Title

Nitinol Self-Expanding Stents vs. Balloon Angioplasty for Very Long Femoropopliteal Lesions

Journal

Journal of Endovascular Therapy, 21(1)

ISSN

1526-6028

Authors

Armstrong, Ehrin J
Saeed, Haseeb
Alvandi, Bejan
et al.

Publication Date

2014-02-01

DOI

10.1583/13-4399mr.1

Peer reviewed

◆CLINICAL INVESTIGATION ◆

Nitinol Self-Expanding Stents vs. Balloon Angioplasty for Very Long Femoropopliteal Lesions

Ehrin J. Armstrong, MD, MSc[1]; Haseeb Saeed, MD[2]; Bejan Alvandi, BS[2]; Satinder Singh, MD[2]; Gagan D. Singh, MD[2]; Khung Keong Yeo, MBBS[2]; David Anderson, BA[2]; Gregory G. Westin, BA[2]; David L. Dawson, MD[3]; William C. Pevec, MD[3]; and John R. Laird, MD[2]

[1]Division of Cardiology, University of Colorado Denver and VA Eastern Colorado Healthcare System, Denver, Colorado, USA. [2]Division of Cardiovascular Medicine and the Vascular Center and [3]Division of Vascular and Endovascular Surgery and the Vascular Center, University of California, Davis Medical Center, Sacramento, California, USA.

Purpose: To compare the patency rates and clinical outcomes of balloon angioplasty vs. nitinol stent placement for patients with short (≤150 mm) as compared to long (>150 mm) femoropopliteal (FP) occlusive lesions.

Methods: Between 2006 and 2011, 254 patients (134 men; mean age 68 years) underwent FP angioplasty. The majority of patients (64%) were treated for critical limb ischemia. One hundred thirty-nine (55%) patients had short FP lesions ≤150 mm, while 115 patients had long FP lesions >150 mm. The mean lesion length was 78±43 mm in the short FP lesion group and 254±58 mm in the long FP lesion group. Duplex ultrasound follow-up with a peak systolic velocity ratio ≥2.0 was used to define restenosis.

Results: The overall procedure success rate was 98%. One hundred forty-eight (58%) patients underwent stent placement. The mean number of stents deployed for treatment of short FP lesions was 1.0±0.4 vs. 2.0±0.7 for long FP lesions ($p<0.001$). The primary patency rate of short FP lesions treated with balloon angioplasty vs. stenting was 66% vs. 63% at 1 year ($p=0.7$). For long FP lesions, the 1-year primary patency rates of balloon angioplasty vs. stenting were 34% vs. 49% ($p=0.006$). Balloon angioplasty of long FP lesions was also associated with significantly lower assisted primary and secondary patency compared to stenting ($p<0.05$ for all comparisons). Sustained clinical improvement was >90% at 30 days but declined to 62% to 75% at 1 year.

Conclusion: Balloon angioplasty and stent placement result in similar patency rates and clinical outcomes for shorter to medium-length FP lesions. In comparison, stent placement in long FP lesions is associated with superior outcomes to balloon angioplasty, even when multiple stents are required. Procedure success and clinical improvement can be achieved in the majority of patients, but rates of restenosis remain high.

J Endovasc Ther. 2014;21:34–43

Key words: peripheral artery disease, superficial femoral artery, popliteal artery, femoropopliteal segment, stenosis, chronic total occlusion, critical limb ischemia, nitinol stent, balloon angioplasty, lesion length, restenosis

◆ ◆

John Laird is a consultant for and advisory board member of Boston Scientific, Covidien, Abbott, Bard Peripheral Vascular, and Medtronic. Khung-Keong Yeo is on the Speaker's Bureau of Abbott Vascular and has received research funding from Medtronic. All other authors declare no association with any individual, company, or organization having a vested interest in the subject matter/products mentioned in this article.

Corresponding author: John R. Laird, MD, Professor of Medicine, Medical Director of the Vascular Center, UC Davis Medical Center, 4860 Y Street, Suite 3400, Sacramento, CA 95817 USA. E-mail: *john.laird@ucdmc.ucdavis.edu*

Endovascular management of femoropopliteal (FP) lesions is increasingly common, both for intermittent claudication and for limb preservation among patients with critical limb ischemia (CLI). Early studies reported that a strategy of balloon angioplasty is a reasonable approach to treatment, especially for lesions <50 mm in length.[1] Initial investigations of FP stenting were also limited by high rates of fracture and restenosis with early-generation stents.[2,3] In comparison, recent trials with newer generation self-expanding nitinol stents have reported that FP stenting has superior long-term outcomes compared to balloon angioplasty, with excellent freedom from target lesion revascularization (TLR) up to 3 years.[4–6] Most clinical trials of stents have included only lesion lengths <150 mm. Some recent studies have reported outcomes of stent placement for FP lesion lengths >150 mm, but most of these studies lack a balloon angioplasty comparator group.[7–9] Numerous analyses have suggested a linear relationship between lesion length and risk of restenosis, but the applicability of these findings to real-world practice is uncertain.[9–12] Better understanding of contemporary outcomes after endovascular management of long FP lesions will help guide optimal management of these complex patients.

