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Chapter 2

Interventional Strategies for the Superficial Femoral Artery

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Abstract

The incidence of peripheral arterial disease (PAD) is rising due to significant increase in metabolic disease such as diabetes mellitus, increase in aging population, and tobacco use. Superficial femoral artery (SFA) disease is the leading cause of peripheral artery disease and claudication. In the last decades, several technologies/techniques have been developed for the treatment of SFA atherosclerotic disease including balloon angioplasty, balloon expanding stents, self-expanding stents, drug-eluting balloon, and atherectomy. The advances made in technology have significantly improved the quality of the balloons, but they have limitations especially in long and calcified lesions. While the initial studies using stainless steel stents failed to show any significant difference in outcomes, understanding the pathophysiology and improvement in stent technologies has shown significant reduction of restenosis by five- to sevenfold when compared to angioplasty alone. Atherectomy is another modality of plaque modification and treatment, which can be done as a stand-alone treatment or more commonly combined with PTA and/or stenting. Finally, several randomized studies and registries have showed that with improvement in technology, there is significant improvement in long-term outcomes of SFA atherosclerotic disease.

Keywords: superficial femoral artery angioplasty, superficial femoral artery stenting, SFA rotational atherectomy, SFA laser atherectomy, SFA directional atherectomy

1. Introduction

The incidence of peripheral arterial disease (PAD) is rising due to significant increase in metabolic diseases such as diabetes mellitus, increase in aging population and tobacco use.

PAD is the third cardiovascular cause of morbidity following the coronary artery disease and stroke.

Superficial femoral artery (SFA) disease is the leading cause of peripheral artery disease and claudication. According to current estimates, there are over 8 million people affected with PAD and the numbers are rising. Nearly half of the patients affected from PAD are asymptomatic and about 20% have claudication [1–4]. Regardless if the patients are symptomatic or not, patients with PAD have worse quality of life and worse outcomes when compared to people that do not [5].

Nearly 50 years after the first endovascular intervention of the SFA performed by Charles Dotter, endovascular intervention of the lower extremity has increased significantly [6]. The relatively low risk for morbidity and mortality and improvement in technology have seen a high success rate making the endovascular intervention of the SFA the preferred choice, particularly in short-segment disease [7]. Nevertheless, the unique biochemical, anatomical, and hemodynamic forces the SFA is exposed to, makes the endovascular intervention quite challenging.

Rutherford category	Characteristic
0	Asymptomatic
1	Mild claudication
2	Moderate claudication
3	Severe claudication
4	Pain at rest
5	Minor tissue loss
6	Major tissue loss

Table 1. Rutherford classification of chronic limb ischemia.

Trans-Atlantic Inter-Society Consensus II classification of femoropopliteal disease		
Type lesion	**Stenosis or occlusion pattern**	**Procedure**
A	Single stenosis less or equal to 10 cm or occlusion less or equal to 5 cm.	Endovascular
B	Multiple stenosis or occlusion less or equal to 5 cm or a single severely calcified occlusion of 5 cm or less. Single stenosis or occlusion of 15 cm or less, not involving below the knee popliteal artery. Single or multiple lesions in conjunction with occluded proximal infra-geniculate vessels to improve inflow for distal bypass. Single popliteal artery stenosis.	Endovascular
C	Multiple stenosis or occlusion adding to more than 15 cm irrespective of calcification. Two failed attempts for endovascular revascularization.	Endovascular or Surgical bypass
D	Chronic occlusions of the CFA, more than 20 cm of SFA stenosis, popliteal artery or proximal trifurcation vessels.	Surgical bypass

CFA = Common Femoral Artery. SFA = Superficial Femoral Artery.

Table 2. Trans-Atlantic inter-society consensus II (TASC II). Classification of the femoropopliteal disease.

Indications to intervene upon the lower extremities depend on the severity of disease and symptoms with absolute indications in cases with limb-threatening ischemia with resting pain and tissue loss (including Rutherford classification class 4–6). Relative indications are not limb threatening but significantly debilitating and often a reason to intervene upon and include mainly patients with intermittent claudication (Rutherford class 2 and 3), [8] (**Table 1**).

