

Plaque Excision in 2005 and Beyond:

# A Safe and Effective Primary Treatment Option

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**P**eripheral arterial disease (PAD) remains a major cause of disability, loss of work, and lifestyle changes in the US.<sup>1-6</sup> Symptoms of PAD can vary from disabling pain with ambulation (claudication) to limb-threatening ischemia and gangrene. The treatment options for PAD also vary, from medical management to minimally invasive endovascular procedures and surgical bypass procedures. Medical management with exercise programs, weight loss, and medications can be very effective in many patients with mild-to-moderate claudication. Many symptomatic patients will simply adjust or adapt their lifestyles to fit their symptomatic limbs, much the same way patients with congestive heart failure adjust their activities to fit their heart function. Symptomatic individuals may require intervention, but fortunately, fewer than 10% will require amputation.<sup>7</sup> Currently used minimally invasive procedures include angioplasty, angioplasty and stenting, cryoplasty, laser atherectomy, and plaque excision with the SilverHawk device (FoxHollow Technologies, Redwood City, CA).

Minimally invasive techniques are generally associated with a much shorter hospital stay and more importantly, a more rapid return to the patient's normal activities of daily living. The final option is that of surgical bypass, which is the most invasive procedure, but in the presence of adequate autologous venous conduit has the greatest patency. With the advancing age of our population and its increasing comorbidities, the recovery period and the potential complications of surgical bypass are increasing.

Complications of surgical bypass include, but are not limited to, myocardial infarction, pulmonary complications, wound infections, leg swelling, and wound breakdown. The severity of these complications has led to further exploration of new minimally invasive techniques.

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## CURRENT ENDOVASCULAR THERAPEUTIC APPROACHES FOR INFRAINGUINAL PAD

Despite a myriad of endovascular therapies for infrainguinal atherosclerotic disease, this lesion subset still poses a unique technical and long-term challenge for durable therapies. Percutaneous approaches to patients with PAD have improved significantly over the past several years. Catheters, balloons, and wires have become better profiled and less stiff, which has facilitated passage of devices through most stenoses and arterial occlusions such that percutaneous transluminal angioplasty (PTA) and stenting have acute results that appear promising. Long-term patency, however, ranges from 40% to 70% at 1 to 2 years after PTA, with most of the loss occurring in the first year after intervention.<sup>1,8,9</sup> Becquemin et al showed in a randomized clinical trial with 1-year angiographic follow-up, that angioplasty of the superficial femoral artery resulted in a primary patency rate of 66%.<sup>8</sup> Cejna et al<sup>9</sup> showed that primary patency of the angioplasty arm was 74% at 24 months of follow-up.<sup>9</sup> Stenting improves acute results, but intermediate and late outcomes are not maintained and appear to be no better than angioplasty alone.<sup>1,10-13</sup>

Nitinol compressible/deformable-with-shape-memory stents are a default form of endovascular prosthesis for treatment of the superficial femoral artery (SFA) and popliteal arteries. SFA/popliteal occlusions are a difficult subset of patients to approach percutaneously. PTA alone does not provide adequate long-term paten-

cy when compared with surgery.<sup>10,13</sup> In a critical limb ischemia patient population, Mewissen showed a 12-month patency rate of 76%,<sup>10</sup> which declined to 60% at 24 months. Alternative methods of endovascular prosthesis with covered stenting showed a 23% primary patency rate at 12 months in a nonrandomized, 30-patient cohort.<sup>11</sup>

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Further complicating the problem of stenting in the SFA is stent fracture. Allie et al showed that various grades of fracture do indeed occur in the stented SFA.<sup>12</sup> These fractures are not inconsequential. Scheinert further showed in the FESTO data that restenosis was four- to sixfold higher in the fracture group compared with the nonfractured group.<sup>13</sup> The shortcomings of these minimally invasive techniques have stimulated interest in many physicians regarding the SilverHawk plaque excision device.

### HOW DOES THE SILVERHAWK DEVICE WORK?

The SilverHawk device is a novel catheter-based monorail device that enables the directional excision of diffuse atherosclerotic material from the lumen of the arterial wall. Plaque excision is accomplished by activation of the device, which then pivots against the lesion, and a conical carbide cutting disk rotating at 8,000 rpm excises the plaque. The atheromatous debris is stored in a distal nose cone storage compartment. The carbide cutter can then be retracted and repositioned to excise additional plaque burden. Once the storage compartment is full, the SilverHawk device is removed over the 0.014-inch wire, and the atheromatous tissue is removed for later analysis. This procedure is performed without the use of balloons or stents and does not result in the barotrauma associated with angioplasty.

