Atherectomy in the Superficial Femoral Artery

An evidence-based approach for device selection, ideal applications, and cases to avoid.

BY WAEL F. AL-HUSAMI, MD, FACC; MOHAMMED W. AKHTER, MD; AND LAWRENCE A. GARCIA, MD, FACC, FAHA

Currently, there are multiple treatment strategies to address stenotic or occlusive atherosclerotic disease in the superficial femoral artery (SFA). Percutaneous transluminal angioplasty (PTA) results have traditionally been suboptimal and less durable, especially with longer-lesion subsets.[1,2] Self-expanding nitinol stents do not perform as well when considering long-term patency rates (after 2 years) based on recently published stent trials, even though they are accepted as the default therapy for treating the SFA.[3-5]

Atherectomy in the peripheral vasculature has gained interest due to its perceived benefits over simple PTA. The theoretical avoidance of barotrauma and overstretch of the vessel wall is desirable and can prevent acute vessel recoil or dissection. These unwanted side effects can lead to restenosis or reocclusion in the treated vessel. However, it is unclear how often stand-alone therapy is done and what impact a "soft" balloon inflation after atherectomy may have with regard to patency rates.

Various atherectomy methods are available including plaque excision (directional) atherectomy, laser atheroablation, rotational aspiration/atherectomy, and orbital atherectomy. Although direct randomized comparisons are not available for these devices, multicenter prospective registries have made suggestions about their anatomic locations and lesion subsets for optimal use, as well as the locations where their use is suboptimal. In the absence of robust randomized clinical trials, this article reviews the current approach for treating atherosclerotic disease of the SFA, using an evidence-based approach for where the currently available atherectomy devices perform ideally and where they should be avoided.

LASER ATHERECTOMY

The atheroablative laser technology that is currently available is the CVX-300 excimer laser (Spectranetics Corporation, Colorado Springs, CO). Excimer laser uses flexible fiberoptic catheters that produce photoablation of atherosclerotic disease by using an ultraviolet light at 308 nm to penetrate atheroma, dissolve the molecules (producing thermal energy), and create kinetic energy that breaks chemical bonds at the molecular level and vaporizes intracellular water without damaging the surrounding tissue, thus minimizing restenosis.[6] Laser may be useful in several lower extremity applications such as crossing chronic total occlusions or long stenotic lesions.[7,8] Some interventionists have advocated laser use in highly calcified arteries, thrombus-laden vessels, and in-stent restenosis.[9-11] Adjunctive balloon therapy is almost universally required after an atheroablative debulking procedure. However, complications may occur, the most problematic being perforation and distal embolization, occurring in 2% to 4% of cases.[8,12,13]

One of the earliest trials using laser was the PELA (Peripheral Excimer Laser Angioplasty) trial in which 251 patients with claudication and a total SFA occlusion were randomized to either PTA or laser-assisted PTA.[12] Results of this study failed to demonstrate any difference in clinical events or patency rates at 1 year of follow-up, suggesting no benefit to antecedent laser therapy in this patient cohort.[8,14,15] Many potential issues were raised with this trial, and today's laser catheters use less thermal energy to ablate the atheroma, thereby making comparisons to current technology less applicable.

Scheinert et al[8] analyzed data on 411 SFA lesions in which excimer laser-assisted recanalization procedures

were applied for long chronic SFA occlusions averaging 19.4 ± 6 cm in length in 318 patients. The technical success rate was 90.5%, and stenting was needed in 7.3% of cases. Complications included acute reocclusion (4, 1%), perforation (9, 2.2%), and distal thrombosis/embolization (16, 3.9%). The primary patency rate at 1 year was 33.6%; however, with surveillance and early reintervention, a secondary patency rate at 1 year was 75.1%.

