Stenting and Laser Debulking in the SFA

Significant progress has been made in the endovascular treatment of SFAs due to the development of dedicated stents that can subsist in this difficult anatomy.

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During the last few decades, endovascular surgery has made remarkable progress in managing chronic ischemia of the lower extremities. In the wide range of treatment modalities, there has been a change from invasive bypass operations to more refined techniques such as endarterectomy and percutaneous dilatation of arterial stenoses.

Long, chronic superficial femoral artery (SFA) occlusions are still mainly treated with surgery; however, patients may be poor surgical candidates due to the absence of adequate distal anastomotic sites, absent venous conduits, and significant medical or cardiac comorbidities.[1] The endovascular treatment of stenotic and occlusive disease of the SFA remains one of the biggest challenges in current vascular practice. Percutaneous transluminal angioplasty (PTA) of SFA lesions historically has a primary technical success rate that varies from 70% to 90% and is compared unfavorably to PTA in other vascular territories.[2] The overall cumulative 5-year primary patency rate ranges from 45% to 60%. The most important factors negatively affecting the outcome of PTA of the SFA is the length of the diseased segment, occlusion instead of stenosis, limited arterial outflow, a high Rutherford classification, and diabetes mellitus.[3] Furthermore, TransAtlantic Inter-Society Consensus 2000 C and D lesions, critical limb ischemia, and a history of congestive heart failure influence primary patency rates negatively.[4] For short focal lesions, a 5-year cumulative patency rate of 75% can be expected, but results of PTA drop dramatically with stenosis or occlusions longer than 3 cm. Lesions longer than 10 cm have a significantly less favorable outcome compared to shorter lesions, with a disappointing 6-month patency rate of only 23%.[5-7] A randomized, multicenter study comparing the outcome of PTA as stand-alone therapy to bypass surgery in 5- to 15-cm-long occlusions of the SFA demonstrated superior patency rates with the surgical procedure.[8]

Figure 1. Angiographic image of a distal superficial femoral and popliteal artery demonstrating complete occlusion (A); a fluoroscopic image shows extensive calcification (B); after recanalization and stent placement (fluoroscopic image [C]), an irregular lumen is obtained despite several attempts with additional PTA (angiographic image [D]).

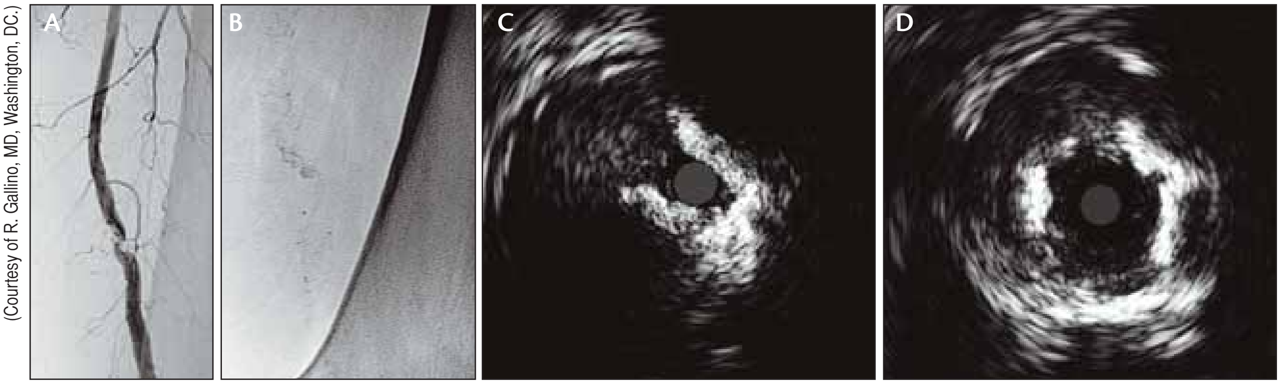

Figure 2. Angiographic image of a distal SFA at the level of the adductor canal demonstrating short stenosis (A); this nonsubtracted image shows severe calcification (B); intravascular ultrasound at the level of the lesion confirms highly calcific content (C); after debulking with excimer laser, an increased lumen with fragmentation of the calcium is seen (D) rendering the vessel more compliant and thus facilitating subsequent stent placement (not shown).

