Session 3

What are the advantages of a prosthetic conduit?

Should Complications and Modes of Failure Affect Our Choice?

BY R. CLEMENT DARLING, III, MD

Patients with rest pain and shallow ulcers likely require a different treatment than patients presenting with profound tissue ischemia. Patients who present with more profound ischemia are best served by more direct blood flow to the affected area, yet surgeons are not often fully aware of the lack of blood flow in these patients.[1] While endovascular therapy may appear to increase blood flow, the volume of direct blood flow may be less than what can be achieved with open bypass therapy, and may also be insufficient to meet a patient's needs. This is reflected in the observation that approximately 60% of patients who receive a distal bypass had previous endovascular interventions. This percentage is continuing to increase because many patients who receive endovascular therapy experience recurrent complications that require surgical intervention. In addition, patients who experience failures from endovascular therapy cross over to open therapy much more aggressively than patients who experience failures from open therapy.[2]

No single treatment modality will cure all patients.[3] As surgeons, we seek a therapy that is effective with low morbidity, low mortality, and high limb salvage rate. On one hand, poor patient selection for surgery can lead to increased morbidity. On the other hand, endovascular therapy can lead to increased limb loss via inadequate increase in perfusion. In an ideal world, patients will have the option of multiple therapies, and surgeons will acknowledge that not all patients with chronic limb ischemia are equal. Patient factors such as diabetes, renal failure, cardiac disease, obesity, and age should affect the choice of therapy.[3] Using these factors, patients can be stratified such that approximately 34% are classified as "high risk" and 45% are classified as "low risk."[4]

SUMMARY

There should be a better, more concise algorithm for predicting complications from endovascular interventions. Such an algorithm will improve the ability of surgeons to inform patients about their alternatives, as well as the risks and benefits of the alternatives. Patients should also be followed closely for objective endpoints, and these outcomes should be constantly evaluated.[3,4] In order to achieve these goals, surgeons must perform an objective evaluation that includes an analysis of failures in order to determine changes that can lead to an improvement in patient outcomes. Surgeons must also have the training and comfort level to execute multiple therapeutic options. To achieve this, endovascular interventions may need to be implemented via a team approach that removes economic imperative as a factor in treatment selection. If surgeons do not lead the effort in making these changes, market forces may dictate better treatment selection, and third-party payers may mandate better treatment algorithms. ■

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CBAS® Heparin Surface

Performance in a technology context.

BY RUSSELL H. SAMSON, MD, FACS, RVT

Heparin has now been incorporated into multiple prosthetic vascular grafts, including Dacron (polyethylene terephthalate) grafts and the GORE® PROPATEN® Vascular Graft (Gore & Associates). A key aspect of heparin-bonding technology is the chemical means by which the heparin is bonded to the device lumen. The functionality of the bonded surface depends not just on the amount of heparin that is bound to the graft, but also the activity of the bonded heparin itself and whether it is able to interact freely with the blood. These three factors—the presence, availability, and activity of heparin dictate the efficacy of the bonded surface as a thromboresistant coating and differ based on which heparin-bonding method is employed.

One way of demonstrating the difference in the functionality of heparin applied to a surface using alternative bonding methods is an in vitro recirculating human blood model. In this model, flexible medical tubing is coated with heparin and exposed to freshly collected, nonanticoagulated whole blood. After 1 hour of blood contact, adsorbed plasma proteins are eluted from the tubing surface and separated by gel electrophoresis. The identities of the proteins are then determined by a Western blot. A tube that is coated with functional, available heparin should have more elutable antithrombin than a tube coated with heparin that is either nonfunctional (having had its active site removed) or not available. The Western blot technique revealed a great deal of antithrombin bound to a tubing surface that was coated using the CBAS® Heparin Surface technique, suggesting that the heparin on the surface is active and available (Figure 1). The presence of active, available heparin should result in very little platelet activation. Indeed, the Western blot revealed minimal platelet activation, as demonstrated by very little platelet factor 4 eluted from the surface. Thus, in an in vitro assay, heparin bonding (using the CBAS® Heparin Surface technique) resulted in a great deal of bound antithrombin and minimal platelet activation. In contrast, under the same assay conditions, a randomly bonded heparin surface activated platelets as much as a nonfunctional heparin surface and did not bind as much antithrombin as the CBAS® Heparin Surface. These results would suggest that the randomly bonded heparin technique does not perform as well as CBAS® Heparin Surface technology in vitro.

