

# Excisional Atherectomy: Workhorse or Niche?

Where does excisional atherectomy work best for lower extremity arterial occlusive disease?

**BY MICHAEL C. NGUYEN, MD, AND LAWRENCE A. GARCIA, MD**

**P**ercutaneous revascularization has revolutionized the treatment of lower extremity peripheral arterial disease (PAD) over the past 10 years, although no single therapy has emerged as the gold standard. Recent stent trials have made self-expanding nitinol stenting the default therapy in the superficial femoral artery (SFA).<sup>1-3</sup> However, to date, the restenosis rates can be more than 35% in longer lesions.<sup>4</sup> As such, numerous novel devices have been used in the endovascular treatment of femoropopliteal, as well as infra-popliteal, disease with improved acute success rates and ease of intervention. Clinical patency remains the key challenge to all endovascular therapies in this critically hostile anatomic location. Newer devices will ultimately be judged on clinical outcomes in addition to those of efficacy and durability.

One class of new technology has concentrated on debulking the plaque either as a stand-alone therapy or as part of a combination modality therapy; however, the lack of uniform performance criteria and reporting standards for these and other devices has resulted in heterogeneous study endpoints, making comparative efficacy difficult. Hopefully, future research can address the need for uniform clinical endpoints to assess the safety and efficacy of these newer devices.

In this article, we review the current use and optimal application for excisional atherectomy with the SilverHawk Plaque Excision System (ev3 Inc./FoxHollow Technologies, Redwood City, CA) in the treatment of lower extremity arterial obstructive disease by a review of the published and relevant literature for this anatomic location.

## **EXCISIONAL ATHERECTOMY**

The data in support of excisional atherectomy (with SilverHawk) in the treatment of lower extremity PAD have mainly stemmed from single-center and multicenter registries with no randomized controlled trials to date (Table 1).<sup>5-9</sup> The largest registry is the TALON (Treating Peripherals with SilverHawk: Outcomes Collection) registry, which involved 19 different US centers.<sup>5</sup> Midterm (6- and 12-month) outcomes for 601 patients with 1,258 symptomatic lesions (mean lengths, 62.5 mm above the knee and 33.4 mm below the knee) treated with the SilverHawk device have been reported with excellent procedural success (97.6%). The 12-month clinical outcomes compare favorably to angioplasty and stenting, which have reported primary patency rates of 61% to 67%.<sup>3,10</sup> However, the data from TALON were self-reported by the operators involved in the study and were not core-lab adjudicated, and thus, clinical reliability with these data has been viewed with skepticism. Regardless, the TALON registry remains the largest single cohort of patients reported using the device.

For obstructive disease in the SFA, there have been several single-center studies that have provided insight into the use and efficacy of excisional atherectomy. For the simplest lesions, focal SFA disease (TransAtlantic Inter-Society Consensus [TASC] A,<sup>10</sup> under 5 cm), Zeller et al demonstrated a primary duplex patency of more than 80% at 1 year.<sup>6</sup> The 12- and 18-month data from this study showed that, in 84 patients, the residual stenosis rate for treating 131 lesions with atherectomy alone was <50% in 126 (96%) of the lesions and <30% in

TABLE 1. REGISTRIES OF PATIENTS TREATED WITH EXCISIONAL ATHERECTOMY\*

Investigator	Patients/ Lesions	Primary Group	Lesion Length (Occlusion %)	Location	Clinical Patency	Primary Patency
TALON	728/1,517	Claudicant/CLI	8.4 cm (28.6)	SFA/BTK	79%	NA
Yancey et al <sup>7</sup>	16/18	CLI	>3 cm	SFA/BTK	NA	22%
Kandzari et al <sup>9</sup>	69/76	CLI	6.4 cm (34)	SFA/BTK		Not reported
Keeling et al <sup>8</sup>	60/66	Claudicant/CLI	8.8 cm (27)	SFA/BTK		67% (90%–40%)
Zeller et al <sup>6</sup>	84/131	Claudicant/CLI	9 cm (8.5)	SFA/BTK	NA	64% (84%–54%)
Total	957/1,808					

\*BTK indicates below the knee; CLI, critical limb ischemia; NA, not applicable; SFA, superficial femoral artery.