With the advancement of catheter-based technology, the technical success of angioplasty procedures in the femoropopliteal segment has increased to well over 90% and can almost reach 100% with the additional use of stents. Several randomized studies have demonstrated, using "old" stent technology, that stenting leads to higher initial success rates. However, long-term results are similar to PTA alone and are less favorable for SFA stenting using either balloon-expandable stents or self-expandable Wallstents (Boston Scientific Corporation, Natick, MA).[9-16] The inferior results of femoropopliteal stents compared to aortoiliac stents may be related to several variables; the most important factor appears to be the smaller diameter of the femoropopliteal segment. Furthermore, the SFA is a relatively hostile environment for implanted stents and stent grafts because of high biomechanical stress due to the combination of nonpulsatile deformations in the adductor canal and the pulsatile movements that are intrinsic to the arterial system.[17] The nonpulsatile deformations that occur include axial compression, bending, and twisting/torsion.[18] Greater platelet and fibrin deposition is seen with infrainguinally placed stents because of decreased flow velocity, higher shear stress, and a vessel wall that is relatively more covered.[19] Therefore, patency rates of femoropopliteal stents only reach acceptable levels when the arteries are at least 7 mm in diameter.

The first indications that clinical outcomes of SFA stenting using new stent technology had improved came from a randomized trial that was performed to evaluate the impact of using drug-eluting nitinol stents. It was noted that in the bare-metal stent group (using uncoated nitinol stents), results at 6 and 18 months were comparable to those obtained with drug-eluting stents but with unexpectedly high patency rates of up to 80%.[20-22] Several other retrospective studies evaluating mid- and long-term results have confirmed these improved results with new stent technology, even when treating longer and more complex lesions.[6,23-26]

Currently, published data of two related randomized trials are available (ABSOLUTE and FAST).[27-29] The data from the ABSOLUTE trial confirm the trend of an improved outcome using nitinol stent technology to treat long lesions (mean lesion length and treated segment length was 101 mm and 132 mm, respectively, in the stented group; 92 mm and 127 mm, respectively, for the PTA group). Control angiography at 6-month follow-up demonstrated a > 50% restenosis rate with 24% in the angioplasty group and 43% in the stent group according to the intention to treat. Reanalysis of these data according to the actual treatment received (per protocol) yielded restenosis rates of 25% after stent implantation and 50% after angioplasty without stenting. This difference in outcome was sustained at 12 months with duplex ultrasound demonstrating restenosis rates of 37% and 63% for stenting and angioplasty, respectively (intention to treat). The walking distance on a treadmill was significantly longer, and the ankle-brachial index was significantly better in the stent group at both 6 months and 12 months.[27] The benefit of stenting persisted at 2-year follow-up, with a statistically significant improved morphological outcome and a trend toward a better clinical outcome of primary stenting compared to balloon angioplasty with optional stenting.[28] Also, reintervention rates tended to be lower after primary stenting. However, the results of the FAST trial, a randomized study of PTA versus primary stenting in a patient group with short lesion length (mean length, 45 mm), failed to demonstrate a difference in outcome. This most likely indicates that PTA as a stand-alone treatment works well in short lesions and that stenting in those cases does not yield a better outcome.[29]

Despite the addition of stents to the interventionist's armamentarium, restenosis still remains the major drawback of endovascular treatment in the SFA. Many factors affect the rates of restenosis, including the anatomical location of the lesion (vessel) and the lesion morphology, stent materials and design, intraprocedural events (such as dissections), and the occurrence of stent fractures.

One of the remaining problems of balloon angioplasty is that luminal enlargement is achieved primarily by overstretching the arterial wall, leaving the lesion volume practically unchanged.[30] In addition, the SFA is very often calcified. Calcified lesions are more difficult to dilate with PTA and may require the use of high-pressure balloon inflations. This will result in a significant vascular wall barotrauma, which in turn stimulates aggressive vascular growth factors that lead to high restenosis rates. Stents placed in calcified arteries need a high radial force to keep the artery open. Additionally, eccentric or diffuse calcification prevents proper stent apposition to the intima of the artery, leading to stent fractures, residual stenosis and restenosis, and thus insufficient clinical improvement (Figure 1).[31]

Several techniques to achieve reduction of plaque burden have been described, such as laser atherectomy and directional atherectomy. The discussion of directional atherectomy is beyond the scope of this article.