Another major study performed with the CVX-300 excimer laser is the Laser Angioplasty for Critical Limb Ischemia (LACI Phase 2) study, which enrolled 145 patients at 15 sites in the United States (US) and Germany.[13] All patients were poor surgical candidates. Laser atherectomy was performed in 99% of the cases, and adjunctive PTA and stenting was performed in 96% and 45%, respectively. Blood flow was restored in 89% with significant improvement in the ankle-brachial index (ABI) (0.54 ± 0.21–0.84 ± 0.2). The 6-month limb-salvage rate was 92.5% with an 8% major amputation rate and 10% mortality rate due to cardiac issues. The study suggested that there is a role for laser atherectomy in this high-risk population with an acceptable complication rate.[13,15]

In the CELLO (ClirPath Excimer Laser System to Enlarge Lumen Openings) clinical, prospective, nonrandomized trial presented by Spectranetics Corporation in 2007 at the Transcatheter Cardiovascular Therapeutics scientific symposium in Washington, DC, 65 patients at 17 hospitals in the US and Europe were enrolled. The goal was to provide clinical data on debulking large amounts of plaque, creating larger lumens, and efficiently treating long, diffuse, diseased lesions in the SFA and popliteal arteries using the Turbo-Booster (Spectranetics Corporation), which functions as a guiding catheter facilitating directed ablation combined with Turbo Elite laser catheters (Spectranetics Corporation). The primary endpoints of the trial were the achievement of a minimum 20% reduction in the stenosis after using the laser compared to preintervention and major adverse events (MAEs). The reduction in percent diameter stenosis after the use of the Turbo-Booster was 35%, and there were MAEs reported through 30 days after the procedure. Furthermore, the durability of the procedure was demonstrated through freedom from reintervention in 86% of the patients through 6 months after enrollment. Significant improvements in all clinical outcomes that were measured 6 months after the procedure were noted, including the Rutherford category, ABI, and walking impairment. Based on this study, the US Food and Drug Administration (FDA) approved the Turbo-Booster for the treatment of arterial stenoses and occlusions in the leg in July 2007.[16]

Unfortunately, despite these data, there is no convincing evidence that laser atheroablation with adjunctive PTA is more favorable than conventional angioplasty in treating

TABLE 1. REGISTRIES OF PATIENTS TREATED WITH LASER

	PELA Trial	Scheinert et al	LACI Phase 2
Study design	Multicenter, prospective, randomized trial of laser-assisted angioplasty vs balloon-dilation alone	Retrospective, single-center study	Multicenter registry of 155 critically ischemic limbs
Patients/lesions	251	318/411	145/423
Lesion location	SFA	SFA	SFA, 41%; popliteal, 15%; infrapopliteal, 41%
Mean lesion length	SFA ≥10 cm	19.4	16.2
Stand-alone treatment	0%	0%	—
Adjunctive balloon angioplasty	100%	100%	96%
Adjunctive stenting	42%	7.3%	45%
Primary patency (by duplex) at 6 months	78%	—	At 6-month follow-up, limb salvage was achieved in 110 (92%)
Primary patency (by duplex) at 12 months	51%	33.6%	—
Device-related SAEs	12.8%	7.1%	—

long SFA lesions. The opportunity for use in long SFA lesions is still questionable as a workhorse device. Furthermore, for lesions in which a subintimal approach has been used to cross a long chronic total occlusion, the use of laser atheroablation may be at higher risk due to the potential risks for perforation. In summary, laser can be used in infrainguinal diseased arteries, especially in atheromatous or fibrotic plaque, as well as TransAtlantic Inter-Society Consensus (TASC) A, B, and C lesions (class IIa). On the other hand, our opinion is that this device has very limited uses in type D and calcified lesions due to the possible risk of embolization and/or perforation (class IIb). Furthermore, the FDA has not yet approved laser in in-stent restenosis due to the lack of evidence and data, but it has been used off label (Table 1). In addition, laser has been limited in terms of the size of vessel it can treat. The large vessel laser can ablate tissue in the 2.5-mm range at high energy levels. The Turbo Boost (Spectranetics Corporation) was designed to help the laser tackle larger vessels. Although sometimes cumbersome to use, this does allow for a greater treatment strategy in larger vessels with the laser.

