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Plaque Excision in the Peripheral Vasculature

The nation's most experienced SilverHawk users present their collective recommendations regarding the technology, procedural techniques, and early outcomes data.

Plaque Excision in the Peripheral Vasculature

One year after the SilverHawk™ System (FoxHollow Technologies, Redwood City, CA) received FDA clearance, many of the system's top users convened for a national consensus meeting. A cross-section of interventional cardiologists, vascular surgeons, and interventional radiologists from across the country met to share their collective experience with the device and establish recommendations on the use of plaque excision in a variety of peripheral indications. This supplement summarizes the National SilverHawk Summit's findings on optimal applications for plaque excision, technique recommendations for each lesion subset, opinions on potential future applications and the use of adjunctive therapy post-plaque excision, as well as early outcomes data from a variety of single-center studies and TALON, a national multicenter registry.

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PLAQUE EXCISION USING THE SILVERHAWK SYSTEM

The SilverHawk System received FDA approval in mid-2003 for the treatment of peripheral arteries, including femoral-popliteal and tibial-peroneal vessels. It provides a unique approach to removing plaque from *de novo* or restenotic lesions of any length. Both calcified and noncalcified lesions are treatable with the device.

Because the cutter is apposed to the plaque mechanically, the catheter excises large amounts of plaque without causing barotrauma to the arterial wall (Figure 1). The SilverHawk can also remove eccentric plaque and create a more optimal environment for laminar flow. By excising plaque and avoiding stretch, the chance of dissection is minimized, and therefore the likelihood of recurrent intimal hyperplasia is postulated to be minimized.

The SilverHawk device itself is a monorail catheter designed for single-operator use. It consists of a motor drive unit that contains the battery pack and a thumb switch to activate the cutter. The working end consists of a hinged housing unit containing a carbide cutting blade. The blade is activated from the motor drive unit at a rate of 8,000 RPM, and the catheter is then advanced through the length of the lesion. Once each pass is completed, the cutter then packs the tissue into the distal end of the nosecone to maximize collection capacity. The SilverHawk can then either be removed or torqued to treat a different quadrant in the same lesion or other lesions. A single device can be used to treat multiple vessels.

Plaque excision also may offer the opportunity to learn more about the underlying atherosclerotic disease process. Histologic analysis can identify inflammatory cell infiltration, the presence of thrombus, calcification, or fibrosis, the degree of smooth muscle cell proliferation, and the lipid content of the plaque removed (Figure 2). Genomic and proteomic analysis of the excised tissue also may provide further insight into the pathophysiology of restenosis and identify predictive markers of restenosis and cardiovascular risk.

OPTIMAL APPLICATIONS

Participants at the forum first focused on determining the optimal applications for SilverHawk use. Summit participants reported using the SilverHawk in the superficial femoral (SFA), common femoral (CFA), popliteal, infrapopliteal, and tibial arteries, and chronic total occlusions (CTOs), as well as additional applications such as the renal, subclavian, and iliac arteries, and in arteriovenous (AV) fistulas and in-stent restenosis. Many participants reported performing the majority of their SilverHawk cases in lower-extremity arteries. Of particular note was the overwhelming agreement that plaque excision was an ideal treatment modality in CFA, SFA, popliteal, and tibial-peroneal lesions; many discussed their successful use of the device for limb salvage cases as well. The following section outlines technique recommendations from the group for specific lesion subsets.

KEY CONSENSUS POINTS

- Adjunctive angioplasty and stenting are typically not required after plaque excision, whether above or below the knee
- Avoid striving for "perfect" or "stent-like" angiographic results; many operators reported observing positive remodeling at 30 days postprocedure and beyond
- Acute procedural data demonstrate a very high safety rate, and a low rate of perforation, dissection, and distal embolization
- Although 12-month data are needed to confirm longer-term clinical efficacy, reported 6-month patency rates are 90% or better

COMMON FEMORAL ARTERY

The use of the SilverHawk in this lesion subset was agreed to be one of the best applications of the device. The LS or LX device size is recommended. The level of experience for the operator should be moderate, somewhere between 10 and 20 SilverHawk cases.

