Low-Profile Primary Stent Placement for the Treatment of Focal Calcified Ulcerated Stenosis in the Infrarenal Aorta

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PURPOSE: To analyze the immediate and midterm success of low-profile stent placement in calcified ulcerated lesions of the infrarenal aorta in patients with arterial occlusive disease.

MATERIALS AND METHODS: In this prospective case series, 13 symptomatic patients (eight men, five women; mean age, 64.8 years ± 12.1; age range, 44–84 years) with focal calcified ulcerated stenoses of the infrarenal aorta were treated with stent placement by using a low-profile technique in a radiology intervention center during a 4-year period. Clinical examinations and duplex ultrasonography were used to evaluate the stents' patency and clinical success. Kaplan-Meier graphs were calculated to analyze the freedom-of-symptom rate.

RESULTS: The initial technical success rate was 92% (12 of 13 patients). Due to extended calcifications, a residual stenosis of 50%–60% remained in one patient. No peri-interventional complications occurred. The mean follow-up was 26 months (range, 5–53 months). During follow-up, one patient had a restenosis after 7 months and presented clinically with Fontaine stage IIb. Two patients had iliac and/or femoral stenoses, and both presented with Fontaine stage IIb. One patient's symptoms originated from the lumbar spine. Primary patency and primary clinical success rates were 85% and 69%, respectively. According to Kaplan-Meier tables, the freedom-from-symptom rates were 92%, 84%, 73%, and 63% at 0, 7, 12, and 21 months, respectively.

CONCLUSIONS: Low-profile stent placement in calcified, ulcerated lesions of the infrarenal aorta is an effective and safe treatment for symptomatic stenoses in patients with arterial occlusive disease after a mean follow-up of 26 months.

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Abbreviations: PSV = peak systolic velocity, PTA = percutaneous transluminal angioplasty

FOCAL stenosis of the infrarenal aorta represents a rare vascular lesion type in patients with arterial occlusive disease and is usually associated with heavy smoking and abnormal blood lipid levels (1,2). Symptoms occur as progressive bilateral claudication, sometimes complicated by acute atheroembolic events in the lower limb (1,3). Until the early 1990s, surgical revascularization has been the method of choice for the treatment of focal and extended aortic lesions (1,4). The literature provides well-documented results for surgery, with patency rates of up to 90% and 75% at 5 and 10 years, respectively, and with perioperative major complication rates of up to 10% (4).

Since the early 1990s, percutaneous transluminal angioplasty (PTA) has become the method of choice for patients with concentric, noncalcified, short stenoses in the aortoiliac region (4–6). Around that time, stent placement was introduced into clinical routine for the treatment of arterial occlusive disease (4,6,7). Initially used to overcome complications of PTA alone (eg, hemodynamically relevant dissection, elastic recoil, and relevant residual stenosis), primary stent placement recently has become an accepted alternative in different vascular abdominal regions, including large-caliber vessels such as the aorta (8,9) and small-caliber vessels such as mesenteric arteries (10,11). However, only a few studies have been performed since then to assess the safety and durability of PTA and stent placement, most of them using predominantly high-profile stent devices, that is, 10–12-F compatible devices (8,9,12–14). The reported re-

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Table 1
Summary of Patient Characteristics