In this study, we examined the outcomes of FP angioplasty and stenting as a function of lesion length. We hypothesized that angioplasty vs. stent placement would yield similar results for short FP lesions, but that stent placement would be superior for long FP lesions. To address these questions, we studied a contemporary, real-world cohort of patients with both claudication and CLI.

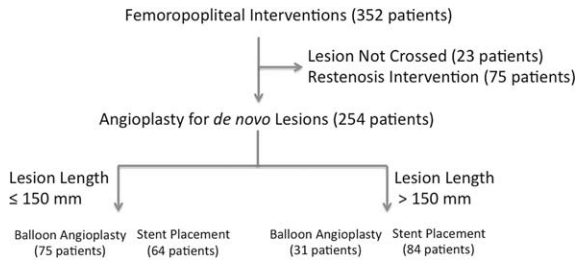

Figure 1 ◆ Study cohort.

METHODS

Patient Cohort

The PAD-UCD Registry consists of all patients with a clinical diagnosis of peripheral artery disease (PAD) who underwent diagnostic angiography or therapeutic endovascular intervention at the University of California Davis Medical Center since June 2006, as previously described.[13] At the time of data analysis, the registry included 975 patients who had undergone a total of 1490 procedures. During the study period, 352 patients underwent endovascular interventions to FP lesions; of these, 254 patients (134 men; mean age 68 years) had balloon angioplasty or stent placement for treatment of de novo FP lesions (Fig. 1). The baseline characteristics of the cohort are summarized in Table 1. The majority of patients (64%) in the overall cohort underwent intervention for treatment of CLI. One hundred thirty-nine (55%) patients had FP lesion lengths ≤150 mm ("short" FP lesions), while 115 (45%) had FP lesion lengths >150 mm ("long" FP lesions).

Study Devices and Procedures

All patients were administered aspirin 325 mg before the procedure and a 300 to 600-mg loading dose of clopidogrel before or at the conclusion of the intervention. Once the decision was made to perform endovascular intervention, intravenous heparin was administered to maintain an activated clotting time >250 seconds. Balloon angioplasty of FP lesions was performed using long inflation times (2–3 minutes) with a balloon matched to the reference vessel diameter. In the case of adequate angiographic results (no flow-limiting dissection and residual stenosis <30%), balloon angioplasty alone was considered acceptable. In the case of residual dissection or significant recoil, a nitinol self-expanding stent was placed. Primary stenting was also performed in some cases at the discretion of the operator. The stent type used was also at the discretion of the operator and included Flexstar (Bard Peripheral Vascular Inc., Tempe, AZ, USA), EverFlex (Covidien, Mansfield, MA, USA), S.M.A.R.T. (Cordis Inc.,

TABLE 1
Baseline Patient Characteristics

	Length ≤150 mm			Length >150 mm		
	Balloon Angioplasty (n=75)	Stent (n=64)	p	Balloon Angioplasty (n=31)	Stent (n=84)	p
Age, y	67±12	67±12	0.8	68±12	70±11	0.4
Men	41 (55%)	32 (50%)	0.6	14 (45%)	47 (56%)	0.3
BMI, kg/m^2	27±5	28±6	0.2	27±3	28±5	0.8
Heart failure	14 (19%)	18 (30%)	0.1	10 (32%)	26 (31%)	0.9
Diabetes	45 (61%)	37 (59%)	0.8	19 (63%)	50 (60%)	0.7
Prior smoker	46 (62%)	45 (71%)	0.3	22 (73%)	67 (83%)	0.3
GFR, mg/dL	62±36	68±35	0.3	51±39	60±36	0.2
Hypertension	65 (87%)	57 (89%)	0.7	29 (93%)	73 (87%)	0.3
CAD	38 (51%)	36 (57%)	0.4	17 (57%)	33 (39%)	0.1
Stroke	14 (19%)	7 (11%)	0.2	7 (23%)	17 (20%)	0.8
Statin use	52 (69%)	40 (63%)	0.4	25 (81%)	56 (67%)	0.1
Rutherford category						
1–3	29 (39%)	23 (36%)	0.7	8 (26%)	32 (38%)	0.2
4–6	46 (61%)	41 (64%)		23 (74%)	52 (62%)	
Ankle-brachial index	0.58±0.17	0.66±0.24	0.08	0.55±0.15	0.53±0.16	0.7
Toe-brachial index	0.29±0.14	0.37±0.17	0.09	0.24±0.12	0.34±0.14	0.09

Continuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage).
BMI: body mass index, GFR: glomerular filtration rate, CAD: coronary artery disease.

