

Prevalence and Clinical Impact of Stent Fractures After Femoropopliteal Stenting

Dierk Scheinert, MD, Susanne Scheinert, MD, Jacqueline Sax, Christopher Piorkowski, MD, Sven Bräunlich, MD, Matthias Ulrich, MD, Giancarlo Biamino, MD, Andrej Schmidt, MD

Leipzig, Germany

- OBJECTIVES** The aim of this study was to investigate the occurrence and the clinical impact of stent fractures after femoropopliteal stenting.
- BACKGROUND** The development of femoral stent fractures has recently been described; however, there are no data about the frequency and the clinical relevance.
- METHODS** A systematic X-ray screening for stent fractures was performed in 93 patients. In total, 121 legs treated by implantation of self-expanding nitinol stents were investigated after a mean follow-up time of 10.7 months. The mean length of the stented segment was 15.7 cm.
- RESULTS** Overall, stent fractures were detected in 45 of 121 treated legs (37.2%). In a stent-based analysis, 64 of 261 stents (24.5%) showed fractures, which were classified as minor (single strut fracture) in 31 cases (48.4%), moderate (fracture of >1 strut) in 17 cases (26.6%), and severe (complete separation of stent segments) in 16 cases (25.0%). Fracture rates were 13.2% for stented length \leq 8 cm, 42.4% for stented length > 8 to 16 cm, and 52.0% for stented length > 16 cm. In 21 cases (32.8%) there was a restenosis of >50% diameter reduction at the site of stent fracture. In 22 cases (34.4%) with stent fracture there was a total stent reocclusion. According to Kaplan-Meier estimates, the primary patency rate at 12 months was significantly lower for patients with stent fractures (41.1% vs. 84.3%, $p < 0.0001$).
- CONCLUSIONS** There is a considerable risk of stent fractures after long segment femoral artery stenting, which is associated with a higher in-stent restenosis and reocclusion rate. (J Am Coll Cardiol 2005;45:312-5) © 2005 by the American College of Cardiology Foundation

Maintaining long-term patency after recanalization of superficial femoral artery (SFA) obstructions is still one of the most challenging aspects of endovascular therapy. According to several recent studies (1-3), results with self-expanding nitinol stents seem to be superior to the results reported with balloon-expandable and first-generation self-expanding stents (4,5). This improvement may be explained by the enhanced flexibility of the stents resulting from the mechanical characteristics of the nitinol alloy and the segmental stent design.

Until recently, fractures of nitinol stent struts have only been reported for single cases after stent implantation across flexion points (6). However, according to a recent study using systematic angiographic follow-up after long segment femoral artery stenting with conventional and sirolimus-eluting self-expanding nitinol stents, stent fractures were observed in 18.2% of the cases (3).

Triggered by this observation and the unclear clinical relevance of this phenomenon, we initiated a systematic X-ray follow-up evaluation of all patients treated in our institution by implantation of self-expanding nitinol stents into the SFA.

METHODS

Between April 2002 and July 2003, a total of 134 patients who underwent implantation of self-expanding nitinol

stents for treatment of SFA obstructions in 180 legs were entered into a prospective registry. In all cases, stent implantation was performed because of an insufficient angioplasty result, defined as persistent diameter reduction >50% or dissection. The implantation regimen of the stents was left to the discretion of the operator. Due to the extent of the dissection, in some cases implantation of more than two overlapping stents or extension of the stented segment into the distal SFA or the first popliteal segment became necessary, which was discouraged in the instructions for use of one of the devices (Luminexx, Bard). The registry adhered to the requirements of the local ethics committee, and all patients gave written informed consent.