CONTEMPORARY DIRECTIONAL ATHERECTOMY

The FDA granted 510(k) clearance to the SilverHawk plaque excision system (ev3 Inc., Plymouth, MN) in 2003 for

TABLE 2. REGISTRIES OF PATIENTS TREATED WITH CONTEMPORARY DIRECTIONAL ATHERECTOMY

	TALON	McKinsey et al	Zeller et al
Study type	Observational, nonrandomized, multicenter registry	Prospective study	Prospective, nonrandomized, single-center study
Patients/lesions	728/1,517	275/579	84/131
Lesion location	SFA/below-the-knee	Infrainguinal	SFA/popliteal
Average lesion length	8.4 cm	SFA, 9.16 cm; popliteal, 3.77 cm; tibial, 4.64 cm	9–10.6 cm
Lesion characteristics	De novo	De novo	Group 1, 34%;[a] group 2, 33%;[b] group 3, 33%[c]
Stand-alone treatment	—	64.8%	—
Adjunctive balloon angioplasty	21.7%	24.3%	59%
Adjunctive stenting	6.3%	7.5%	6%
Primary patency (by duplex) at 12 months	—	62.2%	Group 1, 84%;[a] group 2, 54%;[b] group 3, 54%[c]
18-month primary patency	—	52.7%	Group 1, 73%;[a] group 2, 42%;[b] group 3, 49%[c]
TLR at 12 months	80%	—	Group 1, 16%;[a] group 2, 44%;[b] group 3, 47%[c]
TLR at 18 months	—	—	Group 1, 22%;[a] group 2, 56%;[b] group 3, 49%[c]
Claudication	—	36.7%	—
CLI	—	63.3%	—
Device-related SAEs	5.3%	4.1%	3.8%

[a]Group 1 was de novo lesions.
[b]Group 2 was native vessel restenosis.
[c]Group 3 was in-stent restenosis.

the treatment of peripheral arterial disease (PAD). The SilverHawk device debulks atheroma without a balloon for apposition through a hinge system. It contains a carbide cutter disc with variable height and rotates at speeds of 8,000 rpm. The hinged nosecone acts as a container for atherosclerotic debris and collects it distal to the carbide blade. It can be used without the adjunctive use of balloon angioplasty or stents. Unfortunately, there have been no randomized clinical trials using this device comparing it to angioplasty. There have been several registries or single-center studies using the ev3 device. The TALON (Treating Peripherals With SilverHawk: Outcomes Collection) registry was the largest nonrandomized study on the use of SilverHawk in 19 different US centers. This study showed excellent procedural success rates of 97.6% and < 50% residual stenosis achieved in 94.7% of lesions. Ramaiah et al reported on the 6- and 12-month TALON outcomes for 601 patients with 1,258 symptomatic lesions (mean length was 62.5 mm for above-the-knee and 33.4 mm for below-the-knee) treated with the SilverHawk device.[17] Adjunctive angioplasty was used in 21.7%, and stents were used in 6.3% of the patients. The overall 12-month freedom from target lesion revascularization (TLR) rate was 80%. The limitations of this study, although it is prospective, have been its lack of prespecified inclusion/exclusion criteria, and the outcomes were operator-reported only and did not have independent core laboratory adjudication. Based on these critical limitations, the outcomes from TALON have been suspect.

McKinsey et al recently reported on 579 lesions treated in 275 patients with either claudication (101 patients, 36.7%) or critical limb ischemia (CLI) (174 patients, 63.3%). This study reported that primary patency for all lesions at 12 and 18 months was 62.2% and 52.7%, respectively. Secondary patency at 12 and 18 months for all lesions was 80.3% and 75%, respectively. Limb salvage per patient was 93.1% at 12 months and 92.4% at 18 months. Limb salvage was 100% in claudicants, and overall limb salvage was 92.4% per patient at 18 months; only 4.4% required bypass. Periprocedural complication rates were very low, without procedurally related deaths.[18]

