An Overview of Superficial Femoral Artery Stenting

The history, data, and latest advancements in stenting of the SFA and popliteal arteries.

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During the past decade, multiple technologies have been developed for treatment of superficial femoral artery (SFA) atherosclerotic disease, including balloon angioplasty, bare-nitinol self-expanding stents, drug-eluting nitinol stents, and drug-coated balloons. Although many endovascular treatment options exist, nitinol stents remain a mainstay of SFA therapy.[1] This article reviews the historical development of SFA stent technologies, with an emphasis on recent advances and data supporting the use of stents in the SFA and popliteal arteries.

SUPERIORITY OF SFA STENTS OVER BALLOON ANGIOPLASTY

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.[2] In that study, patients were randomized 1:1 to a Dynalink* or Absolute* stent (Abbott Vascular) versus balloon angioplasty. At 1 year, primary patency was significantly higher for patients treated with a stent (63% vs 37%). However, other randomized studies conducted with the Luminexx stent (Bard Peripheral Vascular) failed to show a benefit of stent placement for shorter-length (mean, 40 mm) SFA lesions.[3] At the same time, concerns regarding a high prevalence of stent fracture in the SFA using early generation self-expanding stents limited the broad application of stents to the femoropopliteal segment.[4]

The RESILIENT trial was the second major randomized trial to show superiority of primary stent placement over balloon angioplasty for the treatment of moderate-length SFA lesions.[5] Patients were randomized 2:1 to placement of a LifeStent (Bard Peripheral Vascular) versus balloon angioplasty. At 12 months, the primary patency rate was significantly higher for patients randomized to primary stent placement based on both intention-to-treat analysis (81% vs 36%) and as-treated analysis (80% vs 61%). The stent fracture rate was only 3% at 1 year. At 3-year follow-up, patients randomized to primary stent placement also had significantly higher freedom from target lesion revascularization (TLR) in the intention-to-treat group (75.5% vs 41.8%).[6] These results provided significant evidence in support of primary stenting to treat moderate-length SFA lesions with modern stent designs.

REGISTRY STUDIES OF SFA STENTS

After completion of early, randomized studies of nitinol self-expanding stents versus balloon angioplasty, the majority of subsequent studies have consisted of registry data supporting the incremental improvement of new-generation stents. These studies have, in general, been based on the VIVA objective performance goals in the SFA and have shown excellent rates of primary patency, as well as extremely low stent fracture rates when compared to earlier stent designs.[7] In most cases, reports of these registries have led to US Food and Drug Administration approval of an SFA-specific indication for these stents (Table 1).

Two of the more recent registries highlight improvements in outcomes with newer-generation self-expanding stents. The SUMMIT study was a prospective, multicenter registry of the Epic* stent (Boston Scientific Corporation), which is a laser-cut nitinol self-expanding stent that contains radiopaque tantalum markers at the proximal and distal ends.[8] At 1-year of follow-up, the binary restenosis rate was 15.7%, with a freedom from TLR rate of 92%. Among patients with available x-rays, there were no stent fractures at follow-up.

The COMPLETE SE multicenter trial studied use of the Complete SE stent (Medtronic, Inc.), which has an

*These devices are investigational or not indicated for use in the SFA in the United States.

TABLE 1. REGISTRY STUDIES OF NITINOL SELF-EXPANDING STENTS IN THE SFA

Stent Name	Study Name	Lesion Length (mm)	% CTO	Primary Patency Rate at 1 Year	TLR Rate at 1 Year	Stent Fracture Rate at 1 Year
Conformexx*	FACT	59	35%	77%	7.4%	NR
EverFlex	Durability I	96	40%	72%	21%	8%
EverFlex	Durability II	89	38%	67%	14%	0.4%
Supera	SUPERB	79	NR	86%	10%	0 %
Supera	Supera SFA Registry	90	30%	85%	NR	NR
Supera	Popliteal Registry	58	48%	88%	7%	0%
Supera	Supera 500	126	53%	84%	NR	NR
Epic*	SUMMIT	69	30%	84%	8%	0%
SMART	Stroll	77	24%	82%	12%	2%
Complete SE	Complete SE trial	61	30%	73%	8%	0%
Misago*	Misago 2	64	38%	88%	10%	3%

Abbreviations: CTO, chronic total occlusion; NR, not reported.
Adapted with permission from Aghel A, Armstrong EJ. Exp Rev Cardiovasc Ther. *2014;12:833–842.*[1]

offset crown design that may minimize crown interaction during flexion.[9] At 1 year, the primary patency rate was 72.6%, with a clinically driven TLR rate of only 8.4%. No fractures were observed, although determination was difficult in some cases due to deployment in heavily calcified lesions.

Based on these recent registry studies, current-generation nitinol self-expanding stents have improved rates of primary patency, with low to zero rates of stent fractures and improved patient-reported outcomes.

RECENT DEVELOPMENTS IN SFA STENTS

SFA stent technologies continue to undergo significant improvement with a goal toward increased durability and conformability in the SFA and popliteal arteries with better long-term patency. The Supera stent (Abbott Vascular) is a recently approved stent with a novel woven design that results in improved flexibility, increased radial strength, and resistance to fracture. The SUPERB study reported a primary patency rate of 86% in the pivotal registry data submitted for US Food and Drug Administration approval.[10]

Other stent designs under investigation include the Tigris* stent (Gore & Associates), which has a nitinol wire frame with ePTFE coating and interconnecting ePTFE linking regions; the SMART Flex* stent (Flexible Stenting Solutions, acquired by Cordis Corporation), which has helical strut bands and flex bridges that provide flexibility while maintaining longitudinal integrity; and the BioMimics 3D* stent (Veryan Medical), which has a helical design that may promote laminar flow. This new generation of flexible stents may provide increased conformability and continue to improve outcomes of femoropopliteal stenting.

DRUG-ELUTING STENTS IN THE SFA

Initial studies of drug-eluting stents (DES) in the SFA were hampered by lack of clinical benefit compared to non-DES. These early DES included both sirolimus-eluting and everolimus-eluting designs using an earlier-generation stent platform.[11,12] Subsequently, a paclitaxel-eluting stent has shown significant benefit in the SFA in comparison to both balloon angioplasty and placement of a bare-nitinol self-expanding stent. The Zilver PTX (Cook Medical) is a nitinol scaffold stent with a polymer-free coating that elutes paclitaxel. 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 acute failure of balloon angioplasty.[13] At 1 year, the primary patency rate was 83% in the DES group and 32% for the PTA group. In the secondary randomization, 12-month primary patency with Zilver PTX was superior to Zilver BMS (89.9% vs 73%). These results support the superiority of the Zilver PTX stent over balloon angioplasty and an additional benefit of drug elution compared to Zilver without the drug coating.

Based on these results, DES provide significant promise for improving patency and long-term outcomes among

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patients with femoropopliteal occlusive disease. Further refinement of drug-eluting technology and application to new stent scaffolds and balloon technologies will significantly improve the outcomes of endovascular interventions in the SFA. ■

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