Patient No/ Sex/Age (y)	Fontaine Stage before Treatment	Mean Gradient Pressure (mm Hg)		Follow-up (mo)	Fontaine Stage at Last Follow-up	PSV Ratio at Duplex US	Patent Stent?	Comment
		Before Treatment (mm Hg)	After Treatment (mm Hg)					
1/M/72	IIb	17	5	47	I	1.14	Yes	—
2/F/65	IIb	17	5	18	IIb	1.33	Yes	Magnetic resonance angiography depicted stenoses in iliac and femoral arteries
3/M/67	IIb	14	0	7	IIb	—	No	Surgery in another hospital, no image data are available
4/M/70	IIb	11	0	48	I	1.00	Yes	—
5/M/75	IIb	18	2	13	I	1.20	Yes	—
6/M/44	IIb	19	1	7	I	1.14	Yes	—
7/M/67	IIb	14	5	27	IIa	1.00	Yes	Gluteal musculoskeletal disorder originating from the lumbar spine
8/F/50	IIb	15	1	53	I	1.17	Yes	—
9/F/65	IIb	40	10	7	IIb	3.00	No	Residual stenosis after stent placement; the patient developed additional iliac stenoses
10/F/84	IV	16	0	5	I	1.00	Yes	—
11/M/54	IIb	16	1	50	I	1.67	Yes	—
12/M/79	IIb	16	0	33	I	1.00	Yes	—
13/F/50	IIb	14	3	26	I	1.00	Yes	—

sults for midterm patency and complication rates range from 43% to 85% and from 0% to 20%, respectively.

This prospective study was conducted to evaluate the efficacy of primary stent placement in calcified, ulcerated lesions of the infrarenal aorta by using low-profile stent devices that should enable easy, precise deployment at a low complication rate.

MATERIALS AND METHODS

Study Population

Institutional review board approval was obtained for this study. Before any interventional procedure was performed, written informed consent was obtained from each patient. From September 2002 to October 2006, 13 patients (eight men, five women; mean age, 64.8 years ± 12.1; age range, 44–84 years) referred to our hospital due to claudication symptoms caused by infrarenal aortic stenosis were selected for interventional treatment with primary stent placement. Risk factors for atherosclerosis were documented before treatment for all patients. Twelve of the 13 patients (92%) had hypertension, nine (69%) had hyperlipidemia, six (46%) were obese, five (38%) were smokers, and two (15%) had diabetes. Two patients each (15%) had one or two risk factors, eight patients (62%) had three risk factors, and one patient (8%) had four risk factors. According the Fontaine classification system, 12 of the 13 patients (92%) had clinical stage IIb and one patient (8%) had stage IV before treatment (**Table 1**).

Inclusion and Exclusion Criteria

Inclusion criteria for each patient to be treated with primary stent placement were as follows: (*a*) clinical Fontaine stage of IIb or worse, (*b*) more than 70% infrarenal aortic stenosis, (*c*) stenosis caused by atherosclerosis, (*d*) stenosis with an irregular surface and calcification and/or ulceration, and (*e*) exclusion of relevant stenosis in the pelvic axis and lower extremity.

Patients were excluded if they had (*a*) partially circumferential calcifications covering more than 75% of the aortic circumference; (*b*) occlusion; (*c*) concentric stenosis with a smooth surface; (*d*) a distance between the stenosed aortic segment to be treated and the aortic bifurcation of less than 1 cm; (*e*) any visual angiographic evidence of intraluminal thrombus, which is thought to increase the risk of plaque fragmentation and distal embolization; (*f*) a cardiac source of embolism; and (*g*) history of bleeding diathesis or coagulopathy.

Preinterventional Procedures and Protocol of Stent Placement

Before the intervention, all patients underwent native computed tomography (CT) to evaluate the extension of the calcifications in the target aortic segment (**Fig 1**). This was mandatory to exclude circumferential calcifications, which might cause aortic rupture at angioplasty and/or stent placement. All patients were given an antiplatelet and antithrombosis regimen, as follows: (*a*) preinterventional injection of a 1,000-mg intravenous bolus of salicylic acid and a 5,000-IU intraarterial bolus of heparin; (*b*) postinterventional medication with intravenous heparin continuously for 24 hours with a target activated partial

