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Balloon Angioplasty versus Implantation of Nitinol Stents in the Superficial Femoral Artery

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ABSTRACT

BACKGROUND

Because stent implantation for disease of the superficial femoral artery has been associated with high rates of late clinical failure, percutaneous transluminal angioplasty is preferred for endovascular treatment, and stenting is recommended only in the event of suboptimal technical results. We evaluated whether primary implantation of a self-expanding nitinol (nickel–titanium) stent yielded anatomical and clinical benefits superior to those afforded by percutaneous transluminal angioplasty with optional secondary stenting.

METHODS

We randomly assigned 104 patients who had severe claudication or chronic limb ischemia due to stenosis or occlusion of the superficial femoral artery to undergo primary stent implantation (51 patients) or angioplasty (53 patients). Restenosis and clinical outcomes were assessed at 6 and 12 months.

RESULTS

The mean (\pm SD) length of the treated segment was 132 ± 71 mm in the stent group and 127 ± 55 mm in the angioplasty group. Secondary stenting was performed in 17 of 53 patients (32 percent) in the angioplasty group, in most cases because of a suboptimal result after angioplasty. At 6 months, the rate of restenosis on angiography was 24 percent in the stent group and 43 percent in the angioplasty group ($P=0.05$); at 12 months the rates on duplex ultrasonography were 37 percent and 63 percent, respectively ($P=0.01$). Patients in the stent group were able to walk significantly farther on a treadmill at 6 and 12 months than those in the angioplasty group.

CONCLUSIONS

In the intermediate term, treatment of superficial-femoral-artery disease by primary implantation of a self-expanding nitinol stent yielded results that were superior to those with the currently recommended approach of balloon angioplasty with optional secondary stenting.

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THE USE OF PERCUTANEOUS TRANSLUMINAL angioplasty to revascularize the superficial femoral artery can result in initial technical success rates of more than 95 percent, with a low risk of complications.¹ However, late clinical failure remains an important concern. Restenosis occurs in 40 to 60 percent of treated segments after one year.¹⁻³ The use of angioplasty to treat extensive disease of the superficial femoral artery has particularly poor results: at one year, the rates of restenosis exceed 70 percent for lesions longer than 100 mm.⁴

Endovascular stenting avoids the problems of early elastic recoil, residual stenosis, and flow-limiting dissection after balloon angioplasty and can thus be used for the treatment of long and complex lesions, even in heavily calcified arteries. Initial studies of stenting of the superficial femoral artery reported promising results, with patency rates of more than 85 percent at 18 months.⁵ However, subsequent studies found that exaggerated neointimal hyperplasia frequently leads to in-stent restenosis, and five randomized, controlled trials failed to demonstrate any benefit of a stainless-steel stent over angioplasty alone.⁶⁻¹⁰ Therefore, stenting of the superficial femoral artery is currently recommended only as a bailout procedure after technical failure of angioplasty.

The use of nitinol stents has been reported to improve the durability of stenting of the superficial femoral artery,¹¹⁻¹⁵ with a restenosis rate of only 7.7 percent at six months.¹⁵ These promising results led us to perform a randomized trial comparing primary implantation of a self-expanding nitinol stent with the currently recommended approach of angioplasty with optional secondary stenting for the treatment of lesions of the superficial femoral artery in patients with chronic limb ischemia.

METHODS

STUDY DESIGN

From June 2003 through August 2004, consecutive patients referred for endovascular treatment of the superficial femoral artery owing to intermittent claudication or chronic critical limb ischemia were screened for enrollment in this randomized, single-institution trial. Before potential candidates for percutaneous intervention were enrolled, their cases were discussed in a twice-weekly consensus meeting of angiologists, vascular surgeons, and interventional radiologists.

The protocol was approved by the institutional ethics committee, and the patients provided written informed consent.