Miami, FL, USA), Absolute (Abbott Vascular, Santa Clara, CA, USA), and Epic (Boston Scientific, Natick, MA, USA) stents. In cases where multiple stents were required, institutional practice was to use the longest stents possible in order to minimize the number of overlap zones and the total number of stents placed. Postdilation of the stent was then routinely performed using a balloon sized to the reference vessel. Patients were continued on aspirin at a dose ≥81 mg daily and clopidogrel 75 mg daily post procedure.

Data Collection

Baseline data were collected from review of electronic medical record documentation and procedure notes. Pre- and post-procedure clinical notes and the admission history and physical documentation were used to identify clinical presentation as well as post-procedure outcomes and medical management. Quantitative vascular angiography (Xcelera; Philips Inc., Amsterdam, The Netherlands) was performed on all target lesions to evaluate the pre- and post-intervention percent diameter stenosis, lesion length, and reference vessel diameter. Two cardiologists (E.A. and G.S.) reviewed all angiographic images to verify lesion location, presence of chronic total occlusion (CTO), extent of calcification, presence of thrombus, and status of the distal runoff vessels. For the purposes of analysis, FP lesions were dichotomized into short (≤150 mm) and long (>150 mm) length lesions. Both lesion length and total stented length were quantified.

Procedure data included the type of intervention, the type and number of stents placed, and whether the intervention involved adjunctive cutting balloon angioplasty, atherectomy, or cryoplasty. Procedure success was defined as <30% stenosis without major adverse event (MAE). Patients were routinely seen 30 days after the revascularization procedure. This visit included an assessment of the patient's clinical improvement as well as interval ankle-brachial index (ABI) measurement and duplex ultrasound (DUS). Postoperative follow-up, consisting of a clinical examination and serial DUS, was then conducted every 3 to 6 months during the first year and every 6 to 12 months thereafter.

Restenosis was defined as the presence of >50% stenosis at the treatment site (peak systolic velocity ratio >2.0) or by TLR. Primary patency was defined as a patent artery or stent without recurrent stenosis or the need for further intervention. Assisted primary patency was defined as continued patency after reintervention for stenosis, and secondary patency was defined as continued patency after reintervention for occlusion. Continuous clinical improvement was defined as improvement in Rutherford category by ≥1 level with a concomitant increase in ABI by ≥0.15 and no need for TLR.[14] Major amputation was defined as any amputation above the level of the ankle joint.

Outcomes and Data Analysis

The primary outcome measure was primary patency. Secondary outcomes included TLR (repeat intervention to the treated region), assisted primary patency, secondary patency, major amputation, and death.

Mean values with standard deviations were used to describe continuous variables, and numerical values (percentages) were used for categorical variables. Continuous variables were compared using the Mann-Whitney rank sum test. Categorical values were compared using the chi-square or Fisher exact test. Restenosis, TLR, freedom from major amputation, and survival rates were estimated using Kaplan-Meier survival analysis and log-rank test. All analyses were performed using STATA (version 11.2; STATA Corporation, College Station, TX, USA). $P<0.05$ was considered significant.

RESULTS

Baseline demographic characteristics, including prevalence of diabetes and smoking status, were not significantly different between patients who underwent balloon angioplasty only vs. those who underwent stent placement. Patients in the short FP lesion group who had successful balloon angioplasty had slightly shorter lesions (66±40 vs. 93±41 mm, $p<0.001$) than those treated with stent placement, but there was no difference in lesion length among patients with long FP lesions (247±59 for balloon angioplasty vs. 257±59 mm for stent placement, p=0.4). Preprocedure stenosis was similar among all groups. The presence of a CTO ranged from 30% to 63%, with CTOs most common in the long FP patients who underwent stent placement. Lesions treated with balloon angioplasty were more likely to extend into both the superficial femoral artery (SFA) and popliteal arteries (47% vs. 27%, p=0.01). The baseline infrapopliteal runoff did not differ between the groups. Additional outflow angioplasty was performed in 62 (25%) patients overall and exclusively among the subgroup of patients with CLI (Table 2).

