

Role of Atherectomy Devices in the Treatment of Lower Extremity Peripheral Arterial Disease

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Received: January 12, 2014; Published: March 16, 2015

Abstract

Atherosclerosis is a systemic disease affecting all major vascular beds. Risk factors for atherosclerosis, and therefore, for PAD, include active smoking, advance age, dyslipidemia, diabetes mellitus, and hypertension. Due to continuous increase in aging population and diabetes, incidence of peripheral arterial disease will continue to increase. While atherosclerotic coronary disease usually have focal lesions and can successfully be treated with balloon angioplasty or stent. Lower extremity peripheral arterial occlusive disease however, poses a unique challenge to traditional angioplasty-based endovascular therapies. The diffuse nature of lower extremity atherosclerotic disease, the presence of chronic total occlusions, poor distal runoff, and the presence of critical limb ischemia all have contributed to the disappointing results of balloon angioplasty for complex infrainguinal arterial disease. This results in development of a host of new technologies such drug eluting balloon and atherectomy in an attempt to improve the safety and effectiveness of percutaneous revascularization for lower extremity peripheral arterial occlusive disease. This review summarizes the available atherectomy devices their mechanism of action and literature supporting their use.

Keywords: *Peripheral arterial disease; Atherosclerosis; Atherectomy; Claudication; Dissection; Debulking; Recanalization; Subintimal; Restenosis; Thrombosis*

Introduction

Peripheral arterial disease (PAD) comprises the vascular diseases caused primarily by atherosclerosis and thromboembolic pathophysiological processes that alter the normal structure and function of the aorta, its visceral arterial branches, and the arteries of the lower extremity [1]. The incidence of PAD is high as 12-15 million adults living in USA suffer from PAD [2]. Patients with PAD can present with a myriad of symptoms, or can remain asymptomatic despite having advanced disease. PAD is a powerful independent predictor of coronary artery disease and cerebrovascular disease. In the Coronary Artery Surgery Study (CASS) registry, for patients with known CAD, the presence of PAD increased cardiovascular mortality by 25% during 10 years of follow-up [3].

In last two decades, significant advances have been made in the treatment of PAD especially involving the lower extremities. Treatment of lower extremity PAD includes medical therapy with risk factor modifications, endovascular therapy, and surgery. Endovascular treatment of PAD includes percutaneous transluminal angioplasty (PTA), stenting, and atherectomy. In this article we will discuss role of atherectomy in the treatment of PAD. The atherosclerotic process in the lower extremity is usually diffuse. Vessels are calcified, have poor runoff, and are often chronically occluded. Balloon angioplasty alone may not result in long-term patency [4]. In addition PTA could result in barotrauma, intimal/medial hyperplasia, and dissection. Stenting, on the other hand, precludes the use of surgical bypass at a future stage if deployed on particular anatomic locations. Atherectomy devices have advantage of reducing the atherosclerotic burden without causing barotraumas or precluding future bypass surgery.

Citation: Syed Mashood Ahmed. "Role of Atherectomy Devices in the Treatment of Lower Extremity Peripheral Arterial Disease". *EC Cardiology* 1.1 (2015): 1-9.

Atherectomy techniques can broadly be classified into two categories: (1) Athero-ablative (ablation or fragmenting plaque into smaller particles), which include laser atherectomy, rotational atherectomy, and orbital atherectomy; and (2) excisional atherectomy.

