

BACKGROUND

Surgical sealants are commonly used to prevent bleeding following vascular repair and reconstruction, but their use can lead to various side effects. An adverse response to a tissue sealant could result in poor healing, leading to the need for re-operation. An ideal sealant for use on vascular tissue should be biocompatible and combine elasticity and flexibility with strong tissue adhesion.

To date, no head-to-head comparison of the vascular tissue reactions induced by COSEAL and BioGlue have been performed.

STUDY OBJECTIVE

To directly compare the aortic and peri-aortic tissue reactions to COSEAL and BioGlue in a preclinical model

STUDY DESIGN

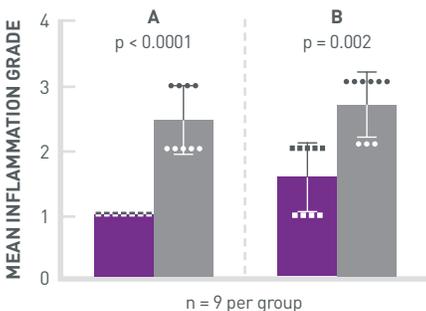
A total of 20 male New Zealand white rabbits underwent surgery. Following the administration of heparin, standardized suture holes in the abdominal aorta were created and then treated with either BioGlue or COSEAL per a 1:1 randomization scheme. Two-weeks following surgery, aorta puncture sites were collected and underwent histopathological analysis for tissue inflammation and material degradation.

RESULTS

In all applications, both sealants sealed the suture holes at the time of application. A typical foreign body reaction characterized by granulomatous inflammation was associated with both materials. However, BioGlue provoked eosinophilic cell infiltration. In addition, lymphocytes, plasma cells and B cells were more prevalent in BioGlue-treated tissue samples.



BioGlue was associated with a more severe inflammatory response than COSEAL

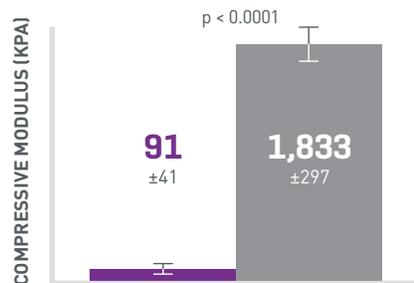


A: Mean (±standard deviation (SD)) of grades given by investigators at Center 1

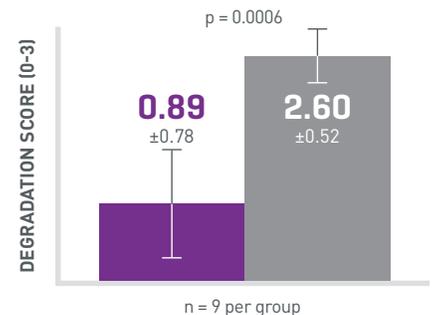
B: Mean (±SD) of grades given by investigators at Center 2

P-Values: Calculated using a Mann-Whitney U test. Inflammation grade: none (0); mild (1); moderate (2); severe (3).

COSEAL was more elastic than BioGlue



BioGlue degraded more slowly than COSEAL



Residual presence estimated at 2 weeks via HE staining

*When residual sealant was quantified using a scale of 0 (no residual sealant) to 3 (large quantity of residual sealant)

CONCLUSIONS

BioGlue and COSEAL demonstrated notable differences in type and severity of the resulting tissue reaction.

Compared to COSEAL, BioGlue stayed at the application site longer, and correlated with a more severe inflammatory response in the aortic and peri-aortic tissues. The presence of an acute inflammatory reaction and slower degradation suggests that BioGlue may be associated with a greater, long-term inflammatory response than COSEAL.¹

Due to the low level of inflammatory response, shortened length of inflammation in vascular tissue, and greater elasticity, the study suggests that COSEAL is superior in safety and tissue reaction with elastic tissues (eg. the aorta) in comparison to BioGlue.

To access the complete study, visit <https://journals.sagepub.com/doi/10.1177/0885328219900078>

For questions or ordering information, please contact your Baxter representative.

COSEAL Surgical Sealant Indications

COSEAL is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.

Important Risk Information

COSEAL is not to be used in place of sutures, staples or mechanical closure.

COSEAL swells up to four times its volume within 24 hours of application and additional swelling occurs as the gel absorbs. Therefore, surgeons should consider the maximum swell volume and its possible effects on surrounding anatomic structures potentially sensitive to compression.

Do not inject Coseal into vessels.

Rx Only. For safe and proper use of these devices, refer to the appropriate full device Instructions for Use.

1. Slezak P, et al. Tissue Reaction to a Polyethylene Glycol-based and Glutaraldehyde-based surgical sealant in a Rabbit Aortic Anastomosis Model [abstract]. In: Scientific Forum; 2019 March 5. Chicago, IL. The Online Abstract Submission and Invitation System, CTI Meeting Technology, 2019. Abstract No. 019-SF-2034-ACS.