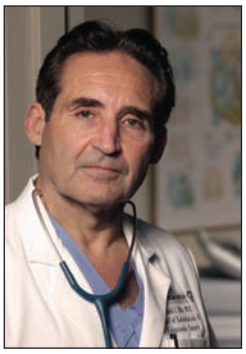

Written by David E. Allie, MD, Medical Director, Director of Cardiothoracic and Endovascular Surgery Louisiana Cardiovascular and Limb Salvage Center, APMC

Reasons for Adopting the PeriPatch™ Biologic Pericardial Patch

As a classically trained cardiothoracic and vascular surgeon from the early 1980s, I have performed over 4,000 carotid artery endarterectomies over the last 25 years and have utilized every conceivable and contemporary carotid patch available. The classic carotid endarterectomy has always, and continues to be, even today, my favorite operation.

My experience as an endovascular surgeon has opened my eyes to the rapid evolution of new technology and therefore, I have a low threshold for trying new technologies and exploring how they may benefit my patients. With that as a backdrop, I was willing to try the PeriPatch biologic pericardial patch. With excellent results and handling, I have now adopted PeriPatch as my primary patch in all carotid endarterectomies and in other similar sized vessels such as the common femoral artery when an endarterectomy and patch angioplasty is required. Similarly, the other three surgeons in my group have made the same conversion to PeriPatch.

As a cardiac surgeon with a long history of handling greater saphenous vein (GSV), my initial impression after my first case was that PeriPatch handled very much like a large sturdy 5-6 mm GSV. The consistency of the patch feels like a natural vascular structure opposed to the stiffness that is inherent to all synthetic graft material. The consistency of PeriPatch conforms to the edge of the internal and common carotid artery which facilitates the anastamosis and positions the artery edge and patch edge in a fashion that I believe is more conducive to hemostasis and less incidence of pseudoaneurysm. (See Figure 1)

I have always been concerned about fraying of synthetic patches, especially braided patches and the occurrence of suture line pseudoaneurysms. PeriPatch cuts easily and consistently without fraying. I never have to reshape the precut distal tapered tip. This saves me several scissor cuts and maneuvers during the procedure that lessens overall procedure time. I have not experienced this consistency and ease with any of the other synthetic patches. I have found reshaping the patch, when necessary, even easier than a GSV. With synthetic patches, I have frequently seen fraying when cutting or suturing. This is disruptive during the procedure and has required additional steps, sutures, pledgeted reinforcement, etc. The concern of patch fraying that I have experienced with synthetic patches has been removed from my practice with the adoption of PeriPatch. (See Figure 2a & b on page 2)

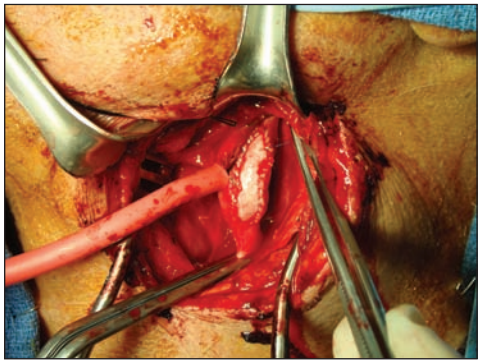

Figure 1"Final results demonstrating excellent PeriPatch conformation to the native vessel edges."

When suturing PeriPatch I can use less bite than is generally required with synthetic grafts. This provides a larger lumen with less patch edge narrowing. I believe that this may have some clinical implications in endarterectomy patches placed in internal carotid arteries in females. The needle tip easily penetrates PeriPatch and is more conducive to a needle throw that allows for easier retrieval of the needle and a much easier needle passage each time over the multiple throws to close the arteriotomy. My experiences with synthetic patches are that they are much stiffer and the initial needle tip passage into the stiffer graft material is more difficult and not as conducive to easy passage. This often results in awkward retrieval of the needle and even bending of the fine needle tips which further complicate the catch closure process. It is not unusual to bend the needle tip and have to begin a new suture with synthetic patches. With PeriPatch, needle hole sites do not stretch like I have experienced with synthetic patches. I experience minimal to no ooze from the PeriPatch as soon as flow is instituted regardless of the blood pressure. This has greatly shortened the total operative time and has given us the confidence to close the wound quicker and