Athero-ablative Atherectomy

Chiropractic Care

The excimer laser atherectomy catheters consist of a bundle of flexible optical fibers, encased within medical grade tubing. The optical fibers conduct ultraviolet laser light (excimer laser light at 308 nm) from a source to the tip of the catheter. The UV light has the advantage of its short penetration depth of 50 micrometers, ability to bond directly by a photochemical rather than a thermal process, and its direct lytic action. The catheter is inserted into a patient's vasculature along the length of a previously inserted medical guide wire, and thus allowing the interventionist to deliver laser energy targeted to the blockage in the blood vessel. The catheter delivers intense bursts of UV energy in short pulse durations, and it removes a tissue layer of about 10 micrometers with each pulse of energy. This laser energy ablates or debulks the lesion material thus opening the vessel, and permitting placement of the devices used in vascular interventions [5]. At this time, 3 different type of laser atherectomy (Spectronetics Corporation, Colorado Springs, CO) catheters are available: Turbo-Booster (Spectronetics), Turbo-Tandem (Spectronetics) for large infrainguinal arteries (above the knee), and Turbo-Elite (Spectronetics) for infrainguinal arteries above and below the knee.

In a prospective trial in 312 patients with short occlusions of the SFA, excimer laser angioplasty for recanalization was applied. The average occlusion length of the SFA was 7.5 cm (range 1-10 cm). Percutaneous excimer laser angioplasty (PELA) produced successful recanalization of the SFA in 286 of 312 patients (91.7%). In 26 patients (8.3%), recanalization was not possible due to calcified lesions or due to an aberrant anatomy of the SFA resulting in vessel injury or perforation. After a follow-up period of 36-months, there was a primary, primary assisted and secondary patency rate of 49.2%, 76.5% and 86.3% [7][6]. In addition, the multicenter, prospective, randomized PELA study comparing PTA alone to excimer laser and PTA in chronic occlusions > 10 cm in superficial femoral artery showed a significantly reduced use of stents in the laser group (42%) versus the PTA alone group (59%) [8][7]. However, the 1-year reintervention rate was the same for both groups (51%). Overall, the use of the excimer laser does not appear to improve procedural durability over PTA and stenting.

Limb salvage following laser-assisted angioplasty for critical limb ischemia (LACI trial) was a prospective registry in which 145 patients with 155 critically ischemic limbs and 423 lesions were enrolled at 15 sites in the US and Germany. All patients had evidence of systemic vascular disease, with a high incidence of diabetes (66%), hypertension (83%), previous stroke (21%), and myocardial infarction (23%). The patients were poor surgical candidates due to inadequate target vessel or saphenous vein, or significant co-morbidities.

Of the 423 lesions, 41% were in the SFA, 15% were in the popliteal artery and 41% were in the infrapopliteal arteries. Most of the patients (70%) had a combination of stenosis and occlusions. Endovascular treatment included guide wire traversal and excimer laser angioplasty followed by balloon angioplasty with optional stenting. Laser treatment was successfully delivered in 99% of the cases, with adjunctive balloon angioplasty successfully performed in 96%. Procedural success, defined as < 50% residual stenosis in all treated lesions, was seen in 86% of limbs. During hospital stay, no deaths or surgical interventions occurred as a result of the procedure and no patients experienced acute limb ischemia after the intervention.

LACI resulted in a limb salvage rate of 92% in survivors at 6-months. Only 2% of LACI patients required surgical revascularization during follow-up. Most of the patients showed improvement in Rutherford category (69%) [9][8].

In another study Excimer laser was used in patients (n = 318) with long SFA lesions (average length 19.4 + 6.0 cm in length). More than 75% of patients had severe claudication while fewer had critical limb ischemia. The initial attempt to cross the lesion with an excimer laser catheter was successful in 83.2% of the lesions; secondary attempt was successful in 90.5% of the lesions. The primary patency at 1 year was 33.6%. The 1-year assisted primary and secondary patency were 65.1% and 75.9% respectively. Complications in the first and second attempt included reocclusion (4,1.0%), perforation (9,2.2%), and distal thrombosis/embolization (16,3.9%). The

author concluded that for long SFA occlusions, ELA can be safely used for recanalization. However, to maintain patency and quality of life, intensive surveillance using objective testing followed by prompt repeat intervention is mandatory [10] [9].

In summary, ELA is an expensive therapeutic modality that does not have definitive data to improve outcomes compared to conventional PTA for the treatment of CLI. Without evidence of superiority compared to conventional therapies, it cannot be recommended for routine use in CLI [6] [10].

