

Plaque Excision Treatment of Infrainguinal PAD

An update on this nonstenting alternative, with intermediate-term results of the ongoing TALON Registry.

BY ROGER GAMMON, MD

Despite surgical options and an array of percutaneous revascularization techniques, peripheral arterial disease (PAD) continues to present substantial challenges to treatment for the 12 million Americans who suffer from the disease.¹ In particular, the smaller peripheral arteries and those located in the joint space pose unique technical challenges, as do heavily calcified lesions. Although acute results often look promising, long-term data typically reveal high rates of restenosis and the need for secondary intervention. The need for improved intervention is driven by the substantial loss of both physical functional capacity and psychological quality of life experienced by patients with PAD. At least 10% of PAD patients older than 70 years of age experience lifestyle-limiting claudication due to crural vessel atherosclerosis, whereas intermittent claudicants show mortality rates from all causes of 30% and 50% at 5 and 10 years, respectively.²

In the absence of treatment, PAD may progress to critical limb ischemia (CLI), which is characterized by profound, chronic pain and by extensive tissue loss that restricts revascularization options and frequently leads to amputation. CLI is estimated to have an incidence of approximately 500 to 1,000 per million per year and is associated with mortality rates as high as 20% at 6 months after onset.² Another 25% of CLI patients require major amputation by 1 year, despite receiving

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available standard therapy; of these, 50% will die within 5 years.²

Stents and percutaneous transluminal coronary angioplasty have proven effective in managing coronary arterial disease. However, these modalities have seen less success in PAD patients due to the tendency toward calcified lesions, high rates of occlusion, diffuse disease, and large plaque burden. Stents deployed peripherally must be able to withstand extreme biomechanical forces, including compression, flexion, and stretching. A recent study reported stent fractures in 24.5% of self-expanding nitinol stents placed in the superficial femoral artery (SFA) after a mean follow-up time of 10.7 months.³ Stent studies to date show poor long-term patency in PAD patients,⁴ and drug-eluting stents have not yielded statistically significant improvements over uncoated stents.⁵ Moreover, at this time, only one stent is approved by the FDA for use in the SFA. Percutaneous transluminal angioplasty has become more widely used in treating PAD, yet even when PTA is applied to carefully screened PAD patients with relative-

ly focal lesions and limited calcification, the 1-year patency rate is approximately 60%, diminishing to as low as 14% at 10 years.⁶ The addition of laser angioplasty has expanded the range of lesions treated by balloon angioplasty, yet calcified lesions remain resistant to recanalization.⁷ Finally, the technical treatment challenges that stem from the nature of the disease are exacerbated in the distal arteries where the lumen diameter is very small.

PLAQUE REMOVAL WITH THE SILVERHAWK PLAQUE EXCISION SYSTEM

In May 2003, the FDA cleared the SilverHawk Plaque Excision System (FoxHollow Technologies, Redwood City, CA) for the treatment of peripheral arteries. The system is composed of a low-profile monorail catheter and palm-sized drive unit with a single on/off switch to control plaque excision. Upon activation, a minute carbide cutting blade located on the catheter tip rotates at 8,000 rpm. The operator places the catheter tip just proximal to the target lesion, activates blade rotation, and advances the cutter through the length of the lesion. With each pass, thin shavings of plaque are excised and packed into the distal end of the nosecone to maximize plaque collection capacity. The device can then be removed, the nose cone emptied of plaque, and reinserted to treat additional lesions.

Stents and angioplasty balloons are known to induce

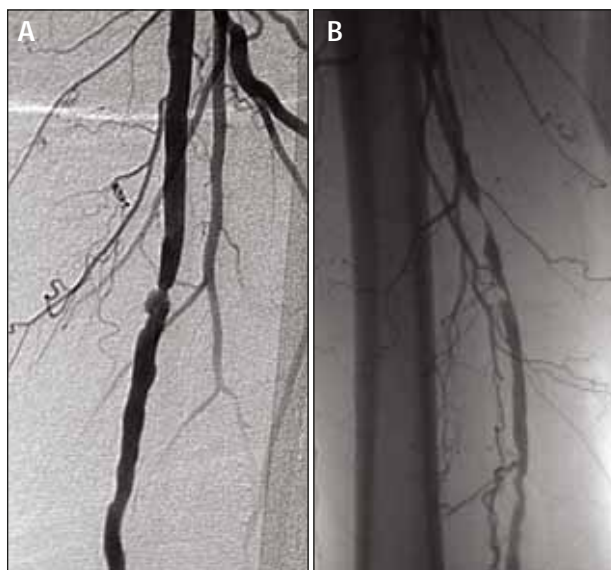


Figure 1. Preprocedural diagnostic angiography of the left lower extremity revealed 60% to 70% stenosis in the proximal left common iliac artery (A). In the right lower extremity, a focal 95% stenosis was revealed in the proximal SFA, with a 40% to 45% stenosis in the distal SFA (B).