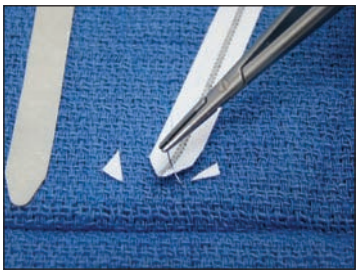

Figure 2a "Synthetic patch requiring cutting and shaping with potential for edge fraying and compensatory larger needle bite."

Figure 2b "PeriPatch requiring no shaping and demonstrating small needle bite resulting from no concern of fraying."

decrease our need for topical agents such as Thrombin, SurgiSeal, etc. We have fewer concerns about hematoma and all neck related complications that are associated with bleeding. In addition, the decrease in needle hole and anastomotic bleeding and oozing has allowed me to now perform many carotid endarterectomies without stopping Aspirin and Plavix. I have drastically decreased my use of Protamine immediately post release of the clamp and I believe the elimination or at least decrease in Protamine use is of value for our patients. Protamine is associated with its own risks that include life threatening reactions, hypotension, rebound thrombosis, etc. In many patients, Protamine can be eliminated with good technique, blood pressure control and use of PeriPatch.

Early in my career, I experienced an embolic stroke in a patient that I believe accumulated periprocedural thrombus in the very most distal cul-de-sac of the internal carotid artery anastamosis in a female patient who had a very small vessel and required an intraluminal shunt. Since then, I have been very meticulous with examining the luminal surface of the patch and the endarterectomized artery where the circumferential sewing in of the patch occurs. It is not uncommon to have the blood accumulate from the endarterectomized media and remaining adventitia, which can accumulate on the intraluminal surface and form thrombus clinging to the undersurface of the patch during the anastamosis. I have found the PeriPatch surface to be extremely resistant to the formation of periprocedural thrombus. Thrombus simply does not accumulate on the undersurface of PeriPatch, allowing me to easily "rinse" the undersurface of the patch and the carotid lumen with less likelihood of leaving residual thrombus. (See Figure 3)

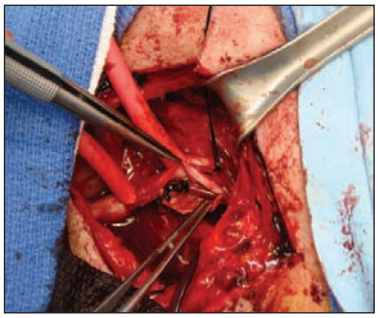

Figure 3"Luminal surface of the PeriPatch. Note: Shunt in place and pick ups in the distal cul-de-sac."

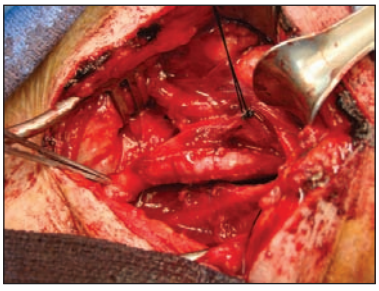

Figure 4"Minimal to no bleeding or suture line oozing immediately post clamp release without Protamine."

Unfortunately, today in our healthcare environment, prices and costs have become a major issue. PeriPatch is comparably priced with the current existing patches. With many of the advantages that I have experienced; quicker procedural time, less oozing and bleeding, less waiting for hemostasis to occur and the elimination of costly topical agents, today, PeriPatch has resulted in cost savings for my hospital. Over an entire year, this has the potential to significantly provide cost savings to hospitals, especially high volume centers. (See Figure 4)

PeriPatch™ is manufactured by Neovasc Inc.