Large parent vessels with daughter vessels are a key focal point with plaque excision. The ability to appose against the primary or parent vessel significantly impacts how effectively the cutter will perform its plaque excision. Appropriate plaque excision is key; be knowledgeable in the area you excise. Most importantly, the user should be very cognizant of the location of the carina, which can be a very problematic area. The carina should be approached using few but deliberate excisions, paying careful attention to where the cuts have been made and trying not to hit the same spot more than once.

It may be beneficial to wire into the profunda to gain a different angle, which can help to achieve adequate excision in the CFA. This is similar to the idea of a wire bias. A stiff wire is generally used; however, as with the internal iliac bifurcation, a softer wire may provide less bias and allow the cutter to more fully engage a lesion than with a stiffer wire. If there is a particularly angulated or tortuous segment, the user may want to employ a soft wire. The approach in the CFA is almost invariably contralateral. The short-tip SilverHawk (LS) is helpful because it avoids the nose bias in this anatomy.

SUPERFICIAL FEMORAL ARTERY

The SFA was identified as the best lesion subset for new users attempting their first several cases with the device. SFA disease is not ordinarily focal; rather, it is usually chronic and diffuse. It has considerable calcification, and the degree and nature of calcification may require staging from a small device (ES, SX, or SS) to a larger device (LX or LS). The SS or SX is usually ideal if the vessel is relatively small in diameter (<3.5 mm), and the LS or LX device should be used in vessels ranging from 4.5 mm to 7 mm. As is the case with the CFA, using the short tip avoids tip bias and may allow the user to achieve better-directed plaque excision. In long lesions, using the longer tip (LX) is helpful for several reasons, not the least of which is reduced radiation exposure due to shorter procedure times. Approximately four passes of the device in each lesion location should provide ade-

SILVERHAWK SIZING REFERENCES

SilverHawk	Min. Vessel Diam.	Max. Profile	Tip Length
LS Large Vessel, Standard Tip	4.0 mm	2.7 mm	6.0 cm
LX Large Vessel, Xtended Tip	4.0 mm	2.7 mm	9.0 cm
SS Small Vessel, Standard Tip	2.5 mm	2.2 mm	2.6 cm
SX Small Vessel, Xtended Tip	2.5 mm	2.3 mm	4.3 cm
ES Extra-Small Vessel, Standard Tip	2.0 mm	1.9 mm	2.2 cm

quate circumferential excision. Slow and methodical cuts yield the most favorable results.

Accessing the SFA is often done in a contralateral fashion; however, for distal disease, an antegrade approach, which provides increased tip control and an ability to work fairly distally, may be preferred. A very stiff, .014-inch wire is commonly the wire of choice in this anatomy. Diffuse calcification can sometimes become problematic and can require several cuts directed at diminishing the ridges. Deep wall calcium has not been noted to be particularly problematic. Although the SFA is the recommended starting point for new SilverHawk users, profunda bifurcation lesions and total occlusions are best attempted by those with moderate levels of experience with the device.

POPLITEAL ARTERY

The popliteal is a fairly short vessel, but it is generally angled both proximally and distally, and it is almost invariably calcified; popliteal disease frequently coexists with proximal and/or distal disease. Patients often present with either stenoses or total occlusions in this area, which historically has been considered a difficult interventional subset because of limitations in stenting across high-motion areas. Because the SilverHawk can be used to achieve very low residual stenosis without the need for adjunctive therapy, popliteal disease was cited as an optimal application for the system (Figure 3A,B).

Diffuse and/or calcified popliteal vessels may require staging from a smaller device to a larger one. Focal lesions are generally very easily treated with the SS or SX, although the LS is commonly preferred because the diameter of the popliteal lesions approaches 4.5 mm. For smaller vessels, particularly for advances from the popliteal into the angulated tibial vessels, the user should start small and try to use wire bias to achieve the most aggressive cut early and avoid the carina for those particular locations. Access is most often contralateral, unless distal vessel access is required. A stiff wire is helpful in cutting passes made straight down the popliteal and into the tibial-peroneal trunk, but a very soft wire should be used in an angled anterior-tibial approach.

