

Vascular Sealants

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Overview

Vascular sealants are commonly used to reinforce sutures or staples during cardiovascular and vascular surgeries, helping to reduce blood loss.^{1,2,3,4} Surgical sealants are generally classified as either natural polymer based (fibrin, collagen, albumin), synthetic polymer based (polyurethane, polyethylene glycol, polyester), or cyanoacrylate based (not recommended for vascular applications).^{4,5,6} Utilization of sealants in vascular procedures is dependent upon their polymerization time, burst pressure strength, cytocompatibility, elasticity, and time to degradation.⁴ Vascular sealants can have varied indications for use and physician preference plays a key role in selection.

Actions for Consideration

Partner: Identify cardiovascular and vascular surgeons, operating room nurses and technicians, and appropriate additional value analysis team members (including both clinical and non-clinical). If considering consolidation of vendors, leverage supplier support as it will be crucial for evaluation of cross references and gaps. Due to the clinical sensitivity of this category, engaging a physician champion early on in the process will be integral.

Connect: Given the variety of sealants available with varying indications for use, a careful review of all products utilized within the vascular sealant category is helpful. Collecting and reviewing physician data including usage across various procedures/populations, cost, and clinical outcomes will help inform decisions. Identify evidence related to specific products including acute and long-term outcomes.

Communicate: Share product and physician utilization with team and develop a common goal. Discuss pricing, reimbursement, clinical outcomes, and feasibility of streamlining products and/or consolidating vendors. Robust data sharing will not only enhance discussions, but may lead to actionable conversations between peers.

HealthTrust Resources: Access the [Clinical Knowledge Insights Library](#) to find other relevant documents and toolkits with actionable information. Examples for this product include resources on product conversion, vendor consolidation, and value analysis.⁷ Network on [HealthTrust Huddle](#), our member community that shares ideas and seeks guidance from colleagues.⁸

Physician Advisor Insight

A panel of vascular surgeons within our HealthTrust Physician Advisor Network offered the following insight with regard to vascular sealants⁹:

- Bioglue: Not absorbable, potentially beneficial for high-pressure, anastomotic, large lesions like aortic aneurysm replacements that can tolerate the glutaraldehyde. It is heavier and used on graft to vessel sites.
- CoSeal: Potentially less adhesive but more flexible than Bioglue, which would benefit vascular procedures and lung surgery where sealing off leaks is important. Aids in holding things in place and can be used for vascular anastomosis due to its absorbable and not rigid properties.
- Preveleak : A little bit flexible and absorbable, sticks very well for vascular anastomosis, on the heart for Saphenous veins, and left internal mammary artery anastomoses. Additionally, it may be used for smaller, finer anastomoses.

- All have specific purposes and indications, depending on the area in the cardiovascular system.
- Sealants in this category are varied, some are "equivalent" but some are unique in efficacy in cardiothoracic surgery; others are non-equivalent.
- Sealants can be used on all patients, but especially those with fragile tissues, elderly patients, large cardiovascular cases (like dissections), and aneurysm repair.
- Important considerations for product choice may include: absorbability when needed, ease of preparation, ease of use, ease of application, knowledge of staff handling, and simple storage (room temperature vs refrigerated).

FDA Approval

Vascular sealants are reviewed through the Food and Drug Administration (FDA) Premarket Approval (PMA) process for Class III medical devices. Specific product FDA PMA approval information can be searched [here](#).¹⁰

Clinical Evidence

There is a variety of evidence available evaluating sealants in various clinical settings including direct comparison. A sample is included below:

- A 2019 study by Azadani et al. evaluated the mechanical properties of four surgical sealants (BioGlue, CoSeal, Tisseel, Crosseal) used in cardiovascular surgeries and compared the results with the properties of aortic root replacements in order to evaluate potential for suture less anastomoses. They concluded that all four glues had a linear elastic response to stress with Bioglue being "significantly stiffer" than the others. They also determined BioGlue is "much stiffer" than aortic root replacement grafts with CoSeal and Tisseel having increased compliance to the grafts. They suggest further research is needed as bonding strength of the included glues is "likely not" adequate as a sole tool for anastomosis; however, they have greater elasticity to soft tissue than suture. Limitations include the use of cited values of stiffness in the aortic root materials used for comparison and air trapping in the sealant samples that may affect stiffness and bonding.²
- A 2019 study by Murdock et al. compared the cytocompatibility, burst strength, elasticity, degradation, and hydrated swelling properties of BioGlue, PreveLeak, Tridyne VS, and Coseal. They concluded that the sealants each had differing properties to be considered for sealant choice in vascular and cardiovascular applications. BioGLue had the lowest compatibility with the highest burst strength, PreveLeak had limited hydrated swelling with lower elasticity than tissues and months to years degradation rate. Tridyne showed the highest compatibility with moderate hydrated swelling as well as high elasticity and degradation rate of weeks. Coseal had the third highest compatibility with a high rate of swelling, high elasticity, and a degradation rate of days. Limitations were the testing being in invitro and exvivo systems which do not "perfectly reflect invivo conditions".⁴
- A 2021 systematic review by Allotey et. al compared hemostatic agents used on patients in carotid, aortic, femoral, and peripheral artery open procedures for bleeding rates, operative time, and complications. Twelve prospective randomized controlled trials with greater than 10 participants were included. They concluded that with limited data on direct comparison (due to patient, procedure, and surgeon variability) and additional outcomes (transfusion rates, length of stay, morbidity, mortality) they "cautiously recommend" surgical correction of bleeding be addressed before applying an agent, a history of anaphylaxis should be evaluated prior to use of bovine/porcine products, "less expensive" absorbable agents may be utilized for limited suture lines, and that use of biologically active adhesives may be supported in high-risk procedures.¹¹

Summary

Vascular sealants are utilized to reinforce sutures or staples, helping to reduce blood loss during and after cardiovascular and vascular surgeries. There are a variety of sealants available with varying indications for use. This is a high physician preference category therefore; early engagement of a physician champion will be integral for successful initiatives. Review of physician product preferences, specific patient population needs, cost, and available product clinical evidence will inform the decision-making process.

References

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