## Plaque Excision in 2005 and Beyond:

# Issues of the Past Have Yet to Be Resolved

BY MICHAEL H. WHOLEY, MD, MBA; RAJEEV SURI, MD; DARREN POSTOAK, MD; RYAN T. HAGINO, MD; AND BOULOS TOURSARKISSIAN, MD

The success of percutaneous angioplasty of infrainguinal vessels continues to be limited by high rates of restenosis.[1,2] This has prompted the development of alternative endovascular therapies. One such approach has been the use of atherectomy devices designed to debulk the atheroma load. One device currently available is the SilverHawk atherectomy catheter (FoxHollow Technologies, Redwood City, CA). The SilverHawk is a coaxial system composed of a cutting chamber located proximally to the storing section.

Although there have recently been impressive reports regarding use of the current device, there remain several important unaddressed issues. First, a potential complication with the device has been the issue of embolic debris created by the cutting mechanism and subsequently sent downstream. Second, there are no data that prove SilverHawk atherectomy's superiority or at least equivalency to standard and novel means of treating atherosclerotic lesions involving the superficial femoral and popliteal arterial segments. We believe these issues need to be addressed before atherectomy can be considered a viable therapeutic option in these patients.

## SINGLE-CENTER EMBOLIC DEBRIS STUDY

We have had previous success with the use of distal protection in a small series of peripheral interventions in patients with poor distal runoff and with high risk of embolic debris.[3] Our initial use of the SilverHawk atherectomy catheter in tibial vessels in two patients resulted in occlusions that did not respond to angioplasty or aspiration. We subsequently decided to employ distal embolic protection in the popliteal artery with the SilverHawk atherectomy of superficial femoral and popliteal segment.[4] The major reason to take this approach in our next 13 consecutive patients from August 2004 to date was to avoid the risk of distal embolic occlusion in patients with already compromised runoff. The results of this small series are as follows.

### Materials and Methods

The study population consisted of 10 men and three women with a mean age of 72 years. The data were collected prospectively. Risk factors included diabetes in all, hypertension in 10, hypercholesterolemia (under treatment) in eight, coronary artery disease in six, and smoking in five. One patient was on dialysis. Indication for intervention was claudication in four cases and tissue loss in the remaining nine. The pre-intervention ankle-brachial index averaged 0.70±0.10, and the toe-brachial index averaged 0.29±0.22.

Nine of the 13 lesions consisted of calcified plaques. Four patients had smooth lesions without calcification. Lesion lengths ranged from 1 cm to 10 cm. Using the TransAtlantic Intersociety Conference (TASC) Morphologic Classification of femoropopliteal lesions,[5] three patients were classified as having "A" lesions, six had "B" lesions, and four had "C" lesions (Table 1). All cases were performed under systemic anticoagulation with heparin, and all patients had been receiving clopidogrel and/or aspirin pre- and postintervention.

The distal embolic protection devices used were the EPI FilterWire EX and EZ models (Boston Scientific Corporation, Natick, MA). The FilterWire was inserted after vascular access had been achieved and the patient heparinized. The atherectomy was carried out according to manufacturer's instructions.

### Results

Antegrade common femoral access was used in all but one case. The FilterWire was used to cross the lesions primarily in 10 of the 13 cases. In the remaining three cases, the presence of a tight stenosis required the use of a 0.014-inch buddy wire with minimal 2.5 mm angioplasty prior to

FilterWire deployment.

No more than four short forward cutting passes were done before the device chamber was cleaned of excised tissue. In cases when the stenosis was very significant, we usually initiated the atherectomy with the smaller-profile SS device before proceeding with the larger LS device if the angiographic result was unsatisfactory.

Adjunctive superficial femoral artery, popliteal, and tibial artery angioplasty was performed in 10 cases, three of which also required stent placement because of residual disease or dissections at the site of atherectomy. Atherectomy was an isolated procedure in the other three cases.

Debris was retrieved in the filter in every case. In one case, a no-flow phenomenon was observed after the atherectomy was performed; flow was promptly restored after removal of the filter basket, which was full of debris; there was no thrombus within the filter. In every case, we verified that the retrieved debris consisted of cut atherectomy plaque pieces, ranging in size from 0.5-mm to 10-mm lengths, similar in appearance to the pieces retrieved from the SilverHawk chamber.

Postintervention, the ankle-brachial index rose to 0.95±0.35, while the toe-brachial index did not change at 0.26±0.17. The foot wounds of one patient failed to heal despite a successful revascularization, and the patient underwent above-the-knee amputation. Amputation was required for this patient because intervention did not restore his extremely poor distal runoff. A second patient, who was receiving dialysis, underwent a planned transmetatarsal amputation; when this failed to heal, she required a below-the-knee amputation. A third patient also underwent a planned transmetatarsal amputation, which healed. The other 10 patients had improvement in their symptoms of claudication or tissue loss. Follow-up for all patients averages 11±7 weeks (range, 4 to 24 weeks).