Between October 2003 and February 2004, all registry patients returning for routine follow-up visits underwent plain X-ray investigations of the implanted stents, irrespective of the clinical symptoms and additional findings. By February 2004, X-ray screening for stent fractures had been performed in 93 patients with 121 treated legs. SMART stents (Cordis, Miami, Florida) were used in 52, SelfX stents (Abbott Medical Devices, Beringen, Switzerland) in 24, and Luminex stents (BARD, Murray Hill, New Jersey) in 45 limbs, respectively. Overall, 261 femoral stents with a mean stent length of 8.6 cm were investigated. The mean length of the total stented segment was 15.7 ± 5.9 cm, and the mean number of stents per limb was 2.1 ± 1.0 . There were 48 legs with one, 34 legs with two, and 39 legs with three or more implanted femoral stents. Regarding the anatomic implantation site, 62 stents were implanted in the proximal and 102 stents in the middle segment of the SFA.

From the Clinical and Interventional Angiology, Heart Center-University of Leipzig, Leipzig, Germany.

Manuscript received April 1, 2004; revised manuscript received October 17, 2004, accepted November 15, 2004.

Abbreviations and Acronyms

SFA = superficial femoral artery

A total of 97 stents were implanted in the distal third of the SFA and the first popliteal segment. The assignment of an individual stent to a specific vessel segment was made by visual estimate based on the position of the main part of the stent.

Plain X-ray examinations of the stents were performed in the angiography suite using at least two different angulations (>45° difference) and the highest available magnification. During the same visit, all patients received a clinical examination including a standardized treadmill test and the calculation of the ankle-brachial index.

Stent patency was defined as the absence of reocclusion or restenosis of more than 50% diameter reduction. Color-coded duplex sonography was performed in all patients to assess stent patency. A peak systolic velocity ratio (intra-stenotic/prestenotic) of ≥ 2.5 was considered to be indicative for a restenosis of more than 50% diameter reduction. All patients with symptomatic re-obstruction, as well as all patients with evidence of stent fracture were rescheduled for angiography. Angiographic restenosis was defined as more than 50% diameter reduction based on visual assessment.

Statistical analysis. Categorical variables are expressed as number and percentage of patients. Comparisons between groups were performed using cross table methods with chi-square testing between all individual groups and Bonferroni correction for multiple testing. Continuous variables are presented as mean \pm SD, if appropriate. In case of a non-gaussian distribution, median and range values are given. Stent patency rates were calculated on the basis of color-coded duplex sonography findings using Kaplan-Meier survival analysis. Inter-group comparisons were performed using the log-rank test.

RESULTS

X-ray examinations were performed after a mean follow-up of 10.7 months. Stent fractures were detected in 45 of 121 treated legs (37.2%). There was no difference in the time of the X-ray examination for fractured versus non-fractured stents (10.3 vs. 10.9 months, $p = ns$).

Of 261 implanted stents, 64 (24.5%) showed stent fractures, which were classified as minor (single strut fracture) in 31 cases (48.4%), moderate (fracture of >1 strut) in 17 cases (26.6%), and severe (complete separation of stent segments) in 16 cases (25.0%) (Figs. 1 and 2). The occurrence of stent fractures was related to the length of the stented segment and the number of implanted stents. The fracture rate was significantly lower for stented segments ≤ 8 cm with 13.2% (5 of 38 limbs) as compared with stented segments >8 to 16 cm with 42.4% (14 of 33 limbs, $p = 0.005$) and stented segments >16 cm with 52.0% (26 of 50 limbs, $p < 0.0001$). Furthermore, fracture rates were lower

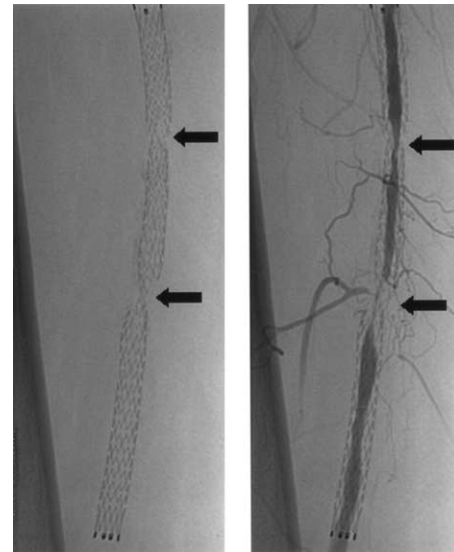


Figure 1. Self-expanding nitinol stent nine months after implantation showing a severe stent fracture in the distal and a moderate stent fracture in the proximal part of the stent. Angiographically, both lesions were associated with a restenosis >50% diameter reduction.