The consensus among the group was that the least traumatic access approach is contralateral, although antegrade and, in rare instances, retrograde (from the tibial) approaches may also utilized. Antegrade access has the potential

TABLE 1. OPTIMAL APPLICATIONS

Lesion	Recommended Size	Recommended Experience Level	Comments
Common Femoral	LS or LX	Low to moderate	Primary advantage lies in avoiding plaque shift; user should be aware of the carina of the femoral bifurcation and make only a few directed cuts
Superficial Femoral	LS or LX	Low	Best anatomic location to begin SilverHawk use; equally effective in long, diffuse lesions as in short, calcified lesions
Popliteal	LS or LX	Low to moderate	Accurate vessel sizing is key, usually for a large vessel (>5 mm) the LS will provide adequate excision with little to no risk of perforation; for the smaller arteries (<4 mm) the SX is preferred
Infrapopliteal/Tibial	SS, SX, or ES	Moderate to high	Almost invariably, the smallest size cutter (ES) will provide adequate excision with limited residual stenosis; for proximal lesions of the TPT and PA/PT, the SX and SS devices may be used if the artery is sizeable (>2.0 mm to 3.5 mm); the angle of the origin of the AT may make use challenging; careful positioning and conscientious fluoroscopy is imperative

User experience is a relative assessment that depends not only on experience with the device and related catheter techniques, but also the physician's previous experience in the respective lesion/application. Low user experience is defined in this instance as, on average, less than 10 SilverHawk cases; Moderate experience is defined as 10 to 20 cases; High experience is defined as more than 20 cases.

Figure 1. An example of the long strips of plaque that can be excised using the SilverHawk System.

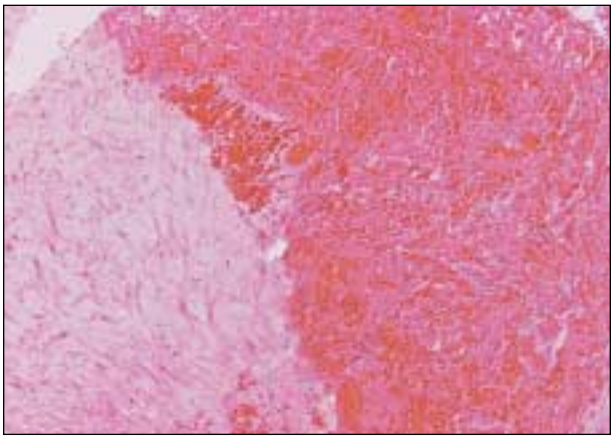

Figure 2. Histologic analysis of the plaque removed can be conducted postprocedurally.

advantage of providing better visualization and torque control, but it can be a disadvantage if the user is trying to work with proximal SFA disease. In a contralateral crossover approach, it may be necessary to use a sheath that is a half-French size bigger than the catheter. The sheath should be advanced close to the targeted lesion (use a 45-cm or 65-cm sheath for a crossover approach and a 24-cm sheath for an antegrade approach).

Long cuts should be utilized if possible; even focal lesions require plaque excision a few centimeters proximal and distal to the lesion. Use of a ruler is recommended to ensure excision only within the lesion area. The number of passes attempted will increase incrementally with the severity of plaque burden. A minimum of four cuts is recommended, but smaller devices may require additional passes.The number of cuts attempted should be based on the nature of the disease and the size of the catheter. To prevent the possibility of air embolus, the sheath should be aspirated before angiography.

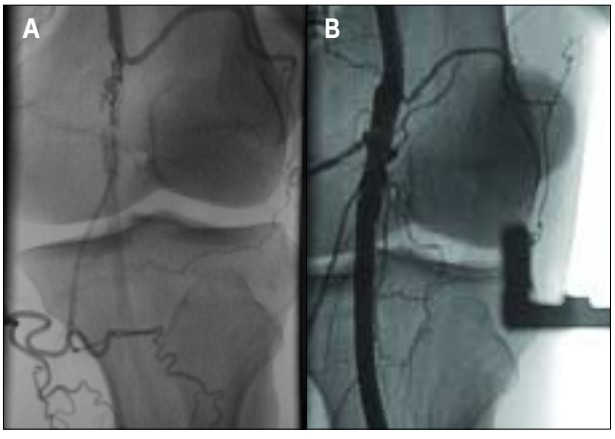

Figure 3. Plaque excision is ideal for popliteal occlusions (A), with good results shown here 30-days postprocedure (B).

