◆ CLINICAL INVESTIGATION ◆

Percutaneous Peripheral Atherectomy of Femoropopliteal Stenoses Using a New-Generation Device: Six-Month Results From a Single-Center Experience

Thomas Zeller, MD; Aljoscha Rastan, MD; Uwe Schwarzwälder, MD; Ulrich Frank, MD; Karlheinz Bürgelin, MD; Pietro Amantea, MD; Christian Müller, MD*; Peter-Christian Flügel, MD; and Franz-Josef Neumann, MD

Department of Angiology, Herz-Zentrum Bad Krozingen, Germany.
*Department of Internal Medicine, University Hospital Basel, Switzerland.

Purpose: To report the early and 6-month results after atherectomy of femoropopliteal lesions using a new atherectomy device compatible with a 7-F sheath.
Methods: Fifty-two patients (36 men; mean age 67±7 years) with stable, chronic lower limb occlusive disease were enrolled prospectively in a study of percutaneous directional atherectomy using the SilverHawk Atherectomy Catheter. The 71 femoropopliteal stenoses were grouped for analysis according to pathology: 30 (42%) primary stenoses, 27 (38%) native vessel restenoses, and 14 (20%) in-stent restenoses. The overall average stenosis length was 48±64 mm (range 10–300). There were more diabetics in the primary lesion cohort, whereas the lesion length of the in-stent restenoses was nearly twice as long as the other groups.
Results: After atherectomy alone, residual stenosis was ≤50% in 68 (96%) lesions and ≤30% in 54 (76%). Additional balloon angioplasty was used in 41 (58%) lesions, primarily to smooth the arterial contour; stents were implanted in 4 (6%) arteries. Acute results after atherectomy and additional therapy were identical for the 3 groups (mean residual stenosis 15% in primary lesions, 8% in restenoses, and 14% in in-stent lesions). At the beginning of the study, 5 cases of tissue embolism were successfully treated with aspiration (device modification solved this problem). Restenosis rates after 6 months were not significantly lower in primary lesions (27%) compared with the other groups (41% for restenoses and 36% for in-stent restenoses). Reintervention after 6 months was also lowest for primary lesions (20% versus 37% for restenoses and 29% for in-stent lesions; p=NS). The ankle-brachial index was significantly improved after 6 months in all groups. At the 6-month follow-up, >80% of all patients were symptom free or had no lifestyle-limiting claudication.
Conclusions: Short and medium-length femoropopliteal lesions can be treated successfully and safely in most cases with this new atherectomy catheter. Technical and 6-month clinical outcomes seem to favor primary lesions compared with restenoses.

J Endovasc Ther 2004;11:676–685

Key words: percutaneous directional atherectomy, peripheral occlusive disease, femoropopliteal segment, stenosis, restenosis

Balloon angioplasty of femoropopliteal lesions is limited by a low primary patency of 30% to 61% after 3 years, depending on lesion length and clinical stage.[1–11] Even stent implantation or the use of ablative methods, such as laser angioplasty, has not led to a sig-

Address for correspondence and reprints: Dr. Thomas Zeller, Department of Angiology, Herz-Zentrum Bad Krozingen, Südring 15, D-79189 Bad Krozingen, Germany. Fax: 49-7633-4028208; E-mail: *thomas.zeller@herzzentrum.de*

nificant improvement in long-term results.[6,10–24] However, patency seems to be dependent on the type of stent implanted, with 1-year primary patency rates of 22% for the Palmaz stent,[25] 30% for the Wallstent, and 61% for the SMART nitinol stent.[26]

Percutaneous removal of obstructive material via directional atherectomy represents a theoretical approach for reducing the rate of restenosis. Older single-center studies examining the Simpson AtheroCath reported high initial success and acceptable long-term results for the treatment of femoropopliteal stenosis and occlusions.[27–58] Randomized comparisons, however, demonstrated a tendency toward poorer results in comparison to balloon angioplasty.[36,44] This, along with the demanding technique, probably hindered atherectomy from becoming established as a routine treatment method.

In an ongoing examination of our clinical experiences with a new-generation atherectomy catheter,[59] we present the 6-month results with this device in the treatment of femoropopliteal lesions.

METHODS

Study Design

In this prospective single-center study, patients with stable chronic peripheral occlusive disease (POD) (e.g., no change of the Rutherford category during the last 6 months) and a resting ankle-brachial index (ABI) <0.85 were eligible for percutaneous directional atherectomy of stenoses (70% to 99%) in femoropopliteal vessels between 2.5 and 7 mm in diameter. Patients were excluded from the study according to the generally accepted contraindications to performing angiography or angioplasty. In addition, patients with acute occlusions, extreme calcification detected by ultrasound, and/or angiographically visible thrombus were not eligible. The study was approved by the local ethics committee, and all patients gave written consent to participate.