barotrauma and dissection.⁸ The SilverHawk Plaque Excision System achieves plaque apposition without the use of a balloon, which may reduce the potential for these events. The catheter design facilitates plaque excision from vessels over a wide range of diameters (2-7 mm) and from the infrainguinal arteries that are often refractory to traditional treatments and/or subject to restenosis. Hundreds of milligrams can be removed from long, diffuse lesions—including those that are calcified. In some instances, as much as 750 mg of tissue have been collected during a single procedure. No previous atherectomy devices reported tissue capture of this magnitude. An individual SilverHawk catheter can be used to treat multiple lesions and vessels, potentially reducing costs.

The importance of plaque removal extends beyond the acute procedural results and improved patient outcomes. Excised plaque presents a unique opportunity to perform a wide range of analyses ranging from histology to genomics. Histologic analysis can be used to identify cells, calcification, lipid content, and other plaque components. Proteomic and gene expression analyses will likely provide insights into the molecular pathways that influence plaque deposition and composition, as well as markers for restenosis, vulnerable plaque formation, or vascular disease.

CASE STUDY: SFA PLAQUE EXCISION IN A BILATERAL CLAUDICANT

Case Performed By Barry Weinstock, MD, FACC, Mid-Florida Cardiology Specialists, Florida Hospital, Orlando, Florida

Clinical History

A 69-year-old man had bilateral claudication, a history of type II diabetes, dyslipidemia with elevated triglycerides, and low HDL, moderate-to-severe bilateral carotid artery disease, hypertension, and extensive known coronary disease with prior stenting of the RCA, circumflex artery, and circumflex marginal branch. Noninvasive studies showed markedly reduced ankle-brachial index bilaterally. Duplex arterial examination was consistent with SFA disease, and the patient was referred for angiography and revascularization.

Angiography

Left Lower Extremity: Diagnostic angiography revealed 60% to 70% stenosis in the proximal left common iliac artery (Figure 1A). A 30 mm Hg to 35 mm Hg pressure gradient was recorded across the stenosis when measured by pullback of the contralateral sheath. In the left internal iliac artery, a focal stenosis of 80% was observed proximal-

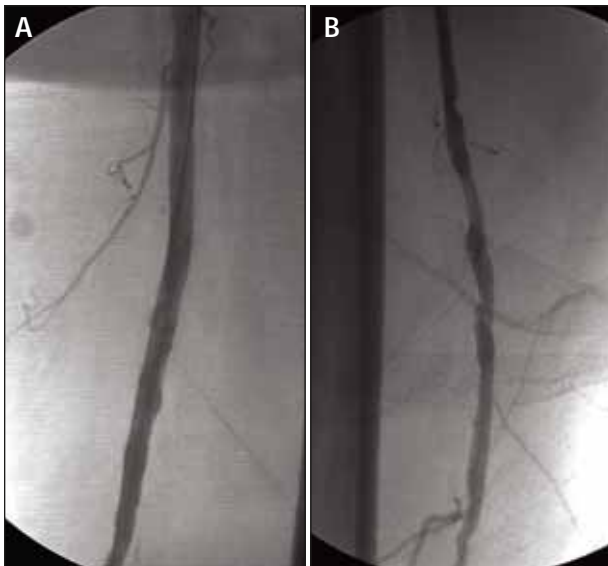


Figure 2. Postprocedurally, brisk, normal flow in the left SFA was noted, with 75% to 80% stenosis reduced to 0% (2A). In the right SFA, the 95% stenosis was reduced to 10% (2B).

ly. The left SFA showed a focal 75% to 80% stenosis proximally. More distally, above the level of the adductor canal, a longer 70% to 75% stenosis was observed. The popliteal artery was normal, and the patient had single-vessel runoff via the anterior tibial artery.

Right Lower Extremity: Diagnostic angiography revealed a focal 95% stenosis in the proximal SFA in the same location as in the left leg (Figure 1B). However, in the distal right SFA, only a 40% to 45% stenosis was observed. The right popliteal artery was normal, with two-vessel runoff distally via the posterior tibial and peroneal arteries. The right anterior tibial artery appeared occluded.