While both in vitro and in vivo studies have demonstrated that heparin bonding is effective in the short term,

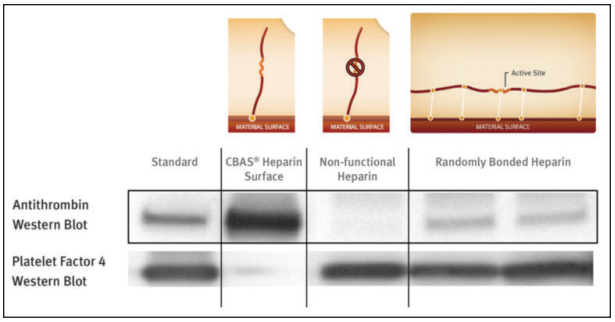

Figure 1. Three different covalently immobilized heparin surfaces were applied to separate loops of flexible medical tubing and exposed to freshly collected, nonanticoagulated whole blood. After 1 hour of blood contact, adsorbed plasma proteins were eluted from the tubing surface, separated by gel electrophoresis, and the identity of the proteins analyzed by Western blot. Note: Data presented are derived from an in vitro recirculating human blood model (modified Chandler loop).

researchers are beginning to investigate whether heparin bonding works in the long term.[1,2] An evaluation of an 8-year-old GORE® PROPATEN® Vascular Graft explant suggested that the heparin technology continued to be effective as measured by an assay for heparin activity (antithrombin binding). Results from one nonrandomized study comparing 3-year experience with standard expanded polytetrafluoroethylene (ePTFE) to the CBAS® Heparin Surface on the GORE® PROPATEN® Vascular Graft suggest that the latter technology affords better long-term outcomes for femoropopliteal grafts.

Currently there are no long-term data on alternative heparin-bonded grafts. In the absence of such data, surgeons cannot assume that all heparin-bonding technologies will be equally effective.

SUMMARY

CBAS® Heparin Surface bonding is likely providing long-term antithrombotic protection to the ePTFE surface. It is possible, however, that other methods of "attaching" heparin to ePTFE may not have such long-term protective effects. Vascular surgeons need to be aware of the construct of newer grafts in order to make valid determinations regarding the potential benefits of trying new, nonautogenous materials. ■

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When to Use Graft Versus Multisegment Spliced Vein

BY PROF. THOMAS SCHMITZ-RIXEN

Despite advances in endovascular techniques, surgeons acknowledge that there is still a role for infrapopliteal bypasses for limb salvage. This is especially the case for patients with critical limb issues, when surgeons must get pulsatile blood flow down to the foot—regardless of which artery is available. Although the greater saphenous vein is the best replacement material, arm vein is considered the last autogenous option for infrainguinal bypass surgery, and several studies have evaluated the efficacy of long arm veins as an alternative conduit for treating critical limb ischemia (CLI).[1,2] While the results have varied, bypass surgeries performed using arm vein are generally safe and result in favorable patency and high rates of limb salvage.[3] Moreover, a direct comparison of arm vein versus prosthetic graft for infrapopliteal bypasses for CLI found that, even when spliced, arm vein conduits are superior to prosthetic grafts in terms of midterm-assisted primary patency, secondary patency, and leg salvage.[4] Despite the documented superiority of arm veins to prosthetic grafts, there appears to be a role for the GORE® PROPATEN® Vascular Graft (Gore & Associates) for the treatment of claudication and noninfected CLI, particularly when the patient does not have an available vein.

Our group performed a retrospective analysis of patients who received surgical bypass as a treatment for peripheral artery disease (PAD) between January 2011 and July 2014. The GORE® PROPATEN® Vascular Graft was used for two different indications: claudication (n = 8) and noninfected CLI (n = 67). Overall, 1-year patency was 69% and 2-year patency was 65%. Thus, most failures occurred in the first year. Patients who received alternative veins had an 81% patency rate in the first year and a 75% patency rate in the second year. Complication rates were low for both groups. There were no differences in wound-healing complications and cardiac complications between patients who received the GORE® PROPATEN® Vascular Graft and those who received spliced vein. However, there was one death in the GORE® PROPATEN® Vascular Graft group from an acute, infected graft. During the study period, there were 25 failed grafts in the below-knee popliteal artery and femorocrural groups, including three infected grafts that required explant. There were no problems with the other grafts. Graft failures resulted in 10 major amputations.

SUMMARY

The treatment approach used at our facility appears to have delivered results that fall within the expected range. The next step is to extend the analysis of PAD treatment policy to a nationwide registry. ■

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TAKE HOME POINTS

R. CLEMENT DARLING, III, MD

To optimize limb preservation, one must use a balanced approach of endovascular and open reconstruction. Groups must have expertise in both endovascular and open infrainguinal reconstructions. Each patient's procedure must be selected based on their indications, anatomy, and availability of conduit.

RUSSELL H. SAMSON, MD, FACS, RVT

In order for heparin bonding to be efficacious, it has to be present, available, and active. Because there are various methods of bonding heparin to PTFE, it is possible that not all methods will be equally beneficial. In vitro and in vivo studies have shown that the CBAS® technology incorporated into the GORE® PROPATEN® graft is effective in binding antithrombin and reducing platelet deposition. These effects are well demonstrated in short-term tests. Data suggest that heparin may still be active years after implantation. Vascular surgeons need to be aware of the construct of newer grafts that incorporate heparin in order to make valid determinations regarding the potential benefits of trying new, nonautogenous materials.

PROF. THOMAS SCHMITZ-RIXEN

At the University of Frankfurt in Germany, our goal is to facilitate personalized medicine for patients with PAD. Patients with claudication who do not have infection are treated with endovascular therapy whenever possible. Long occlusions and ultimately failed endovascular therapy are treated with bypass surgery. Patients with CLI who have an infection are treated first with endovascular therapy and then with surgical intervention. The treatment approach used at our facility appears to deliver results that are consistent with published data.