The pre and postinterventional (before discharge and after 3 and 6 months) evaluations included clinical examination, Doppler pressure measurement with calculation of the ABI, segmental pulse oscillography, color duplex sonography, and determination of routine laboratory parameters. Angiographic measurements of the vessel and lesion diameters were performed using the automated contour detection program in our department's angiography unit (Angiostar and Multistar; Siemens, Erlangen, Germany). Based on these measurements, the degree of diameter stenosis was calculated.

Patient Sample

Fifty-two patients (36 men; mean age 67±7 years) with stable, chronic lower limb POD (11 [21%] Fontaine stage IIa; 36 [69%] stage IIb; 3 [6%] stage III; and 2 [4%] stage IV) were enrolled in the study. The 71 femoropopliteal lesions meeting the treatment criteria were in the common femoral artery (CFA) (n=2, 3%), superficial femoral artery (SFA) (n=52, 73%), and the popliteal artery (n=17, 24%). More than 1 lesion was treated in 8 (15%) patients during the same procedure. The average lesion length was 48±64 mm (range 10–300).

For purposes of analysis, the lesions were divided into groups according to pathology: 30 (42%) primary lesions, 27 (38%) native vessel restenoses, and 14 (20%) in-stent stenoses. The majority of lesions (63, 89%) were eccentric or ostial lesions (no difference among the subgroups, Table 1).

Atherectomy Procedure

The SilverHawk Atherectomy Catheter (Fox Hollow, Redwood City, CA, USA) consists of a flexible, smooth-coated shaft with a cutting unit on the distal end, containing a rotating blade in a conical, tapered housing (6 cm in length) with a lateral window (Fig. 1). The proximal end of the catheter, which has a locking mechanism, connects to a disposable, battery-operated electric motor. The device was designed for vessels measuring 3 to 7 mm in diameter.

Patients were begun on antiplatelet therapy (100 mg/d aspirin) prior to treatment but at least by the day before; a 600-mg loading dose of clopidogrel was given the day before the procedure. The catheter was loaded into a 7-F sheath (Avanti [Cordis, Haan, Germany]; Balkin

Table 1
Baseline Characteristics of 71 Femoropopliteal Lesions Treated With the SilverHawk Atherectomy Catheter

	Primary Lesion (n=30)	Restenotic Lesion (n=27)	In-Stent Restenosis (n=14)	p
Men	19 (63%)	16 (60%)	8 (61%)	NS
Age, y	63±9	65±12	65±12	NS
Diabetes mellitus	12 (40%)	8 (30%)	3 (21%)	NS
Smoker	17 (57%)	11 (41%)	9 (64%)	NS
Hypercholesterolemia	19 (63%)	16 (59%)	12 (86%)	NS
Hypertension	18 (60%)	13 (48%)	10 (71%)	NS
Family history	5 (17%)	4 (15%)	7 (50%)	0.02
CFA	1 (3%)	1 (4%)	0 (0%)	NS
SFA	25 (83%)	18 (67%)	9 (64%)	NS
Popliteal artery	4 (14%)	8 (29%)	5 (36%)	NS
Lesion length, mm	40±60	40±26	77±88	NS
Reference diameter, mm	5.00±0.70	4.78±0.73	4.86±0.72	NS
MLD, mm	0.79±0.61	0.84±0.58	0.77±0.52	NS
Diameter stenosis, %	82±11	80±10	86±7	NS
ABI at baseline	0.57±0.18	0.55±0.15	0.63±0.06	NS

Continuous data presented as mean ± standard deviation.
NS: not significant, MLD: minimal lumen diameter, CFA: common femoral artery, SFA: superficial femoral artery, ABI: ankle brachial index.
Multiple lesions treated in 8 patients.

[Cook, Bjaeverskov, Denmark]), using the monorail technique over a 0.014-inch guidewire. Via a percutaneous access, the sheath was introduced over the wire and passed to the femoropopliteal segment. Intra-arterial heparin (2500 to 5000 units) was administered.

With the catheter proximal to the stenosis, the electric motor was started by retracting the positioning lever, which deflected the tip of the catheter so that the window with the rotating blade was placed against the vessel wall. The device was slowly advanced through the stenosis. Pushing forward on the positioning lever turned off the blade and returned it to the housing. Simultaneously, the tip straightened, pushing the atherectomized tissue forward into the conical catheter tip. The catheter was then pulled back, rotated ~45°, and directed toward a new area of stenosis. After 4 passes through stenosed areas, the catheter tip must be emptied of atherectomized material (Fig. 2). If necessary, the system can be reintroduced, and the procedure repeated. Completion angiography confirms successful recanalization of the vessel. In our series, clopidogrel (75 mg/d) was given for 4 weeks after the procedure and aspirin indefinitely.