for single stents: 16.7% (8 of 48) versus 41.2% (14 of 34) for two stents ($p = 0.014$) and 59.0% (23 of 39) for three or more stents ($p < 0.0001$). Stents with fractures were equally distributed through the SFA with 12 stent fractures (19.4%) in the proximal, 29 fractures in the middle (28.4%), and 23 fractures (23.7%) in the distal segment of the SFA ($p = ns$). Again, the time of the X-ray follow-up was similar for stents in different anatomic locations, for single or multiple stents, and for different stented segment lengths.

Analyzing the performance of different stents, there was a 26.9% (14 of 52) fracture rate for SMART, 29.2% (7 of 24) for SelfX, and 53.3% (24 of 45) for Luminex. No differences between the groups were seen regarding the baseline characteristics, including stented segment length and number of implanted stents.

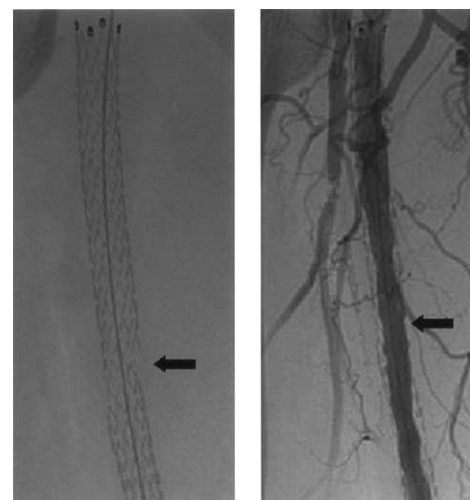


Figure 2. Minor stent fracture (single strut separation). Angiographically, no restenosis at the site of stent fracture.

Table 1. Angiographic Findings at the Site of Stent Fracture

Stent Fracture		Stent Occlusion	Restenosis*	No Reobstruction
Mild	31 (48.4)	9 (29.0)	8 (25.8)	14 (45.2)
Moderate	17 (26.6)	6 (35.3)	6 (35.3)	5 (29.4)
Severe	16 (25.0)	7 (43.7)	7 (43.7)	2 (12.5)
Total	64 (100)	22 (34.4)	21 (32.8)	21 (32.8)

Values are n (%). *Restenosis is defined on the basis of angiography as >50% diameter obstruction. Differences in the rate of reobstruction at the site of stent fracture (occlusion and restenosis) for fractures of different severity were tested for statistical significance. No significant differences were seen for mild versus moderate or moderate versus severe stent fractures. However, the reobstruction rate was significantly lower for mild fractures, 17 of 31 (55%) versus severe fractures, 14 of 16 (88%), $p = 0.025$.

The correlation of plain X-ray pictures with angiographic findings showed that at 21 stent fracture sites (32.8%) a restenosis of >50% diameter reduction was detected and at 22 fracture sites (34.4%) a stent occlusion was present. In the remaining 21 cases (32.8%), stent fractures were not associated with re-obstructions (Table 1). In general, the presence of stent fractures significantly influenced the patency of the stented segment. According to Kaplan-Meier estimates, the primary patency rate at 12 months was 84.3% for patients without stent fractures and only 41.1% with stent fractures ($p < 0.0001$) (Fig. 3).

DISCUSSION

The femoropopliteal arterial segment is known to be exposed to special mechanical influences. The superficial course of the artery with crossing of flexion points as well as interaction with the surrounding musculature, potentially exposes the artery to relevant external forces, including compression, torsion, and elongation. This may have a negative impact on vessel patency after both angioplasty and stenting. In fact, stent compression has been identified as one of the principal causes of restenosis, particularly after implantation of balloon-expandable stents (7).