The clinical criterion for study entry was symptomatic peripheral-artery disease with severe intermittent claudication (Rutherford stage 3), chronic critical limb ischemia with pain while the patient was at rest (Rutherford stage 4), or chronic critical limb ischemia with ischemic ulcers (Rutherford stage 5).¹ The anatomical inclusion criteria, based on biplane digital subtraction angiography (DSA) performed at the time of intervention, were stenosis of more than 50 percent or occlusion of the ipsilateral superficial femoral artery, a target-lesion length of more than 30 mm, and at least one patent (less than 50 percent stenosed) tibioperoneal runoff vessel. The exclusion criteria were acute critical limb ischemia, previous bypass surgery or stenting of the superficial femoral artery, untreated inflow disease of the ipsilateral pelvic arteries (more than 50 percent stenosis or occlusion), and known intolerance to study medications or contrast agents.

END POINTS

The primary study end point was the rate of binary restenosis (stenosis of at least 50 percent of the luminal diameter) in the treated segment six months after intervention, as determined by computed tomographic angiography (CTA) or DSA. Restenosis was defined as a reduction in the luminal diameter of more than 50 percent according to the worst angiographic view at the narrowest site within the treated segment plus the 10-mm segments proximal and distal to the treated segment.

The secondary end points were determined anatomically, clinically, and hemodynamically. The anatomical end points were restenosis of more than 50 percent, as determined by duplex ultrasonography at 3, 6, and 12 months; the angiographic degree of restenosis (the percent reduction in diameter at 6 months); and the occurrence of stent fractures, as determined by biplane radiography at 6 and 12 months. The clinical end points were the Rutherford stage of peripheral-artery disease and the maximal walking capacity on the treadmill, both measured at 24 hours, 3 months, 6 months, and 12 months; amputation by 6 or 12 months; and death by 6 or 12 months. The hemodynamic end point was the resting ankle-brachial index measured at 24 hours, 3 months,

6 months, and 12 months. Two independent observers evaluated all follow-up data in a blinded fashion and adjudicated the primary and secondary end points. Disagreements were resolved by consensus with a third investigator who was also unaware of patients' treatment assignments.

INTERVENTIONS

Interventions were performed percutaneously by an antegrade or an over-the-bifurcation approach with the use of 6-French sheaths. Biplane DSA was performed in two views at least 30 degrees apart to evaluate the structure of the lesion, inflow disease (obstruction or stenosis of the iliac artery), and runoff (the number of patent tibioperoneal vessels). To document the precise location of the lesion and the site of intervention, a ruler was fixed on the patient's thigh with the distal end exactly overlapping the upper edge of the patella.

After the guidewire had passed through the target lesion, patients were randomly assigned to undergo either primary stent implantation or angioplasty with optional secondary stenting. Randomization was performed in blocks of four with the use of computer-generated random digits, and the assignments were placed in sealed envelopes. Patients were stratified according to the reason for revascularization (claudication vs. critical limb ischemia) and the length of the target lesion (≤ 60 mm vs. > 60 mm).

The patients in the stent group underwent primary stenting without predilation except for those who had very tight stenoses or heavily calcified lesions that did not allow primary passage of the stent-introducer device. The stents were implanted to extend 10 mm proximally and distally from the margins of the target lesion. When multiple stents were required, the margins of the stents overlapped 10 mm. Dilation after stenting was performed strictly within the stented segment, with up to 10 percent oversizing of the postdilation balloon.

In patients undergoing angioplasty, each balloon was inflated at 10 to 12 atm for at least two minutes. After dilation of the entire target segment, biplane angiograms were obtained. In cases with a suboptimal primary result, which was defined as a residual stenosis of more than 30 percent or the presence of a flow-limiting dissection in the worst angiographic view, a second prolonged (more than two minutes) balloon dilation of the target segment was performed. In

patients with a persistently suboptimal result after the second balloon dilation, secondary stenting was performed.

