From the Society for Vascular Surgery

Evolution and current use of technology for superficial femoral and popliteal artery interventions for claudication

Peter A. Schneider, MD, *Honolulu, Hawaii*

ABSTRACT

An important facet in caring for patients with claudication is the development of a plan for managing the technology available for superficial femoral artery (SFA) and popliteal artery interventions. Although this is a field in evolution, clinical experience and data are emerging that assist the clinician in making informed choices as to the best method of endovascular treatment. Algorithms for SFA and popliteal artery interventions are developing. Methods for assessing a wide range of technologies are discussed. This article reviews the evolution of technology for SFA and popliteal artery interventions, describes the recent developments in data and clinical experiences, and discusses some potential methods of device assessment and incorporation into clinical practice. (J Vasc Surg 2017;66:916-23.)

Technology that supports interventions of the superficial femoral artery (SFA) and popliteal artery has evolved significantly in the past 20 years. As devices and the techniques for using them have become more sophisticated, several parallel developments have occurred. Extremely complex lesion morphology that could have been treated only with open surgery a couple decades ago can often be addressed by an endovascular approach. There is a growing and dedicated work force of clinicians that is continuously developing skills and knowledge to support lower extremity interventions. Open surgery is less likely to be the first choice for revascularization of the SFA and popliteal artery. The tools are available to fix most of the complications that are encountered during a procedure. Most lesions can be traversed. The vascular field is maturing with respect to study design and data accumulation. This evolution of the discipline has also resulted in the development and availability of multiple competing and complementary devices for the treatment of SFA and popliteal artery occlusive disease. Randomized trial data are available for balloon angioplasty (percutaneous transluminal angioplasty [PTA]), stents, drug-eluting stents (DESs), stent grafts, and drug-coated balloons (DCBs). The broad array of devices represents needed progress, but it also poses uncertainties about how they should be incorporated into clinical practice. As clinical experience and research accumulate, updated algorithms for SFA and popliteal artery interventions will develop. In the meantime, clinicians must confront the major challenge of assessing these technologies and incorporating them into practice paradigms. The purpose of this article was to review the evolution of technology for SFA and popliteal interventions and recent developments and to discuss some of the practicalities of device assessment and incorporation into clinical practice.

EVOLUTION OF VASCULAR CARE IN THE SFA AND POPLITEAL ARTERY

In the era when the only broadly functional tool was balloon angioplasty, in the early 1990s and before that, endovascular treatment was usually limited to the simplest lesion morphology.[1-3] Even then, open surgical bailout was sometimes required.[3-5] Long-term results were poor, and it was not possible to routinely manage occlusions of the SFA and popliteal artery using endovascular techniques.[5,6] Balloon angioplasty functions by creating dissections, and post-PTA dissection is associated with higher technical failure, worse patency, and more repeated revascularization.[7,8]

The development of balloon-expandable stents was a major milestone in the advancement of vascular care, but these were not particularly effective in the SFA and popliteal artery.[9] Self-expanding nitinol stents dramatically improved what could be offered to patients requiring treatment of the SFA and popliteal artery.[10-19] The compressible, flexible nature of these stents was more consistent with the highly dynamic infrainguinal arteries, and they could be used to manage the types of dissections produced by angioplasty, especially in treating occlusions and long lesions.[20,21] Since the first

From the Division of Vascular Therapy, Kaiser Foundation Hospital.

Author conflict of interest: P.A.S. received modest royalty for intellectual property from Cook.

Presented at the E. Stanley Crawford Critical Issues Forum of the 2016 Vascular Annual Meeting of the Society for Vascular Surgery, National Harbor, Md, June 8-11, 2016.