Among patients who were treated with a self-expanding nitinol stent, Flexstar and EverFlex stents were the most common (Table 3). The stent type did not differ significantly for treatment of short vs. long FP lesions. The mean number of stents deployed for treatment of short FP lesions was 1.0±0.4, while long FP lesions had an average of 2.0±0.7 stents deployed ($p<0.001$). The total stent length was 110±45 mm in the short FP lesion group and 240±109 mm in the long FP lesion group ($p<0.001$). Adjunctive therapies, including cutting balloon angioplasty, cryotherapy, or laser atherectomy, were performed in only a small number of cases.

The overall procedure success rate was 98%, with low overall rates of distal embolization or perforation and no significant differences between groups (Table 4). The mean post-procedure ABI was >0.90 for both balloon angioplasty and stenting of short FP lesions (p=0.8), but was significantly lower for patients with long FP lesions who underwent balloon angioplasty (mean ABI 0.82±0.16 for balloon angioplasty vs. 0.93±0.15 for stenting, p=0.02). Follow-up ABI values were available for 102 patients at 1 year. There were no significant differences in ABIs between groups at 1 year, with mean values ranging from 0.79 to 0.85 (Table 4). Sustained clinical improvement was >90% at 30 days for all groups and ranged from 61% to 79% at 1 year, with no significant between-group differences.

During routine DUS follow-up, the primary patency rates of short FP lesions treated with

TABLE 2
Angiographic Characteristics

	Length ≤150 mm			Length >150 mm		
	Balloon Angioplasty (n=75)	Stent (n=64)	p	Balloon Angioplasty (n=31)	Stent (n=84)	p
Lesion length, mm	66±40	93±41	<0.001	247±59	257±59	0.4
Proximal reference diameter, mm	4.9±0.9	5.6±0.6	<0.001	4.8±0.8	5.6±0.7	<0.001
Preprocedure stenosis, %*	79.2%±11.8%	81.0%±7.3%	0.3	82.0%±10.0%	86.3%±5.8%	0.09
Lesion location						
SFA only	27 (37%)	37 (58%)	0.01	24 (77%)	40 (48%)	0.02
SFA and popliteal	47 (64%)	27 (42%)		7 (23%)	44 (52%)	
Total occlusion	22 (30%)	20 (31%)	0.8	12 (39%)	52 (63%)	0.02
Occlusion length, mm	61±41	52.0±18.6	0.3	140±97	180.7±82.3	0.08
Calcification						
None-mild	43 (81%)	37 (80%)	0.9	18 (82%)	30 (61%)	0.09
Moderate-severe	10 (19%)	9 (20%)		4 (18%)	10 (39%)	
Runoff vessels						
0–1	32 (56%)	25 (43%)	0.5	12 (42%)	24 (32%)	0.5
2–3	26 (44%)	33 (57%)		17 (58%)	51 (68%)	
Inflow angioplasty	2 (3%)	10 (16%)	0.01	3 (10%)	11 (13%)	0.8
Outflow angioplasty	31 (42%)	16 (25%)	0.05	7 (23%)	8 (10%)	0.1
Fluoroscopy time, min	27±15	32±16	0.07	36±20	40±18	0.4
Total contrast, mL	167±69	208±92	0.006	186±82	195±87	0.6

Continuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage).
SFA: superficial femoral artery.
* Excluding patients with chronic total occlusion.

balloon angioplasty vs. stenting were 66% vs. 63% at 1 year (p=0.7, Fig. 2A). For long FP lesions, the 1-year primary patency rate of balloon angioplasty vs. stenting were 34% vs. 49% (p=0.006, Fig. 2B). One-year assisted primary patency for short FP lesions was 75% for balloon angioplasty vs. 77% for stent placement (p=0.8, Fig. 2C). Assisted primary

TABLE 3
Procedural Characteristics Among Patients Undergoing Nitinol Self-Expanding Stent Placement

Variable	Length ≤150 mm (n=64)	Length >150 mm (n=84)	p
Type of stent			
Flexstar	30 (47%)	47 (56%)	0.2
EverFlex	15 (23%)	25 (30%)	
S.M.A.R.T.	8 (13%)	4 (5%)	
Absolute	6 (9%)	4 (5%)	
Other	5 (8%)	4 (4%)	
Total number of stents	1.0±0.4	2.0±0.7	<0.001
Total stent length, mm	110±45.2	240±109	<0.001
Postprocedure stenosis	5.0±6.1	5.5±4.2	0.5
Adjunctive therapies			
Cutting balloon	3 (5%)	0	0.08
Cryoplasty	1 (2%)	2 (2%)	0.9
Laser atherectomy	1 (2%)	4 (5%)	0.3

Continuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage).