Orbital Atherectomy

It is performed with the Diamondback 360° Orbital Atherectomy System (Cardiovascular Systems, Inc., St. Paul, MN). The device consists of an eccentrically shaped wire coil that rotates a diamond-coated ablating crown at high speed in an orbital path around the periphery of the lumen. As crown rotation increases, centrifugal force presses the crown against the lesion to effect plaque removal, while the less diseased, more elastic arterial wall flexes away from the crown, minimizing the risk of vessel trauma.

The design also allows blood and saline to flow through the treatment area, thereby minimizing the risk of thermal trauma and ischemia. Orbital atherectomy is performed over a 0.014" guide wire (Viper wire), in contrast to a 0.009" wire with rotational atherectomy. The larger diameter guide wire makes it easier to advance across a tight stenosis. More than 99% of the particles are smaller (1-2 microns) than a red blood cell and they are washed away with the patient's blood flow [31][11].

In one study (European study of orbital atherectomy), 56 patients with 86 lesions were treated with diamond back atherectomy device at seven European centers. The vessel size range from 1.5-4 mm and included the femoral artery as well as vessels distal to it. The average diameter stenosis was 89.5%, and the mean lesion length was 35.1 mm (range, 3-200 mm). Stand-alone treatment was used in 39.5%, and adjunctive therapy was used in another 65%. Acute procedural success (< 30% residual stenosis) was achieved in 90.7% of lesions. Complications noted during the procedure included slow flow, dissection, or distal embolization in 24% of patients. After 6-month follow-up, TLR was 13.6% and the mean Rutherford class was 3.5 ± 1.2 at baseline and became 0.7 ± 1.4 after 6 month [21][12].

The Orbital Atherectomy System for the Treatment of Peripheral Vascular Stenosis (OASIS) trial was a prospective non-randomized multicenter registry in which 124 patients (201 stenoses) with severe infrapopliteal disease were enrolled at 17 sites in the United States from January 2006 to January 2007. The mean lesion length was 30.2 ± 26.6 mm with a reference vessel diameter of 1.5 to 4 mm. Orbital atherectomy was used alone in 57.7% of lesions, with adjunctive therapy (PTA and/or stenting) used in 42.3%. The procedural success (achievement of < 30% residual diameter stenosis) was met in 90.1% of lesions. Major adverse events (MAE) at 30-days and 6 months (death, myocardial infarction, amputation, or repeat revascularization) were observed in 3.2% and 10.4% of patients. At 6-months, no patients required surgical bypass or unplanned amputation, and improvement in Rutherford classification scale was observed in 78.2% of patients [11][13].

CALCIUM 360 was a prospective, randomized study in which 50 patients were randomized to orbital treatment (25) or balloon angioplasty (25). In the DB360 arm, primary treatment was followed by low-pressure balloon starting at 2 atmospheres and increasing to 1 ATM every 10 seconds until no waist was seen. In the balloon arm, the physician's standard protocol was to achieve full balloon expansion with no visible waist as viewed in two planes. The primary endpoint was acute procedural success of < 30% residual stenosis with no type C-F dissection. The primary endpoint was met in 92.6% of lesions treated with the DB360 and 78.8% with balloon. One dissection (3.3%) occurred in the DB360 arm versus 4 dissections (11.4%) and 1 perforation (2.8%) in the balloon arm. Bailout stenting was performed in 2 (6.7%) lesions in the DB360 arm versus 4 (11.4%) in the balloon arm [12][14]. In another registry 728 patients with a total of 1,138 infrainguinal and infrapopliteal lesions were treated with the diamond atherectomy device. Moderate or severe calcium was noted in 87% of lesions. Average lesion length was 77 mm. Balloon angioplasty was performed in 76% of the patients. Bailout stenting due to dissection occurred in 2.2% of the lesions, with an overall stent rate (elective and bailout) of 5.6%. Stenosis averaged 88.8%

pre-procedure and 31.7% post-orbital treatment. Procedural events included minor and major dissection (7.6%), perforation (0.5%), slow flow (5.1%), abrupt closure (1.2%) and distal embolization (0.7%) [13][15].