Zeller et al published a prospective, nonrandomized, single-center study on 84 patients for 100 legs and 131 lesions with peripheral occlusive disease Rutherford categories 2 to 5 that were included in a prospective registry between June 2002 and May 2004. The patient population was divided into three groups: 45 had de novo lesions (group 1, 34%), 43 had native vessel restenoses (group 2, 33%), and another 43 had in-stent restenoses (group 3, 33%). The average lesion length was 90 to 106 mm (range, 10–400 mm). The technical success rate for this study was 86% for atherectomy only and 100% after additional therapy. Primary patency was 84%, 54%, and 54% at 12 months and 73%, 42%, and 49% at 18 months for group 1, group 2, and group 3, respectively. Secondary patency rates were 100%, 93%, and 91% at 12 months and 91%, 65%, and 76% at 18 months, respectively. Based on this study, long-term technical and clinical results after directional atherectomy of femoropopliteal lesions are favorable for de novo lesions compared with restenotic lesions. The limitations of this study are the small, mixed population including de novo lesions, restenotic nonstented and stented vessel segments, and the inclusion of SFA and popliteal artery lesions, thereby suggesting benefit but scientifically limited in scope.[19]

In summary, there are numerous single-center registries, but unfortunately, to date there are no randomized trials on the current technology. However, individual single-center studies have shown positive 1-year results.[20-28] The SilverHawk plaque excision system performs ideally in heavily calcified femoropopliteal lesions that may require staging from a small device to a larger one[29] or when using the new RockHawk device (ev3 Inc.). Zeller et al have suggested that stenoses may be treatable with primary atherectomy, although occlusions should be predilated with an undersized balloon to ensure that the wire crosses intraluminally. They also counseled against using the device when subintimal crossing is involved.[30] Although distal embolization is a rare event, consideration should be given to the possible value of using distal embolic protection in procedures that may be at risk for embolization and in patients with single-vessel runoff.[31-33] Long lesions (> 15 cm) remain a problem, and there are no current data to support using SilverHawk in this situation or in in-stent restenosis, and it should be avoided in chronic total occlusions (Table 2). In summary, the SilverHawk plaque excision system can be used in infrainguinal diseased arteries to include atheromatous, fibrotic plaque, calcified lesions, as well as TASC A and B lesions (class IIb). However, this device has limited uses in type C and D lesions due to lower primary patency outcomes (class IIb). The use of directional atherectomy in patients with CLI is efficacious with limb salvage rates near 90% at 6 months (class IIb).

ROTATIONAL ATHERECTOMY

Pathway Medical Technologies, Inc. (Kirkland, WA) was previously granted 510(k) clearance by the FDA in 2008 for its atherectomy device that debulks plaque in the lower extremities. More recently, it was further granted 510(k) clearance in March 2009 to market the Jetstream G2 peripheral atherectomy catheter for removing thrombus in the upper and lower extremity peripheral arteries in addition to atherectomy.[34]

The Pathway atherectomy device is composed of a control pod and a reusable compact console that mounts to a standard intravenous stand. The catheter has an expandable

cutting surface that debulks both hard and soft plaque as well as calcium. Furthermore, as it debulks, it flushes distally and aspirates proximally, thereby removing the liberated plaque material as well as any thrombus, necrotic, or fibrotic material.[35]

The fluted differential cutting catheter tip remains at a defined diameter of 2.1 mm when activated in a clockwise rotation and expands to 3 mm when rotated counterclockwise. The excised material is aspirated via a proximal port in the fluted tip into the catheter lumen and transported to a collection bag located on the device console. Its application is for arteries between 3 to 5 mm in diameter. The fluted tip rotates at approximately 55,000 rpm with a delivery system that is 8 F compatible and uses a 0.014-inch guidewire.

A multicenter registry using the first-generation Pathway device treated 172 patients with 210 lesions in nine European centers.[36] 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 ($P < .05$) 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 at 1.1%.

Thus, with limited data, the Pathway system appears safe and effective in treating calcific lesions in the femoral and popliteal location. However, because of this restricted exposure, the durability and use in other locations including the common femoral and tibial vessels is less robust and clear. Furthermore, the need for distal protection in a heavily calcified lesion subset has not been studied, but based on the available data, our recommendation would be to consider using a distal protection device in this cohort of patients. Likewise, because the efficacy of this therapy from a TASC A, B, C, or D lesion is not described, we are left to draw our own conclusions regarding the appropriateness of its use in different lesion morphologies. Despite these limitations, we can safely conclude that this therapy is likely effective for focal lesions in the femoropopliteal vasculature in appropriately sized vessels (class IIb).