LASER ATHERECTOMY

Laser atherectomy is the application of light energy to plaque, thus altering and ablating plaque in a beneficial manner, ideally without creating damage to the surrounding artery. Laser and tissue interaction is defined by three parameters: absorption depth, pulse width, and average power. The absorption depth is dependent on the wavelength. The ablative process with old laser systems (Nd:YAG and carbon dioxide devices, wavelength 1,060 nm and 10,600 nm, respectively) led to vessel charring secondary to heat accumulation around a zone of thermal necrosis with associated vasospasm and platelet aggregation.[32] This technique had a considerable failure and complication rate,[33] usually leading to surgical intervention. Using old laser technology, no significant benefit was found by adding laser to balloon angioplasty, and the long-term success was found to be modest for lesions otherwise considered suitable for angioplasty.[34] In brief, a lack of full understanding of the working principles of laser, and the use of an improper laser technique ("hot tip") led to a poor clinical outcome.[35]

In contrast to old laser techniques, the XeCl Excimer laser (Spectranetics Corporation, Colorado Springs, CO) uses light in the ultraviolet region (308 nm). The ablative action of laser is mediated by three mechanisms: (1) the breaking of molecular bonds in cellular structures (including plaque), thus weakening these structures by a photochemical effect exerted by pulsed ultraviolet light;[36] (2) a photothermal effect with heat production caused by the vibration of molecules; and (3) a photomechanical effect caused by expansion and collapse of vapor bubbles.[37] Excimer laser has a very shallow penetration depth of 50 µm; it removes a layer of 10 µm with each pulse. In comparison to the first laser systems (Nd:YAG and carbon dioxide), no relevant thermal damage occurs.[38] Advances in catheter development, which include optimally spaced laser fibers, athermic (308-nm wavelength, Excimer) catheters and the introduction of saline infusion, resulted in the minimization of thermal injury, significant reduction of vessel dissection, and larger channels obtained after catheter passage.[39]

With the use of excimer laser angioplasty, the resulting recanalized channel is small and irregular, but no thermal injury is induced.[40] The irregular aspect of the recanalized channel is most likely related to the heterogeneous composition of plaque and various components having various ablation thresholds. The ability to ablate obstructions can transform complex disease patterns into a treatable artery. Furthermore, the photoablation process acoustically modifies calcium, changing the global lesion morphology, which leads to increased vascular compliance and thus better stent appositioning. Plaque burden, as measured by intravascular ultrasound, can be significantly reduced with the use of directed excimer laser atherectomy (Figure 2).[41] Tissues with higher ablation thresholds are left as remnants. In most cases, laser angioplasty cannot be used as a stand-alone technique but will facilitate subsequent balloon angioplasty and stent placement. Therefore, the arterial wall stress occurring during balloon inflation will be reduced, which may favorably affect the restenosis rate.[42]

TECHNICAL ASPECTS

The occlusion can be crossed in two ways. The first technique is the so-called step-by-step technique, in which the guidewire is advanced for only a distance of a few millimeters into the occlusion. Subsequently, the laser is activated, and the laser catheter is advanced until its tip is flush with the guidewire. These steps are repeated until the occlusion is crossed completely.[1] Alternatively, wire passage can be achieved first, followed by advancement of the laser catheter. With the latter technique, it is extremely important to verify the intraluminal position of the guidewire throughout the entire lesion. When treating very calcified lesions of the SFA, an antegrade access will provide better support for crossing the lesion.[42]

Slow catheter advancement (< 0.5 mm/sec) is essential for optimal debulking. During excimer laser atherectomy, normal saline should be infused to clear contrast media and blood from the ablation site. In vitro testing and clinical experience have shown that microbubble formation and collapse can occur, resulting in transient acoustic pressure waves. This acoustic phenomenon can vibrate the plaque and vessel walls, creating microfissures in the tissue that are similar to the stretching effects of balloon angioplasty, thus increasing the risk of dissection. This phenomenon also increases and can generate higher transient pressures if excimer laser atherectomy is performed in an undiluted blood field or where contrast media has not been cleared by a compatible crystalloid solution. Blood and contrast media greatly absorb excimer laser energy. Normal saline is a crystalloid solution that transmits laser energy, resulting in less acoustic effect when the blood and contrast media are displaced by infusion. Saline infusion can either be administered through the introducer sheath, guiding catheter, and/or the laser catheter inner lumen. When infusing saline through the guidewire lumen, the use of guidewires with smaller diameters will improve the infusion flow rate at the treatment site.