There was a case report in which use of orbital atherectomy was resulted in hemolysis and hemolysis-induced pancreatitis [14] [16]; however, in another study in which hemolysis was assessed with the use of DB atherectomy, 31 patients underwent DB orbital atherectomy. Although 11 (35.5%) had laboratory evidence of hemolysis but none of them had clinically symptoms/signs potentially related to hemolysis [15][17].

The above data suggests that device is effective in treating short, localized and calcified (TASC A, B, C) lesions in vessels < 4 mm in diameter. Adverse events during follow-up probably due to hemolysis or distal embolization are concerning. A large randomized trial is needed to clarify these issues.

Rotational Atherectomy

Jet Stream (Bayer health Care, Bayer, Whippany, NJ)

Jet stream is a rotational atherectomy device that consists of a jetstream catheter, control pad, and a PV console. The Jet stream catheter utilizes a differentially cutting tip that debulks and removes both hard and soft plaque, calcium, and fibrotic lesions [16][18]. Separate lumens within the catheter allows for continuous aspiration and infusion during device use. The control pad provides a user interface with keypad control. The control pad consists of electrical connectors, tubing, and an aspiration bag. While the reusable PV console consist of two peristaltic pumps for aspiration and infusion, power supply, system controller, and LED indicators for device operational status. Active aspirations during the procedure minimize the risk of distal embolization [19] [19].

A multicenter registry using the first-generation Pathway device treated 172 patients with 210 lesions in nine European centers [36][20]. The mean lesion length was 35 mm with moderate to high calcium in 52%. The lesion location was in the SFA in 64% of patients and was equally divided between men and women (49% and 51%, respectively). The primary endpoint was freedom from device-related serious adverse events (SAEs) at 6 months. Stand-alone atherectomy was performed in 33% of the patients, adjunctive balloon angioplasty in 59%, and stenting in 7%. TLR at 6 and 12 months was 13% and 26%, respectively. The ABIs increased from 0.59 ± 0.21 at baseline to 0.77 ± 0.26 and 0.82 ± 0.26 ($P < 0.05$) at 6 and 12 months, respectively. Based on this limited data set, the Pathway system appears to be effective in treating SFA atherosclerotic disease, including cases with the presence of significant calcification. MAEs that were attributable to the device included distal embolization in 1.1% [17][21].

Another study showed that rotational aspirational atherectomy was associated with significant increase in luminal gain (pre-intervention 3.9 ± 0.4 , post-athero-ablation 8.0 ± 1.7 mm (2), $P < 0.05$), and reduction in plaque area (27.5 ± 4.0 vs. 23.7 ± 3.1 mm (2), $P = 0.001$). The authors concluded that the increase in luminal area was due to aspiration during rotational atherectomy [18][22]. There was one isolated case report of intravascular hemolysis following peripheral atherectomy with the pathway Jet stream catheter with no clinical sequelae [20][23].

No definite data are available in assessing the efficacy of this therapy for different TASC (Trans-Atlantic Inter-Society Consensus) lesions. With the limited data discussed above, the device appears to be safe and effective in treating calcific lesions in the SFA and popliteal vessels. Its role in atherosclerotic, calcific lesions in other vessels such as common femoral arteries, and tibial vessels is not well defined.