Once intervention is indicated, the decision to intervene via endovascular approach rather than open surgical approach is mainly based upon the Trans-Atlantic inter-Society Consensus II Classification (TASCII) recommendations [7] (**Table 2**).

2. Vascular access technique

Like all endovascular interventions, SFA interventions begin with vascular access. The most common vascular access is the common femoral artery (CFR). In selected cases, brachial artery can be used as well. For safety purposes and in attempting to reduce complications, the recommended technique is the ultrasound (US)-guided technique and if possible micropuncture needle can be used as well.

Using the ultrasound permits direct visualization of the artery and its branches. US-guided access reduces multiple punctures and as such reduces the incidence of arteriovenous fistulas. US-guided technique is an excellent choice in patients with no palpable pulse, heavily diseased common femoral artery (CFR), obese patients, and high bifurcation [9].

Puncture using anatomical landmarks is another approach several operators use. The point of maximal pulsation correlates with the midpoint of the CFA in over 92% of the cases. When the pulse is difficult to palpate, the midpoint between the anterior superior iliac spine and pubic tubercle by palpation is used. The groin crease is an unreliable marker and is located distal to the CFA bifurcation and is located distal to the CFA bifurcation in about three out of four patients. Fluoroscopy-guided puncture can be used as well, aiming the inner lower third of the femoral head. The femoral head provides a solid surface for firm compression of the CFA necessary for hemostasis following arterial puncture [10–12].

Arterial access can be obtained on either side with the contralateral side being the preferred in most cases. The contralateral access remains the preferred choice as it allows an adequate working length to image and treat the sequential lesions within the entire target extremity. Once the access is obtained, a guide wire is introduced with size 0.018–0.035-in depending on if it is a micropuncture or not. Sheath sizes used for the SFA intervention range from 4 to 7 French. Sheaths protect the access vessel during the catheter intervention and wire exchanges during a procedure. The smallest size sheath to complete the intervention should be used. A reverse curved catheter and a 0.035-in guide wire are usually used to crossover the aortic bifurcation. The guide wire is then advanced to the level of the CFA and at that point allows to advance a catheter to the distal external iliac artery. At this point, serial lower extremity angiograms can be performed at the target extremity. Patency of the runoff vessels is very important to assess prior to intervention. Clinically assessing the presence of pulses is very important because distal vessels can be occluded secondary to embolization from the SFA

intervention. In presence of single-vessel runoff, an embolic protection filter can be used prior to intervention to minimize distal embolic occlusion. Prior to starting intervention, the patient should be heparinized with an activated clotting time (ACT) of 250 seconds or more [13].

After the patient is anticoagulated, the target SFA lesion must be crossed. This is achieved using a directional catheter and a 0.035-in wire, usually a hydrophilic wire. The catheter is usually positioned just proximal to the target lesion providing wire support and pushability to cross the stenosis. Remaining intraluminal is the preferred technique to cross the lesion, but it is not possible with a 0.035-in wire. Therefore, an attempt can be made by using a 0.018-inch or a 0.014-inch guide wire and catheter. If there are still difficulties in crossing the lesion, then a subintimal approach can be attempted. When the reentry with a hydrophilic wire is not possible, then the use of a reentry device is recommended. Subintimal angioplasty can be performed effectively with excellent technical success and acceptable patency [14–16].

3. Balloon angioplasty

Balloon angioplasty remains the most frequently used technique in the treatment of SFA disease as either primary or adjunctive therapy for stents and other devices. After crossing the lesion, an appropriate balloon must be selected. There are several balloons that can be used in different scenarios as we describe later [20].

The noncompliant balloons inflate to a uniform diameter regardless of the amount of pressure introduced in the balloon. As such, the noncompliant balloons are often preferred because they are less likely to cause injury to the native vessel and are more effective in treating atherosclerotic lesions. Balloon catheters can be over the wire, and they offer more pushability and often times are better in crossing tight lesions. Furthermore, these balloons can be used as catheters as well. Monorail or the rapid exchange balloons are less cumbersome and easier to handle as they use shorter wires. However, these advantages come at the expense of the pushability, and crossing a tight lesion with a monorail balloon can be more challenging. The diameter of a normal SFA segment distal to the lesion is used as a reference to size the angioplasty. To size the length of the balloon, a radiopaque external ruler is used. The proper length of the balloon must treat the target lesion without disruption of the normal segment proximal and distal to the lesion [17].

