Recent Advances in Atherectomy

The role of this treatment option in critical limb ischemia patients.

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Peripheral arterial disease (PAD) continues to increase in an ever-aging society and consumes a significant part of health resources. Its manifestations range from symptoms of claudication to critical limb ischemia (CLI) and limb loss and has strong associations with coronary and cerebrovascular disease.[1-3] A CLI diagnosis is based on hemodynamic criteria (ankle systolic pressure <50 mm Hg and persistent or recurring rest pain requiring analgesia) and/or clinical criteria (ulceration, gangrene, or nonhealing lower-extremity wounds).[4,5] CLI can be a life-threatening condition associated with substantial morbidity and mortality rates. Strategies to revascularize patients with CLI are limited, in part due to unsuitable anatomy for distal bypass graft anastomosis, comorbidities, or extensive tissue necrosis and loss. Concern also persists regarding failure of clinical patency and periprocedural complications with both tibioperoneal bypass surgery and angioplasty in this population with extensive comorbidities.[6-10] Therefore, major lower-extremity amputation is still a commonly performed treatment, with more than 100,000 cases annually within the US.[11,12]

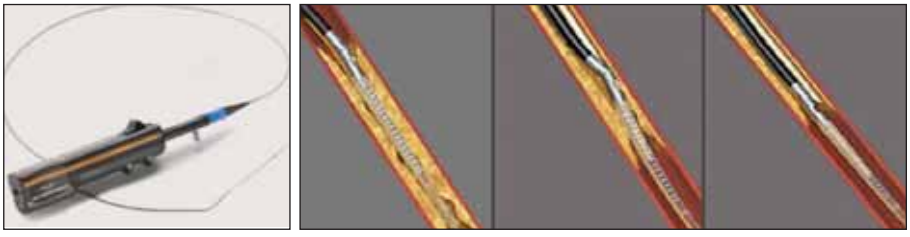

Figure 1. The SilverHawk plaque excision system (FoxHollow Technologies, Redwood City, CA).

With the growing need for advances in CLI treatment, the past few years have led to a proliferation of endovascular therapies available to treat peripheral atherosclerosis. These technologic advances include laser catheters, cryoplasty, mechanical thrombectomy, bare-metal and drug-eluting stents, and plaque excisional atherectomy. Atherectomy is a growing therapeutic modality in the treatment of multilevel and small-vessel disease, either alone or with adjunctive treatment, such as balloon angioplasty or stenting. The intermediate outcomes in the treatment of CLI have been encouraging. With further technical advances, as well as research into the long-term durability of this treatment modality, atherectomy may prove to be a useful tool in the treatment of small-vessel disease and, specifically, CLI.

We review the current data in the treatment of CLI for excisional atherectomy and atheroablative technologies. These technologies include excisional atherectomy, excimer laser atherectomy, and newer technologies on the horizon.

ATHERECTOMY DEVICES

Atherectomy refers to the physical removal of material from the blood vessel. The presumed benefit of atherectomy is that it debulks/removes obstructing material rather than displacing it, as angioplasty does. Atherectomy devices fall into two main categories: excisional (removing and collecting atheromatous material) and ablative (fragmenting the atheroma into small particles).

Directional Atherectomy

The Simpson Coronary AtheroCath (Devices for Vascular Intervention, Redwood City, CA) was the original atherectomy device for coronary vessels. In the early 1990s, atherectomy was considered a major advancement

TABLE 1. REGISTRIES OF PATIENTS TREATED WITH EXCISIONAL ATHERECTOMY

Author	Patients/ Lesions	Primary Group	Lesion Length (occlusion%)	Location	Lesion Type	Limb Salvage	Clinical Patency	Primary Patency	Complications
Ramaiah[15]	728/1,517	Claudicant/ CLI	8.4 cm (-28.6)	SFA/BTK	*De novo* (87.5%)	n/a	79%	n/a	5.3%
Yancy[21]	16/18	CLI	>3 cm	SFA/BTK	*De novo*	70%	n/a	22%	12%
Kandzari[19]	69/76	CLI	6.4 cm (-34%)	SFA/BTK	*De novo*	82%		Not reported	
Keeling[22]	60/66	Claudicant/ CLI	8.8 cm (-27%)	SFA/BTK	*De novo*	87%		67% (90% to 40%)	7%
Zeller[20,27]	84/131	Claudicant/ CLI	9 cm (-8.5%)	SFA/BTK	*De novo* (34%)	n/a	n/a	64% (84% to 54%)	3.8%
Total	**957/1,808**								

BTK=below the knee.