Self-expanding nitinol stents (Dynalink or Absolute, Guidant) with a nominal diameter of 6 mm were used in both treatment groups. Biplane angiography was performed after the intervention in both groups, with the use of the same angles and magnifications used in the baseline angiograms.

MEDICAL THERAPY

All patients received aspirin (100 mg daily) indefinitely and clopidogrel (75 mg daily) for three months after the intervention. Most patients started taking clopidogrel at least two days before the intervention; for those who did not, a loading dose of 300 mg of clopidogrel was given during the intervention.

SURVEILLANCE PROTOCOL

Examinations were performed at baseline and at 24 hours, 3 months, 6 months, and 12 months after randomization. The examination included staging of peripheral-artery disease according to the Rutherford classification,¹ measurement of the ankle-brachial index while the patient was at rest, treadmill exercise testing (3.2 km per hour at a 12-degree slope), and color duplex ultrasonography.¹⁶ At 6 and 12 months, radiograms in two planes were obtained for evaluation of stent fractures.

Angiographic evaluation for restenosis was performed at six months with the use of either 16-slice CTA or conventional intraarterial DSA. CTA was performed with a 16-row multislice computed tomographic (CT) scanner (Somatom Sensation 16, Siemens Medical Systems). The accuracy and specificity of multislice CT with automated reconstruction have been reported to be similar to those of intraarterial DSA.¹⁷⁻²⁰ All patients in whom CTA identified restenosis (of more than 50 percent of the vessel diameter) underwent conventional DSA to confirm the diagnosis. We performed DSA first rather than CTA in patients who were scheduled to undergo ipsilateral or contralateral intervention or reintervention at the six-month follow-up visit.

STATISTICAL ANALYSIS

We estimated that 100 to 110 patients would need to be enrolled for the study to have a statistical

power of 80 percent to detect an absolute difference in restenosis rates of 25 percent, given six-month rates of restenosis of 50 percent in the angioplasty group³ and 25 percent in the stent group and a maximal dropout rate of 10 percent.¹¹ A two-sided P value of 0.05 was considered to indicate statistical significance. Analysis of the

data for the primary and secondary end points was performed according to the intention to treat. A secondary analysis according to the treatment actually received (per protocol) compared the results of stent implantation (primary or secondary) with those of angioplasty alone with respect to the primary study end point.

Table 1. Demographic and Clinical Characteristics of the Patients.*

Characteristic	Stent Group (N=51)	Angioplasty Group (N=53)
Age — yr	65±10	68±10
Male sex — no. (%)	30 (59)	25 (47)
Body-mass index†	27.5±3.8	27.4±4.0
Family history of atherosclerosis — no. (%)	25 (49)	30 (57)
Hypertension — no. (%)	48 (94)	47 (89)
Antihypertensive medication — no. (%)		
Baseline	47 (92)	46 (87)
6 Mo	47 (92)	46 (87)
Hyperlipidemia — no. (%)	47 (92)	46 (87)
Statin treatment — no. (%)		
Baseline	47 (92)	48 (91)
6 Mo	47 (92)	49 (92)
Diabetes mellitus — no. (%)	22 (43)	17 (32)
Glycosylated hemoglobin at baseline — %		
Baseline	6.6±1.2	6.4±1.1
6 Mo	6.3±1.1	6.3±1.0
Smoking at baseline — no. (%)	27 (53)	19 (36)
Coronary artery disease — no. (%)	34 (67)	40 (75)
History of myocardial infarction — no. (%)	10 (20)	4 (8)
History of stroke — no. (%)	2 (4)	5 (9)
Rutherford stage of peripheral-artery disease — no. (%)‡		
3	45 (88)	46 (87)
4	1 (2)	2 (4)
5	5 (10)	5 (9)
Treated side — no.		
Left	25	26
Right	26	27
Maximal distance walked on a treadmill — m§		
Median	92	87
Interquartile range	45–113	44–118
Baseline ankle-brachial index	0.57±0.19	0.54±0.20

* Plus-minus values are means ±SD. There were no significant differences between groups.