The risk of perforation is highest in the trifurcation region of the popliteal artery, requiring additional caution. To reduce risk, the inner curve should be avoided during interventions at the anterior and posterior tibial origins. The ES SilverHawk is most often the best device to initiate cutting in this location, with size increases as necessary.

Physicians attempting to use the SilverHawk in the popliteal and infrapopliteal anatomy should have experience using stent grafts and balloons in the event that perforation does occur. The operator should also have the ability to perform both retrograde and antegrade CFA access. Lesions in the proximal and midpopliteal artery require skill sets similar to those needed for SFA interventions and are appropriate for users with low levels of SilverHawk experience. Plaque excision in the distal popliteal or trifurcation region, however, is more difficult and should only be performed by more advanced operators.

In most popliteal procedures, the SilverHawk should be used as a stand-alone therapy. Although several physicians had at times employed balloon angioplasty to achieve a "perfect" angiographic result, most agreed that with experience, they had learned such a result was not truly necessary, and therefore the risk of balloon-induced dissection after angioplasty is also mitigated. The tendency to use stents and other adjunctive nonpharmacologic therapies was also noted to have declined as the users became more experienced with the SilverHawk.

INFRAPOPLITEAL ARTERIES

Summit participants reported using the SilverHawk in a variety of infrapopliteal applications, with considerable suc-

TABLE 2. SPECIAL APPLICATIONS

Special Applications	Recommended Size	Recommended Experience Level	Comments
CTO	Vessel dependent	Low to moderate, depending on vessel	SilverHawk is very effective in this application; begin with a down-sized catheter; after a channel is created and directionality/eccentricity of the lesion is identified, upsize catheter
Subclavian	LS	Moderate	For distal axillary lesions where stenting would be questionable, SilverHawk may provide an excellent opportunity for excision
AV Grafts	LS	Low	Very promising application based on early 6-month data presented; limited per user experience to date
Iliac	LS or LX	High	Although results have been favorable, SilverHawk use in the iliacs is not recommended, as devices are not designed for these vessel ranges; if attempting, be very aware of the carina of the iliac bifurcation and make few directed cuts in this location
Renal	SS	Moderate to high	Use in renals advocated by some but not all; angulated take-off and possibility for loosening emboli should be considered; may be a good option for renal in-stent restenosis if anatomy will accommodate tip length

User experience is a relative assessment that depends not only on experience with the device and related catheter techniques, but also the physician's previous experience in the respective lesion/application. Low user experience is defined in this instance as, on average, less than 10 SilverHawk cases; Moderate experience is defined as 10 to 20 cases; High experience is defined as more than 20 cases.

cess treating critical limb ischemia (CLI) and limb salvage.

Although the tibial arteries are the same size as the coronaries and are often revascularized using devices designed for the coronary anatomy, long-term results cannot be extrapolated to be the same, and coronary strategies are not directly transferable. The volume of the material responsible for stenosis is exponentially higher in the periphery than in coronary vessels, and a typical coronary lesion requiring PTA and stenting is 15 mm to 22 mm long, with an expected restenosis rate of 40% to 50% if it is 3 mm to 4 mm in diameter (with bare-metal stents). In CLI cases, the lesions may be 10 to 100 times longer and the opportunity for restenosis is significantly higher.

The major problems encountered in CLI are: (1) the arterial flow is reduced to less than 10% of the normal rate; (2) there is an overwhelming volume of obstructive plaque to treat; (3) there are multilevel obstructions, and most are long-term total occlusions; and (4) there is ongoing tissue ischemia and necrosis due to extremely low tissue oxygenation.

Plaque excision of below-the-knee lesions should include frequent clinical and angiographic surveillance; ruler use is also recommended to ensure accurate device positioning. Most importantly, the operator must work to create and maintain straight-line flow to the foot.

Subintimal access is not a common problem with the SilverHawk device; when it occurs, it is usually due to wire tip problems. Many operators employ prolonged PTA once luminal access is verified as a means of subintimal access management. In the rare cases of perforation reported by the group, prolonged PTA was used.