The problem of external stent compression was thought to be overcome with the introduction of self-expanding stents and particularly with the clinical use of the new generation of nitinol stents. Overall, the published results with this new stent generation (1-3) compared favorably with previous data (4,5).

So far, compression or fracture of nitinol stents in peripheral arteries has only been reported for single cases and was mainly restricted to arteries crossing flexion points such as the popliteal or common femoral artery (6). However, the recently published observation of 18.2% stent fractures in the Sirolimus Coated Cordis Self-expandable Stent (SIROCCO) trial (3) demonstrated impressively that mechanical stress in the femoropopliteal arteries is not restricted to articulation sites or external compression caused by muscle activity. In contrast, a significant amount of internal stress seems to be transmitted to the stent material as a result of the pulsatile blood flow.

This phenomenon has been described in stents positioned near pulsatile structures such as the heart or the proximal great vessels, where a fracture rate of 15% to 30% has been reported (8-10). Similarly, metal fatigue with nitinol strut

fracture has been reported for both thoracic and abdominal aortic stent grafts (11).

Until now, the underlying mechanisms leading to stent fractures in the SFA have not been completely understood. Similar to the observations in the SIROCCO trial, stent fractures in our series occurred more frequently in long stented segments with multiple overlapping stents. This observation supports the hypothesis that the implantation of multiple overlapping stents critically increases the axial stiffness of the stented segment. The arising question, whether changes in the implantation regimen with avoidance of stent overlap or the use of single long stents as a substitute for two shorter stents would result in a reduction of stent fractures, can not be answered from our data set.

Further, in our series, stent fractures were equally distributed throughout the SFA and there was no increased frequency of strut fractures in the distal part of the artery. These observations suggest that external mechanical influences from the surrounding musculature, as expected in the adductor canal, seem to be less relevant than previously assumed. However, the analysis of the impact of the anatomic stent location on strut fracture is somehow limited by the fact that assignment of stents to one or the other segment is difficult if stents are placed across vessel segment borders. Furthermore, the fact that in many cases multiple overlapping stents were implanted, covering more than one vessel segment, precludes definitive conclusions for the individual stent.

The most important objective of this study was to investigate the clinical impact of stent fractures. In contrast

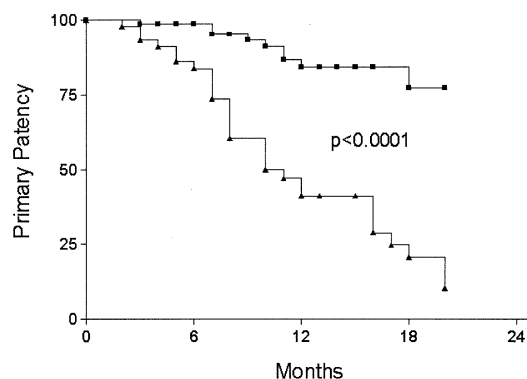


Figure 3. Primary stent patency rates for fractured and non-fractured stents. Squares = no stent fracture; triangles = stent fracture.

to the observation in the SIROCCO trial, where no correlation between stent fractures and re-obstructions could be established (3), our data demonstrate that stent fractures were associated with stent restenosis or reocclusions in about two-thirds of the cases. Particularly when stent fractures were categorized as severe, relevant re-obstructions were observed in almost all cases. Furthermore, the primary patency rate of the stented segment was significantly lower for patients with stent fractures, demonstrating the clinical relevance of this finding.

