Factors Affecting Reduction in SFA Stent Fracture Rates

From first-generation to new stents, examining how design has an impact on fracture rates in the SFA.

BY MARTIN WERNER, MD

The superficial femoral artery (SFA) is highly exposed to biomechanical forces occurring during leg movement. The superficial course of the artery, with crossing of flexion points as well as interaction with the surrounding musculature, exposes the artery to external forces, including compression, torsion, and elongation.[1] The implantation of metallic stents is standard for the treatment of SFA atherosclerotic disease; however, concerns exist about the potential for nitinol stents to fracture and the clinical implications of these stent fractures.[1] Some reports suggest that stent fractures are associated with a higher incidence of in-stent restenosis, thrombosis, or embolism.[2-4] Others do not report a significant association between stent fracture and clinical deterioration.[5,6-8]

Within the last few years, new stent designs have been developed to meet the demands in the SFA. This article reviews the factors leading to the reduction of SFA stent fracture rates in newer stent designs.

EVOLUTION OF FEMOROPOPLITEAL STENTS

First-generation balloon-expandable stainless steel stents did not perform well against the biomechanical stresses in the SFA due to their limited flexibility and susceptibility to permanent deformation from extrinsic pressure.[9] The failure of this approach led to the development of self-expanding shape-memory alloy stents. These alloys, usually nitinol, were more flexible and provided better stability and resistance to repeated stress. Based on the results of several randomized trials,[10-12] nitinol stents are now the mainstay in the treatment of femoropopliteal artery disease. However, nitinol stent fractures were observed in up to 20% of cases (Table 1).

For that reason, new stent designs were developed with the objective to reduce the incidence of stent fractures in the SFA.

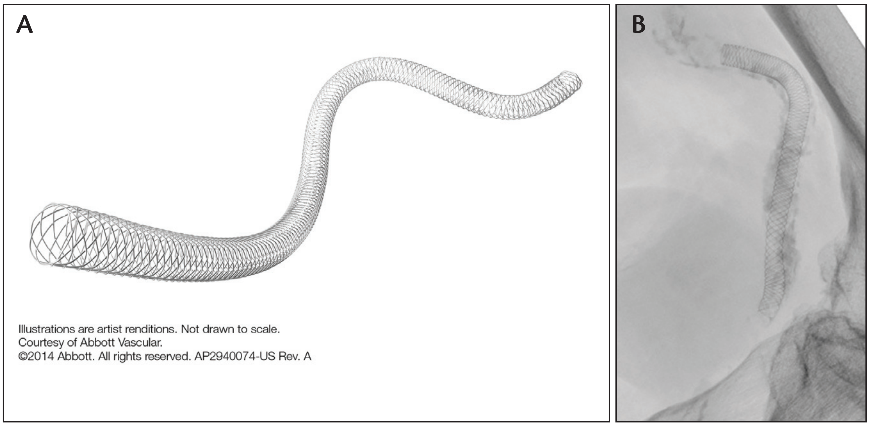


Figure 1. The Supera stent consists of six pairs of nitinol interwoven wires (A). Plain x-ray of the Supera stent in a calcified popliteal artery and distal SFA (B).

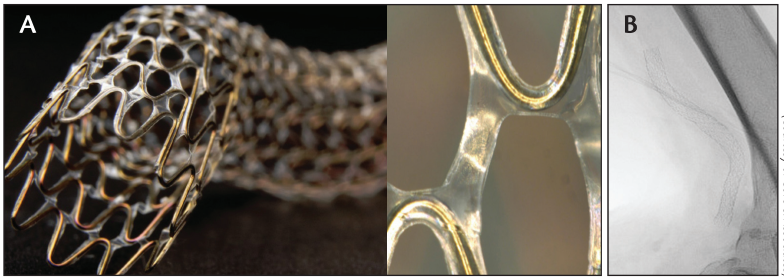
From a technical standpoint, the flexibility and adaptability of a stent is determined by the number and arrangement of the interconnectors between the stent struts, strut length, and strut cross-sectional shape, strut angles, stent material, and surface. New-generation nitinol stents, such as the EverFlex stent (Covidien), have gained better flexibility by a reduction of cell interconnections and spiral orientation of interconnections.