Plaque excision of the tibial-peroneal trunk can usually be performed with beginner-level SilverHawk experience. Lesions involving the trifurcation, however, should be managed by operators with intermediate SilverHawk experience. Complex lesions involving more than one vessel at the trifurcation, long lesions, and distal lesions should be managed by users with higher levels of experience.

ADDITIONAL APPLICATIONS

CHRONIC TOTAL OCCLUSIONS

The SilverHawk was frequently reported to work exceptionally well in CTO therapy. The use of the SilverHawk in this subset is not difficult; the challenges of vascular access and wire crossing are the determining factors regarding the levels of experience necessary for success and safety to be achieved. Once across the lesion, the level of experience with the SilverHawk can be low to moderate (5-15 cases), depending on the length of the occlusions. Long occlusions should be attempted only by users with moderate-to-advanced experience. The optimal CTO technique requires some patience, with multiple passes and frequent contrast puffs. If the SilverHawk will not pass, the user should not force the device, but consider exchanging it for a smaller one and retry.

In addition to crossing the CTO, the critical factor in treating is whether the wire is deep in the subadventitial plane, which may lead to perforation with excision if appropriate precautions are not considered. Adjunctive IVUS may be useful to help answer this key question.

For total occlusions of the SFA, if the occlusion is relatively straightforward, it can be approached with an LS or LX device. For smaller vessels, the user can start with a small device and increase the size if necessary, depending on the reference vessel. For total occlusions of the popliteal artery, if the vessel appears large, begin with an SS or SX device, or start with the ES if the vessel is smaller.

ILIAC

The forum participants urged new users to exercise caution if attempting to use the SilverHawk in iliac lesions; in fact, many suggested not using the device in iliac anatomies—specifically common iliac lesions. This risk was said to be lower in the bifurcation with the internal iliac and the distal external iliac as it exits the retroperitoneum and becomes the CFA. Several operators noted the need to be particularly aware of the carina of the bifurcation and make only a few directed cuts in this location if attempting at all.

SUBCLAVIAN AND RENAL

SilverHawk use in the subclavian arteries was advocated more so in distal axillary lesions (in which stenting is particularly questionable) than in aorto-ostial lesions. The recommended experience level in this setting is more than 10 SilverHawk cases. Plaque excision in the renal arteries can be performed successfully, but not all respondents advocated its use in these vessels. Because the SilverHawk devices are not optimized to address the anatomical angulation and often ostial nature of renal disease, this application is possible, but not ideal.

CASE PRESENTATIONS

Dozens of cases were presented during the 2-day forum. Two notable examples are included here.

PLAQUE EXCISION OF A HEAVILY CALCIFIED THREE-TIER CFA OCCLUSION

BY LAWRENCE A. GARCIA, MD, BETH ISRAEL DEACONESS, BOSTON, MASSACHUSETTS

An 82-year-old man with diabetes, hyperlipidemia, coronary artery disease, and hypertension came to our facility suffering from right lower-extremity claudication, which had progressively worsened. Noninvasive evaluation suggested an ankle-brachial index of the affected limb of approximately 0.6, with monophasic waveforms in the common femoral artery. Duplex ultrasound was unavailable.

The patient presented with no inflow disease, but with a heavily calcified three-tier occlusion of the distal CFA at the level of the bifurcation with the profunda and SFA (Figure 4A). We approached the occlusion contralaterally, placing a 7-F Rabbe sheath (Cook Incorporated, Bloomington, IN) over the aortic bifurcation, and we initially crossed the lesion using a Shinobi wire (Cordis Corporation, a Johnson & Johnson company, Miami, FL). Once distal position was confirmed in the SFA, we advanced a 4-F multipurpose catheter and exchanged the wire for a PercuSurge distal protection balloon (Medtronic Vascular, Santa Rosa, CA).