Procedure

The patient underwent a left SFA intervention. A .035-inch guidewire and 7-F Pinnacle Destination contralateral sheath (Terumo Medical Corporation, Somerset, NJ) were exchanged for the 5-F sheath and flush catheter used previously for diagnostic angiography. The patient was anticoagulated with bivalirudin. A .014-inch Cougar (Medtronic, Inc., Santa Rosa, CA) guidewire was advanced to the left peroneal artery without difficulty, and was used to advance a SilverHawk LX catheter over the bifurcation to the left superficial femoral artery. The more proximal stenosis was treated with multiple passes of the SilverHawk catheter, with an excellent angiographic result. Plaque was then removed from the catheter, followed by sever-



Figure 3. Sixty-day follow-up angiography of the left SFA.

al passes of the SilverHawk LX catheter along the more distal stenosis. Extensive plaque was removed. The angiographic result was highly satisfactory, and the interventional system was removed.

Conclusions/Results

Plaque excision was performed using the SilverHawk LX catheter in both the proximal and distal segments of the left SFA. The proximal 75% to 80% stenosis was reduced to 0%. The distal 75% stenosis was reduced to approximately 15% to 20%. There was no dissection or thrombus at either interventional location. There was brisk, normal flow through treated areas at the conclusion of the procedure (Figure 2A). Sixty days after the left leg intervention, the patient returned for plaque excision in the right SFA with the SilverHawk LS catheter. The 95% stenosis in the right proximal superficial femoral artery was reduced to 10% (Figure 2B). Left leg angiography showed a patent left SFA with only 30% stenosis in the midsegment of the vessel, an area not treated previously (Figure 3). Symptoms of claudication

TABLE 1. PATIENT BASELINE DEMOGRAPHIC DATA (% WITH CONDITION)

Claudication history	96.8
Hypertension history	81.7
Smoking history	67.4
Prior MI, CABG, CAD*	53.5
Diabetes	51.3
Prior peripheral intervention	45.3

*MI: myocardial infarction; CABG: coronary artery bypass graft; CAD: coronary artery disease

resolved postintervention, and the patient remains asymptomatic 5 months later.

Comments/Lessons Learned

The SilverHawk Plaque Excision system is an excellent therapy for lifestyle-limiting claudication. Both the left and right superficial femoral artery stenoses were well treated with the SilverHawk device. Optimal results were achieved without additional angioplasty or stenting after plaque excision with the SilverHawk catheter.

INTERMEDIATE DATA FROM THE ONGOING TALON MULTICENTER REGISTRY

Methods

Treating Peripherals with SilverHawk: Outcomes Collection (TALON) is a prospective, multicenter, non-randomized, observational outcomes registry that enrolled consecutive patients undergoing plaque excision for lower-extremity PAD. In addition to demographics, risk factors, and procedure results, TALON collects acute, mid-term (6-month), and long-term (12-month) outcomes data. Tissue and blood samples were also collected from consenting participants.

All sites received institutional review board approval prior to patient enrollment. Informed consent was obtained from each of the study participants in advance of their interventional procedure. Once a patient consented to participate in the registry all data from subsequent procedures were also captured. Consecutive patients were enrolled to the extent possible. Patients were enrolled irrespective of the lesion complexity or treatment indication. In some instances, patients were not enrolled due to the patient's inability or refusal to provide informed consent or in cases for which research personnel were not available to collect the necessary data. The registry was designed to collect real-world data following treatment with the SilverHawk device. As such, all data in the registry are

TABLE 2. LESION CHARACTERISTICS

Location	%	Length (average, mm)
ATK*	75	
BTK	25.1	
Iliac	4.7	37.8
Common femoral/profunda	6.2	25.1
SFA	49.2	77.1
Popliteal	14.8	42.2
AT/PT	12.4	40.9
TPT/peroneal	11.9	29.1
Other	0.8	15.2

*ATK (above the knee) and BTK (below the knee) percents do not add up to 100 due to rounding. AT/PT: anterior/posterior tibial; TPT: tibioperoneal trunk

self-reported. Vessel size, lesion length and severity, angiographic outcomes, and complications are recorded by the investigator immediately at the time of the procedure. Final angiograms are performed of the run-off vessels to assess embolization. Postprocedure outcomes and complications are monitored prospectively. No independent adjudication of angiographic results, complications or outcomes data was conducted. The TALON registry is accessible via the internet. All data was stored on a secure server managed by Outcome, a Harvard-based independent data management center.

The primary objective of this analysis was to evaluate the safety and efficacy of the SilverHawk device in patients with lower extremity PAD. Six-month target lesion revascularization (TLR) is reported herein. TLR was determined by either office visit, chart review, or telephone call. Investigators reported any percutaneous or surgical procedure that affected the SilverHawk treated lesion as a TLR.