The SMART Vascular Stent (Cordis Corporation), for example, has a unique 36-strut, six-bridge construction with an offset peak-to-valley design providing smooth lumen and stent contourability without strut overlapping or fish scaling. The fracture rate in an unpublished trial was only 2% after 2-year follow-up (STROLL trial, data on file, Cordis Corporation).

Another new-generation stent is the Zilver stent (Cook Medical), which is also available as a drug-eluting stent (Zilver PTX).[13] Here, the manufacturers have paid special attention to improve the stent surface, thereby eliminating the imperfections that can lead to stent fractures (Table 1).

The EPIC stent (Boston Scientific Corporation) has radial tandem architecture combined struts of varying lengths, which allowed a reduction of connectors. Enhanced surface finishing processes might have additionally added to improved stent integrity, durability, and the 0% fracture rate after 1 year.[19]

Fracture rates are related to lesion length. In the FESTO registry,[22] the incidence of stent fractures increased with lesion length, and major stent fractures were associated with restenosis. This was also observed for the Everflex stent in the DURABILITY I study.[14] The Lifestent (Bard Peripheral Vascular, Inc.), for example, received FDA approval based on the results of the RESILIENT trial,[12] with a low 3.1% fracture rate (Table 1). The mean lesion length in this study was 7.1 cm. Another prospective trial, the STELLA study for long TASC C and D lesions,[5] investigated the same device in femoropopliteal lesions with a mean lesion length of 22 cm and reported a nearly 18% fracture rate. This clearly illustrates the direct correlation of lesion length and stent fracture rate.



(Courtesy of Gore & Associates)

Figure 2. The Tigris stent has a dual-component stent design (A). The close-up view shows the nitinol struts with PTFE interconnectors. Plain x-ray of the Tigris stent in the distal femoropopliteal segment (B).

TABLE 1. FRACTURE RATES IN CONTEMPORARY SFA STENTING TRIALS

Study	Year	Stent	No. of Patients	Lesion Length (cm)	12-Month Primary Patency (%)	Fracture Rate (%)
SIROCCO[8]	2006	SMART	46	8.1	68.1 (2 y)	20
FAST[11]	2007	Luminexx 3	101	4.5	68.3	12
DURABILITY I[14]	2009	Everflex	151	9.6	72.2	8.1
RESILIENT[12]	2010	Life Stent	134	7.1	81.3	3.1
ZILVER-PTX[13]	2011	Zilver PTX	241	6.6	83.1	0.9
MISAGO 2[15]	2012	Misago	744	6.4	87.6	3.1
STELLA[5]	2012	LifeStent	58	22	66	17.7
DURABILITY 200[16]	2011	Everflex	100	24.2	64.8	6
SUPERB[17]	2012	Supera	264	7.8	86.3	0
SUPERA 500[18]	2013	Supera	490	12.6	83.3	0
SUMMIT[19]	2013	Epic	100	7	85.1	0
VIBRANT[20]	2013	Viabahn	72	18	53	2.6
COMPLETE SE[21]	2014	Complete SE	196	6.1	72.6	0

CONCEPTS FOR IMPROVED BIOMECHANICAL COMPATIBILITY

The Supera Stent

The Supera stent (Abbott Vascular) (Figure 1) also offers a new stent design. This stent has been proven to be fracture resistant in several registries[18,23,24] and its US IDE trial.[25] The stent is not made from a laser-cut nitinol tube but rather consists of six pairs of nitinol interwoven wires formed in a helical pattern to provide improved radial and longitudinal characteristics, answering the need for a fracture-resistant stent with high flexibility and compression resistance. The longest follow-up was in the SUPERB IDE trial. At 1 year, in 264 patients there were no fractures. At 2 years, one fracture was detected; however, it is important to note that this patient had undergone directional atherectomy three times in the same vessel. Additional trial follow-up was obtained in the SUPERA-500 registry.[18] Follow-up radiographs of 304 stents, obtained in 229 patients at a mean follow-up of 16.6 months, confirmed the absence of stent fractures in 100% of examinations.