We then advanced the LS SilverHawk device over the PercuSurge wire and made several plaque excision passes. After cutting away much of the plaque, there was a residual ridge affecting the profunda femoral artery (PFA). After cleaning out the SFA and aspirating over the PercuSurge balloon, we flipped the PercuSurge wire

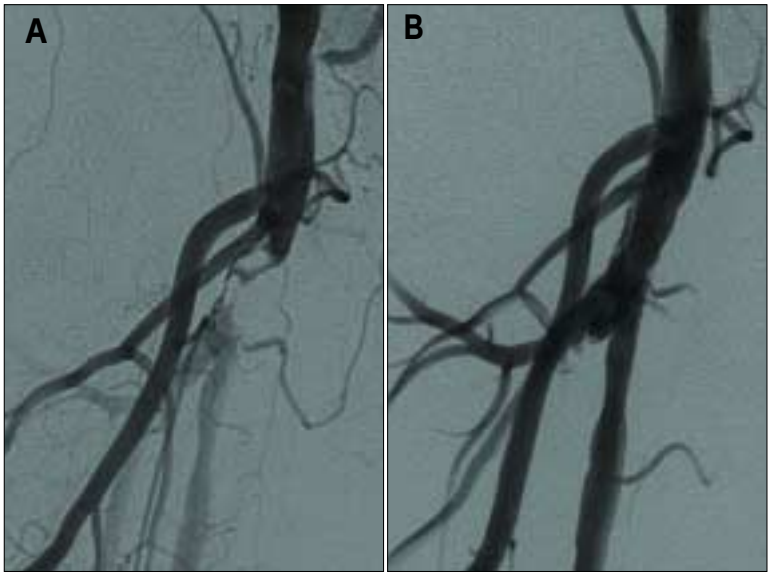

Figure 4. A heavily calcified three-tier occlusion of the distal CFA at the level of the bifurcation with the profunda and SFA (A); an excellent result with stenosis dramatically reduced (B).

into the PFA, and then performed plaque excision on the ridge into the profunda. We made six passes in the common femoral artery to the SFA, and three passes into the PFA.

After the procedure, the resultant stenosis, which was originally 99%, was 20% with excellent flow and no use of adjunctive angioplasty or stenting. Restoration of pulses was felt in the lower extremities (Figure 4B).

INFRAPOPLITEAL LIMB-SALVAGE USING PLAQUE EXCISION

BY STEVAN HIMMELSTEIN, MD, BAPTIST EAST HOSPITAL, MEMPHIS, TENNESSEE

A 64-year-old male patient with a history of smoking, hypercholesterolemia, chronic renal failure with hemodialysis, congestive heart failure, multivessel coronary disease, and a previous coronary artery bypass grafting presented to our facility with multiple symptoms. The patient had progressive difficulty with claudication that had not previously been treated, and he presented with an ischemic ulcer on his right leg, as well as necrotic toes.

During his evaluation period, he underwent surgical debridement, was administered antibiotics, and was placed in whirlpool therapy. The evaluation to that point had not produced significantly favorable results, prompting the orthopedics division to recommend amputation of his leg. The general surgeon who was performing the debriding, however, recommended that before amputation the patient should have an arteriogram performed.

Our group performed an arteriogram, which showed that the patient had a total occlusion of his right anterior tibial artery that poorly reconstituted, as well as a total occlusion of the proximal segment of the tibial-peroneal trunk that reconstituted very quickly (Figure 5A).

We elected to attempt crossing the lesion and perform plaque excision using the SilverHawk System. We were successful in getting a guidewire across the tibial-peroneal trunk, placing the wire into the posterior tibial artery, after which we performed plaque excision. We first used the ES SilverHawk cutter, then upsized to the SS device. The acute and most recent results have been excellent (Figure 5B). After 3 months, the patient's pain has resolved, his ischemic toes and ulcer are healing nicely, and he has begun walking again.