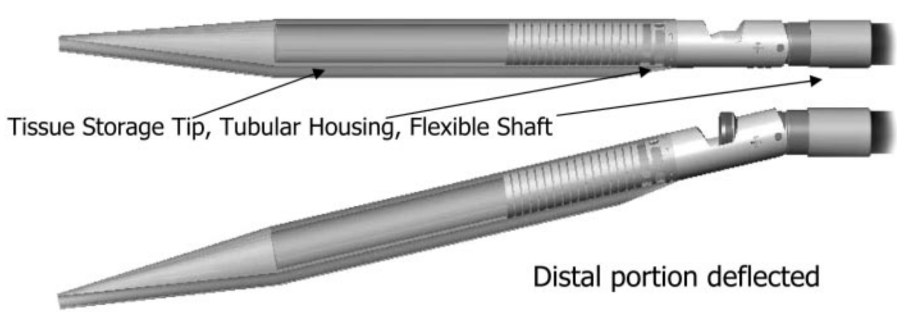

Figure 1 ◆ Drawing of the tip of the SilverHawk atherectomy catheter.

Figure 2 ◆ Excised tissue after atherectomy of a long restenotic superficial femoral artery lesion.

Definitions and Statistical Analysis

Continuous variables are given as the mean ± standard deviation and categorical variables as the counts and percentages. Technical success after atherectomy was defined as ≤50% residual stenosis; primary treatment success was defined as ≤30% residual stenosis. The 2-tailed *t* test was used to analyze comparisons; $p<0.05$ was considered significant.

RESULTS

All interventions were primarily successful and carried out according to the prospectively defined criteria. One lesion was atherectomized after predilation, but the other 70 (99%) were treated primarily. After atherectomy alone, residual stenosis was ≤50% in 68 (96%) lesions and ≤30% in 54 (76%). Nevertheless, 41 (58%) lesions were balloon dilated, primarily to smooth the contour of the lesion without any measurable reduction in stenosis. A stent was implanted in 4 (6%) lesions. One type C dissection occurred after predilation of a functional occlusion, and it could not be removed by the atherectomy catheter. In another, a preprocedurally detected deformation of a previously implanted stent was found. The last 2 cases involved 50% and 60% residual stenoses, respectively, owing to eccentric calcification.

The average diameter stenosis after atherectomy was reduced from 84%±10% (range 70%–100%) to 27%±23% (range 0%–100%), and the minimal lumen diameter (MLD) was increased from 0.88±0.70 to 3.69±0.90 mm. After additional balloon dilation or stent implantation, the diameter stenosis was reduced to 12%±9% (range 0%–30%) and the MLD reached 4.5±0.7 mm (proximal reference diameter: 5.0±0.7 mm).

Duration of the intervention, number of device insertions, and number of lesion passes was significantly higher in the in-stent stenoses compared to the other groups (Table 2) because of the nearly doubled lesion length in this cohort. Acute results after atherectomy and additional therapy were nearly identical for the 3 groups.

One patient died 2 months after the intervention from a myocardial infarction; otherwise, follow-up was complete in the remaining 51 patients. Restenosis rates after 6

Table 2
Acute Atherectomy Results

	Primary Lesion (n=30)	Restenotic Lesion (n=27)	In-Stent Restenosis (n=14)	p
Lesion passes	7.1±2.9	6.8±3.6	9.9±3.2	0.02
Device insertions	2.0±1.2	2.0±1.1	3.5±1.7	0.01
Duration of atherectomy, min	11±8	11±4	20±14	0.04
MLD postatherectomy, mm	3.6±1.0	3.8±0.7	3.3±1.2	NS
DS postatherectomy, %	29±18	22±15	31±23	NS
MLD final, mm	4.4±0.7	4.4±0.7	4.2±0.5	NS
DS final, %	15±9	8±9	14±8	0.01
Balloon angioplasty	17 (57%)	16 (59%)	8 (57%)	NS
Stenting	1 (3%)	2 (8%)	1 (7%)	NS
ABI before discharge	0.84±0.19	0.77±0.15	0.85±0.12	NS

Continuous data presented as mean ± standard deviation.
MLD: minimal lumen diameter, NS: not significant, DS: diameter stenosis, ABI: ankle-brachial index.