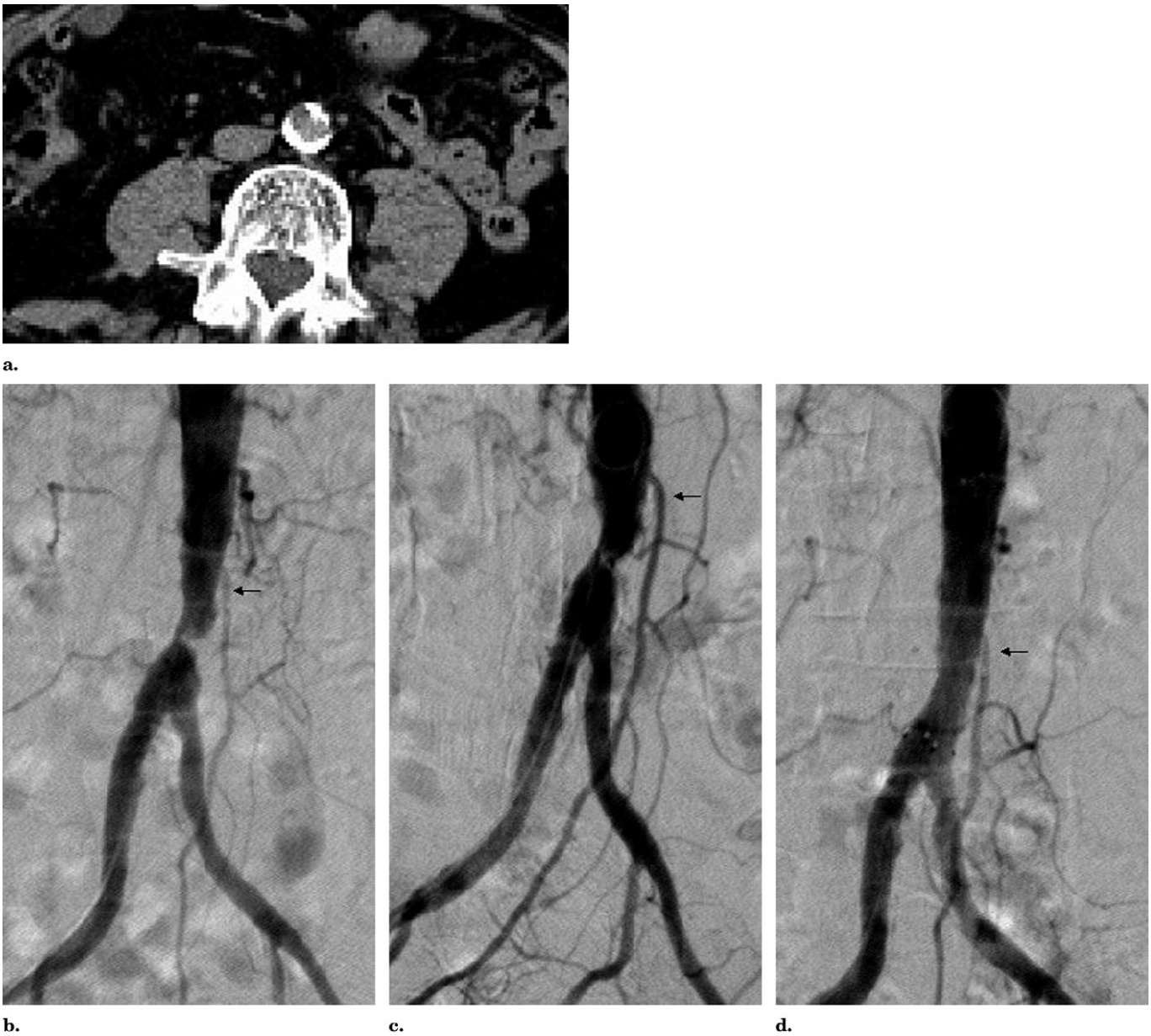


Figure 1. Images in a 75-year-old man with a severe focal stenosis of the infrarenal aorta. **(a)** Native CT scan obtained before stent placement shows calcified plaques extending about 60% of the aortic circumference. **(b, c)** Anteroposterior **(b)** and right anterior oblique **(c)** angiograms clearly demonstrate an eccentric stenosis of more than 80% below the origin of a patent inferior mesenteric artery (arrow). The mean pressure gradient before stent placement was 18 mm Hg. A 14-mm-diameter, 60-mm-long stent was deployed and balloon dilation performed with a 14-mm-diameter, 40-mm-long balloon. **(d)** Final anteroposterior angiogram documents no residual relevant stenosis and the patent inferior mesenteric artery. The mean pressure gradient after the intervention was 2 mm Hg.