The nominal pressure of a balloon is the pressure at which the balloon will achieve the manufacturer's stated diameter. With noncompliant balloon, increasing the pressure will not result in increase in diameter, while with compliant or semi-compliant balloons, an increase in pressure will result in balloon overinflation to a larger diameter. Overinflation and over-sizing the balloon can cause trauma to the artery or significant dissection. The burst pressure is the pressure at which 99.9% of the balloon will not rupture. This pressure should not be exceeded. Balloon can rupture due to overinflation or if the atherosclerotic plaque is heavily calcified. Balloon rupture can cause embolization of balloon fragments or air embolization if the balloon is not properly prepped [17, 18].

When planning on performing only angioplasty without stent placement, longer balloon inflation times are used to stabilize the luminal surface of the arterial segment being treated. The longer inflation times may reduce a flow-limiting dissection. After the intervention, angiography is performed; if there is any vessel recoil, persistent stenosis, or a flow-limiting dissection, repeat angioplasty is recommended. In these circumstances, increase of inflation times is recommended [17, 19].

Conventional balloons are associated with a high rate of uncontrolled dissections that may require bailout stenting, particularly in more complex and diffuse SFA lesions. Cutting balloons are reinforced with microtomes that provide a leading edge to cut through stiff fibrotic lesions at lower pressures. These types of balloons are suggested instead of using larger diameter balloons and may be associated with less hemodynamically significant dissections. Studies have shown that use of cutting balloons have shown better long-term patency in peripheral artery interventions. When there is a persistent residual stenosis of more than 50% or a flow-limiting dissection after the PTA, provisional stenting is performed [20].

With improvement in technology, development of newer balloons, such as drug-coated balloons (DCB), have significantly improved outcomes in percutaneous interventions of the peripheral arteries including the SFA disease. Tepe G et al. conducted a randomized controlled study of 331 patients with symptomatic femoropopliteal artery disease up to 18 cm in length. At 24 months, outcomes from the trial revealed a durable and superior treatment effect of the DCB versus percutaneous transluminal angioplasty (PTA) with significantly higher primary patency, lower clinically driven target lesion revascularization (TLR), and similar functional status improvement with fewer repeat interventions [21].

Drug-coated balloons have been also studied in complex stenosis such as in-stent restenosis (ISR). Brodmann et al. performed a study to assess the effectiveness and safety of the use of paclitaxel-coated drug-coated balloon (DCB) in patients with de novo in-stent restenosis (ISR). A total of 131 patients were enrolled. Procedural success was achieved in 98.5% of subjects. Primary patency estimate was 88.7% in the ISR cohort at 12 months. Freedom from clinically driven target lesion revascularization (CD-TLR) estimated at 92.9% at 12 months [22].

4. Stenting

The efficacy of stenting over the balloon angioplasty failed to show any significant advantage in the early randomized trials where mainly stainless steel bare-metal stents were used [7, 23, 24]. However, with the advancement in stent technology, further newer studies compared primary angioplasty to Nitinol stents in the SFA. Interestingly, these studies revealed that angioplasty alone results in equivalent patency rates when compared to primary stenting in patients with short lesions. On the other hand, longer stenosis are best treated with primary stenting and that offers longer time patency (**Table 3**).

The FAST trial, a multicenter randomized controlled trial, compared the SFA PTA and nitinol stenting in 244 patients. The indication to treat was claudication in 97% of patients in both groups. The mean lesion length was relatively short, 4.4 cm in the stenting group and 4.5 cm in