The Tigris Stent

Another novel approach in optimizing the stent architecture in the femoropopliteal segment is the dual-component design of the Tigris vascular stent (Gore & Associates) (Figure 2). This device consists of a helical spiral frame formed by a single nitinol wire. The helical segments of the frame are interconnected by fluoropolymers with heparin coating. The ePTFE bridges allow the segmental structures to be shifted against each other. This results in high flexibility, low straightening force, resistance to stent elongation, and the ability to absorb longitudinal forces.[25]

OTHER FACTORS

There is some evidence that occurrence of stent fractures is not only determined by the stent architecture and stent length but also by technique of implantation. In a post-hoc analysis of the DURABILITY I study, stent elongation occurred during implantation in 90% of all fractured stents.[14] The investigators argued that elongated stent placement increases the amount of continuous strain exerted on the stent struts, resulting in more fractures.

Furthermore, the implantation of multiple overlapping stents increases the axial stiffness of the stented segment. It is unclear if avoidance of stent overlap by using a single long stent instead of two shorter stents would result in a reduction of stent fractures.

SUMMARY

In general, the fracture rate reported in recent SFA trials has declined within the last few years (Table 1). Besides completely new stent designs, as described, manufacturers have also improved stent characteristics of slotted tube stents by reducing cell interconnections and spiral orientation of interconnections, as well as improved surface finishing processes. Avoidance of stent elongation during deployment may have also contributed to a decrease in stent fractures. However, although stent fracture rates in the SFA are declining to very low levels, restenosis remains an issue, and hampers the long-term success of stent-based treatment of the SFA. ■

Martin Werner, MD, is with the Department of Angiology, Hanusch Hospital, Vienna, Austria. He has disclosed no financial interest related to this article. Dr. Werner may be reached at office@viennavascular.at.