† The body-mass index is the weight in kilograms divided by the square of the height in meters.

‡ Rutherford stage 3 corresponds to intermittent claudication, stage 4 to ischemic pain while the patient is resting, and stage 5 to ischemic ulcers.

§ The walking distance was assumed to be 0 m in patients with critical limb ischemia (ischemic pain at rest or ischemic ulcers).

Descriptive data are given as means \pm SD or, for non-normal distributions or censored data sets, as medians with interquartile ranges. Descriptive data were analyzed by the Mann–Whitney U test. Proportions were compared by the chi-square test with Yates' correction or by exact tests, as appropriate. Kappa statistics with 95 percent confidence intervals were used to assess agreement between the results of angiography and those of duplex ultrasonography. Multivariable logistic-regression analysis was performed to assess the association between treatment and restenosis and to adjust for potentially confounding factors. We converted the odds ratios derived from the multivariable model to risk ratios with 95 percent confidence intervals. Multiplicative interac-

tion terms and log-likelihood ratios were used to test for interactions. Calculations were performed with Stata Release software (version 8.0).

RESULTS

PATIENTS

A total of 252 patients were screened for participation in the study. Of these, 143 did not meet the inclusion criteria: 21 had acute critical limb ischemia, 43 had major tissue loss related to ischemia (Rutherford stage 6), 55 had previously undergone stenting of the superficial femoral artery, 12 had previously undergone bypass surgery, 11 had untreated pelvic-artery occlusion, and 1 could not tolerate clopidogrel. Five patients were exclud-

Table 2. Baseline Angiographic and Interventional Data.*

Variable	Stent Group (N=51)	Angioplasty Group (N=53)	P Value
Length of target lesion — mm	101 \pm 75	92 \pm 64	0.11
Degree of stenosis — %	90 \pm 10	90 \pm 10	0.96
Occlusion — no. of patients (%)	19 (37)	17 (32)	0.73
Target-lesion calcification — no. of patients (%) [†]			0.82
None or mild	10 (20)	8 (15)	
Moderate	28 (55)	30 (57)	
Severe	13 (25)	15 (28)	
No. of crural runoff vessels — no. of patients (%)			0.49
1	7 (14)	12 (23)	
2	19 (37)	17 (32)	
3	25 (49)	24 (45)	
Crossover access — no. of patients (%)	40 (78)	40 (75)	0.90
Duration of fluoroscopy — min	15 \pm 8	14 \pm 5	0.77
Amount of contrast agent — ml	180 \pm 60	180 \pm 60	0.89
Predilation necessary — no. of patients (%)	22 (43)	NA	—
Stent implanted — no. of patients (%)	51 (100)	17 (32)	<0.001
No. of stents implanted — no. of patients (%)			<0.001
1	29 (57)	9 (17)	
2	14 (27)	6 (11)	
3	3 (6)	1 (2)	
4	4 (8)	1 (2)	
5	1 (2)	0	
Length of treated segment — mm	132 \pm 71	127 \pm 55	0.45
Peripheral embolization — no. of patients (%)	0	1 (2)	0.99
Early thrombotic reocclusion — no. of patients (%)	1 (2)	0	0.99
Major complication — no. of patients (%)	0	0	—

* Plus–minus values are means \pm SD. NA denotes not applicable.

[†] Calcification was determined by fluoroscopy.

ed because the guidewire did not cross the lesion; no suitable candidates declined to participate. The remaining 104 patients were enrolled; 51 were randomly assigned to the stent group, and 53 to the angioplasty group. Demographic and clinical characteristics were similar in the two groups, with no significant differences between groups in the frequencies of atherothrombotic risk factors or coexisting cardiovascular conditions (Table 1). Of the 13 patients with critical limb ische-

mia, 9 were considered unacceptable candidates for surgery and 4 were offered the choice of undergoing surgery or percutaneous intervention before enrolling in the trial.

