58.2

Note: Due to the fast-setting nature of PleuraSeal only a low number of samples could be tested.

Burst Pressure Testing

Table 2 shows the comparative performance of the products tested.

The mean burst pressure of Tisseel was statistically lower than that of TissuePatch3 (t-test, p=0.01). There was no significant difference between the mean burst pressures of any of the other sealants, which can probably be attributed to the relatively high standard deviations observed and low sample sizes of PleuraSeal and TachoSil tests.

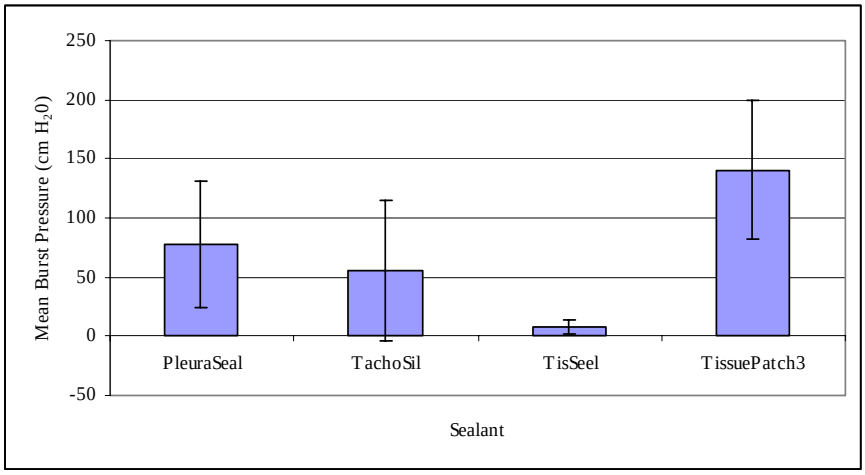

Figure 1 Mean Burst Pressure of PleuraSeal, TachoSil, Tisseel and TissuePatch3

Conclusions

This *in vitro* assessment of the clinically relevant physical characteristics of TissuePatch3 suggests that it provides acute performance significantly better in some parameters and equivalent in others when compared with commercially available comparators.

Tensile Strength

The tensile strength of TissuePatch3 was statistically greater (t-test, p=0.01) than the tensile strength of TachoSil, when tested under both dry and wet conditions.

Tensile testing of the liquid sealants according to the established model rendered no meaningful results. Consequently new methods for assessing tensile strength of these polymerising liquids may need to be established, although the fundamental lack of strength in these polymer matrices may ultimately mean such tests yield no useful data.

Burst Pressure

The mean burst pressure of Tisseel was statistically lower (t-test, p=0.01) than that of TissuePatch3 (TP3-015-08). There were no statistical differences in the mean burst pressures of the other surgical sealants, probably due to the high standard deviations observed.

References

Data on file at Tissuemed

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

Note:
Tisseel is a trademark of Baxter International Inc PleuraSeal is a trademarks of Covidien AG or its affiliate
TachoSil is a registered trademark of Nycomed International Management GmbH

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