TABLE 4
Procedural and Clinical Outcomes

	Balloon Angioplasty (n=75)	Stent (n=64)	p	Balloon Angioplasty (n=31)	Stent (n=84)	p
Procedure success	72 (97%)	64 (100%)	0.2	30 (97%)	83 (99%)	0.5
Perforation	0	1 (2%)	0.5	2 (6%)	2 (2%)	0.3
Distal embolization	0	1 (2%)	0.5	0	2 (2%)	0.5
ABI at 30 days	0.92±0.18	0.90±0.23	0.8	0.82±0.16	0.93±0.15	0.03
ABI at 1 year	0.82±0.23	0.85±0.21	0.6	0.79±0.27	0.79±0.20	0.9
Sustained clinical improvement at 30 days	70/75 (93%)	58/64 (91%)	0.9	29/31 (94%)	81/84 (96%)	0.8
Sustained clinical improvement at 1 year	34/43 (79%)	28/46 (61%)	0.06	12/16 (75%)	35/57 (62%)	0.3
Major amputation at 1 year	5/75 (7%)	1/64 (2%)	0.2	4/31 (13%)	6/84 (7%)	0.5

Continuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage).
ABI: ankle-brachial index.

patency was lower for long FP lesions treated with balloon angioplasty vs. stenting (45% vs. 65%, p=0.001, Fig. 2D). Secondary patency was 76% vs. 83% (p=0.5) for short FP lesions (Fig. 2E) and 57% vs. 78% (p=0.004) for long FP lesions (Fig. 2F) at 1 year. There was no significant difference in the rates of restenosis or overall patency for patients who underwent stenting for claudication vs. CLI.

Among the subgroup of patients with CLI, the freedom from major amputation at 1 year was 92%, with limb salvage rates of 97% for patients with short FP lesions and 86% for patients with long FP lesions. There was no significant difference in amputation rates in the balloon angioplasty vs. stenting groups. None of the patients who underwent FP interventions for claudication required subsequent major amputation or surgical bypass grafting. During 1-year follow-up, there were 29 deaths, all in the subgroup of patients with CLI (19%).

DISCUSSION

In this study, we compared the outcomes of balloon angioplasty vs. stenting for short (≤150 mm) as well as long (>150 mm) FP lesions. A significant percentage (45%) of the overall cohort had lesions >150 mm, and the mean length of that group was over 250 mm, emphasizing the clinical importance of better understanding outcomes after treatment of long FP lesions. The technical success rate was high, with a very low complication rate despite the presence of complex disease with long segments of occlusion. For short FP lesions, we found no significant difference in patency rates over 1-year follow-up for balloon angioplasty vs. stent placement. In comparison, stenting of very long FP lesions was associated with superior patency compared to balloon angioplasty, with significantly higher rates of primary, assisted primary, and secondary patency. These results suggest that stent placement may the preferred strategy for treatment of very long FP lesions, even if an adequate angiographic result is achieved with balloon angioplasty.

A number of recent studies have reported the outcomes of FP stenting for shorter lesion lengths. In the RESILIENT trial,[4] the 1-year primary patency rate was 81.3%. These results remained favorable during extended follow-up, with a 3-year TLR rate of 24.5%.[5] Similar results have been reported in large registries of nitinol self-expanding and interwoven (e.g., Supera) stents, with primary patency rates ranging from 71% to 85% at 1 year.[8,9] The short FP lesions ≤150 mm in length from our study had lesion lengths averaging 93 mm, which is comparable to or longer than the lesion lengths studied in most previous trials but similar to the lesion length in DURABILITY II, which reported 1-year primary patency of 67.7%.[15] In this regard, our reported primary patency of 63% is consistent with prior studies. Other reasons