### QUESTIONS REGARDING SILVERHAWK PLAQUE EXCISION SYSTEM

There are four major questions regarding the SilverHawk plaque excision device that we would like to address in this article:

1. Why has there not been a prospective randomized trial comparing SilverHawk to other modalities?
2. How is SilverHawk different from previous “atherectomy” devices?

3. Is there increased risk of distal embolization associated with use of the SilverHawk plaque excision device?

4. What are some of the new advances in management of PAD that may come forward through the use of the SilverHawk device?

In response to the question regarding why there is no prospective, randomized trial comparing SilverHawk to other modalities, the “gold standard” is surgical bypass, and it would be exceptionally difficult to randomize patients to undergoing a long open surgical bypass when offered the alternative of a minimally invasive 1-day procedure. The crossover rate certainly would be very high. This then leads us to the potential for a prospective, randomized trial comparing SilverHawk to one or more of the other minimally invasive procedures. The leading minimally invasive procedure for PAD is angioplasty and stenting. Unfortunately, most of the commonly used stents in the lower extremity are not FDA approved for that purpose, but rather for biliary applications. This would require further FDA approval for a prospective randomized trial to use arterial stents. Many of the major stent companies are looking to get lower-extremity arterial approval for their stents and are not interested in collaborating in a trial that could slow their application to the FDA. There are only two FDA-approved stents for this indication, and they are not the devices most frequently used in most centers. In addition, one of the two, (the Viabahn covered stent [W. L. Gore & Associates, Flagstaff, AZ]) requires a very large sheath for delivery (potentially increasing the morbidity of the procedure above that already expected).

Another alternative to a prospective, randomized clinical trial is a prospective registry. The intermediate and long-term results of the TALON (Treating Peripherals with SilverHawk: Outcomes Collection) registry was presented at the Society for Vascular Surgery meeting in Chicago in June 2005. The TALON registry is a prospective, nonrandomized, consecutive, multicenter registry evaluating patients treated with the SilverHawk device for symptomatic lower-extremity PAD. It was reported that 601 patients (748 limbs, 822 procedures) underwent treatment of 1,258 lesions with plaque excision. The device and procedural success rates were 97.6% and 94.7%, respectively. The intermediate and long-term (6- and 12-month) data revealed freedom from reintervention rates of 90% and 80%, respectively. The use of stents as an adjunct to plaque excision was low at 6.3%. The incidence of acute radiographic documented embolic complication was 0.1%, and the acute perforation rate was 0.8%. These outcomes have been

reproduced in multiple single-center studies with similar outcomes (Ramaiah VR, oral communication, June 2005; Garcia LA, oral communication, July 2005).

One of the major criticisms of the TALON registry is the use of the target lesion revascularization rate endpoint rather than patency rates. To more thoroughly investigate the effectiveness of the SilverHawk plaque excision system, there is now preparation for a prospective clinical registry that will follow pre- and postprocedural ankle brachial index, arterial duplex, and, when indicated, angiogram or other definitive imaging studies to assess patency. Results will be reviewed by an independent core lab to validate the findings.

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The second question pertains to the differences between the SilverHawk plaque excision system and previous atherectomy devices. The main difference between SilverHawk and the "old" atherectomy devices is that the older generation of devices would require a balloon inflation to position the device's cutter to remove a segment of the plaque, which can cause injury to the arterial wall due to barotrauma from the balloon inflation. Every time a balloon is inflated in an artery, it induces injury not only to the intima, but more importantly, the media and adventitia that is left behind in the arterial wall. The SilverHawk device does not create this trauma to the arterial wall and will excise a smooth continuous channel of plaque. The carbide blade pivots into the plaque and excises it as the SilverHawk device advances forward. When plaque excision is complete, the device is retracted and the catheter is removed. The earlier atherectomy devices were mainly used for the SFA, whereas the SilverHawk is available in multiple sizes so that it is able to treat a range of vessels from the common femoral artery to the distal tibial artery. The main limitation of the SilverHawk device is for the very calcific arteries, and there has been considerable advancement in that regard with the new MS device. Additional investigation is ongoing for a coronary application. The benefit of no barotrauma, no adjunctive balloon inflation, and leaving nothing behind in this unique arterial circulation is likely beneficial to the flow characteristics inherent to this anatomic location and contributes to the overall durable results at 1 year regarding arterial patency.