Excisional atherectomy

Silver Hawk (Covidien, Mansfield, MA)

Silver Hawk is the only excisional atherectomy device available at this time. The system consists of a catheter with a mounted blade and collection area and a handheld battery-powered drive unit. It is a monorail rapid exchange system with a 135 cm flexible shaft that can be introduced through a 6-8 Fr sheath and tracked over a 0.014 inch guide wire. The catheter tip consists of a rotating cutting blade proximally and a nosecone that acts as the plaque collection chamber distally. A switch on the handle activates the device. When the device is activated, the distal tip of the nose cone is deflected away from the plaque, which pivots the catheter against the lesion and exposes the cutting blade. The blade rotates at 8,000 rotations per minute and as the catheter is slowly advanced across the length of the lesion, it shaves off the occlusive plaque from the vessel wall and packs it into the distal nose cone. Multiple passes are made through the lesion and the catheter is rotated to allow plaque excision in all quadrants. The excised atherosclerotic material is removed from the nose cone intermittently, as necessary. The collecting nosecone on the larger catheters has a packing mechanism that compresses the shavings into the cone for increased carrying capacity. Either forceful saline flushing empties the nosecone or mechanical evacuation using specially designed instruments.

The Silver Hawk catheter comes in various sizes to allow treatment of femoral, popliteal, tibial, and even pedal vessels. Two of the catheters, LX-M (large-vessel Xtended tip) and LS-M (large-vessel standard tip) have extra-large nose cones for greater plaque capacity and are mainly used in the large vessels (4.5-7 mm) above the knee, whereas the Silver Hawk-MS catheter has a slightly lower-profile blade (0.2 mm vs. 0.3 mm) that was designed for greater efficacy in calcified lesion and less aggressive stance against calcium or vessel walls. The Silver Hawk SS+ (small-vessel standard tip) and ES+ (extra-small vessel standard tip) are mainly used for smaller infrapopliteal vessels (2-3.5 mm). A lower-profile version of the device, the Silver Hawk-DS, or "Mini Hawk," was approved by the FDA in 2007 and allows treatment in tibial and pedal vessels down to 1.5 mm in diameter. This device can be used with or without the distal wire in position to allow greater flexibility and ability to deliver the device in the distal vasculature.

Excisional atherectomy with the Silver Hawk offers the advantage of directional control for debulking lesions, which is especially helpful in the case of eccentric lesions. This aspect of excisional atherectomy provides a key difference compared to other currently available atherectomy devices [22][24].

A retrospective single center analysis was done in 2008 in patients who underwent Silver hawk atherectomy. A thorough retrospective chart review of 22 patients (10 women, 12 men) who underwent 37 infrainguinal atherectomy procedures was performed. Mean patient age was 67 years. Co-morbidities included hypertension (94%), hyperlipidemia (74%), DM (61%), CAD (59%), active smoking (26%), and end-stage renal disease (20% on dialysis or s/p transplant). Indications for intervention included critical limb ischemia (65%), claudication (32%), and atheroembolism (2%); 35% of patients had undergone previous infrainguinal interventions. Treatment was confined to the femoro-popliteal (FP) segment in 70% of patients; 30% underwent tibial artery (TA) atherectomy + FP atherectomy. The Trans-Atlantic Inter-Society Consensus (TASC) distribution of FP lesions was: A (44%), B (40%), C (12%) and D (4%). Angioplasty of the atherectomized lesion was performed in 38% of cases and adjunctive therapy for tandem lesions in 41%. The mean follow-up was 6 months. Primary patency was 63%, and 56% at 6, and 12 months. Primary assisted patency was 71%, and 62% at 6, 12 months. Patients with prior Infrainguinal interventions had a nearly 10-fold decrease in primary patency. Insulin-requiring diabetes is considered a significant risk factor for failed atherectomy. The authors stated that future studies should focus on cost comparisons with other treatments such as angioplasty and stenting, and prospective randomized trials should be performed to compare these treatment alternatives [23] [25].