Trial	Device	Sample size	Average lesion length (mm)	Primary end point	Stent patency rate %
Bare metal stents					
Resiliant Laird et al. [27]	LifeStent versus PTA	206	71 ± 44 BMS 64 ± 41 PTA	TLR at I year	81/37, 1 year (p = 0.0001)
FAST Krachenberk et al. [25]	Bard Luminexx vs. PTA	244	53.4 ± 29.5 BMS 51.1 ± 24 PTA	Binary restenosis at 1 year	68/62, 1 year (p = 0.377)
Absolute Schillinger et al. [26]	Dynalink/Absolute vs. PTA	104	132 ± 71 BMS 127 ± 55 PTA	Binary restenosis at 6 months	75/55, 6 months (p = 0.05) 63/37, 1 year (p = 0.01)
Drug-eluting stents					
SIROCCO I Duda et al. [34]	Sirolimus coated vs. SMART	36	82.9 DES 88.6 BMS	In-stent luminal stenosis at 6 months	100/77, 6 months (P = 0.10)
SIROCCO II Duda et al. [55]	Sirolimus coated vs. SMART	57	86.5 ± 37 DES 76.3 ± 46 BMS	In-stent luminal stenosis at 6 months	100/93, 6 months (p = 0.46)
SIROCCO Long term Duda et al. [56]	Sirolimus coated vs. SMART	93	85 ± 44 DES 81 ± 52 BMS	In-stent luminal stenosis at 6 months	77/79, 2 years (p > 0.05)
Zilver PTX Drake et al. [34]	Zilver PTX vs. PTA	479	66.4 ± 38.9 63.2 ± 40.5	Event free survival and patency	83/33, 1 year (p < 0.001) 75/27, 2 years (p < 0.01)

Table 3. Landmark trials for PAD and stenting.

the PTA group. Results revealed comparable amputation and mortality rates. No significant differences were noted in the restenosis rates (38.6% in the PTA group vs. 31.7% in the stent group) or change in clinical status between the two groups. The ankle-brachial index remained the same at 12 months [25].

The Vienna-ABSOLUTE study was the first randomized study to show superiority of primary stenting over balloon angioplasty for the treatment of moderate-length SFA lesions, 13.2 cm in the stenting group, and 12.7 in the PTA group. In this study, 104 patients were included, and patients were randomized 1:1 to a Dynalink or Absolute stent versus balloon angioplasty. The indication for treatment was claudication in the majority of cases, 88% in the stent group and 87% in the PTA group. The groups did not defer in limb salvage or mortality. The restenosis rate was greater in the PTA group (43 vs. 24%, p = 0.05). Duplex ultrasound at 12 months also demonstrated a greater restenosis rate in the PTA group (63 vs. 37%, p = 0.01). Furthermore, the maximal walking distance was significantly less in the PTA group at 6 and 12 months (267 vs. 387 m, p = 0.04) [26]. The groups did not defer in limb salvage or mortality. The restenosis rate was greater in the PTA group (43 vs. 24%, p = 0.05). Duplex ultrasound at 12 months also demonstrated a greater restenosis rate in the PTA group (63 vs. 37%, p = 0.01). Furthermore, the

maximal walking distance was significantly less in the PTA group at 6 and 12 months (267 vs. 387 m, $p = 0.04$).

Another study that showed significant superiority of stenting versus PTA is the RESILIANT trial. A multicenter randomized controlled trial (RCT) comparing the PTA to nitinol stenting in 206 patients [27]. Indication for treatment was claudication and the lesion length was in the moderate range (7.7 cm in the stent group and 6.4 cm in the PTA group). The 6-month primary patency was worse in the PTA group when compared with primary stenting (47.4 vs. 94.2%, $p = 0.0001$). Patients were followed up at 12 months and results remained statistically significant in the stenting group (36.7% in the PTA group vs. 81.3% in the stenting group, $p = 0.0001$). Even longer term, 3-year follow-up, patients randomized to primary stent placement had significantly higher freedom from target lesion revascularization (75.5 vs. 41.8%) [28]. The earlier-mentioned studies provided strong evidence favoring the primary stenting as the treatment choice for moderate-length SFA lesions.

Based on recent registry studies, current-generation nitinol self-expanding stents have improved primary patency, with low to zero rates of stent fractures [29, 30]. The SUMMIT study was a prospective multicenter registry study of the Epic stent, which is a laser-cut nitinol self-expanding stent [29]. At 1-year follow-up, the restenosis rate was 15.7%, with a freedom from the target lesion revascularization (TLR) rate of 92%. No stent fractures were noted on follow-up patients with available X-rays.