Table 3
Atherectomy Results at 3 and 6 Months

	Primary Lesion (n=30)	Restenotic Lesion (n=27)	In-Stent Restenosis (n=14)	p
Three months				
Restenosis, %	2 (7%)	8 (30%)	3 (21%)	NS
Reintervention, %	1 (3%)	8 (30%)	3 (21%)	0.02
ABI	0.84±0.19	0.77±0.15	0.86±0.12	0.049
Six months				
Restenosis, %	8 (27%)	11 (41%)	5 (36%)	NS
Reintervention, %	6 (20%)	10 (37%)	4 (29%)	NS
ABI	0.72±0.2	0.64±0.16	0.72±0.27	NS
Primary patency, %	80	63	71	NS
Assisted primary patency, %	100	96	79	NS
Secondary patency, %	100	96	93	NS

ABI: ankle-brachial index, NS: not significant.

months (Table 3) were not significantly lower in the primary lesions (27%) compared with the others (41% for restenoses and 36% for in-stent restenoses). The rate of reinterventions after 6 months was the lowest in the primary lesions (20% versus 37% versus 29%; p=NS).

The average ABI in the entire study cohort increased from 0.62±0.12 to 0.87±0.27 after treatment, 0.84±0.24 after 3 months, and 0.72±0.21 after 6 months. In the subgroup analysis (Table 3), the ABI was significantly improved after 3 and 6 months in all groups, with the lowest indices in the restenotic lesions (primary lesions: 0.57±0.18 to 0.84±0.19 and 0.72±0.20; restenoses: 0.55±0.15 to 0.77±0.15 and 0.64±0.16; in-stent restenoses: 0.62±0.06 to 0.86±0.12 and 0.72±0.27). The course of the POD stage according to the Fontaine classification[60] is plot-

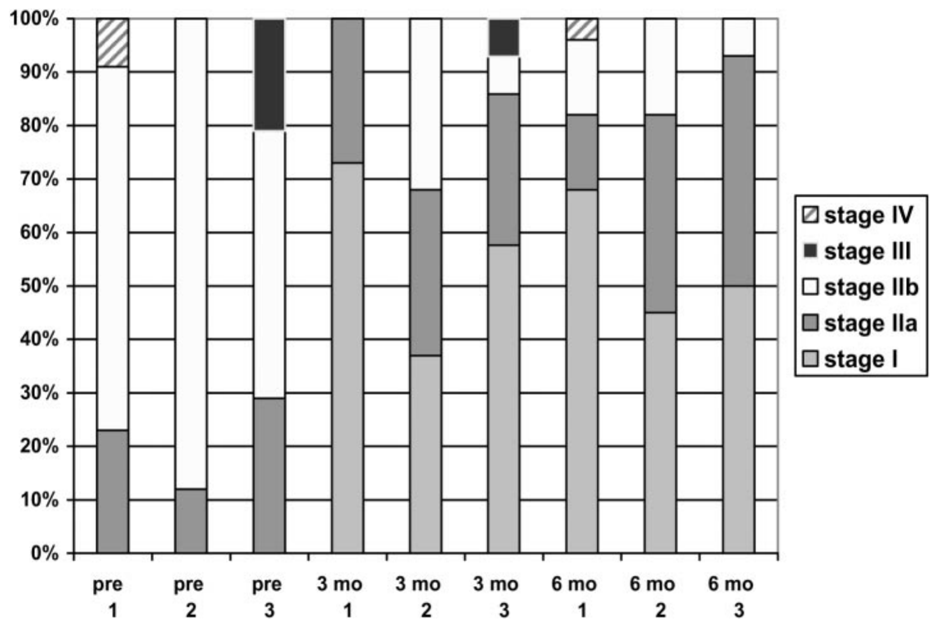

Figure 3 ◆ Fontaine classification of lower limb ischemic symptoms at different time periods according to subgroups: 1=primary lesions, 2=restenosis, and 3=in-stent restenoses.