TABLE 3. ACUTE POST-SILVERHAWK MINOR COMPLICATIONS (%)

Grade A/B dissection	2.2
>Grade C dissection	0.5
Perforation	0.8
Occlusion/thrombosis	0.4

*Only potential device-related complications included herein. Additional complications on file with the registry sponsor.

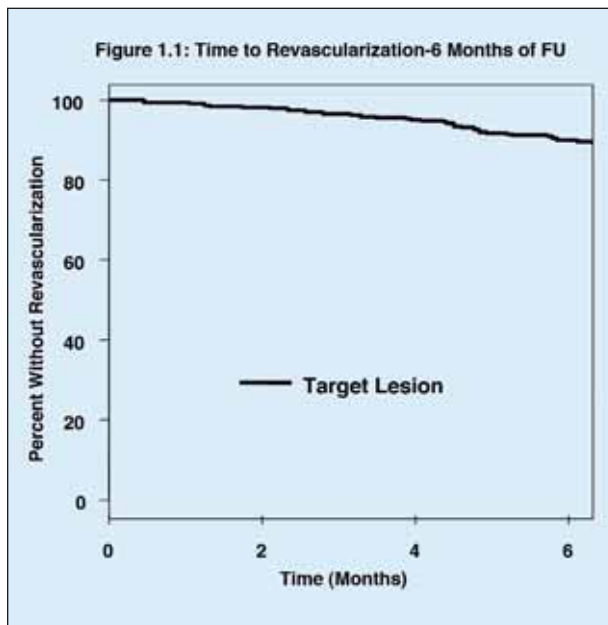


Figure 4. At 6 months, Kaplan-Meier analysis indicated 90% of patients remained free of TLR.

Results

As of May 2005, the registry has enrolled more than 700 patients at 21 sites. The results of 505 patients with 664 procedures and 1,047 lesions enrolled before January 1, 2005, are summarized below. Demographics are presented in Table 1. The patient population was 60% male and had a mean age of 69.5 years. Sixty-seven percent had a history of smoking. More than half were diabetics (51.3%), and 53.3% had a history of heart disease. Fourteen percent had CLI (defined as Rutherford Becker score ≥ 5).

Tissue was captured from 99.2% of all lesions. Two or more lesions were treated in 40.5% of the procedures with a mean SilverHawk time of 29 minutes (range, 1-2:26 min; SD, 22 minutes).

Lesion characteristics are presented in Table 2. Of the lesions treated, 75% were located above the knee, and 25% were located below the knee. Moderate-to-severe calcification was present in 67.4% of treated lesions. Chronic total occlusions comprised 27.9% of the lesions. Mean lesion length was 77.1 mm for SFA lesions, and the mean length ranged from 15 mm to 42.2 mm for all other lesions. Nearly 75% of lesions received stand-alone SilverHawk treatment. Only 5.3% of all treated lesions required adjunctive stent placement. Most stenting was performed due to dissections or suboptimal angiographic results in heavily calcified lesions. Stents were also placed in iliac lesions where the device was used to debulk bifurcation areas prior to planned

stenting. In stand-alone SilverHawk plaque excision cases, a reduction in stenosis of 75% occurred, from a mean of 85.77% (range, 40-100%; SD, 13%) to 10.07% (range, 0-50%; SD, 9.8%).

Investigators reported complications following each SilverHawk procedure. Additionally, pre-, post-SilverHawk and post-adjunctive therapy data were collected for distal run-off, dissection, and loss of side branch. Dissections were classified according to NHLBI (National Heart Lung and Blood Institute) standards. Post-SilverHawk complications were site adjudicated and reported and included 0.5% major dissection (type C or greater), 0.8% perforation, and 0.4% occlusion.

Six-Month Outcomes

Six-month follow-up data are available for 232 of 248 patients in this cohort (93%), with 461 lesions. At 6 months, Kaplan-Meier analysis indicated 90% of patients remained free of TLR (Figure 4). The TLR rate for patients with a single lesion treated was 6%.

CONCLUSIONS

Acute and 6-month data from TALON demonstrate that the SilverHawk device has promising safety and efficacy profiles in treating lesions in peripheral arteries, including multiple lesions, long and calcified lesions, and those located in challenging areas, such as joint spaces and below the knee. The registry results show high procedural success and low complication rates in both femoropopliteal and tibioperoneal lesions of any length (Table 2) and reference vessel diameter (range, <2-7 mm) and are consistent with data compiled on over 400 patients treated with SilverHawk at various centers. SilverHawk's mid-term efficacy is exemplified by the low 6-month TLR rate of 10% across all lesions and 6% for single lesions. Collection of longer-term 12-month data is underway. ■

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