COMPLETE SE trial is a prospective multicenter, single-arm study that evaluated the self-expanding stent in SFA and proximal popliteal for de novo and/or restenotic lesions in patients with symptomatic PAD [30]. At 1-year follow-up, the primary patency rate was 72.6%, with a clinically driven.

5. Recent development in SFA stents

Technology continues to undergo significant improvement in SFA stents with the goal to increase durability and conformability with better long-term patency. The Supera stent (Abbott Vascular) is a recently approved stent with a novel woven design that results in improved radial strength, flexibility, and resistance to fracture. The SUPERB study reported a primary patency rate of 86% in the pivotal registry [31]. Other stent designs under investigation include the Tigris stent (Gore and Associates), which has a nitinol wire frame with Extended polytetrafluoroethylene (ePTFE) coating and interconnecting ePTFE-linking regions. The SMART Flex stent (Flexible Stent Solutions) has a helical strut bands and flex bridges that provide flexibility while maintaining longitudinal integrity. The BioMimics 3D stent (Veryan Medical) has a helical design that may promote laminar flow.

Considering the success of the drug-eluting stents over the bare-metal stents in the coronary arterial disease, similar stent technology was developed for the peripheral arterial disease hoping for similar results. Several early studies failed to demonstrate clinical superiority when

Figure 1. There is an example of retrograde approach of the SFA CTO (chronic total occlusion) intervention with PTA and two Zilver PTA self expanding drug eluting stents (pre intervention).

compared to bare-metal stents in the SFA. These early studies included both sirolimus-eluting and everolimus-eluting designs using an earlier-generation platform [32, 33].

With subsequent development of DES technology, paclitaxel-eluting stent has shown significant benefit in the SFA treatment when compared to both balloon angioplasty and placement of a bare-metal stent. The Zilver-PTX is a nitinol scaffold stent with a polymer-free coating that elutes paclitaxel [34]. In the ZILVER PTX study, patients were randomized to placement of a paclitaxel-eluting Zilver stent versus balloon angioplasty. A second arm of the study randomized patients to Zilver PTX versus bare-metal stenting in cases of failure of balloon angioplasty. At 1 year, the primary patency rate was 83% in the DES group versus 32% in the PTA group. In the second-arm randomization, 1-year primary patency with Zilver PTX was superior to the Zilver BMS (89.9% vs. 73%). These results showed significant superiority of the Zilver PTX to both angioplasty alone and the Zilver bare-metal stent (**Figures 1** and **2**).

Based in the above results, DES use in SFA provides significant promise for improving patency and long-term outcomes. In the years to come, further improvement in technology of the stent scaffolds and refinement of drug-eluting technology will further improve outcomes in endovascular interventions.

Figure 2. There is an example of retrograde approach of the SFA CTO (chronic total occlusion) intervention with PTA and two Zilver PTA self expanding drug eluting stents (post intervention).

6. Atherectomy

Treatment options for the PAD have significantly increased in number, but they remain limited in scope, as they are lacking substantial scientific data and large-scale randomized trials to help define the best therapy.

The majority of interventionalists use balloon expansion as a principal therapy which can or may not be followed by the stenting depending on weather the results of the angioplasty are satisfactory. This can be associated with vascular barotrauma leading to increase in incidence of restenosis and the need for re-interventions as the lesions are longer and heavily calcified. Stent use in SFA disease has shown significant improvement in vessel patency after intervention. [27, 28, 34]. However, the success rate of intervention decreases significantly as the lesions increase in size of more than 20 cm.

Changing arterial compliance through debulking specifically highly calcified plaques has been shown to be of benefit. Recent data suggest that atherectomy with or without adjunctive PTA and/or stenting has shown increased benefit [35].

Atherectomy devices remove plaque by physically shaving, drilling, or pulverizing by sanding the plaque resulting in modification of the vessel and its compliance. Atherectomy usually causes minimal trauma to the vessel and as such the incidence of acute complications including dissection and acute vessel occlusion may be reduced [36].

Initially, atherectomy devices were used in coronary artery disease without much success when compared to the contemporary bare-metal stents. Potential complication of atherectomy is the embolization of the debris distally. Shammas NW et al. performed a small study of 40 patients. In all patient that underwent atherectomy with SilverHawk device macro-embolization occurred. The study concluded that distal embolic filter protection is very effective in capturing macro debris and that is associated with good angiographic outcome. To determine the clinical outcome more randomized controlled studies need to be performed in the future [37].