The characteristics of the target lesions and interventional data were similar in the two groups (Table 2). The average length of the treated segment was 132 mm in the stent group and 127 mm in the angioplasty group. Seventeen patients in the angioplasty group (32 percent) underwent secondary stenting after two attempts at balloon dilation: nine had a flow-limiting dissection, and eight had a residual stenosis of more than 30 percent.

One patient in the stent group had an early thrombotic reocclusion the day after the intervention. One patient in the angioplasty group had a minor complication consisting of peripheral embolization to the tibioperoneal trunk; this complication was resolved by thrombus aspiration during the intervention, without clinical sequelae.

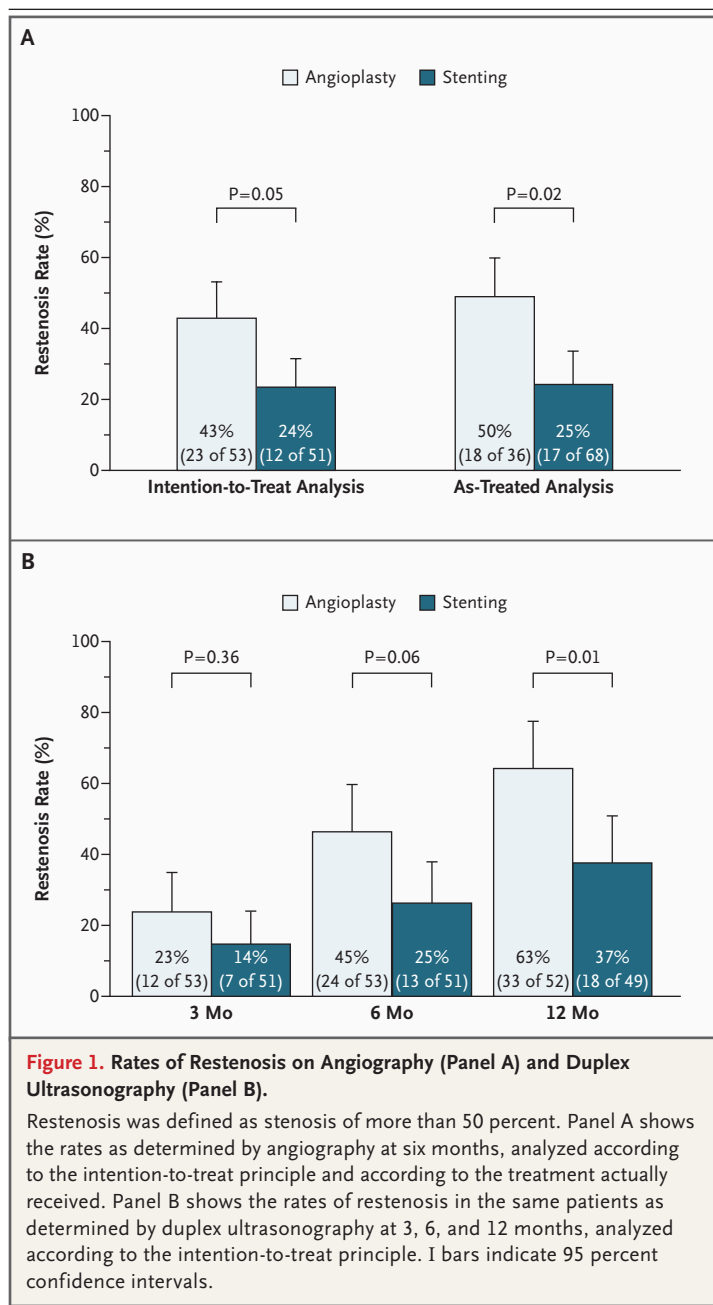
FOLLOW-UP

Complete follow-up data were obtained from all 104 patients at three and six months. Data were not available for three patients at 12 months (one died and two declined to be reevaluated). For evaluation of the primary end point at six months, 70 patients underwent CTA and 34 underwent conventional DSA; there were no significant differences between the two groups ($P=0.45$).