TALON (Treating Peripherals with Silver Hawk : Outcomes collection) was an observational, nonrandomized, multicenter registry. A total of 601 patients with 1258 symptomatic lower extremity atherosclerotic lesions (748 limbs) treated by plaque excision with the

Silver Hawk catheter in 19 institutions. The mean length of the treated lesions was 62.5 ± 68.5 mm above the knee and 33.4 ± 42.7 mm below the knee. Half of the enrolled patients had diabetes and nearly one third had Rutherford ischemia category ≥ 4 . Technical success was achieved in 97.6% of procedures and residual stenosis of less than 50% was achieved in 94.7% of lesions. Adjunctive therapy was required in 21.7% of lesions, and stent placement in 6.3% of the treated lesions. The primary endpoints of the study were target lesion revascularization (TLR) at 6 and 12 months. Outcome data at 6 months was available from 248 patients, which showed a rate of survival free from target lesion revascularization of 90%. At 12 months, the available data from 87 patients showed that 80% of these patients survived free from target lesion revascularization. Predictors of target lesion revascularization at 6 months, includes history of myocardial infarction or coronary revascularization, multiple atherosclerotic lesions and increasing Rutherford category, and a lesion length (> 50 mm). The authors concluded that the Silver Hawk atherectomy device is safe and effective in the endovascular treatment of PAD [24] [26]. Lack of long-term follow-up data from only 87 (14.5%) of the total 601 patients were available at 12 months was an important limitation of the study.

Another prospective non-randomized single center study was done in which de novo and re-stenotic lesions of the femoro-popliteal segments were treated with the Silver hawk device: 161 consecutive patients (164 lesions) with peripheral artery disease (PAD) Rutherford classes 2 to 5 were included (59% male, mean age 67 ± 11 years, range 40 to 88) and the outcomes analyzed according to the TASCII classification. Direct Atherectomy (DA) was performed successfully in 28% ($n = 46$), adjunctive balloon angioplasty in 65% ($n = 107$) and stenting in 7% ($n = 11$). The overall technical success rate was 76% (124/164) and the procedural success rate 95% (154/164). At 12-months, the primary patency rate was 61% (85/140) and the secondary patency rate was 75% (105/140) in the entire cohort, being less favorable in TASC D compared to TASC A to C lesions ($p = 0.034$ and $p < 0.001$, respectively). Furthermore the restenosis rate differed trend wise ($p = 0.06$) between de novo and re-stenotic lesions. Changes in the ABI and the Rutherford classes were significantly in favor of TASC A to C lesions compared to TASC D after 12 months ($p = 0.004$). The event free survival rate (MI, TIA, or restenosis) was 48% at 12 months and 38.5% at 24 months. Predictors for restenosis on the multivariable analysis was only male gender ($p = 0.04$). The authors concluded that the results of Silver Hawk atherectomy treatment in TASC D lesions are inferior to those in the lesser stages. Direct atherectomy of femoro-popliteal arteries showed a trend to better long-term technical and clinical outcomes in de novo lesions compared to restenotic lesions [25] [27].

In another study, 69 patients (37 women; mean age 70 ± 12 years, range 43-93) with CLI (Rutherford category ≥ 5) involving 76 limbs were enrolled. Clinical outcomes were prospectively followed for 6 months. The primary endpoint was major adverse events (death, myocardial infarction, unplanned amputation or repeat target vessel revascularization) at 30 days. Visible healing of ulcerated tissue, avoidance of any amputation and performance of less extensive amputation than initially planned were also assessed. Procedural success was achieved in 99% of cases. Major adverse events occurred in 1% of patients at 30 days and 23% at 6 months. The target lesion revascularization rate was 4%, and there were no unplanned limb amputations. Amputation was less extensive than initially planned or avoided altogether in 92% of patients at 30 days and 82% at 6 months. The authors concluded that catheter-based plaque excision with the Silver Hawk atherectomy device is a safe and effective revascularization method for patients with CLI but did suggest that further study was required to support this modality as a singular or adjunctive endovascular therapy for limb salvage in CLI [26] [28]. In one small study Silver Hawk atherectomy was used to evaluate the outcome in patients who have TASC type C femoro popliteal lesions and critical limb ischemia. There was an improved ankle-brachial index noted from 0.39 ± 0.08 (mean \pm SEM) before the procedure to 0.75 ± 0.08 in the immediate post procedure period ($P = 0.02$). However, it returned toward baseline at 6 months after the procedure, with a mean of 0.48 ± 0.07 , suggesting that peripheral atherectomy can achieve good early clinical and hemodynamic success in patients with TASC C lesions and critical limb ischemia. However, mid-term restenosis rates are high in this challenging cohort of patients [27] [29].