1. Scheinert D, Scheinert S, Sax J, et al. Prevalence and clinical impact of stent fractures after femoropopliteal stenting. J Am Coll Cardiol. 2005;45:312-315.
2. Rits J, van Herwaarden JA, Jahrome AK, et al. The incidence of arterial stent fractures with exclusion of coronary, aortic, and non-arterial settings. Eur J Vasc Endovasc Surg. 2008;36:339-345.
3. Adlakha S, Sheikh M, Wu J, et al. Stent fracture in the coronary and peripheral arteries. J Interv Cardiol. 2010;23:411-419.
4. Iida O, Nanto S, Uematsu M, et al. Effect of exercise on frequency of stent fracture in the superficial femoral artery. Am J Cardiol. 2006;98:272-274.
5. Davaine JM, Azema L, Guyomarch B, et al. One-year clinical outcome after primary stenting for trans-atlantic inter-society consensus (TASC) C and D femoropopliteal lesions (the STELLA "stenting long de l'artere femorale superficielle" cohort). Eur J Vasc Endovasc Surg. 2012;44:432-441.
6. Bosiers M, Deloose K, Callaert J, et al. One-year results with the Protege EverFlex 200-mm-long nitinol stent (ev3) in Trans-Atlantic inter-society consensus C and D femoropopliteal lesions: DURABILITY-200 study. J Vasc Surg. 2011;54:1042-1050.
7. Bosiers M, Torsello G, Gissler HM, et al. Nitinol stent implantation in long superficial femoral artery lesions: 12- month results of the DURABILITY I study. J Endovasc Ther. 2009;16:261-269.
8. Duda SH, Bosiers M, Lammer J, et al. Drug-eluting and bare nitinol stents for the treatment of atherosclerotic lesions in the superficial femoral artery: long-term results from the SIROCCO trial. J Endovasc Ther. 2006;13:701-710.
9. Heuser RR, Henry M. Textbook of peripheral vascular interventions. 2nd ed. London Boca Raton, FL: Informa Healthcare; Distributed in North and South America by Taylor & Francis; 2008.
10. 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.
11. Krankenberg H, Schluter M, Steinkamp HJ, et al. Nitinol stent implantation versus percutaneous transluminal angioplasty in superficial femoral artery lesions up to 10 cm in length: the femoral artery stenting trial (FAST). Circulation. 2007;116:285-292.
12. Laird JR, Katzen BT, Scheinert D, et al. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve month results from the RESILIENT randomized trial. Circ Cardiovasc Interv. 2010;3:267-276.
13. Dake MD, Ansel GM, Jaff MR, et al. Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month Zilver PTX randomized study results. Circ Cardiovasc Interv. 2011;4:495-504.
14. Bosiers M, Torsello G, Gissler HM, et al. Nitinol stent implantation in long superficial femoral artery lesions: 12-month results of the DURABILITY I study. J Endovasc Ther. 2009;16:261-269.
15. Schulte KL, Kralj I, Gissler HM, et al. MISAGO 2: one-year outcomes after implantation of the Misago self-expanding nitinol stent in the superficial and popliteal arteries of 744 patients. J Endovasc Ther. 2012;19:774-784.
16. Bosiers M, Deloose K, Callaert J, et al. Results of the Protégé EverFlex 200-mm-long nitinol stent (ev3) in TASC C and D femoropopliteal lesions. J Vasc Surg. 2011;54:1042-1050.
17. Garcia L. SUPERB Pivotal IDE Trial. 2-year update on the SUPERB study using an interwoven biomimetic nitinol stent in the SFA. Presented at LINC 2014, in Leipzig, Germany.
18. Werner M, Paetzold A, Banning-Eichenseer U, et al. Treatment of complex atherosclerotic femoropopliteal artery disease with a self-expanding interwoven nitinol stent: midterm results from the Leipzig SUPERA 500 registry. EuroIntervention. Published online ahead of print March 31, 2014.
19. Werner M, Piorkowski M, Thieme M, et al. SUMMIT registry: one-year outcomes after implantation of the EPIC self-expanding nitinol stent in the femoropopliteal segment. J Endovasc Ther. 2013;20:759-766.
20. Geraghty PJ, Mewissen MW, Jaff MR, Ansel GM; VIBRANT Investigators. Three-year results of the VIBRANT trial of VIABAHN endoprosthesis versus bare nitinol stent implantation for complex superficial femoral artery occlusive disease. J Vasc Surg. 2013;58:386-395.
21. Laird JR, Jain A, Zeller T, et al; Complete SE Investigators. Nitinol stent implantation in the superficial femoral artery and proximal popliteal artery: twelve-month results from the COMPLETE SE multicenter trial. J Endovasc Ther. 2014;21:202-212.
22. Scheinert D, Scheinert S, Sax J, et al. Prevalence and clinical impact of stent fractures after femoropopliteal stenting. J Am Coll Cardiol. 2005;45:312-315
23. Scheinert D, Grummt L, Piorkowski M, et al. A novel self-expanding interwoven nitinol stent for complex femoropopliteal lesions: 24-month results of the SUPERA SFA registry. J Endovasc Ther. 2011;18:745-752.
24. Scheinert D, Werner M, Scheinert S, et al. Treatment of complex atherosclerotic popliteal artery disease with a new self-expanding interwoven nitinol stent: 12-month results of the Leipzig SUPERA popliteal artery stent registry. JACC Cardiovasc Interv. 2013;6:65-71.
25. Piorkowski M, Freitas B, Schmidt A, et al. The use of the Gore Tigris Vascular Stent with dual component design in the superficial femoral and popliteal arteries at 6 months. J Cardiovasc Surg (Torino). 2013;54:447-453.