The third question pertains to the potential for embolization during the plaque excision procedure. In the TALON registry, angiographic identifiable embolization occurred in 0.1% to 0.2% of cases. Studies have shown that distal embolization as documented by particle capture in a distal protective device does occur with any endovascular procedure.<sup>14-16</sup> Wholey et al reported a 100% distal embolization rate for angioplasty and stenting in a small study.<sup>16</sup> The real questions are, what is the significance of these emboli and how much of them may actually be platelet aggregates and clot that dissolve naturally? Certainly, the TALON data indicate that clinical and angiographic incidence of embolization is very low. The potential for embolization is greater if the SilverHawk is not used appropriately and if the nose cone storage device is overpacked, allowing for overflow emboli, or if the SilverHawk device is advanced too quickly to allow for incomplete capture of the atheroma in the storage compartment. The reported rates of embolization may be underreported, but the registry and core lab review of future cases will help determine the occurrence of these events. However, the argument that clinically significant embolization occurs with regularity is difficult to accept because there has not been a noted increase in limb loss or distal amputations following treatment with the SilverHawk.

Finally, there is the question of what the future holds for plaque excision technology. We have already alluded to the potential for better devices for the treatment of calcific lesions. Also, in evaluation is the potential of coupling the plaque excision system with a visualization modality such as intravascular ultrasound to assist in exactly localizing the atheroma, then precisely excising it. The SilverHawk device is able to recover plaque that can then be analyzed to gain further insight into the nature of a particular patient's atherosclerotic process and potentially target pharmacologic therapy to inhibit further accumulation of plaque.

### CONCLUSION

The basis for endovascular intervention to the peripheral arterial system has progressed much like that of coronary intervention. Balloon technology, stent design, and wire styles have greatly enhanced the ability to perform and the success rates for percutaneous intervention in the periphery. The critical issues regarding the best therapy are predicated on the understanding of the disease process, the anatomic nature of the disease, and the long-term outcome sought.

Clearly, standard therapies of balloon dilatation, regardless of technology, do not support long-term

success. Further, stenting has not been met with great long-term success. All major trials have shown a 1-year patency rate between 40% and 65%. Laser therapy does not provide an adequate lumen for the SFA proper without further angioplasty and stenting.

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Believing there are alternative therapies that may not be in the mainstream may also drive a new technology to redefine the problem, which would then define a therapy to achieve a greater long-term success. The corollary with this anatomical subset would be the debate that raged about carotid revascularization. Despite advances in technologies for endovascular stenting, many continue to argue the lack of data. Many of our colleagues have argued time and again that the registry data of high-risk patients supported the use of carotid stenting and that a randomized clinical trial would be difficult to perform given the lack of standardization of technology or patient cohort. Despite these limitations, registries continue to be performed to answer specific questions about the patient population treated.

SilverHawk is no different. There is no standard therapy for infrainguinal revascularization. The data thus far for SilverHawk, which consist of single-center experiences and a large-scale registry have been exceedingly compelling and consistent among various operators. However, the patient's best interest remains, maintenance of limb and ambulation. Thus far, the data with plaque excision have been most compelling at 1 year from intervention.

The Holy Grail for infrainguinal revascularization has not been defined. What is clear is that the “mainstream” default therapy of PTA and stenting has never been “mainstream” based on its success, but rather because this was all we as interventionists could offer. The future of lower-limb revascularization will depend on advances in technology that redefine what is optimal in regard to acute success and long-term patency in an exquisitely challenging anatomic location with devices such as the SilverHawk plaque excision device.

## CONSEQUENCES

The question remains, do we have the answer to treat infrainguinal disease with the therapies used in

the past or are there new possibilities for acute and long-term success? The response will remain, do we bury our heads in the sand, oblivious to the shortcomings of current endovascular therapies, or do we look forward, investigating and embracing novel interventions, studying their actions, outcomes, and durability of results? Without science and willingness to investigate new ideas, we fail as scientists, and most importantly, we fail our patients. ■

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