ORBITAL ATHERECTOMY

The Diamondback 360° Orbital Atherectomy System (OAS) (Cardiovascular Systems, Inc. [CSI], St. Paul, MN) consists of an eccentric, diamond-grit-coated, abrasive crown that creates an ablative surface proportional to the displaced radius of the crown through centrifugal force when the device is rotated at various speeds. It can create a lumen that is > 1.75 times the crossing profile depending on the size of the grit and the eccentricity of the offset. The greater the speed of the crown, the larger the arc of debulking is and, ultimately, the resultant lumen size. As with any rotational atherectomy device, healthy elastic tissue flexes away and is not generally affected by the diamond grit. The diseased tissue, however, provides resistance and is "sanded" away with the debris being relatively small (1–7 µm). All debris, both small and potentially large, are embolized distally to pass through the distal capillary beds and are filtered from the circulation in the lungs or other filter organs. This device uniquely delivers 360° of plaque removal and may be effective in calcified plaque. The off-centered shape of the crown allows for continuous blood flow around the device, which allows particles to move downstream, and reduces localized heating of the vessel.[37]

The only major study on this device led to FDA clearance. This was the multicenter OASIS (Orbital Atherectomy System for the Treatment of Peripheral Vascular Stenosis) trial, which was a nonrandomized prospective Investigational Device Exemption study of the OAS. The trial enrolled 124 patients (202 lesions) at 17 sites in the United States between January 2006 and January 2007. This was carried out to establish patient safety and acute procedural effectiveness of the Diamondback 360° OAS.[38,39] The mean lesion length was 30.2 ± 26.6 mm (range, 0.5–100 mm) with a reference vessel diameter of 1.5 to 4 mm. The main cohort of patients treated were claudicants (55%). The procedural success (achievement of < 30% residual diameter stenosis) was met in 90.1% of lesions. Orbital atherectomy was used alone in 57.7% of lesions, with adjunctive therapy (PTA and/or stenting) used in 42.3%. MAEs out to 30 days were 9.7% (of the 13 events, 6 were device related). Symptom-driven TLR at 6 months was 2.4%. Finally, the mean Rutherford categories were 3 ± 1.3 at baseline and 1.2 ± 1.5 at 6 months. Interestingly, 14% of the patients demonstrated worse ABIs at the end of 30 days compared to baseline. This detriment in ABI may be secondary to procedural complications due to hemolysis[40] or distal embolization.

The clinical performance of this platform was evaluated in PAD II (Study of the Orbital Atherectomy System for the Treatment of Peripheral Vascular Disease) in conditions of usual care and in treating symptomatic stenoses in arteries distal to and including the femoral artery ranging in diameter from 1.5 to 4 mm. Sixty-six patients and 86 lesions were treated at seven European centers between August 2005 and January 2007.[41] The average stenosis diameter was 89.5%, and

TABLE 3. REGISTRIES OF PATIENTS TREATED WITH ROTATIONAL AND ORBITAL ATHERECTOMY

	Pathway System		Diamondback 360° OAS (CSI)	
Study	Pilot study	Multicenter, prospective registry	OASIS trial	PAD II
Patients/lesions	15/15	172/210	124/201	66/86
Lesion location	47% SFA	64% SFA	94% popliteal and tibial	Reference vessel diameter of 1.5–4 mm
Mean lesion length	61 mm	35 mm	30 mm	35 mm
Calcified	—	—	55%	—
Chronic total occlusion	—	—	12%	—
Stand-alone treatment	6 (40%)	33%	58.2%	39.5%
Adjunctive balloon angioplasty	7 (47%)	59%	39.3%	60.5%
Adjunctive stenting	2 (13%)	7%	2.50%	—
Primary patency (by duplex) at 6 months	73%	—	—	—
TLR at 6 months	0%	13%	2.4%	13.6%
TLR at 12 months	—	26%	—	—
Preprocedure ABI	0.54 ± 0.3	0.59 ± 0.2	0.68 ± 0.2	—
ABI at 6 months	0.81 ± 0.2	0.77 ± 0.3	0.82 ± 0.1	—
ABI at 12 months	—	0.82 ± 0.3	—	—
MAEs[a] at 1 month	—	—	4 (3.2%)	—
MAEs[a] at 6 months	—	15%	13 (10.4%)	37.9%
Device-related SAEs	—	—	2.9%	6%