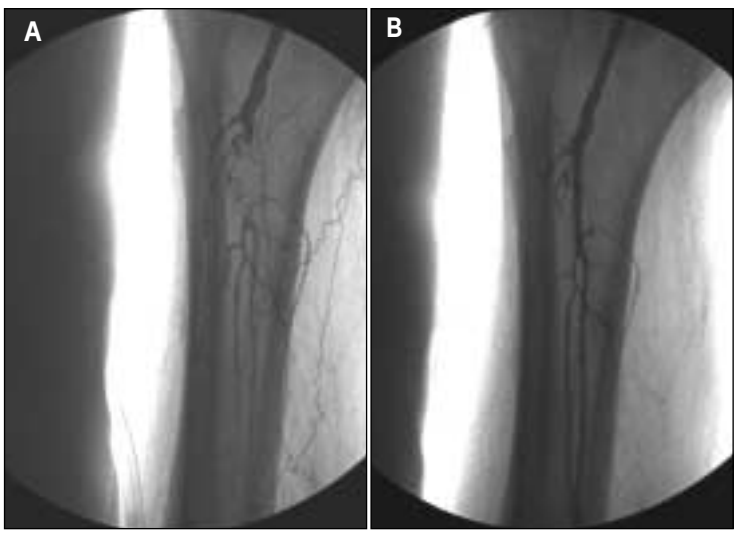

Figure 5. A preprocedural arteriogram shows a total occlusion of the patient's right anterior tibial artery and a total occlusion of the proximal segment of the tibial-peroneal trunk (A). After plaque excision, the patient has regained flow with resolution of symptoms and avoidance of amputation (B).

OUTCOMES DATA

THE TALON REGISTRY

TALON is a national registry for tracking outcomes after treatment with the SilverHawk System. The registry provides both site-specific and aggregate data on the acute and long-term results of plaque excision in the femoral-popliteal and tibial-peroneal arteries. Excised plaque from each enrolled patient is collected to allow for histologic evaluation and genomic research.

At the time of the National SilverHawk Summit, a total of 230 patients (287 limbs, 466 lesions) had been enrolled for a total of 281 reported procedures. Endpoints for the TALON Registry are 6- and 12-month target lesion revascularization (TLR) and patency.

BASELINE CHARACTERISTICS

The average patient age was 69.6 years, and 59.4% were male. Ninety-seven percent presented with a history of claudication, and 56% had a history of myocardial infarction, coronary artery bypass graft surgery, or coronary artery disease. Forty-eight percent had undergone a prior peripheral intervention.

PROCEDURAL CHARACTERISTICS

The average plaque excision treatment time was 31 minutes, and nearly half of the procedures involved the treatment of two or more lesions. Successful device crossing was reported in 99.5% of attempts, and 100% of tissue removal attempts were successful.

TABLE 3. TALON REGISTRY MINIMUM LUMINAL DIAMETER AND PERCENT DIAMETER STENOSIS

SILVERHAWK ALONE

	Preprocedure	Post-SilverHawk
MLD	1.6 mm	4.5 mm
% Diameter Stenosis	87.1%	9.9%

LESION CHARACTERISTICS

Eighty-seven percent of lesions were *de novo*; 12% were restenotic. Moderate-to-severe calcification was noted in 66% of lesions, and 46.8% were described as eccentric lesions. The average SFA lesion length was 71.9 mm (maximum, 398). Popliteal lesions averaged 38.5 mm (maximum, 300), and infrapopliteal lesions averaged 41.5 mm (maximum, 300).

Twenty-six percent of lesions treated were total occlusions. Predilation was employed in 12.5% of cases, and adjunctive stenting was required in 4% of cases.

ANGIOGRAPHIC DATA

A summary of the minimum luminal diameter (MLD) and percent diameter stenoses angiographic data from the TALON Registry can be found in Table 3. In cases during which the SilverHawk was the only therapy utilized, the MLD improved from 1.6 mm preprocedure to 4.5 mm postprocedure, with percent diameter stenosis improving from 87.1% to 9.9%.

TABLE 4. TALON REGISTRY COMPLICATION OCCURRENCE

	Post-SilverHawk	Post-Adjunctive Therapy	Post-Procedure
Major Complications			
Emergency Surgery (access site)			0.2%
Retroperitoneal Bleed			0.9%
Minor Complications			
Perforation	0.7%		
Grade A/B Dissection	2.5%	9.7%	
Grade ≥C Dissection	0.5%		
Hematoma			2.0%
Rash			0.4%
Pseudoaneurysm (access site)			0.2%
Aneurysm			0.9%
GI Bleed			0.2%

COMPLICATIONS

The rates of major and minor complications reported in the TALON Registry are notably low. A complete listing of complication rates is shown in Table 4. Perforations occurred in 0.7% of patients after SilverHawk alone. Grade A or B dissections occurred in 2.5% of patients after SilverHawk alone, whereas 9.7% were noted post-adjunctive therapy. There were no reports of distal embolization or thrombosis.