**TABLE 1. ANGIOGRAPHIC LESION CHARACTERISTICS**

| Patient No. | TASC Lesion Grade | Calf Runoff Score | No. of Calf Vessels Patent |
|---|---|---|---|
| 1 | C | 6.5 | All 3 |
| 2 | C | 8.5 | Bypass * |
| 3 | B | 8 | 1 (PT) |
| 4 | B | 7.5 | 2 (PT & PER) |
| 5 | B | 9 | 1 (PT) |
| 6 | B | 3 | All 3 |
| 7 | B | 8 | Bypass * |
| 8 | B | 9 | 1 (AT) |
| 9 | A | 8 | 1 (PT) |
| 10 | A | 8 | 1 (PT) |
| 11 | C | 7 | 1 (AT) |
| 12 | A | 6.5 | 1 (PT) |
| 13 | C | 8 | 1 (PT) |

**Refers to the presence of popliteal-to-distal bypass graft.*

## Discussion

The significance of distal embolization remains to be determined. In our judgment, the pieces seen in the filter, ranging in length of from 0.5 mm to 10 mm, were significant enough to potentially cause occlusions of the tibial vessels, which only have diameters of 1 mm to 3 mm. This may be particularly relevant in patients with single-vessel runoff. Such patients already face a serious risk, and should an abrupt occlusion with an embolic plaque occur, medical therapy will not reopen these vessels. With an abrupt occlusion of the distal anterior, posterior tibial, or pedal dorsalis artery, the only recourse would then be to emergently recanalize these occluded distal vessels. Also, smaller debris may possibly not cause such occlusions, but may result in occlusions of more distal branches that may be difficult to detect on completion angiograms. From the numerous carotid and saphenous vein bypass graft data, distal embolization has been shown to occur in 20% to 80% of cases.[5-11] Hence, with femoropopliteal intervention, such as with the SilverHawk device, distal showering of cut plaque particles will occur. We believe the significance of the showering varies depending on the patient's underlying runoff status as well as the dispersion of emboli.

## THE DATA

Concerns regarding potential negative consequences of using the SilverHawk device have prompted many to examine the data that support its use. Although the SilverHawk has notable differences from previous

atherectomy devices, its US availability comes via an FDA 510(k) clearance, meaning the technology has been cleared based on its demonstrated similarity to a previously approved device. For this reason, as well as the lack of comparable data for the SilverHawk device, an overview of the data from previous atherectomy devices is necessary to understand the SilverHawk's potential clinical risks and benefits.

**Previous Atherectomy Modes and Studies**

Mechanical atherectomy has been used extensively in coronary and peripheral intervention. There are three different types of atherectomy:

1. Rotational atherectomy uses an abrasive burr near the tip of the catheter to grind the plaque into small particles that float harmlessly away in the bloodstream.
2. Directional atherectomy such as the SilverHawk and its predecessor, the Simpson Atherectomy Device (Devices for Vascular Intervention [DVI], now part of Guidant Corporation, Indianapolis, IN), position the catheter window over the blockage. A rotating blade shaves the plaque and collects it in the catheter tip.
3. Extraction atherectomy uses an abrasive burr near the tip of the catheter to grind the plaque into small particles that are collected on the tip and extracted.

There have been data presented showing unfavorable results with debulking techniques of directional and rotational mechanical atherectomy devices in the coronary literature. Results from the ARTIST trial showed that rotational atherectomy did not reduce in-stent restenosis rates.[12] Likewise, results from the OARS, BOAT, and CAVEAT II trials showed that debulking was a failed strategy.[13-15] Based on well-constructed coronary trials, the question has been raised as to why debulking would prove any more effective in the periphery with smaller vessels farther from the heart and with known worse patency results than coronary intervention.

Additionally, data from peripheral atherectomy in the past have not been impressive. The original atherectomy catheter was the Simpson AtheroCath Device (DVI), which was a double-lumen atherectomy catheter with a cylindrical-windowed metal chamber and an eccentrically mounted balloon. In the metal housing, there is a rotating cylindrical knife, which can be pushed forward and backward. By inflating the balloon, the window in the metal housing is pressed against the atheromatous plaque, which is then cut by advancing the rotating knife. The atheromatous material is caught distal to the window in the metal housing and can be saved when the catheter is pulled out.