Currently, there are several atherectomy devices available including directional, rotational, orbital, and laser atheroablative.

6.1. Laser atheroablative technique

Laser therapy received the FDA approval with the Laser Angioplasty for Critical Limb Ischemia (LACI) trial, where a total of 145 patients were enrolled. The diseased segments were equally distributed involving superficial femoral artery and infrapopliteal segments (41%) with 15% who had popliteal lesions. In this study, a 308-nm Excimer laser was used to ablate the plaque and thrombus, restoring the flow in diseased segments. Laser was delivered through a flexible fiberoptic catheter using short bursts of ultraviolet energy, which vaporized the plaque into small particles with minimal thermal injury in the surrounding tissues and lower chance for distal embolization [38].

In the CliRpath Excimer Laser System to Enlarge Lumen Openings (CELLO), Dave RM et al. evaluated the safety and efficacy of a modified laser catheter designed for the endovascular treatment of the PAD including the SFA and proximal popliteal artery. The study included 65 patients with intermediate claudication and stenotic lesion of more than 70% by visual assessment. Results revealed that laser ablation reduced the diameter stenosis from 77% to 34.7%. Patency rates were 59% and 54% at 6 and 12 months, respectively. There was significant functional status improvement with increased walking distance that was hemodynamically significant [39].

Laser atherectomy has shown to be effective also in patients with in-stent restenosis. Dippel EJ et al. conducted a multicenter, prospective, randomized controlled trial to assess the safety and efficacy of the Excimer laser atherectomy (ELA) in addition to PTA alone in patients who developed in-stent restenosis. The primary efficacy end point was TLR at 6 months follow-up. The primary safety end point was major adverse event (death, amputation or TLR) at 30-day post procedure. A total of 250 patient were included in the study, Rutherford class 1–4 and target lesion length was >4 cm. The lesion length was approximately 20 cm in both groups. ELA + PTA subjects demonstrated superior procedural success (93.5 vs. 82.7%; $p = 0.01$) with significantly fewer procedural complications and less target lesion revascularization (73.5 vs. 51.8%, $p < 0.005$) [40].

6.2. Rotational atherectomy

Rotablator system was first used in 1988 and it is currently available as Rotablator System and consists of an elliptical, nickel-plated, brass burr which is coated with 2000–3000 microscopic diamond crystals on the leading edge, and the burr rotates at 140,000–190,000 RPM. There are several available burr sizes available ranging from 1.25 to 2.5 mm. The majority of the debris, approximately 98%, is smaller than 10 micrometer, which traverses the microvasculature and is cleared by the reticuloendothelial system [41–43].

Clinical data currently lack any benefit in preventing restenosis in native and restenotic lesions. Rotational atherectomy is used to prepare a calcified lesion for stenting when a stent is not deliverable, or it cannot be properly expand [42].

In a single-center Excimer Laser, Rotablator Atherectomy, and Balloon Angioplasty study (ERBAC), a total of 685 patients were randomized to various atherectomy methods. RA had the greatest initial success, 89% in RA, 77% in Excimer laser, and 80% in balloon angioplasty. No differences were observed in major complications at the hospital and at 6 months follow-up. Revascularization of the original target lesion was performed more frequently in the RA group (42.4%) and the Excimer laser group (46.0%) than the angioplasty group (31.9%, $p = 0.0013$) [44]. Similar results were replicated in a multicenter, prospective trial of 502 patients, Comparison of Balloon Angioplasty versus Rotational Atherectomy in Complex Coronary Lesions (COBRA) [45].

Pathway Jetstream PV Atherectomy system consists of a single-use catheter with control pod and a reusable console. The system is indicated for both thrombectomy and rotational atherectomy. The catheter is advanced over a 0.014″ with a maximum rate of 1 mm/sec to avoid significant drops in rotational speeds; it has a front-cutting tip that makes it go through tight lesions. The electric motor spins catheters at 60–70 krpm, and for every 40 sec of treatment, a 10-sec pause is recommended. Jetstream expandable catheters 2.1/3.0 mm and 2.4/3.4 mm have a catheter tip that remains at a defined nominal diameter (2.1 or 2.4 mm) when spinning clockwise but expands to a maximum diameter when rotating counterclockwise. These sizes are recommended for larger-diameter arteries, typically above the knee. During atherectomy, the device offers a continuous active aspiration [46].