in percutaneous coronary intervention. However, concerns were raised regarding high rates of restenosis, both short and long term, with no improved efficacy over balloon angioplasty.[13] The use of this device in the periphery had technical limitations (ie, limited to vessel diameters of 4 mm), and the long-term results were also not superior to those of contemporary balloon angioplasty.[14]

The SilverHawk Plaque Excision System was approved in 2003 by the FDA to treat PAD and has become the dominant directional atherectomy device in use (Figure 1). The SilverHawk device debulks without a balloon for apposition. Rather, the device self-apposes the atheroma through a hinge system and contains a carbide cutter with variable height depending on the device used, which rotates at speeds up to 8,000 rpm. It shaves atherosclerotic material from the luminal portion of the arterial wall rather than compressing the plaque and is contained within a distal storage chamber. It can be used without the adjunctive use of balloons or stents, and its palm-sized drive unit, with an on/off thumb switch, allows single-operator use. The evidence for excisional atherectomy with the SilverHawk has mainly stemmed from single-center and multicenter registries.

To date, there has been no randomized controlled trial for excisional atherectomy with the SilverHawk in CLI. The largest of the registries is the TALON (Treating Peripherals with SilverHawk: Outcomes Collection) registry, which involved 19 US centers.[15] 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 an excellent procedural success rate (97.6%). Adjunctive therapy was required in 21.7% of patients, and stents were required in only 6.3%. Total lesion revascularization at 6 and 12 months was 90% and 80%, respectively. The 12-month outcomes compare favorably to angioplasty and stenting, which have reported patency rates of 61% to 67% (Table 1).[16,17]

Excimer Laser Atherectomy

Another significant atherectomy modality currently available is the Excimer laser (Spectranetics Corporation, Colorado Springs, CO) (Figure 2). Laser atherectomy's key feature is the ability to debulk and ablate tissue (thrombus or plaque) without damaging surrounding tissue, thus minimizing restenosis. The Excimer laser employs exact energy control (shallow tissue penetration) and safer wavelengths, thereby decreasing perforation and thermal injury to the treated vessels. It is a cold-tipped laser that delivers bursts of ultraviolet/ xenon energy (308 nm) in short pulse durations, which ablates on a photochemical, rather than a thermal, level. The ultraviolet light provides a direct lytic action that ablates 5 µm of tissue on contact without a rise in surrounding tissue temperature. Early studies, such as the Peripheral Excimer Laser Angioplasty (PELA) trial, compared Excimer laser-assisted percutaneous transluminal angioplasty (PTA) versus PTA alone for long total superficial femoral artery (SFA) occlusions.[18] The acute procedural success was similar in both groups (85% in the laser group, 91% in the PTA group) as were the complication rates (12.8% vs 11.4%). The 12-month primary patency rates were 49% for both groups.

Excisional Atherectomy in CLI

Excisional atherectomy for patients with CLI has been

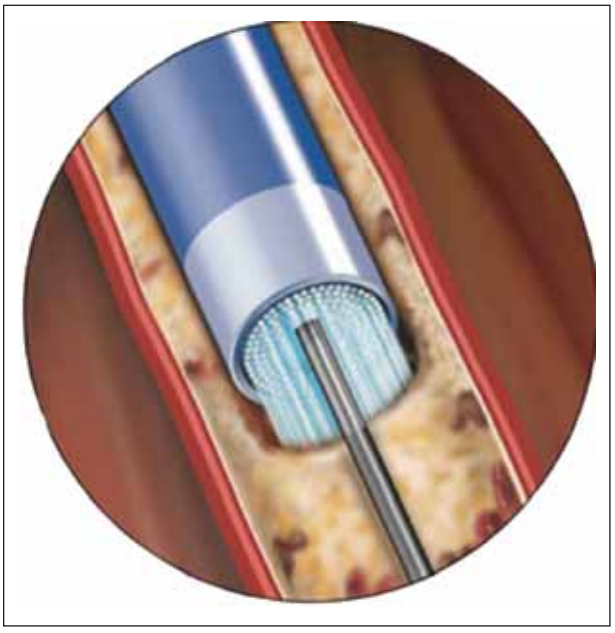

Figure 2. Spectranetics Corporation's CVX-300 Excimer laser catheter.

evaluated (Table 1). 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.[19] 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% of patients at 6 months. In this patient cohort, all patients had evidence of tissue loss and/or impaired wound healing (Rutherford category 5 or 6), and amputation was initially advised before attempted percutaneous revascularization for 63% of limbs. In this study, despite reductions in amputations, the mortality rate at 6 months was considerable (10 deaths, 14.5%), reflecting the high-risk population requiring intensive secondary prevention and close clinical observation and follow-up.