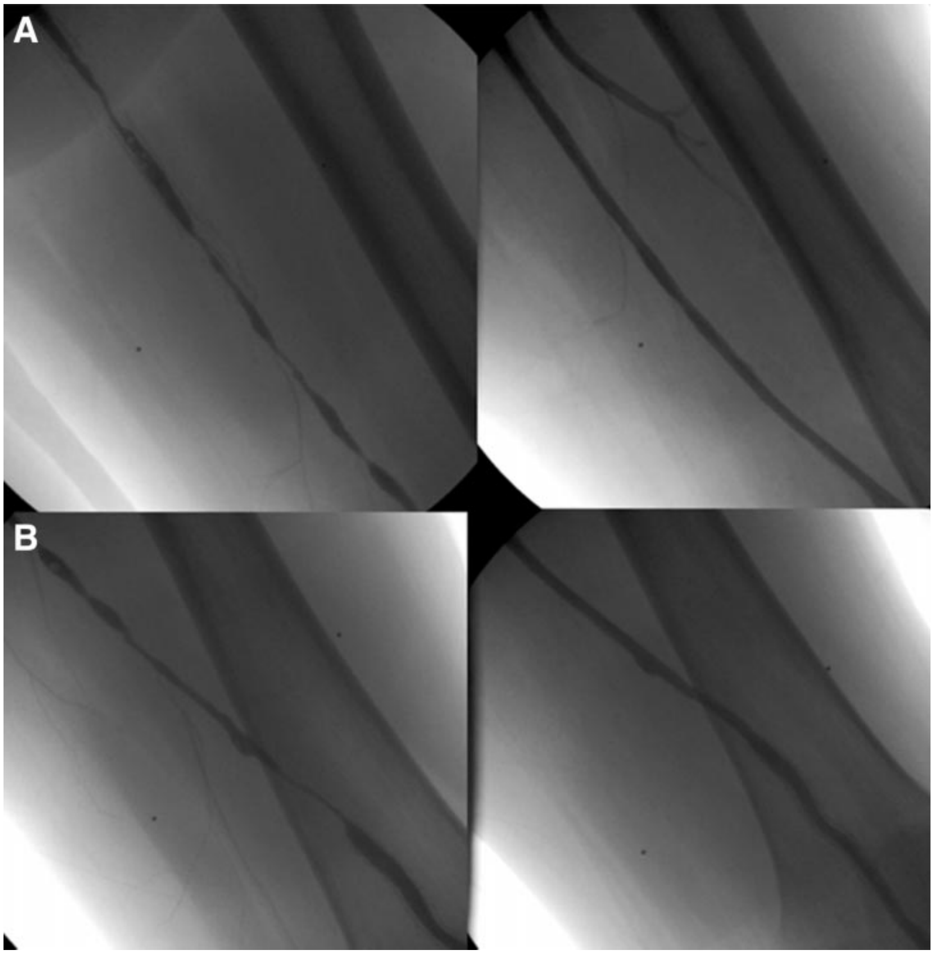

Figure 4 ◆ Long, diffuse, in-stent lesion in the SFA (**A**) and proximal popliteal artery (**B**) before (left images) and after (right images) atherectomy.

ted in Figure 3. At the 6-month follow-up, >80% of the patients in all subgroups were symptom free or had no lifestyle-limiting claudication.

Complications

During the first 8 interventions, there were 5 distal embolizations of atherectomized wall components. In each case, the embolus was completely removed with a 5-F or 6-F aspiration catheter in a single maneuver. The embolized material came from the small vent hole near the end of the catheter tip. The reservoir tip was modified by the manufacturer, and a maximum of 4 passes was imposed before the catheter tip had to be emptied. After this, we encountered no further embolic events. As mentioned above, a type C dissection after postatherectomy balloon dilation had to be treated with a stent. There were 7 occasions on which the blade became temporarily locked in the forward position in the catheter tip. This usually happened (n=6) when the vessel had a bend or turn, but once it occurred during crossover application of the device. The blade could always be freed by turning the locking mechanism.

DISCUSSION

The evolution of percutaneous atherectomy has not been as successful in the peripheral vessels as it has in the coronary arteries. The

Simpson AtheroCath, for example, did not become established for treatment of femoropopliteal lesions in the early 1990s because of its complex operation and poorer results compared to balloon angioplasty[27–58]; however, the system presented here, which is simple to operate, could lead to a rebirth of directional atherectomy.

Atherectomy alone in the majority (96%) of our cases was technically successful, but additional balloon dilation in ~60% of cases served to visually improve the angiographic appearance of the recanalized artery. Only about 24% required dilation to achieve primary treatment success. Thus, the initial use of the system tested here is more successful than the Simpson AtheroCath, which had primary success rates of 82% to 100%.[42–43] Additional stent implantation was indicated only in a minority of lesions, which is noteworthy since most of the lesions were eccentric or ostial. The treatment of these types of lesions, along with intrastent restenoses, represents the main indication for directional atherectomy in our view. However, we also successfully treated lengthy lesions up to 30 cm (Fig. 4).

The only randomized trial of balloon dilation versus atherectomy with the Simpson AtheroCath was not able to demonstrate any advantage for atherectomy in the treatment of femoropopliteal lesions.[36,44] However, individual single-center studies provided overwhelmingly positive long-term results.[27–35,37–43,45–58] In our small cohort, midterm results are encouraging, considering that technically challenging lesions were included in the study. The lowest 6-month restenosis rate we saw was in primary lesions (27%). However, even the in-stent restenotic lesions had a lower restenosis rate (36%) than previously reported for a rotational thrombectomy device (59%[61]).