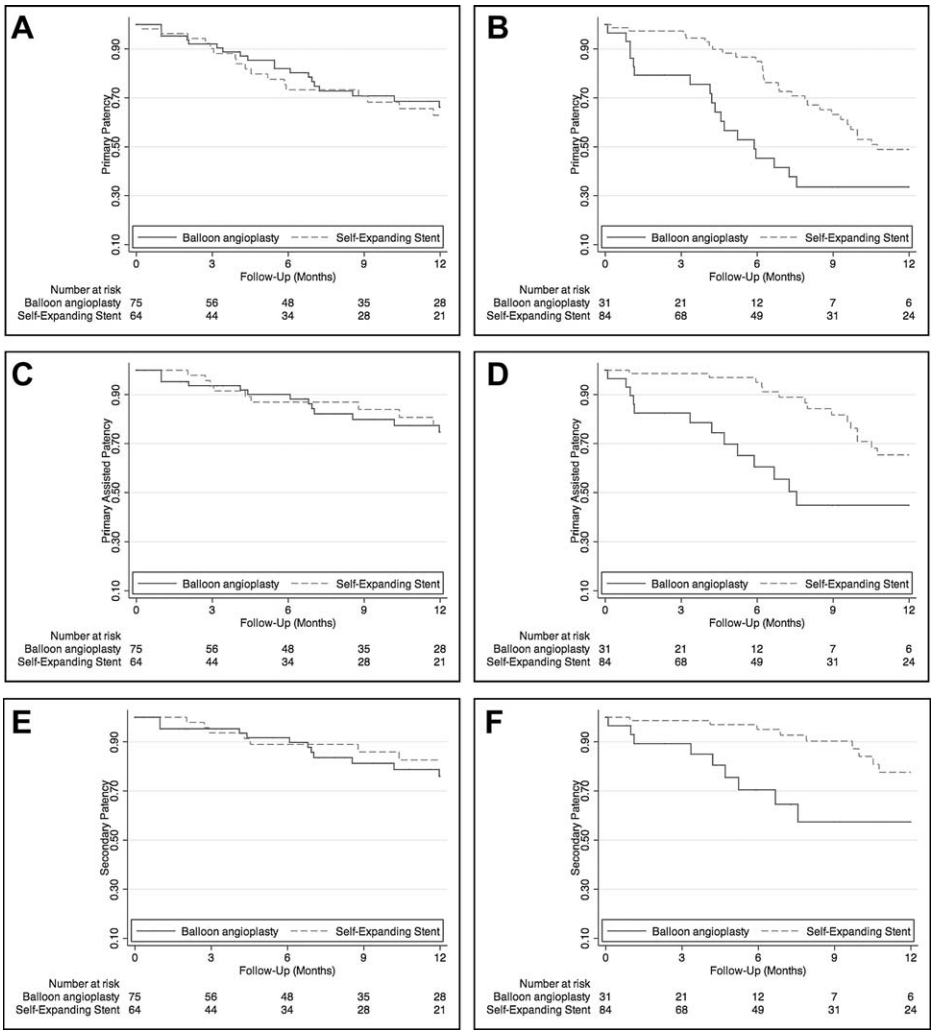

Figure 2 ◆ (**A**) Primary patency for lesions ≤150 mm; there was no significant difference in 1-year primary patency. For lesions >150 mm (**B**), nitinol stent placement was associated with improved 1-year primary patency (p=0.006). (**C**) Assisted primary patency was similar at 1 year for lesions ≤150 mm and (**D**) significantly higher (p=0.001) for stent placement in lesions >150 mm. (**E**) In lesions ≤150 mm, secondary patency did not differ for balloon angioplasty vs. stent placement at 1 year. For lesions >150 mm (**F**), balloon angioplasty was associated with significantly lower (p=0.004) secondary patency.

for the lower patency rate may also include the high percentage of patients with CLI, as well as the use of a peak systolic velocity ratio of 2.0 (rather than 2.5) to define duplex-derived restenosis. Interestingly, the results of this study are similar to the recently reported SUPER study,[16] which found no difference between primary stenting and balloon angioplasty for complex FP lesions (primarily CTOs), with a mean lesion length of ~120 mm. The relatively good performance of balloon angioplasty for shorter lesions in our cohort also reflects the fact that patients with an initial suboptimal angiographic result underwent stent placement.

In comparison to FP lesions <150 mm in length, little data are available on the outcomes of patients with longer lesions. The DURABILITY-200 study included 100 patients with an average lesion length of 242 mm who were treated with at least one 200-mm-long EverFlex stent.[17] The primary patency rate at 12 months was 64.8%, with a TLR rate of 32%. The STELLA study of TASC (TransAtlantic

Inter-Society Consensus) C and D FP lesions also reported a primary patency rate of 66% among patients with a median lesion length of 220 mm.[12] A separate study of TASC C/D FP lesions reported high procedure success and clinical improvement, but stents were utilized in only a minority of these patients.[18] Our subgroup of patients with lesions >150 mm long is comparable to the patient cohorts from these studies with the exception that only a minority (29%) of patients in the DURABILITY-200 study had CLI.[17] The CTO status of patients was also not specifically reported in any of the above trials. In our study, the majority (63%) of patients in the >150-mm stent subgroup had FP CTOs, which are independently associated with a higher rate of in-stent restenosis.[19]