Recently, Zeller et al also reported outcomes with the use of SilverHawk treatment in 33 patients (52 infrageniculate lesions) with both claudication and CLI.[20] Primary atherectomy was the treatment of choice in 37 (71%) of the lesions, while 15 (29%) received balloon predilatation. Rates of restenosis at 3 and 6 months (defined as >70% on duplex ultrasound) were 14% and 22%, respectively, suggesting favorable outcomes for primary treatment of small-vessel disease with excisional atherectomy. Further, Yancy et al also reported on complicated TASC (TransAtlantic Inter-Society Consensus) C 9 femoropopliteal lesions with SilverHawk atherectomy.[21] The patient cohort consisted of only 16 patients with CLI and advanced PAD with severe diffuse inflow disease, gangrene, tissue loss, and diabetes. 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, total 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.

Recently, Keeling et al published on the outcomes of SilverHawk atherectomy as a primary treatment for infrainguinal lesions in claudicants and CLI.[22] A prospective database was created that assigned Society for Vascular Surgery 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 reported for a 17-month period on 66 limbs in 60 patients who underwent 70 plaque excisions. The technical success rate was high (87.1%). The 1-year primary patency rate was 61.7%, and restenosis developed in 16.7% of patients at a mean of 2.8 months ±.7 months. Restenosis was significantly higher in TASC C or D lesions than TASC A or B lesions. The investigators concluded that SilverHawk atherectomy was a viable option for infrainguinal revascularization and that ischemia and lesion severity significantly contributed to 12-month patency outcomes.

Many aspects of directional atherectomy with the SilverHawk device still need to be studied in randomized, controlled trials to ensure data quality regarding long-term outcomes and safety. At present, registry data and single-center cohorts in the treatment of CLI have indicated promising short-term outcomes with high rates of limb salvage, which is a critical measure of success in this patient cohort. With continued research and device improvements, excisional atherectomy may prove to be a reliable and consistent endovascular therapy for this high-risk population.

Laser Atherectomy in CLI

A major study performed with the Excimer laser in CLI is the LACI (Laser Angioplasty for Critical Limb Ischemia) phase 2 study,[23] which was a clinical study that evolved from a 25-patient phase 1 registry. This study enrolled 145 patients with CLI at 14 sites in the US and Germany and examined the Excimer laser in 155 limbs and 423 lesions: 41% SFA, 15% popliteal, 41% infrapopliteal, and 70% combination of stenoses. The patients were all

deemed poor surgical candidates. Straight-line flow to the foot was restored in 89% of the patients, with adjunctive PTA and stenting in 96% and 45% of cases, respectively. The 6-month limb salvage rate was 92.5% with a major amputation rate of 8%. There was a high 6-month mortality rate of 10% (mostly cardiac death), reflecting the high-risk vascular comorbidities of this patient population. Based on these data and with further advancements, laser therapy may play a greater role in the treatment of CLI.

Future Devices

Other newer atherectomy devices under development include the CSI Orbital Atherectomy device (Cardiovascular Systems, Inc., St. Paul, MN), which utilizes an eccentrically shaped wire coil and diamond-coated abrasive crown, unlike the symmetric rotating burr of traditional rotational atherectomy. Another technology is the rotational aspirating atherectomy device (Pathway Medical Technologies, Redmond, WA). It combines the two actions of aspiration with differential plaque removal and may be useful in calcified lesions. These devices will be undergoing clinical trials, and their roles in the future of PAD treatment remain uncertain.

CONCLUSION

Despite advances in catheter design and catheterization technique, outcomes following balloon angioplasty for CLI have been varied. Angioplasty alone has been avoided in patients with CLI due to concerns about consistent performance, abrupt vessel closure, distal embolization, restenosis, and lack of clinical patency, which can often be greater than 50% after 18 months mainly due to the small-caliber vessels, high flow resistance, and heavy disease burden in this population.[24-26] However, despite these limitations, successful restoration of in-line flow to an ischemic limb is critical in limb salvage, which is especially relevant as an outcome in CLI. Currently, there remains a great deal of interest in alternative therapies, such as atheroablative, for this patient subset. Devices for the treatment of infrapopliteal/tibial disease will require ease of use, deliverability, consistent performance, and limited cost to achieve high rates of limb salvage in patients with CLI. Excisional atherectomy is an evolving therapy that has been shown to have good acute and midterm clinical outcomes in most patients, including those with CLI. Further research is required to assess the safety, efficacy, and the cost/benefit of excisional atherectomy before it can be recommended as the predominant therapy for this patient population. ■

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