In 1996, Tielbeek at al published the results of a prospective randomized trial comparing clinical and angiographic results of balloon angioplasty and Simpson directional atherectomy in patients with short lesions in the femoropopliteal artery causing symptoms of claudication.[16] The investigators found the 2-year primary angiographic patency rates were 67% in patients treated with balloon angioplasty and 44% in patients treated with directional atherectomy (*P*=.06). The secondary angiographically determined patency rates were 80% and 65%, respectively (*P*=.15). In another study by Vroegindeweij et al in 1995, 73 patients with femoropoliteal disease were randomized to angioplasty versus directional atherectomy with a median follow-up of 13 months.[17] By life-table analysis, the cumulative rate of clinical and hemodynamic success at 2 years was 52% in patients treated with atherectomy and 87% in patients treated with balloon angioplasty (*P*=.06).[17] The patency rate of treated segments at 2 years was 34% in the atherectomy group and 56% in patients treated with balloon angioplasty (*P*=.07). In patients with lesions greater than 2 cm, the 1-year patency rate of atherectomy was significantly lower than balloon angioplasty (*P*=.03). Atherectomy was not shown to result in improved clinical and hemodynamic outcomes. Furthermore, atherectomy of segmental atherosclerotic femoropopliteal disease did not result in a better patency rate than balloon angioplasty, and in lesions with greater length than 2 cm, the atherectomy results were significantly worse.[17]

**Evaluating SilverHawk**

The atherectomy device currently available is the SilverHawk catheter. Improvements since the original AtheroCath include the replacement of the balloon segment with a new angled tip, a larger chamber for debris, and modifications with the cutting mechanism to improve cutting and reduce torque. Still, we question what clinical improvements really have been achieved. The argument of reducing barotrauma created by angioplasty is questionable at best, especially since pre- and postprocedural balloon angioplasty are frequently involved.

Although this device is presently available in the US, there are few peer-reviewed articles on its use in the medical or surgical literature, all four of which come from the same author.[18-21] In Zeller et al, a study of 71 femoropopliteal stenoses after atherectomy alone, residual stenosis was 50% or less in 68 (96%) lesions and 30% or less in 54 (76%).[18] However, as was the case in our study, distal emboli were encountered: there were 5 cases (7%) of tissue embolism that were successfully treated with aspiration. Additional balloon angioplasty was used in 41 (58%) lesions, and stents were implanted in four (6%) arteries.[18] Restenosis rates after 6 months were not significantly lower in primary lesions (27%) compared with the other groups (41% for restenoses and 36% for in-stent restenoses).

One major issue that persists with the SilverHawk has

been the need for adjunctive treatment. Angioplasty is frequently needed to smooth out the angiographic appearance. Although proponents of the SilverHawk point to positive remodeling without the use of adjunctive angioplasty, this phenomenon was not observed in the 1995 and 1996 trials, and there have been no data published showing any evidence that this has changed. In fact, in another Zeller et al study of the SilverHawk in 52 infrapopliteal cases, 15 lesions (29%) were treated after predilation, and 15 (29%) required additional balloon angioplasty; two lesions required stent implantation as a result of dissection.[19]

**Cost Benefit?**

As with all new medical therapies, we need to weigh the benefit of the technology against the cost. SilverHawk as a standalone therapy is in the range of $1,800 for one device, and multiple devices are often needed. In addition, the need for adjunctive treatments brings with it added costs. Adjunctive balloons and stents could make a simple femoral stenosis cost anywhere from $2,000 to $4,000 per case. Furthermore, should embolic debris become a major issue medically or legally, we must then include the $1,000 embolic filter device. Accordingly, we must ask if the results obtained using atherectomy are that much better than those we can achieve using a $200 angioplasty procedure. Finally, there is the additional time required to prepare the device and clean the chamber after every four passes. Angioplasty and/or stent placement is quicker and less expensive. So the major question remains, why would physicians and third-party payers choose a more expensive and time-consuming device to achieve the same results?

**The TALON Registry**

In the TALON Registry, which was originally presented as an abstract at the TCT Meeting in September 2004, Gammon et al reported results of a nonrandomized registry of 220 patients with 442 lesions that required predilatation in 13% of cases and postdilatation needed in 26%; stents were needed in less than 5%.[22] There were minimal complications and no reported emboli. A 6-month target lesion revascularization rate of 11.1% was reported. At the Society of Vascular Surgery Meeting in June 2005, Venkatesh Ramaiah, MD, reported an 80% clinical patency rate at 1 year for all blockages treated with plaque excision.[23]

However, numerous criticisms have been raised about the TALON Registry's design. The most important of these are that SilverHawk is not being randomized against another therapy, and that the validity of the registry is questionable at best because of its voluntary nature, which did not provide for any solid exclusion or inclusion criteria. Compounding the latter element is the subjective nature of target lesion revascularization as an endpoint of the registry. No objective means of determination for this endpoint was applied, such as evaluation under duplex ultrasound, CTA, or MRA. When combined with the voluntary nature of case submission, this soft endpoint leaves all data virtually impossible to interpret or compare in relation to other therapies, such as angioplasty and/or stenting.