The current rates of restenosis and lack of long-term sustained clinical improvement for very long FP lesions emphasize the need for improved technologies for these challenging lesion subsets. Other emerging endovascular treatment options for very long FP lesions include endoluminal bypass with polytetrafluoroethylene (PTFE)-covered nitinol stents, drug-eluting stents, or drug-coated balloons. The VIPER trial included patients with TASC C/D FP lesions (mean lesion length 190 mm) who underwent placement of PTFE-covered nitinol stents.[20] The primary patency rate with this approach was 73% and the patency rates were significantly higher (88%) if the device was not oversized. The VIASTAR trial[21] found improved patency with PTFE-covered stents compared to bare nitinol stents. The lesion lengths in the VIASTAR trial were also longer than previous trials (mean 19.0±6.3 cm for PTFE-covered stents vs. 17.3±6.6 cm for bare stents). These results suggest that newer iterations of the Viabahn endoprosthesis may have significant clinical application for very long FP lesions.

Additional approaches, including the use of drug-eluting stents or drug-coated balloons, may also have specific application to long FP lesions.[11,22–24] A substudy of the Zilver paclitaxel-eluting SFA stent examined outcomes among 135 lesions with a mean length of 226 mm.[7] The authors reported a 12-month primary patency rate of 77.6% and 85.4% freedom from TLR. Preliminary results therefore suggest that these new technologies offer the potential advantage of decreased restenosis rates relative to nitinol stents, which should be studied in future trials.

The current TASC II guidelines[25] recommend a surgical approach for TASC II C/D lesions. The lesions in the long FP lesion subgroup were all TASC C/D due to either lesion length or the presence of a long CTO segment. While the rates of restenosis and TLR were high in the long FP lesion group, the rate of major amputation among patients with CLI and long FP lesions was 14% at 1 year. This represents an amputation rate that meets current objective performance goals for CLI and suggests that stenting of these lesions may have significant efficacy while obviating the need for surgical bypass.[26] In comparison, other groups have reported higher failure rates after stenting of TASC C/D lesions in patients with CLI and that such failure may negatively impact surgical options. Gur et al.[27] reported that endovascular stenting of TASC C/D lesions may limit future surgical bypass options. Al-Nouri et al.[28] also reported a negative impact of stent failure in TASC D lesions on subsequent surgical graft patency. Because none of these patients was randomized to stenting vs. surgery, it remains unclear whether the worse clinical outcomes among patients with TASC C/D lesions reflect greater severity of underlying atherosclerotic disease vs. a negative impact of endovascular treatment on subsequent limb outcomes. Future studies should carefully assess distal vessel runoff and the impact of endovascular intervention on the feasibility of subsequent surgical bypass.

Limitations

First, this was an observational cohort study in which the operator determined treatment; we therefore did not prospectively define criteria for stent placement after balloon angioplasty. It is possible that additional confounders, such as operator interpretation of suboptimal angioplasty result and the type of adjunctive therapies performed, may have influenced the decision to place a stent and the total length of stent placed.

Second, the subjects in this study who underwent stent placement were primarily treated with uncovered nitinol self-expanding stents, and a mixture of stent types was used. We therefore cannot make any conclusions regarding a specific stent type and subsequent outcomes.

Third, plain films of the stent were not mandated as part of usual clinical practice during follow-up, so neither the prevalence of stent fracture nor the long-term clinical outcomes of stent placement could be assessed. However, these results do represent a real-world cohort that is understudied in clinical trials (long lesions, high prevalence of CLI).

Conclusion

Balloon angioplasty vs. stent placement resulted in similar rates of restenosis and clinical outcomes for FP lesions $\leq$150 mm, but stent placement was associated with superior outcomes for lesions $>$150 mm. Although procedure success rates are high, with associated early clinical improvement, the 1-year rates of restenosis and TLR remain elevated. Among patients with CLI, the "endovascular first" approach to treating very long FP lesions results in excellent freedom from major amputation.