SINGLE-CENTER STUDIES

A number of facilities have initiated single-center studies to monitor acute and long-term procedural success, and several SilverHawk Summit participants shared their current outcomes data. The largest such studies are taking place at the Arizona Heart Hospital in Phoenix, Arizona, and the Cardiovascular Institute of the South in Lafayette and Houma, Louisiana.

ARIZONA HEART HOSPITAL

PRESENTED BY VENKATESH G. RAMAIAH, MD

Between June 2003 and June 2004, 202 limbs in 181 patients were treated using the SilverHawk System. One hundred seven patients (53%) presented with claudication of Rutherford-Becker categories 1, 2, and 3, and 95 patients (47%) presented with rest pain and tissue loss of Rutherford-Becker categories 4, 5, and 6. Single run-off vessels were noted in 94 patients (46%), two run-off vessels were observed in 64 patients (32%), and 44 patients (22%) had three run-off vessels.

Lesion Characteristics

One hundred nine lesions (53%) were in the SFA; 28 (13.5%) were in the popliteal; 18 were in the tibial-peroneal trunk; 33 (16.3%) were in the anterior tibial/posterior tibial/peroneal region; 10 (4.9%) were in the external iliac; and 4 (1.9%) were in the profunda femoris. Eighty-two of the lesions (41%) were stenoses, 52 (26%) were occlusions, and 96 (48%) were both. Below-the-knee interventions were performed on 78 patients (39%), and 48 patients (24%) were treated for in-stent restenosis. Moderate-to-severe calcification was seen in 62% of cases.

Results

Technical success was achieved in 194 (96%) of the lesions attempted. The mean ABI increase was .27. There were no embolic events or thromboses, and one perforation occurred; 14 patients (6.9%) had stents placed post-SilverHawk. On average, 140 mg of tissue was collected (range, 30-410 mg). The average length of stay was 1.2 days. Of the 92 patients (45.5%) who have completed 6-month follow-up, primary patency is 96%; assisted primary patency is 100%.

CARDIOVASCULAR INSTITUTE OF THE SOUTH

PRESENTED BY CRAIG M. WALKER, MD

During the period spanning from September 1, 2003, and June 1, 2004, 133 SFA lesions were treated using the SilverHawk System.

Lesion Characteristics

Of those lesions, 60 (45.1%) were TASC B, and 34 (25.6%) were TASC C; 39 (29.3%) were treated for in-stent restenosis. In 119 (89.7%) of the procedures, plaque excision was the sole therapy used. Nine lesions (6.7%) were treated with plaque excision and adjunctive angioplasty and stenting, and five (3.7%) underwent plaque excision and adjunctive angioplasty without stenting. The mean lesion length was 16.2 cm (range, 4-33 cm).

Results

Procedural success was achieved in 131 lesions (98.4%); in two patients, the plaque was calcified to such a significant degree that plaque excision was not possible. No device-related complications, embolic events, or SFA thromboses occurred. All of the 64 patients observed at 6-month follow-up were examined using Duplex ultrasound, and 42 (65.6%) were examined using CTA. The overall restenosis rate observed using Duplex ultrasound was 9.4% (6 of 64), which was very close to the 9.6% (5 of 42) rate observed using CTA.

CONCLUSIONS

The cases submitted to the TALON Registry indicate a high level of safety and efficacy associated with using the SilverHawk device in lower-extremity lesions. This experience has been confirmed in a number of single-center studies in high-volume facilities across the country. High rates of procedural success were observed in both above-the-knee and below-the-knee lesions, with remarkably low complication rates. Multiple lesions of varying lengths were shown to be efficiently treated with a low number of devices. One of the more remarkable observances in many centers was the increasing number of patients who were at one time scheduled for either above- or below-the-knee amputation, but in whom limb salvage procedures using the SilverHawk System were successful.