

ADHESIVE SEALANT BIOMATERIALS

Technical Bulletin

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Improved adhesion and tensile properties of TissuePatch3™ when tested at 37°C compared with 20°C.

Abstract

The purpose of this study was to investigate the characteristics of TissuePatch3 at 37 °C in order to better understand the key performance characteristics of the product in the surgical setting.

The data gathered in this study has shown that the energy of adhesion of Terpolymer is higher when tested at 37 °C, presumably due to a greater rate of reaction. It is possible that the standard test procedure undertaken at ambient (~20 °C) underestimates the true *in vivo* energy of adhesion, however it is not proposed that the test method should be altered.

Introduction

The purpose of this study is to investigate the characteristics of TissuePatch3 at 37 °C. Tissuemed undertakes routine analysis at room temperature (R&D lab=20 °C), however the product is designed for *in vivo* use at 37 °C and it is thus desirable to determine how the two key parameters of adhesion and tensile strength behave at this temperature.

Experimental

Using TissuePatch3 batch TP3-008-08, a standard 10 minute adhesion test was conducted under typical conditions (liver and DPBS at ambient) in accordance with Tissuemed standard operating procedures¹. A second test was undertaken whereby the liver and DPBS were heated to 37 °C (PL240) for >30 minutes prior to the test. After application of the stub the liver was returned to the incubator for 5 minutes at which point the test subject was submerged in (warm) DPBS and returned for the final 5 minutes prior to testing.

A wet tensile test was conducted on both materials under typical conditions (DPBS at ambient) in accordance with TissuePatch3 standard testing protocol² with the exception that the test article was soaked for 10 minutes in DPBS prior to testing. A second test was undertaken whereby DPBS was heated to 37 °C for >30 minutes prior to the test. The test strip was immersed and returned to the incubator.

Results and Discussion

The results are shown in Table 1. The energy of adhesion increased when the temperature was raised to 37 °C (although this was not statistically significant in either case due to the large standard deviation, t-test, $p=0.01$). It is reasoned that the extra heat energy increases the rate of the chemical reaction between patch and tissue.



Figure 1 At ambient temperature product typically lifts off tissue as a flat sheet.



Figure 2 At 37°C product conforms to tissue throughout adhesion testing.

Increasing temperature has negligible effect on the tensile strength of TissuePatch3. At 37 °C the PLGA component of TissuePatch3 is still below its glass transition temperature (45°C), thus to observe a notable increase in elongation it may need to be raised to an unrealistic 50°C+.

Table 1 TissuePatch3 performance at 20°C and 37°C

Temp. °C	Energy of Adhesion mJ	Wet Tensile Strength MPa	Elongation at Break %
20	16.27 (± 4.19)	0.95 (± 0.54)	2.38 (± 0.85)
37	24.14 (± 6.01)	0.70 (± 0.30)	5.10 (± 2.38)

Conclusion

The data gathered in this study has shown that the energy of adhesion of Terpolymer is higher when tested at 37 °C, presumably due to a greater rate of reaction. It is possible that the standard test procedure undertaken at ambient (~20 °C) underestimates the true *in vivo* energy of adhesion. However it is not proposed that the test method should be altered.

References

- ¹ TP3 SOP 5.7
- ² TP3 SOP 5.12