At six months, the rates of restenosis on angiography were 24 percent in the stent group and 43 percent in the angioplasty group, according to the intention to treat ($P=0.05$) (Fig. 1). Reanalysis of these data according to the actual treatment received (per protocol) yielded restenosis rates of 25 percent after stent implantation (including both patients who underwent primary stenting and those who underwent secondary stenting after failure of angioplasty) and 50 percent after angioplasty without stenting ($P=0.02$).

At six months, the rates of restenosis on duplex ultrasonography were 25 percent in the stent group and 45 percent in the angioplasty group ($P=0.06$) (Fig. 1). There was excellent agreement between the results of duplex ultrasonography and those of angiography ($\kappa=0.92$). At 12 months, the restenosis rates on duplex ultrasonography were 37 percent in the stent group and 63 percent in the angioplasty group ($P=0.01$).

Multivariable analysis adjusted for age, sex,



presence or absence of diabetes, smoking status, stage of peripheral-artery disease, and lesion length confirmed that as compared with patients who underwent angioplasty, patients who underwent stenting had a reduced risk of restenosis at 6 months (adjusted relative risk, 0.45; 95 percent confidence interval, 0.20 to 0.94) and 12 months (adjusted relative risk, 0.40; 95 percent confidence interval, 0.19 to 0.80). There was no significant interaction between treatment assignment and the risk of restenosis according to the stage of peripheral-artery disease or the length of the lesion, indicating that the benefit of stenting did not vary according to these strata.

The results for other secondary end points reflecting the patients' anatomical outcomes are presented in Table 3. The maximal angiographically determined degree of restenosis at six months was significantly lower in the stent group than in

the angioplasty group. Clinical worsening was rare in either group, and the reintervention rates were similar in the two groups. Among the patients who received a stent, stent fractures were observed in 2 percent at both 6 and 12 months.

Data on clinical and hemodynamic outcomes are given in Figure 2. Patients in the stent group were able to walk significantly farther on a treadmill than were those in the angioplasty group at 6 months (average distance, 363 vs. 270 m; $P=0.04$) and 12 months (average distance, 387 vs. 267 m; $P=0.04$). The ankle-brachial index was also significantly better at 12 months in the stent group than in the angioplasty group ($P=0.03$).