[a]*Death, myocardial infarction, amputation, or repeat revascularization.*

the mean lesion length was 35.1 mm (range, 3–200 mm). Acute procedural success (< 30% residual stenosis) was achieved in 90.7% of lesions. Stand-alone treatment was used in 39.5%, and adjunctive therapy was used in another 65%.

Of concern was the observation of 20 SAEs (four device-related) in 16 subjects (24.2%) through 30 days of follow-up; most were due to slow flow or dissection with one embolization. Twenty-five patients (37.9%) experienced 37 SAEs from 31 through 180 days. The TLR rate at 6 months was 13.6%, and the mean Rutherford categories were 3.5 ± 1.2 at baseline and 0.7 ± 1.4 at 6 months.

The key conclusions from these two limited studies are that OAS is an effective tool for achieving acute procedural success in vessels ≤ 4 mm in diameter and in relatively short lesions (class IIb indication). Its utility in treating calcified lesions is inherently appealing, although this enthusiasm is tempered by the high SAE rates in the follow-up period and a lack of understanding regarding the mechanisms of injury (hemolysis vs distal embolization) (Table 3).[40] In summary, OAS can be used in infrapopliteal diseased arteries, especially in calcified plaque and in TASC A, B and C lesions (class IIb). However, this device may have limited uses in thrombotic or TASC D lesions (class IIb).

CONCLUSION

Durability and long-term patency remain the major challenges to therapy in SFA endovascular treatment. Despite newer devices and advancements of older endovascular procedures, the principal failure continues to be recurrent restenosis. There are many tools available to treat the SFA, ranging from simple balloon angioplasty to endovascular self-expanding nitinol stents. Furthermore, other technologies include cryoplasty, laser atheroablative technology, rotational atherectomy, and directional atherectomy. To date, there are little to no data and no direct comparative trial comparing all of these devices to each other. Stenting

TABLE 4. DATA FOR EVIDENCE-BASED DEVICE SELECTION				
	Laser	SilverHawk Plaque Excision	Pathway Medical	CSI
Lesion location				
Common femoral artery	+/–	+++	–	+
SFA/popliteal	++	+++	++	++
Infrapopliteal	++	++	+	+++
Morphology				
Fibrotic/ atheromatous	+++	+++	+++	++
Thrombotic	++	–	+++	–
Calcified	–	++	+++	+++
In-stent restenosis	N/A	N/A	N/A	N/A
TASC				
A	++	+++	+++	+++
B	+	++	++	++
C	+	+/–	++	++
D	+/–	–	+/–	–
CLI	++	–	N/A	+/–

N/A, not available; –, not useful/contraindicated; +/–, unknown; + may be helpful/useful; ++, useful; +++, very useful (niche).

as a primary therapy for common iliac and external iliac artery stenosis and occlusions was endorsed by the American College of Cardiology/American Heart Association guidelines (class I); however, that was not the case for the treatment of femoropopliteal arterial lesions where primary stent placement is not recommended in the femoral, popliteal, or tibial arteries (class III, level of evidence C)[42] (Table 4). ■

Wael F. Al-Husami, MD, FACC, is with the Interventional Cardiology and Peripheral Vascular Division at St. Elizabeth's Medical Center, Tufts University School of Medicine in Boston, Massachusetts. He has disclosed that he holds no financial interest in any product or company mentioned herein. Dr. Al-Husami may be reached at wael.f.alhusami@lahey.org.