100 (76%) of the lesions. At 12-month follow-up, the primary patency rates (defined as <50% restenosis on duplex ultrasound) were 84%, 54%, and 54% for the three groups, respectively (de novo, native vessel restenoses, and in-stent restenoses). At 18-month follow-up, the primary patency rates were 73%, 42%, and 49% for the three groups. Importantly, the ankle-brachial index significantly improved for all groups at 12 and 18 months.

Further data from Keeling et al showed that for TASC A or B lesions in a patient population that included patients with chronic limb ischemia, duplex-derived primary patency rates at 1 year were more than 90%.<sup>8</sup> The results were derived from a prospective database that assigned the Society for Vascular Surgery (SVS) ischemia scores and femoropopliteal TASC lesion criteria in patients undergoing atherectomy with 1-, 3-, 6-, and 12-month duplex ultrasound follow-up. Follow-up was for a 17-month period on 66 limbs in 60 patients who underwent 70 plaque excisions. The technical success was high (87.1%) with a 1-year primary patency rate of 61.7% and restenosis developing in 16.7% of the patients at a mean of  $2.8 \pm 0.7$  months from the index procedure. Restenosis was significantly higher in TASC C or D lesions than TASC A or B.

Therefore, from the available data (focal to moderate lesion lengths in both claudicants and patients with chronic limb ischemia), excisional atherectomy has a safe and durable success rate when performed optimally, with primary patency rates higher than 80%.<sup>6,8</sup> When the lesion lengths become longer (TASC C or D), the use of excisional atherectomy as stand-alone therapy or with adjunctive percutaneous transluminal angioplasty has a much lower primary patency rate at the end of 1 year as

compared with the simple TASC A or B lesions. In patients with chronic limb ischemia and TASC C or D lesions, Keeling et al demonstrated that primary patency declines significantly to 40%.<sup>8</sup>

For critical limb ischemia (CLI), the use of excisional atherectomy has proven to be safe and efficacious in preventing limb or tissue loss; however, primary patency rates in these patients (treating primarily tibial lesions) are very poor (near 20%).<sup>7</sup> Yancey et al reported on a 16-patient cohort with CLI (advanced PAD with severe diffuse inflow disease, gangrene, tissue loss, and diabetes) consisting of complicated TASC C (Table 1) femoropopliteal lesions.<sup>7</sup> Results showed resolution of the initial symptoms in 12 limbs and partial healing in two others. Early amputation was required in three patients for progressive foot ischemia and inframalleolar disease. Three of the patients had no flow to the foot before or after treatment. The 1-year patency rates were low at 22%; however, target lesion revascularization was only required in 18%, and limb salvage was achieved in 70%. Despite the high-risk cohort with advanced CLI, excisional atherectomy resulted in significant limb salvage.

Despite high rates of limb salvage in this population, mortality rates remain significant, reflecting a high-risk population with multiple vascular comorbidities. Kandzari et al published data on a prospective nonconsecutive registry of 76 limbs in 69 CLI patients who were treated with the SilverHawk atherectomy device.<sup>9</sup> The 30-day event rate (death, myocardial infarction, unplanned amputation, or repeat target vessel revascularization) was 1% and increased to 23% by 6 months. Amputations were avoided or less extensive in 92% of patients at 30 days and 82% at 6 months; however, the mortality rate at 6 months was considerable (10 deaths, 14.5%).

Beyond the overall data that have been published regarding SilverHawk atherectomy, optimal targeted use is still an evolving process. To date, the key locations where excisional atherectomy seems best suited appear to be in those locations where stenting or placing an endovascular prosthesis may be suboptimal (such as the common femoral or popliteal arteries where the option for future surgical access would be compromised).

There have been no published data regarding the specific use of excisional atherectomy at the level of the common femoral artery or specifically for the popliteal artery. Our own data suggest these locations can be easily treated with excisional atherectomy resulting in durable outcomes and without significant complication rates, and future studies will likely concentrate on specific locations in which excisional atherectomy may play a more important role.

One final area of continued evaluation is with distal embolization. To date, all major studies with the exception of the TALON registry have an average embolic event rate of 3% to 4% when done optimally with good technical skill. Although all atheroablative technologies produce emboli, this concern with excisional atherectomy has not translated to a larger number than that seen with other atheroablative technologies such as laser-mediated atherectomy.