## THE NEED FOR EVIDENCE-BASED MEDICINE

It is true that angioplasty did not become the gold standard endovascular approach to femoropopliteal disease treatment by being shown to be superior to another therapy such as surgery or best medical care, and the lack of published level 1 data showing this superiority makes evaluating newer therapies such as SilverHawk atherectomy, laser atherectomy, cryoplasty, and stenting with new self-expanding designs difficult. With no clearly established gold standard, designing a randomized trial could prove to be even more perilous and fraught with pitfalls than is usually the case. This does not, however, make the results from nonrandomized, voluntary registries or studies with soft, subjective endpoints sufficient for showing clinical benefit as compared to other therapeutic options, nor does it sufficiently show the safety of the therapy tested.

Even stenting, which has previously been shown to be superior to other therapies such as angioplasty and surgery in other anatomies, is being scrutinized regarding its long-term efficacy in the femoropopliteal segment. Numerous trials with concrete endpoints have already been completed, some of which showed benefit, whereas others revealed areas of concern. C.R. Bard, Inc. (Murray Hill, NJ) and Edwards Lifesciences (Irvine, CA) are presently conducting trials randomizing their stents against balloon angioplasty in the FAST and RESILIENT trials, respectively. Atherectomy using the SilverHawk device should be held to the same standard, but has not been to date.

As a result, clinicians are left to make decisions based upon single-center results and anecdotal studies. In our own anecdotal experience, we have still found a 30% restenosis rate at 3 to 6 months using this device. We believe there is a place for this technology in treating peripheral vascular disease, but it has not yet been determined in which cases it is best applied. Femoral and common femoral lesions appear to be those best suited for atherectomy. However, the current device is too large to deliver for infrapopliteal lesions, and it cannot yet cut through calcifications, which we encounter in many of our patients. Sufficiently powered trials in these anatomies and disease states are required.

Also, the risk of dissection is real and warrants care. Finally, the risk of harmful embolic debris must be considered seriously. Before adopting this device (as well as other newer technologies such as cryoplasty, laser atherectomy,

etc.) into regular use, we must see data that can in some way be compared to traditional methods, such as balloon angioplasty and stent placement, and shown to provide benefit. In our opinion, a randomized study versus angioplasty alone with concrete endpoints (eg, primary and secondary patency at 1 year, embolization occurrence, perforation, procedure time, contrast volume, etc.) is the only way to achieve this.

## CONCLUSION

The emergence of the SilverHawk atherectomy device has been controversial. The majority of the material in peer-reviewed journals has been based on an earlier model, and did not show superiority to traditional angioplasty. Newer data have been primarily from one source and a registry that is not truly objective. There is a real need for solid data from a randomized trial of SilverHawk versus traditional angioplasty and/or stent placement in terms of technical and clinical success, time and cost of procedures, and long-term results.

Based on our own experience, we have been impressed with the debulking capabilities of the SilverHawk and continue to use it today in select patients. However, we found in a limited study that the rate of embolic debris created by SilverHawk atherectomy in treating simple and complex femoropopliteal lesions was 100% in 13 cases with the use of distal embolic protection. The risk of embolic debris migrating and occluding distal vessels, in a patient population already compromised with poor runoff, is likely significant. It is too early to tell whether distal protection is needed for all or most cases, and if so, whether the additional cost is justified. Our data and this publication should be taken as a word of caution and emphasis of the need for large prospective and controlled trials for infrainguinal endovascular therapies. ■

*Michael H. Wholey, MD, MBA, is from the Departments of Cardiovascular and Interventional Radiology at the University of Texas Health Science Center at San Antonio. He has disclosed that he holds no financial interest in any product or company mentioned herein. Dr. Wholey may be reached at (210) 567-5564, wholey@uthscsa.edu.*

*Rajeev Suri, MD, is from the Departments of Cardiovascular and Interventional Radiology at the University of Texas Health Science Center at San Antonio. He has disclosed that he holds no financial interest in any product or company mentioned herein.*

*Darren Postoak, MD, is from the Departments of Cardiovascular and Interventional Radiology at the University of Texas Health Science Center at San Antonio. He has disclosed that he holds no financial interest in any product or company mentioned herein.*

*Ryan T. Hagino, MD, is from the Department of Vascular Surgery at the University of Texas Health Science Center at San Antonio. He has disclosed that he holds no financial interest in any product or company mentioned herein.*

*Boulos Toursarkissian, MD, is from the Department of Vascular Surgery at the University of Texas Health Science Center at San Antonio. He has disclosed that he holds no financial interest in any product or company mentioned herein.*

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