From a technical standpoint, the catheter could easily be controlled in both antegrade and crossover use, despite wire guidance of the monorail system over only a short distance. The few occasions in which the blade became temporarily locked in the forward position occurred primarily when the vessel had a bend or turn; the blade could always be easily freed. The atherectomy catheter we tested in this study was limited to lesions with a slight degree of calcification because the rotating stainless steel blade did not cut through pure calcium. Since this study, the company has developed a system with a rotating carbide blade that can remove calcified plaques and stent struts.

The only noteworthy complication was the peripheral embolizations at the beginning of our experience. An overly large volume of atherectomized material in the reservoir forced material through the vent hole in the catheter tip, but the embolized plaque was easily aspirated. A new version of the reservoir has been engineered by the manufacturer so that atheroma components can no longer pass out the hole. Moreover, the modified tip makes flushing of the reservoir very simple.

Further studies have to investigate the best use of this new atherectomy device: solo atherectomy to avoid the barotrauma induced by the balloon or atherectomy combined with balloon angioplasty to achieve the best acute MLD. Furthermore, a randomized trial comparing atherectomy, balloon angioplasty, and stenting is needed to find out if atherectomy has favorable long-term results.

REFERENCES

1. Hunink MG, Wong JB, Donaldson MC, et al. Revascularization for femoropopliteal disease: a decision and cost-effectiveness analysis. *JAMA.* 1995;274:165–171.
2. Johnston KW. Femoral and popliteal arteries: reanalysis of results of balloon angioplasty. *Radiology.* 1992;183:767–771.
3. Gallino A, Mahler F, Probst P, et al. Percutaneous transluminal angioplasty of the arteries of the lower limbs: a 5 year follow-up. *Circulation.* 1984;70:619–623.
4. Krepel VM, van Andel GJ, van Erp WF, et al. Percutaneous transluminal angioplasty of the femoropopliteal artery: initial and long-term results. *Radiology.* 1985;156:325–328.
5. Matsi PJ, Manninen HI, Söder HK, et al. Percutaneous transluminal angioplasty in femoral artery occlusions: primary and longterm results in 107 claudicant patients using femoral and popliteal catheterization techniques. *Clin Radiol.* 1995;50:237–244.
6. Vroegindeweij D, Vos LD, Tielbeek AV, et al. Balloon angioplasty combined with primary stenting versus balloon angioplasty alone in