Mohammed W. Akhter, MD, is with the Interventional Cardiology and Peripheral Vascular Division at St. Elizabeth's Medical Center, Tufts University School of Medicine in Boston, Massachusetts. He has disclosed that he holds no financial interest in any product or company mentioned herein. Dr. Akhter may be reached at mohammed.akhter@caritaschristi.org.

Lawrence A. Garcia, MD, FACC, FAHA, is Chief of Interventional Cardiology and Associate Director of the Vascular Medicine Program at St. Elizabeth's Medical Center in Boston, Massachusetts. He has disclosed that he is an unpaid consultant to Ev3, Spectranetics, and Pathway. Dr. Garcia may be reached at (617) 789-5027; lawrence.garcia@caritaschristi.org.

1. Dorrucci V. Treatment of superficial femoral artery occlusive disease. J Cardiovasc Surg (Torino). 2004;45:193-201.
2. Jeans WD, Armstrong S, Cole SE, et al. Fate of patients undergoing transluminal angioplasty for lower-limb ischemia. Radiology. 1990;177:559-564.
3. Ferreira M, Lanziotti, 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.
4. 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.
5. 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.
6. Lawrence JB, Prevosti LG, Kramer WS, et al. Pulsed laser and thermal ablation of atherosclerotic plaque: morphometrically defined surface thrombogenicity in studies using an annular perfusion chamber. J Am Coll Cardiol. 1992;19:1091-1100.
7. Rogers JH, Laird JR. Overview of new technologies for lower extremity revascularization. Circulation. 2007;116:2072-2085.
8. Scheinert D, Laird JR Jr, Schroder M, et al. Excimer laser-assisted recanalization of long, chronic superficial femoral artery occlusions. J Endovasc Ther. 2001;8:156-166.
9. Taylor K, Harlan K, Branan N. Small 0.7-mm diameter laser catheter for CTO. Development and initial experience. Euro Interv. 2006;2:265-269.
10. Fretz EB, Smith P, Hilton JD. Initial experience with a low profile, high-energy excimer laser catheter for heavily calcified coronary lesion debulking. J Interv Cardiol. 2001;14:433-437.