There are some limitations of this study that leave our understanding of the mechanisms of stent fractures incomplete. First, this study was based on a single X-ray investigation performed in every patient at different follow-up times. Therefore, no sequential examinations are available, preventing the ability to follow the timing of stent fracture development. Furthermore, in this study only self-expanding nitinol stents with a segmental design were studied. Different fracture rates of the nitinol stent brands used in our patients have to be interpreted cautiously as the allocation of stents was non-randomized. Moreover, the differences noted in our study were detected in relatively long lesions treated with overlapping stents. Stenting of shorter vessel segments or the use of single stents may yield different results. Because the available investigations for nitinol stents with a spiral design were mainly focused on shorter lesions and did not incorporate a systematic X-ray follow-up (12), no conclusions can be drawn as to whether a spiral design provides more longitudinal in situ flexibility leading to more favorable results in diffuse femoral disease. Finally, the question of whether a different implantation regimen without stent overlap can contribute to a reduction of stent fractures needs to be investigated.

In conclusion, stent fractures occur frequently after long segment femoral artery stenting. Although mild or moderate fractures may be a benign condition in some patients, severe stent fractures are associated with stent restenosis or reocclusion in the majority of the cases. In general, the

occurrence of stent fractures is associated with a reduction in the overall patency rate.

Reprint requests and correspondence: Dr. Dierk Scheinert, Clinical and Interventional Angiology, Department of Medicine/Cardiology, University of Leipzig-Heart Center, Strümpellstr. 39, 04289 Leipzig, Germany. E-mail: dierk.scheinert@gmx.de.

REFERENCES

1. Lugmayr HF, Holzer H, Kastner M, Riedelsberger H, Auterith A. Treatment of complex arteriosclerotic lesions with nitinol stents in the superficial femoral and popliteal arteries: a midterm follow-up. *Radiology* 2002;222:37-43.
2. Vogel TR, Shindelman LE, Nackman GB, Graham AM. Efficacious use of nitinol stents in the femoral and popliteal arteries. *J Vasc Surg* 2003;38:1178-84.
3. Duda SH, Pusich B, Richter G, et al. Sirolimus-eluting stents for the treatment of obstructive superficial femoral artery disease: six-month results. *Circulation* 2002;106:1505-9.
4. Gray BH, Sullivan TM, Childs MB, et al. High incidence of restenosis/reocclusion of stent in the percutaneous treatment of long-segment superficial femoral artery disease after suboptimal angioplasty. *J Vasc Surg* 1997;25:74-83.
5. Conroy RM, Gordon IL, Tobis JM, et al. Angioplasty and stent placement in chronic occlusion of the superficial femoral artery: technique and results. *J Vasc Interv Radiol* 2000;11:1009-20.
6. Babalik E, Gülbaran M, Gürmen T, et al. Fracture of popliteal artery stents. *Circ J* 2003;67:643-45.
7. Rosenfield K, Schainfeld R, Pieczek A, Haley L, Isner JM. Restenosis of endovascular stents from stent compression. *J Am Coll Cardiol* 1997;29:328-38.
8. Nakanishi T, Kondoh C, Nishikawa T, et al. Intravascular stents for the management of pulmonary artery and right ventricular outflow obstruction. *Heart Vessels* 1994;9:40-8.
9. Perry SB, Lock JE. Intracardiac stent implantation to relieve muscular and non-muscular obstruction. *J Am Coll Cardiol* 1993;21:261A.
10. Knirsch W, Haas NA, Lewin MA, Uhlemann F. Longitudinal stent fracture 11 months after implantation in the left pulmonary artery and successful management by a stent-in-stent maneuver. *Catheter Cardiovasc Interv* 2003;58:116-8.
11. Jacobs TS, Won J, Gravereaux EC, et al. Mechanical failure of prosthetic human implants: a 10-year experience with aortic stent graft devices. *J Vasc Surg* 2003;37:16-26.
12. Jahnke T, Voshage G, Müller-Hülsbeck S, Grimm J, Heller M, Brossmann J. Endovascular placement of self-expanding nitinol coil stents for treatment of femoropopliteal obstructive disease. *J Vasc Interv Radiol* 2002;13:257-66.