



Multicentral Trial of a Novel Vascular Sealant

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Abstract

Objective: Suture line bleeding from synthetic grafts increases operating time and expense. Numerous sealants are available; however, prophylactic control of suture line bleeding has not been successfully demonstrated. ArterX™ Vascular Sealant is a glutaraldehyde-based agent designed for prophylactic use. The purpose of this study was to evaluate the safety and prophylactic efficacy of this new generation sealant.

Methods: A single-armed multi-institutional study from Europe utilizing the ArterX™ Vascular Sealant for open vascular reconstructions with prosthetic materials was undertaken. Sealant was applied prophylactically to the suture line after completion of the sutured anastomosis. The primary endpoint was immediate hemostasis without clinically significant bleeding. Secondary endpoints were timed hemostasis.

Results: 53 arterial anastomosis with prosthetic graft were performed in 31 patients. 34 (64%) of these were performed with Dacron graft and 19 (36%) were performed with PTFE. The femoral artery was the most common site of anastomosis (23), with aortic (10), iliac (7), popliteal (4), tibial (4), carotid (2), brachial (2) and subclavian (1) arteries also utilized. Immediate hemostasis was achieved in 53 of 53 cases (100%). No clinically significant suture line bleeding occurred following operation. Two patients had minor oozing following application of the sealant, but neither required further intervention. The sealant was easy to apply, quickly formed into a soft gel, which was easily removed from instruments and surrounding tissue if needed.

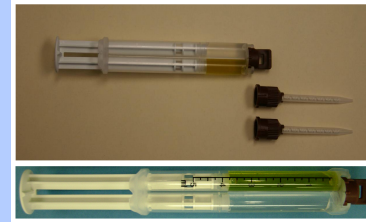
Conclusion: The ArterX™ Vascular Sealant is effective in achieving prophylactic hemostasis following prosthetic arterial anastomosis. It appears safe with no clinically significant adverse events related to the sealant. A full prospective controlled trial of this product for prophylaxis is warranted, but the results of this preliminary trial appear promising.

Background

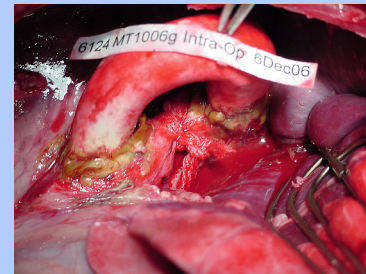
Hemostasis after arterial reconstruction can be challenging to achieve in certain clinical situations. Multiple adjuncts to these reconstructions have been attempted to minimize difficulty with hemostatic control. These include various topical agents as well as sealants. A novel glutaraldehyde-based sealant, ArterX™ Vascular Sealant, was designed for prophylactic use to assist with hemostasis. Glutaraldehyde is commonly found in most vascular sealants, however, it results in significant inflammatory response. ArterX™ Vascular Sealant is unique as it contains a cross-linking agent that maintains the powerful cross linking benefits of glutaraldehyde, but none of the inflammatory response. In addition, vascular sealants either require a completely dry field or a wet, bloody field to obtain hemostasis. The ArterX™ Vascular Sealant will work in either type of environment.

Methods

Initial IRB approval for investigation was first obtained in December 2006 in Germany as a single arm study. Patients included for investigation were those undergoing open vascular reconstructions with prosthetic materials. The recruitment period was June 26-August 17, 2007. The sealant was applied prophylactically to the suture line after completion of the anastomosis, but prior to restoration of arterial flow. Approximately 2 minutes after application, arterial flow was restored and observation of hemostasis was documented immediately following restoration of flow and at 1, 3, 5, and 10 minutes. The primary endpoint was immediate hemostasis without any significant clinical bleeding. Secondary endpoints were timed hemostasis. Other adverse events were noted and documented.



ArterX™ Vascular Sealant is based upon a proprietary technology that uses a powerful crosslinking agent that covalently binds to proteins in both the sealant and human tissue. The two components of the sealant are mixed and applied using a self-mixing syringe that provides accurate placement of the rapidly curing sealant.



Other types of vascular sealants require either a completely dry field or a wet, bloody field to obtain hemostasis. The ArterX™ Vascular Sealant will work in either type of environment. The sealant is applied prophylactically to the suture line after completion of the anastomosis, but prior to restoration of arterial flow. The sealant is easy to apply and quickly forms into a soft gel which is easily removed from instruments and surrounding tissue if needed.

Results

Fifty three arterial anastomoses with prosthetic grafts were performed in 31 patients utilizing the ArterX™ Vascular Sealant in a prophylactic manner. The majority utilized Dacron graft material (34/53, 64%), but a significant percentage were performed with PTFE (19/53, 36%). The femoral artery was the most common location for utilization (23/53), with aortic (10), iliac (7), popliteal (4), tibial (4), carotid (2), brachial (2), and subclavian (1) arteries also utilized. Immediate hemostasis was achieved in 100% (53/53) of reconstructions. No clinically significant bleeding occurred at any reconstruction following restoration of flow. Two patients (3.7%) had minor oozing following application of the sealant, although neither required any further intervention or adjunctive measures. The sealant was noted to be easy to apply, quickly formed into a soft gel, which was easily removed from instruments and surrounding tissue if needed. There were no adverse events or safety issues identified with the use of this sealant.

Conclusions

The ArterX™ Vascular Sealant is effective in achieving prophylactic hemostasis following prosthetic arterial reconstruction. It appears safe with no clinically significant adverse side effects related to the sealant. The sealant is easy to apply and sets into a soft gel firmly adherent to the anastomotic application site. A full prospective controlled trial of this product for prophylaxis appears to be warranted, but the results of this preliminary trial appear promising.