11. Gallino R. Laser treatment: using the Spectranetics Turbo catheter to treat a calcified lesion and a thrombotic occlusion in the SFA. Endovasc Today. 2006;9:96-98.
12. Laird JR. Peripheral Excimer Laser Angioplasty (PELA) trial results. Presented at: Transcatheter Cardiovascular Therapeutics annual scientific symposium; September 2002; Washington, DC.
13. Laird JR, Zeller T, Gray BH, et al. Limb salvage following laser-assisted angioplasty for critical limb ischemia: results of the LACI multicenter trial. J Endovasc Ther. 2006;13:1-11.
14. Biamino G, Scheinert D. Excimer laser treatment of SFA occlusions. Endovasc Today. 2003;2:1-5.
15. Bunting TA, Garcia LA. Peripheral atherectomy: a critical review. J Interv Cardiol. 2007;20:417-424.
16. Spectranetics Corporation. CELLO (ClirPath Excimer Laser System to Enlarge Lumen Openings) trial. Presented at: Transcatheter Cardiovascular Therapeutics annual scientific symposium; September 2007; Washington, DC.
17. 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.
18. McKinsey JF, Goldstein L, Khan HU, et al. Novel treatment of patients with lower extremity ischemia: use of percutaneous atherectomy. Ann Surg. 2008:248:519-528.
19. Zeller T, Rastan A, Sebastian S, et al. Long-term results after directional atherectomy of femoropopliteal lesions. J Am Coll Cardiol. 2006;48:1573-1578.
20. Kim D, Gianturco LE, Porter DH, et al. Peripheral directional atherectomy: 4-year experience. Radiology. 1992;183:773-778.
21. Lugmayr H, Pachinger O, Deutsch M. Langzeitresultate der perkutanen Atherektomie bei peripherer arterieller Verschlusskrankheit. Röfo Fortschr Geb Röntgenstr Neue Bildgeb Verfahr. 1993;158:532-555.
22. Ahn SS, Concepcion B. Current status of atherectomy for peripheral arterial occlusive disease. World J Surg. 1996;20:635-643.
23. Schwarten DE, Katzen BT, Simpson JB, et al. Simpson catheter for percutaneous transluminal removal of atheroma. AJR Am J Roentgenol. 1988;150:799-801.
24. Hoefling B, Polnitz AV, Backa D, et al. Percutaneous removal of atheromatous plaques in peripheral arteries. Lancet 1988;185:384-386.
25. Ahn SS. Status of peripheral atherectomy. Surg Clin North Am. 1992;72:869-878.
26. Dorros G, Iyer S, Lewin R, et al. Angiographic follow-up and clinical outcome of 126 patients after percutaneous directional atherectomy for occlusive peripheral vascular disease. Cathet Cardiovasc Diagn. 1992;22:79-84.
27. von Polnitz A, Nerlich A, Berger H, et al. Percutaneous peripheral atherectomy: angiographic and clinical follow-up of 60 patients. J Am Coll Cardiol 1990;15:682-688.
28. Levade M, Maquin P, Rousseau H, et al. Percutaneous peripheral atherectomy with the Simpson catheter. Long-term results. J Mal Vasc. 1991;16:193-194.
29. Allie D, Berens E, Bramucci E, et al. Plaque excision in the peripheral vasculature. Endovasc Today. 2004;3:2-11.
30. Zeller T, Rastan A, Schwarzwalder U, et al. Midterm results after atherectomy-assisted angioplasty of below-knee arteries with use of the Silverhawk device. J Vasc Interv Radiol. 2004;15:1391-1397.
31. Suri R, Wholey MH, Postoak D, et al. Distal embolic protection during femoropopliteal atherectomy. Cathet Cardiovasc Interv. 2006;67:417-422.
32. Allie DE. To PROTECT or not to PROTECT? In lower extremity angioplasty procedures, "why not?" is the question! J Endovasc Ther. 2008;15:277-282.
33. Garcia LA, Lyden SP. Atherectomy for infrainguinal peripheral artery disease. J Endovasc Ther. 2009;16:1-11.
34. Endovascular Today News. Pathway's Jetstream G2 cleared for thrombectomy. Endovasc Today. 2009;8:11.
35. Zeller T, Krankenberg H, Rastan A, et al. Percutaneously rotational and aspiration atherectomy in infrainguinal peripheral arterial occlusive disease: a multicenter pilot study. J Endovasc Ther. 2007;14:357-364.
36. Zeller T, Krankenberg H, Steinkamp HJ, et al. Percutaneous rotational and aspiration atherectomy in infrainguinal peripheral arterial occlusive disease: a multicenter study. Am J Cardiol. 2008;102(supp 1):38i-39i.
37. Heuser RR. Treatment of lower extremity vascular disease: the Diamondback 360° Orbital Atherectomy System. Expert Review of Medical Devices. 2008;5:279-286.
38. Niazi K, Safian R, Heuser R, et al. Final study results of 124 patients demonstrate safety and acute procedural effectiveness of orbital atherectomy for peripheral vascular stenosis. Am J Cardiol. 2008;102(supp 1):229i.
39. Safian RD, Niazi K, Runyon JP, et al. Orbital atherectomy for infrapopliteal disease: device concept and outcome data for the Oasis trial. Cathet Cardiovasc Interv. 2009;73:406-412.
40. Mehta SK, Laster SB. Hemolysis induced pancreatitis after orbital atherectomy in a heavily calcified superficial femoral artery. Cathet Cardiovasc Interv. 2008;72:1009-1011.
41. Scheinert D, Sievert H, Maleux G, et al. Final results of a European study of orbital atherectomy: a new technology for treating occlusive peripheral arterial disease. J Cardiol. 2008;102(suppl 1):230i.
42. Hirsch AT, Haskal ZJ, Hertzer NR et al. ACC/AHA 2005 guidelines for the management of PAD. J Am Coll Cardiol. 2006;47:1239-1312.