femoropopliteal obstructions: a comparative randomized study. *Cardiovasc Intervent Radiol.* 1997;20:420–425.
7. Bolia A, Miles KA, Brennan J, et al. Percutaneous transluminal angioplasty of occlusions of the femoral and popliteal arteries by subintimal dissection. *Cardiovasc Intervent Radiol.* 1990;13:357–363.
8. Hunink MG, Wong JB, Donaldson MC, et al. Patency results of percutaneous and surgical revascularization for femoropopliteal artery disease. *Med Decis Making.* 1994;14:71–81.
9. Krankenberg H, Sorge I, Walther C, et al. Percutaneous revascularization of long-standing chronic occlusion of the superficial femoral artery. A pilot study [in German]. *Dtsch Med Wochenschr.* 2001;126:491–495.
10. Wagner HJ. Current status of endovascular therapy in the femoropopliteal vascular segment in chronic peripheral arterial occlusive disease [in German]. *Vasa.* 2002;31:153–161.
11. Muradin GS, Bosch JL, Stijnen T, et al. Balloon dilation and stent implantation for treatment of femoropopliteal arterial disease: meta-analysis. *Radiology.* 2001;221:137–145.
12. Cejna M, Thurnher S, Illiasch H, et al. PTA versus Palmaz stent placement in femoropopliteal artery obstruction: a multicenter prospective randomized study. *J Vasc Intervent Radiol.* 2001;12:23–31.
13. Grimm J, Müller-Hülsbeck S, Jahnke T, et al. Randomized study to compare PTA alone versus PTA with Palmaz stent placement for femoropopliteal lesions. *J Vasc Interv Radiol.* 2001; 12:935–942.
14. Martin EC, Katzen BT, Benenati JF, et al. Multicenter trial of the Wallstent in the iliac and femoral arteries. *J Vasc Interv Radiol.* 1995;6: 843–849.
15. Sapoval MR, Long AL, Raynaud AC, et al. Femoropopliteal stent placement: long-term results. *Radiology.* 1992;184:833–839.
16. Krüger K, Bendel M, Zahringer M, et al. Endovascular gamma-irradiation for prevention or restenosis after angioplasty of femoropopliteal de-novo-stenoses-long-term results of a feasibility study [in German]. *Rofo.* 2002;174:321–327.
17. Müller-Hülsbeck S, Schwarzenberg H, Steffens JC, et al. Treatment of arterial femoropopliteal obstructions with Palmaz midsize stents [in German]. *Rofo.* 1998;168:604–609.
18. Steinkamp HJ, Scheinert D, Hettwer H, et al. Results of ''cross-over implantation of Palmaz-stents'' with cross-over sheaths [in German]. *Rofo.* 1999;170:209–213.
19. Lugmayr H, Holzer H, Riedelsberger H. Treatment of longitudinal femoropopliteal vascular lesions with stents–report of individual cases [in German]. *Rofo.* 1999;170:205–208.
20. Zeller T, Frank U, Müller C, et al. First experiences with a 6F-sheath compatible self-expanding nitinol stent [in German]. *Rofo.* 2002; 174:231–235.
21. Manke C, Hackethal S, Müller-Hülsbeck S, et al. Results after placement of Memotherm stents in iliac and femoral arteries [in German]. *Rofo.* 2001;173:240–244.
22. Gottman D, Strecker EP, Boos I, et al. Dose-dependent decrease of the rate of restenosis of stents in peripheral vessels with Reviparin [in German]. *Rofo.* 1999;170:84–88.
23. Scheinert D, Laird JR, Schröder M, et al. Excimer laser-assisted recanalization of long, chronic superficial femoral artery occlusions. *J Endovasc Ther.* 2001;8:156–166.
24. Huppert PE, Duda SH, Helber U, et al. Comparison of pulsed laser-assisted angioplasty and balloon angioplasty in femoropopliteal artery occlusions. *Radiology.* 1992;184:363–367.
25. Gray B, Sullivan TM, Childs MB, et al. High incidence of restenosis/reocclusion of stents in percutaneous treatment of long-segment superficial femoral artery disease after suboptimal angioplasty. *J Vasc Surg.* 1997;25:74–78.
26. Hayerizadeh BF, Zeller T, Krankenberg H, et al. Superficial femoral artery stenting using nitinol stents–a German multicenter experience. In: Marco J, Serruys P, Biamino G, et al., eds. *The Paris Course on Revascularization.* Paris: Europa Organisation; 2002:451–454.
27. Graor RA, Whitlow PL. Transluminal atherectomy for occlusive peripheral vascular disease. *J Am Coll Cardiol.* 1990;15:1551–1558.
28. Sanborn TA. Percutaneous peripheral atherectomy: what are its indications? *J Am Coll Cardiol.* 1990;15:689–690.
29. Kim D, Gianturco LE, Porter DH, et al. Peripheral directional atherectomy: 4-year experience. *Radiology.* 1992;183:773–778.
30. Maynar M, Reyes R, Cabrera V, et al. Percutaneous atherectomy as an alternative treatment for postangioplasty obstructive intimal flaps. *Radiology.* 1989;170:1029–1031.
31. Newman GE, Miner DG, Sussman SK, et al. Peripheral artery atherectomy: description of technique and report of initial results. *Radiology.* 1988;169:677–680.
32. Dolmatch BL, Rholl KS, Moskowitz LB, et al. Blue toe syndrome: treatment with percutaneous atherectomy. *Radiology.* 1989;173:799–804.