DISCUSSION

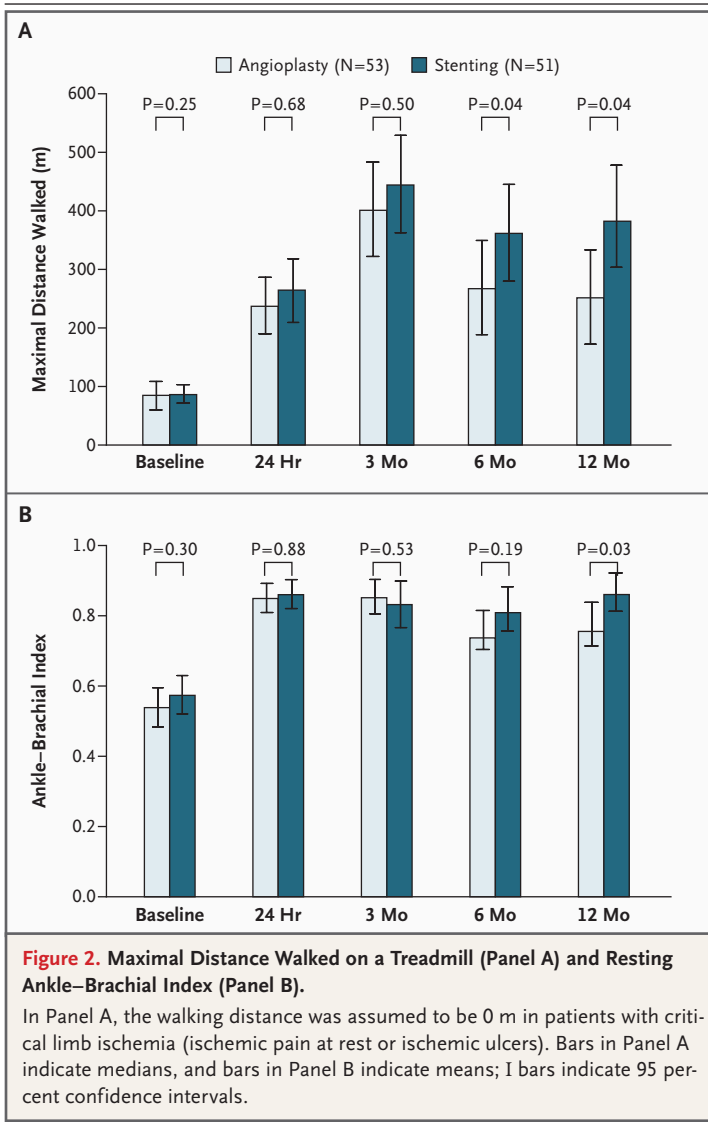
Restenosis is the main drawback of endovascular treatment of the superficial femoral artery, par-

Table 3. Outcomes in the Study Patients.*

Outcome	Stent Group (N=51)	Angioplasty Group (N=53)	P Value
Maximal angiographic degree of stenosis at 6 mo — %	30±30	50±30	0.01
Clinical worsening — no./total no. of patients (%)†			
Within 30 days	0/51	0/53	—
Within 3 mo	0/51	0/53	—
Within 6 mo	1/51 (2)	1/53 (2)	0.99
Within 12 mo	1/49 (2)	1/52 (2)	0.99
Thrombosis or reocclusion within 12 mo — no./total no. of patients (%)	6/49 (12)	6/52 (12)	0.99
Ipsilateral reintervention within 12 mo — no./total no. of patients (%)			
Balloon angioplasty	10/49 (20)	15/52 (29)	0.45
Stent implantation	1/49 (2)	1/52 (2)	0.99
Bypass surgery (supragenicular)	3/49 (6)	0/52	0.22
Stent fracture — no./total no. of patients (%)			
Within 6 mo	1/51 (2)	0/17	0.99
Within 12 mo	1/49 (2)	0/17	0.99
Amputation — no./total no. of patients (%)			
Within 6 mo	0/51	0/53	—
Within 12 mo	0/51	0/53	—
Death — no./total no. of patients (%)			
Within 6 mo	0/51	0/53	—
Within 12 mo	1/51 (2)	0/53	0.99

* Plus-minus values are means ±SD.

† Clinical worsening was defined as deterioration from baseline by two Rutherford stages¹ or the occurrence of critical limb ischemia.



clinical intermediate-term outcome than was balloon angioplasty with optional secondary stenting. The results at 6 months were of only borderline significance, but a sustained benefit of primary stenting was observed at 12 months. The advantages of nitinol stents include improved radial strength, the ability to recover from being crushed, and reduced foreshortening, which allows precise placement. These properties lead to better patency rates than those of stainless-steel stents,¹⁴ although the underlying causes of the evident superiority of nitinol stents remain to be determined. Preliminary data suggest that drug-eluting nitinol stents may have additional advantages in this setting, although an adequately powered trial has not yet been performed.^{11,15}