Preventing lower extremity distal embolization using embolic filter protection (PROTECT) was a single center registry in which the use of distal protection was evaluated during angioplasty, stenting, and silver hawk atherectomy. Out of 56 lesions in forty patients 43 lesions were treated with angioplasty and stenting and 13 lesions were treated with silver hawk atherectomy. Spider FX (ev3) or Embosheild (Abbott Vascular) distal protection was used in all patients. Clinically significant debris was found in 45% of patients and was more frequent in atherectomy group, compared to angioplasty/stenting (91% versus 28%, $p < 0.001$) [30] [30]. Author concluded that the use of distal protection device during atherectomy associated with improved acute angiographic outcome.

Recently a large single center prospective study was published in which 275 patients with 579 lesions were treated with Silver Hawk atherectomy with adjunctive therapy (angioplasty or stenting) or atherectomy alone from 2004 to 2007. Patients either had critical limb ischemia (63.3%) or claudication (36.7%). The most common risk factors of atherosclerosis included diabetes (67.7%) and smoking (46.2%). Lesions characteristics were 199 superficial femoral arteries, 110 popliteal, 218 tibials, and 52 multilevel. Mean follow up was 12.5 months (range, 0.5-48.2). The 18-month primary and secondary patency rates for claudicants was 58% and 83% ($p < 0.0001$), and was 50% and 70%, respectively, for CLI ($p < 0.0001$). Reintervention rates were 25% in claudicants and 30.1% for CLI. The limb salvage rate was 100% in claudicants; the overall limb salvage rate was 92% at 18 months, and only 4.4% required bypass. One small study comparing atherectomy to surgical bypass in patients with TASC C and D lesion showed similar patency in both groups (64% vs. 63%). However, the 1-year limb salvage rate was greater in the bypass group (87% vs. 69%; $P = 0.004$). In the tissue loss subgroup, there was a greater limb salvage rate for bypass patients versus atherectomy (79% vs. 60%; $P = 0.04$). Thus, atherectomy appears to be an attractive and promising option for focal common femoral and bifurcation lesions, there is a lack of large comparative trials involving surgical bypass in patients with TASC C and D lesions.

Available data support excellent short-term patency rates and the ability to use the Silver Hawk plaque debulking system in multiple clinical settings. The device has been safely and effectively used in stenoses, chronic total occlusions, TASC A-C *de novo* lesions, and lesion locations in which PTA and stenting are typically avoided. The larger question of an event rate for distal embolization, the appropriate use of distal protection, long-term durability, the value of and appropriate circumstances for adjunctive angioplasty, and superiority or inferiority to other technologies is still under investigation.

Conclusion

The heterogeneity of peripheral artery disease poses a tremendous challenge to the design, enrollment, and analysis of device trials. Current literature suggests that atherectomy devices are safe, effective and represent a “niche” in the endovascular treatment of PAD. Available data for atherectomy devices mostly characterized by small sample size and lack of randomized, controlled, and adequately powered studies with suggestion of benefits compared with historical controls. Further investigations of this treatment modality are necessary, and these should include clinical end points in addition to arterial patency and limb salvage, such as short-term morbidity, long-term morbidity, procedural mortality, symptomatic improvement, limb salvage, quality of life, functional status, and overall cost of primary and secondary procedures. Armed with this information, physicians can make objective decisions, and patients can be properly advised before a procedure.

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Volume 1 Issue 1 March 2015

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