33. Dorros G, Iyer S, Lewin R, et al. Angiographic follow-up and clinical outcome of 126 patients after percutaneous directional atherectomy (Simpson AtheroCath) for occlusive peripheral vascular disease. *Cathet Cardiovasc Diagn.* 199?;22:79–84.
34. Dorros G, Lewin RF, Sachdev N, et al. Percutaneous atherectomy of occlusive peripheral vascular disease: stenoses and/or occlusions. *Cathet Cardiovasc Diagn.* 1989;18:1–6.
35. von Polnitz A, Nerlich A, Berger H, et al. Percutaneous peripheral atherectomy: angiographic and clinical follow-up of 60 patients. *J Am Coll Cardiol.* 1990;15:682–688.
36. Tielbeek AV, Vroegindeweij D, Buth J, et al. Comparison of balloon angioplasty and Simpson atherectomy for lesions in the femoropopliteal artery: angiographic and clinical results of a prospective randomized trial. *J Vasc Interv Radiol.* 1996;7:837–844.
37. Gonschior P, Hofling B, Backa D, et al. Percutaneous peripheral atherectomy in arterial occlusive disease. Angiographic and clinical acute and long-term results [in German]. *Dtsch Med Wochenschr.* 1991;116:1657–1663.
38. Lugmayr H, Pachinger O, Deutsch M. Long-term results of percutaneous atherectomy in peripheral arterial occlusive disease [in German]. *Rofo.* 1993;158:532–535.
39. Maynar M, Reyes R, Cabrera V, et al. The Simpson atherectomy catheter in the management of complete obstructions [in German]. *Rofo.* 1990;153:547–550.
40. Höfling B, von Polnitz A, Backa D, et al. Angiography and functional results and histologic findings following percutaneous atherectomy in patients with arterial occlusive disease [in German]. *Z Kardiol.* 1989;78:561–566.
41. Gonschior P, von Polnitz A, Backa D, et al. Angiography and clinical follow-up following peripheral atherectomy in patients with arterial occlusive disease [in German]. *Vasa Suppl.* 1991;33:179–180.
42. Ahn SS, Concepcion B. Current status of atherectomy for peripheral arterial occlusive disease. *World J Surg.* 1996;20:635–643.
43. Ahn SS. Status of peripheral atherectomy. *Surg Clin North Am.* 1992;72:869–878.
44. Vroegindeweij D, Kemper FJ, Tielbeek AV, et al. Recurrence of stenoses following balloon angioplasty and Simpson atherectomy of the femoro-popliteal segment. A randomised comparative 1-year follow-up study using colour flow duplex. *Eur J Vasc Surg.* 1992;6:164–171.
45. Walker J, Chalmers N, Gillespie IN. A new use of the Simpson percutaneous atherectomy catheter: resection of retained valve cusps of an in-situ vein graft. *Cardiovasc Intervent Radiol.* 1995;18:50–52.
46. Seth A, Mathur A, Chandra P, et al. Revascularization of a thrombosed, previously stented aorto-renal graft using combined directional atherectomy and AngioJet thrombectomy. *Catheter Cardiovasc Interv.* 1999;46:85–88.
47. Castaneda F, Moradian G, Hunter D, et al. Percutaneous intravascular biopsy using a Simpson atherectomy catheter: technical note. *Cardiovasc Intervent Radiol.* 1990;12:342–343.
48. Schneider PA, Bounameaux H, Cox JN. Endarterectomy using a Simpson catheter in arterial insufficiency of the lower limbs [in French]. *Schweiz Med Wochenschr.* 1988;118:1997–2000.
49. Schwarten DE, Katzen BT, Simpson JB, et al. Simpson catheter for percutaneous transluminal removal of atheroma. *AJR Am J Roentgenol.* 1988;150:799–801.
50. Levade M, Maquin P, Rousseau H, et al. Percutaneous peripheral atherectomy with the Simpson catheter. Long term results [in French]. *J Mal Vasc.* 1991;16:193–194.
51. Kuffer G. Peripheral Simpson atherectomy. Indications and results of a new transluminal procedure for vascular recanalization [in German]. *Radiologe.* 1990;30:60–65.
52. Hoefling B, Polnitz AV, Backa D, et al. Percutaneous removal of atheromatous plaques in peripheral arteries. *Lancet.* 1988;185:384–386.
53. Kumakura H, Yokoi Y, Kusaba H, et al. Atherectomy in patients with arteriosclerosis obliterans: angiographic follow-up study of 186 lesions in 146 patients [in Japanese]. *Nippon Igaku Hoshasen Gakkai Zasshi.* 1996;56:638–643.
54. Kuffer G, Hansen R, Spengel FA, et al. Simpson's atherectomy in embolizing leg artery stenoses [in German]. *Rofo.* 1991;155:235–241.
55. Lugmayr H, Deutsch M, Pachinger O. Simpson atherectomy–long-term results and indications [in German]. *Vasa Suppl.* 1991;33:44–46.
56. Lugmayr H, Deutsch M, Spottl A, et al. Percutaneous atherectomy of the pelvic and leg arteries [in German]. *Rofo.* 1990;153:543–546.
57. Kuffer G, Spengel FA, Hansen R, et al. Simpson's atherectomy of the peripheral arteries: early results and follow-up [in German]. *Rofo.* 1990;153:61–67.
58. von Polnitz A, Nerlich A, Berger H, et al. Percutaneous peripheral atherectomy: angiographic and clinical follow-up of 60 patients. *J Am Coll Cardiol.* 1990;15:682–688.
59. Zeller T, Krankenberg H, Reimers B, et al. Initial clinical experience with a new percutaneous

peripheral atherectomy device for treatment of femoro-popliteal stenoses [in German]. *Rofo.* 2004;176:70–75.

60. Fontaine R, Kieny R, Kim M. Thoughts on the report of 94 cases of peripheral arterial embolism [in French]. *Lyon Chir.* 1956;51:655–678.

61. Zeller T, Frank U, Bürgelin K, et al. Long-term results after recanalization of acute and subacute thrombotic occlusions of the infra-aortic arteries and bypass-grafts using a rotational thrombectomy device [in German]. *Rofo.* 2002; 174:1559–1565.