Bypass surgery with venous grafts must still be considered the most durable revascularization technique for patients with chronic limb ischemia and extensive disease of the superficial femoral artery,¹ although the recently reported Bypass Surgery versus Angioplasty in Severe Ischaemia of the Leg trial found that the rates of amputation-free survival after surgery and balloon angioplasty were similar for at least the first two years.²¹ Nitinol stents may be an effective alternative to surgical revascularization for longer lesions in patients who are poor candidates for surgery, such as those with severe coexisting cardiovascular conditions. Furthermore, stenting may be an option for patients without available saphenous-vein grafts, since the 12-month patency data for stents are similar to those for prosthetic bypass grafts and stenting has a considerably lower rate of complications.¹ However, the endovascular approach seems justified as long as the rates of complications are low and the surgical target zone for the distal anastomosis of a potential secondary bypass operation remains unaffected by the interventional procedure. In our series, the rates of minor complications (1 percent), clinical worsening (2 percent), and amputation (0 percent) at 12 months were low, and all three bypass procedures after stent failure could be performed with the use of supragenicular anastomosis, as would have been the case without the stents in place.

Our patients had long lesions that, for the most part, were heavily calcified (Table 2). The presence of such lesions is reflected in the rather high rate of secondary stenting owing to suboptimal

ticularly for long lesions.² The risk of restenosis limits widespread application of this revascularization technique. In previous reports, placement of stainless-steel stents in the superficial femoral artery was not more beneficial than angioplasty.⁶⁻¹⁰ As a result, the TransAtlantic InterSociety Consensus has recommended the use of percutaneous transluminal angioplasty only for short lesions of the superficial femoral artery and has advised that stents be used only in bailout situations.¹

In our trial, primary implantation of a self-expanding nitinol stent for the treatment of symptomatic disease of the superficial femoral artery was associated with a better anatomical and

results of balloon angioplasty alone in the angioplasty group. Furthermore, one third of the patients had diabetes mellitus, which is an important determinant of the risk of in-stent restenosis associated with nitinol stents.¹² These factors must be kept in mind when our restenosis rate of 24 percent for an average treated length of 132 mm is compared with previous findings. For example, in the Sirolimus-Eluting Stents for the Treatment of Obstructive Superficial Femoral Artery Disease (SIROCCO) I and II trials, the angiographically determined restenosis rates at six months were 23.5 percent and 7.7 percent among patients who received bare-metal stents, respectively (average length of lesion, 80 mm).^{11,15}

Although the use of nitinol stents seems to be a promising strategy to prevent restenosis, the importance of the issue of stent fracture and its clinical consequences is increasingly recognized.^{11,15,22} Fractures of superficial-femoral-artery stents were observed in 18 percent of the patients in the SIROCCO I trial,¹¹ and such fractures are currently a major concern of the Food and Drug Administration. The length of the stented segment has been identified as the most important determinant of material fatigue and subsequent fracture.^{11,12,15,22} Depending on the design and length of the stent, fractures occur in up to 50 percent of procedures involving some stents and may induce clinically relevant restenosis.²² We used a nitinol stent that had particularly low fracture rates in unpublished experimental studies.²³ The low observed fracture rate of 2 percent in our study is consistent with the hypothesis that

differences in stent design may substantially influence the likelihood of fractures.²²

Our study has some limitations. The primary angiographic end point was in-stent restenosis assessed by a combination of CTA and DSA. Although CTA is a promising technique, validated comparison with conventional angiography in large series of measurements in stented arteries is still lacking. Nevertheless, in our trial, all restenoses detected by CTA were confirmed by DSA, and the findings from both CTA and DSA showed excellent agreement with the findings from duplex ultrasonography, which is the standard clinical technique used to evaluate in-stent restenosis. Quantitative angiography was not available at our institution, and data on luminal diameter, residual stenosis, and late loss (the degree of reduction in luminal diameter during follow-up) are therefore lacking.

In this trial, primary implantation of self-expanding nitinol stents for the treatment of lesions of the superficial femoral artery was associated with superior anatomical and clinical intermediate-term results in comparison with the currently recommended approach of balloon angioplasty with optional secondary stenting.

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