## CONCLUSION

After review of the available literature, it can be concluded that excisional atherectomy is a safe and efficacious procedure for the revascularization of infrainguinal arterial obstructive disease in a varied subset of patients. However, as the lesion subsets change, so does the long-term patency rate (as measured at 1 year via duplex evaluation). When excisional atherectomy is performed by experienced operators, focal- to moderate-length lesions in the SFA have a primary patency rate near 80%. For longer lesions, TASC C or D, the primary patency declines to near 50%. However, these data are a compilation of both simple claudicants and chronic limb ischemic patients. Thus, clear definitive conclusions are more difficult to draw. For patients with CLI and still more focal disease (TASC A or B), the primary patency rate may approach 90%. However, for CLI patients and long lesions (TASC C or D), the primary patency rates decline significantly to near 40%.<sup>8</sup> Despite the poor primary patency rates in this population, limb salvage rates still approach 90% at 6 months.<sup>9</sup> Long restenotic lesions have a 50% primary patency rate, as does the use of excisional atherectomy for in-stent restenosis (however, this is an off-label indication in the US). Alternatively, the use of excisional atherectomy provides a good alternative treatment

option in areas where the use of stenting or other endovascular prosthesis should generally be avoided (such as the common femoral artery and popliteal).

Therefore, excisional atherectomy can be used safely as a “workhorse” device in simple to moderate lesions. However, alternative or adjunctive therapy is likely needed to improve primary patency rates for longer lesions, native restenosis, and in-stent restenosis. The use of excisional atherectomy as an adjunct or preliminary device before endovascular stenting has not been studied to date but seems compelling to provide the best expansion of the endoprosthesis before deployment. Further, the use of excisional atherectomy before drug-eluting balloons, infusion, or stents has never been evaluated but would potentially suggest a promising alternative to primary endovascular stenting for longer infrainguinal arterial obstructions. ■

*Michael C. Nguyen, MD, is with the Division of Cardiology at Beth Israel Deaconess Medical Center in Boston, Massachusetts. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Nguyen may be reached at mcnguyen@bidmc.harvard.edu.*

*Lawrence A. Garcia, MD, is Director, Peripheral Cardiovascular Program and Peripheral Interventions and Director, Interventional Fellowship Program at Beth Israel Deaconess Medical Center; and Assistant Professor of Medicine at Harvard Medical School in Boston, Massachusetts. He has disclosed that he is a paid consultant to ev3 Inc. Dr. Garcia may be reached at lagarcia@bidmc.harvard.edu.*

1. Ferreira M, Lanzotti L, Monteiro M, et al. Superficial femoral artery recanalization with self-expanding nitinol stents: long-term follow-up results. *Eur J Vasc Endovasc Surg.* 2007;34:702-708.
2. Zeller T, Tiefenbacher C, Steinkamp HJ, et al. Nitinol stent implantation in TASC A and B superficial femoral artery lesions: the Femoral Artery Conformexx Trial (FACT). *J Endovasc Ther.* 2008;15:390-398.
3. Schillinger M, Sabeti S, Loewe C, et al. Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. *N Engl J Med.* 2006;354:1879-1888.
4. Schlager O, Dick P, Sabeti S, et al. Long-segment SFA stenting—the dark sides: in-stent restenosis, clinical deterioration, and stent fractures. *J Endovasc Ther.* 2005;12:676-684.
5. Ramaiah V, Gammon R, Kiesz S, et al. Midterm outcomes from the TALON Registry: treating peripherals with SilverHawk: outcomes collection. *J Endovasc Ther.* 2006;13:592-602.
6. Zeller T, Rastan A, Sixt S, et al. Long-term results after directional atherectomy of femoropopliteal lesions. *J Am Coll Cardiol.* 2006;48:1573-1578.
7. Yancey AE, Minion DJ, Rodriguez C, et al. Peripheral atherectomy in TransAtlantic Inter-Society Consensus type C femoropopliteal lesions for limb salvage. *J Vasc Surg.* 2006;44:503-509.
8. Keeling WB, Shames ML, Stone PA, et al. Plaque excision with the Silverhawk catheter: early results in patients with claudication or critical limb ischemia. *J Vasc Surg.* 2007;45:25-31.
9. Kandzari DE, Kiesz RS, Allie D, et al. Procedural and clinical outcomes with catheter-based plaque excision in critical limb ischemia. *J Endovasc Ther.* 2006;13:12-22.
10. Dormandy JA, Rutherford RB. Management of peripheral arterial disease (PAD). TASC Working Group. TransAtlantic Inter-Society Consensus (TASC). *J Vasc Surg.* 2000;31(1 Pt 2):S1-S296.