The fluence (mJ/mm^2) and repetition rates should be adjusted according to lesion morphology (eg, soft or hard tissue). When fluence is increased, the potential to ablate tissue with a higher density (as calcified plaque) is increased. Additionally, when the repetition rate is increased, the ablation rate is increased. The available range of fluence and repetition rate differs among laser catheter models and is regulated by the laser system software. If resistance to laser catheter advancement is encountered due to lesion density, increase the fluence and repetition rates, respectively, to advance the device, affect atherectomy, and minimize dottering effects. It is important not to lase in a stationary position for more than 5 seconds.

Additional debulking can be achieved with the Turbo-Booster laser guide catheter (Spectranetics Corporation), which is designed to offset the laser catheter from the guidewire axis and allow for rotation of the laser catheter around the guidewire axis, thus creating larger lumens than what is possible with a laser catheter alone.

As mentioned previously, calcified chronic total occlusions remain a challenge even for excimer laser. As the degree of tissue calcification increases, the XeCl ablation mechanism changes from a photoablative decomposition to a laser-induced plasma shock wave disruption. As the degree of calcification increases, the cut rate will decrease. In heavily calcified lesions, the fluency rate needs to be doubled to achieve a similar cut rate.[43] This fact will increase the risk of perforation and the time needed to cross a lesion. Heterogeneous calcified plaque often contains denser areas that may be difficult to ablate, resulting in a small lumen that stops and potentially deflects the tip of the catheter. The 0.9-mm device may be useful in this scenario because of its higher laser density (80 mJ/mm^2, 80 Hz) and lower total energy and heat production as compared with larger-diameter laser catheters. The smaller size will assist in facilitating navigation. The obtained pilot channel may subsequently serve to facilitate passage of a larger-diameter laser catheter or angioplasty catheter and minimize the risk of perforation or dissection.[32]

REPORTED CLINICAL OUTCOMES

Pulsed excimer laser has been demonstrated to be effective in photoablative recanalization of lesions that are not amenable to conventional PTA.[38,44] In a series of 48 patients with critical limb ischemia (lesion location in 41% of SFA or popliteal artery cases), laser atherectomy could be used as a stand-alone procedure in 14% of cases; the remaining cases were treated with additional PTA (33%), primary stenting (6%), and PTA with stent placement (47%).[36]

A series of 312 patients with short SFA occlusions (average length, 7.5 cm) was reported on by Steinkamp et al. Excimer laser angioplasty yielded successful recanalization of 91.7% of cases. Primary and secondary patency rates at 36 months were 49.2% and 86.3%, respectively.[45]

In a series of 318 patients with a total of 411 long, chronic SFA occlusions (mean length, 19.4 cm), a technical success rate of 90.5% was achieved using excimer laser angioplasty.[46] In all cases, balloon angioplasty was needed after debulking. The need for additional stenting was limited to 7% of the treated limbs. Primary and secondary patency rates at 1 year were 33.6% and 75.9%, respectively. Similar results were seen in another study of long occlusions (mean lesion length, 25.5 cm), with a technical success rate of 85.5%.[46] At 4-year follow-up, a secondary patency rate of 43.2% could be achieved by performing a strict follow-up protocol and additional interventions (primary patency at 4 years was 22.3%).

In all of the studies mentioned above, the principal reason for technical failure of the initial procedure is the presence of calcification. Currently, a single-center study (LASER Rocks) is enrolling patients (Leipzig, Germany; Professor D. Scheinert), and the results are eagerly awaited.

CONCLUSION

The endovascular treatment of SFAs has made significant progress recently, which is mainly due to the development of dedicated stents that can cope with the hostile environment of this difficult anatomy. To further improve long-term patency, there is probably a role for debulking of the lesion to optimize stent apposition and enhance radial force. Overall, initial experience with laser atherectomy looks promising. ■

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