REFERENCES

1. 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.
2. Schlager O, Dick P, Sabeti S, et al. Long-segment SFA stenting—the dark sides: in-stent restenosis, clinical deterioration, and stent fractures. *J Endovasc Ther*. 2005;12:676–684.
3. Scheinert DD, Scheinert SS, Sax JJ, et al. Prevalence and clinical impact of stent fractures after femoropopliteal stenting. *J Am Coll Cardiol*. 2005;45:312–315.
4. 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.
5. Laird JR, Katzen BT, Scheinert D, et al. Nitinol stent implantation vs. balloon angioplasty for lesions in the superficial femoral and proximal popliteal arteries of patients with claudication: three-year follow-up from the RESILIENT randomized trial. *J Endovasc Ther*. 2012;19:1–9.
6. Schillinger M, Sabeti S, Dick P, et al. Sustained benefit at 2 years of primary femoropopliteal stenting compared with balloon angioplasty with optional stenting. *Circulation*. 2007;115:2745–2749.
7. Bosiers M, Peeters P, Tessarek J, et al. The Zilver PTX single arm study: 12-month results from the TASC C/D lesion subgroup. *J Cardiovasc Surg (Torino)*. 2013;54:115–122.
8. 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.
9. 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.
10. Dick P, Wallner H, Sabeti S, et al. Balloon angioplasty versus stenting with nitinol stents in intermediate length superficial femoral artery lesions. *Catheter Cardiovasc Interv*. 2009;74:1090–1095.
11. 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.
12. Davaine JM, Azéma 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'Artère fémorale superficielle" Cohort). *Eur J Vasc Endovasc Surg*. 2012;44:432–441.
13. McCoach CE, Armstrong EJ, Singh S, et al. Gender-related variation in the clinical presentation and outcomes of critical limb ischemia. *Vasc Med*. 2013;18:19–26.
14. Diehm N, Baumgartner I, Jaff M, et al. A call for uniform reporting standards in studies assessing endovascular treatment for chronic ischaemia of lower limb arteries. *Eur Heart J*. 2007;28:798–805.
15. Matsumura JS, Yamanouchi D, Goldstein JA, et al. The United States study for evaluating endovascular treatments of lesions in the superficial femoral artery and proximal popli-

teal by using the Protégé Everflex Nitinol Stent System II (DURABILITY II). *J Vasc Surg*. 2013; 58:73–83.
16. Chalmers N, Walker PT, Belli A-M, et al. Randomized trial of the SMART stent versus balloon angioplasty in long superficial femoral artery lesions: The SUPER Study. *Cardiovasc Intervent Radiol*. 2012;36:353–361.
17. 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.
18. Rabellino M, Zander T, Baldi S, et al. Clinical follow-up in endovascular treatment for TASC C-D lesions in femoro-popliteal segment. *Catheter Cardiovasc Interv*. 2009;73:701–705.
19. Iida O, Uematsu M, Soga Y, et al. Timing of the restenosis following nitinol stenting in the superficial femoral artery and the factors associated with early and late restenoses. *Catheter Cardiovasc Interv*. 2011;78:611–617.
20. Saxon R, Chervu A, Jones P, et al. Heparin-bonded, expanded polytetrafluoroethylene-lined stent graft in the treatment of femoropopliteal artery disease: 1-year results of the VIPER (Viabahn Endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease) trial. *J Vasc Interv Radiol*. 2013;24:165–174.
21. Lammer J, Zeller T, Hausegger K, et al. Heparin-bonded covered stents versus bare metal stents for complex femoro-popliteal artery lesions: the randomized VIASTAR trial. *J Am Coll Cardiol*. 2013;epub ahead of print
22. Dake MD, Scheinert D, Tepe G, et al.; Zilver PTX Single-Arm Study Investigators. Nitinol stents with polymer-free paclitaxel coating for lesions in the superficial femoral and popliteal arteries above the knee: twelve-month safety and effectiveness results from the Zilver PTX single-arm clinical study. *J Endovasc Ther*. 2011;18:613–623.
23. Tepe G, Zeller T, Albrecht T, et al. Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. *N Engl J Med*. 2008;358:689–699.
24. Werk M, Langner S, Reinkensmeier B, et al. Inhibition of restenosis in femoropopliteal arteries: paclitaxel-coated versus uncoated balloon: femoral paclitaxel randomized pilot trial. *Circulation*. 2008;118:1358–1365.
25. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). *J Vasc Surg*. 2007;45:S5–S67.
26. Conte MS. Understanding objective performance goals for critical limb ischemia trials. *Semin Vasc Surg*. 2010;23:129–137.
27. Gur I, Lee W, Akopian G, et al. Clinical outcomes and implications of failed infrainguinal endovascular stents. *J Vasc Surg*. 2011;53: 658–667.
28. Al-Nouri O, Krezalek M, Hershberger R, et al. Failed superficial femoral artery intervention for advanced infrainguinal occlusive disease has a significant negative impact on limb salvage. *J Vasc Surg*. 2012;56:106–112.