Clinical data are not very robust for the Pathway Jetstream atherectomy device as there are only small-sized studies performed. The largest study was conducted by Zeller et al. where 172 patients were included with femoropopliteal and popliteal lesions. The success rate was excellent (99%). Patients were followed up at 1 year and the restenosis rate as per arterial duplex ultrasound was 38.2%. Target lesion revascularization at 6 and 12 months were 15 and 26%, respectively [47].

6.3. Orbital atherectomy

Orbital atherectomy is an atherectomy device used for plaque modification to reduce the total atheroma burden, to change the arterial compliance, and to decrease vessel-wall trauma [48].

The orbital atherectomy device has an eccentrically mounted diamond-coated crown. The crown sizes include 1.25, 1.5, 2.0, and 2.25 mm. As the crown rotates, the centrifugal forces press the crown against the calcified lesion that is less compliant, while the healthy segment complies and moves away from the device reducing the risk for complications such as perforation. The small particles are so small that distal protection is not necessary. Short and slow runs are recommended of approximately 1–10 mm/sec to increase the efficacy and reduce the number of passages. Another advantage of orbital atherectomy over other atherectomy devices is the bidirectional treatment capability [49].

Clinical evidence for the orbital atherectomy use in peripheral artery disease has been shown in a serial of studies called CONFIRM registry series. A total of 3135 patient were included from over 200 centers in the Unites States from October 2009 to June 2011.

Results revealed that treatment with orbital atherectomy (OA) reduced pre-procedural stenosis from 88 ± 12% s to an average of 10% with adjunctive treatments, such as low-pressure BA. Further analysis showed that shorter spin times and smaller crown sizes significantly reduced procedural complications, which included slow flow, embolism, and spasm [50].

Orbital atherectomy can properly treat a calcified lesion, improving lesion compliance. OA also increases the luminal gain and by doing so decreases the need for high-pressure balloon inflation as demonstrated in COMPLIANCE 360°trial [51].

6.4. Directional atherectomy

There are two FDA-approved directional atherectomy devices, SilverHawk and TurboHawk. Both these devices are approved for peripheral vasculature use. SilverHawk is a forward-cutting directional atherectomy device. The device consists of rotating blade inside a tubular housing with a collection area. The TurboHawk device is similar in function but has four inner blades. Both devices come in various sizes to enable atherectomy in vessels with diameters of 1.5–7 mm as the device is advanced and though the lesion plaque is excised and packed in the nosecone. These devices have the advantages to remove eccentric lesions due to the advantage of directional control. Distal embolization remains a major disadvantage and the use of distal protection is recommended, especially in large and heavily plaques.

There is significant clinical data supporting the directional atherectomy devices in peripheral artery disease. In the TALON registry, a total of 601 patients were included with complaints of claudication and acute limb ischemia. The procedural success rates were high (over 97%), and a significant decrease in requirement for stent placement was noted after atherectomy (6.3%). One-year outcomes correlated well with angioplasty and stenting with free of target lesion revascularization in the 80% range. Cautious interpretation of the results is advised as this is an observational registry [52].

A serial of prospective randomized trials were done to assess efficacy of the directional atherectomy. McKinsey et al. enrolled 275 patients with femoropopliteal disease. Nearly two-thirds of patients had critical limb ischemia (63%). Limb salvage ischemia was over 90% at 1.5-year follow-up with a small percentage of patients (4.4%) requiring bypass [53].

OA efficacy was assessed in critical limb ischemia by Kandzari et al. where 69 patients were treated and prospectively followed for 6 months. Procedural success rate was very high (99%) with very low rates of target lesion revascularization (4%) [54].

In conclusion, endovascular therapy has become increasingly common in the treatment of obstructive SFA disease. With the advance in technology, PAD interventions can be performed with high success rate and relatively low clinical risk. New-generation drug-eluting stents have shown very promising results with better long-term patency. However, more randomized clinical trials are needed to prove the durability and safety.

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