Correspondence: Peter A. Schneider, MD, Division of Vascular Therapy, Kaiser Foundation Hospital, 3288 Moanalua Rd, Honolulu, HI 96819 (e-mail: peterschneidermd@aol.com).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

Copyright © 2017 by the Society for Vascular Surgery. Published by Elsevier Inc.

http://dx.doi.org/10.1016/j.jvs.2017.05.110

Table. Nitinol stents approved by the Food and Drug Administration (*FDA*) for use in the superficial femoral artery (SFA)

Parameter	LifeStent RESILIENT	EverFlex DURABILITY II	Complete SE	Zilver PTX	Supera SUPERB	SMART	Misago	Innova	TIGRIS
FDA approval	2009	2012	2010	2012	2014	2012	2015	2015	2016
Subjects	206 (72 PTA)	287	196	479 (241 ZS/238 PTA)	264	250	261	299	274
Lesion length, mm	61.85 57.2 PTA	109.6 (minimum-maximum, 10.0-180.0)	61	54.6 53.2 PTA	78.1	77.3	84	93	108
Primary patency at 1 year, %	81.5 36.7 PTA	67.7	72.6	82.7 32.7 PTA	86.3	81.7	82.9	76.7	60.6 63.2 LifeStent
Freedom from TLR at 1 year, %	94.6 54.1 PTA	13.9	8.4	9.6 16.3 PTA	10	13	13	14.2	23.4
Design	2:1 RCT PTA	OPC	OPC	1:1 RCT PTA	OPC	OPC	OPC	OPC	3:1 RCT LifeStent

OPC, Optimal performance criteria; *PTA*, percutaneous transluminal angioplasty; *RCT*, randomized controlled trial; *TLR*, target lesion revascularization; *ZS*, Zilver stent.

clinically available self-expanding nitinol stent was Food and Drug Administration approved in 2009, multiple additional complementary developments have taken place that have changed the field and are discussed briefly. Ultimately, a number of different competing stents were developed and multiple trials were performed to evaluate them, usually comparing the stent with balloon angioplasty or with angioplasty optimal performance criteria (OPC; Table).[10-19]

Self-expanding stents improved on the patency that could be expected from angioplasty alone. The peak time frame for restenosis after balloon angioplasty is 6 months; with stents, the peak of restenosis is lower, and it is extended to approximately 12 months.[22,23] However, new problems were introduced, including in-stent restenosis, stent thrombosis, and stent fracture.[24,25] Partial solutions to some of these problems have emerged. The concept of the covered stent or stent graft was tested in several randomized trials in hopes of reducing in-stent restenosis.[26-28] A paclitaxel-coated stent was introduced.[14] The concept of drug delivery directly to the vessel wall of the SFA and popliteal artery through balloon angioplasty was also introduced and has shown promise.[7,29,30]

After many years of applying solutions to the SFA and popliteal artery that are based on mechanical solutions, cellular manipulation is now possible with the advent of drug delivery. The concept is that an antiproliferative medication could have a long-term beneficial effect in reducing the cellular response and inflammation that usually occur in response to intervention. The era of drug delivery to improve the potential for longer term patency has arrived. DESs and DCBs have been shown to have an effect that is sustained beyond the often-cited 1-year time frame for SFA-popliteal studies.[31,32]

Most occlusions of the SFA and popliteal artery can be traversed, even very long or heavily calcified lesions, because of further device and technique development in recent years. Devices that have made traversal of occlusions more readily reproducible include chronic total occlusion wires and catheters, re-entry devices, crossing catheters, and tools for retrograde access. However, we are still challenged with the ability to extend the patency of endovascular procedures to be competitive with femoral-popliteal bypass. The field continues to evolve and improve, but challenges remain, including reliable long-term patency, clear guidelines for management of calcification, and device comparisons for efficacy.

Long-term patency after intervention remains a question under active clinical research, and data beyond 12 months are developing. Patency data from both balloon angioplasty procedures and stent procedures demonstrate that beyond 1 year, the likelihood is high that there will be continued loss of patency. Because many SFA interventions are performed in patients with claudication and life span in claudicators is measured in decades, this long term is essential. Several important trials have reported multiyear follow-up, including the Edwards Lifesciences Self-Expanding Stent Peripheral Vascular Disease Study (RESILIENT); the SFA randomized trial of IN.PACT Admiral drug-eluting balloon vs standard PTA for the treatment of SFA and proximal popliteal arterial disease (IN.PACT); the GORE VIABAHN ENDOPROSTHESIS Peripheral Vascular Disease Study (VIBRANT); the U.S. Study for Evaluating Endovascular Treatments of Lesions in the Superficial Femoral Artery and Proximal Popliteal by Using the Protégé EverFlex Nitinol Stent

Download English Version:

https://daneshyari.com/en/article/5617655

Download Persian Version:

https://daneshyari.com/article/5617655

Daneshyari.com