thromboplastin time of 60–80 seconds and 100 mg per os salicylic acid per day for life. Digital subtraction angiography and stent placement were performed with the patient under local anesthesia by experienced interventional radiologists (P.J.S., S.M.-H., T.J.). The procedure was performed with a Multistar T.O.P. unit (Siemens, Erlangen, Germany); the contrast medium used was nonionic iopentol 300 (Imagopaque 300; Amersham, Munich, Germany).

Transfemoral retrograde access was successfull in all patients. After placing a 10-cm-long, 5-F sheath (Terumo, Tokyo, Japan) in the common femoral artery, a 150-cm-long, 0.035-inch guide wire (Radifocus; Terumo) was navigated across the aortic stenosis via a 100-cm-long, 5-F multipurpose A1 catheter (Supertorque; Cordis, Johnson & Johnson, Miami, Fla). Angiography was performed after the 5-F multipurpose catheter was exchanged for a 5-F pigtail catheter and the pigtail catheter placed above the stenosed aortic segment. At least two projection planes in anteroposterior plus right anterior oblique (30°), plus left anterior oblique (30°), or plus lateral (90°)

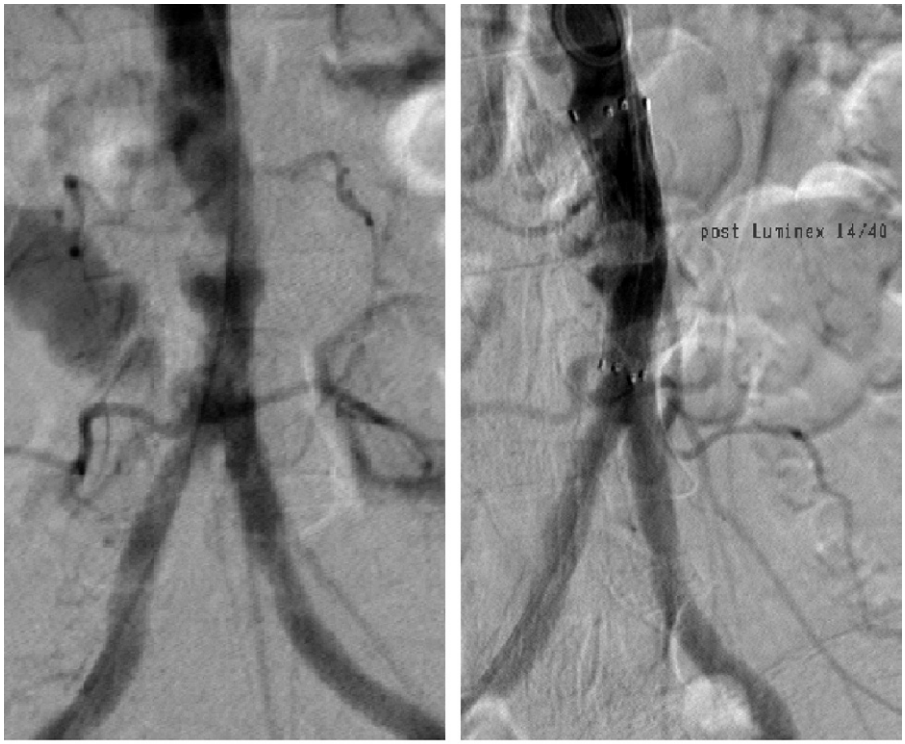
were required to obtain reliable image data for evaluating the degree of the stenosis. The reference diameter, which was determined by measuring 1 cm above and below the stenosed vessel segment, and the length of the stenosis were assessed to help choose the appropriate stent device. In addition, the mean pressure gradient across the lesion was obtained before the intervention.

After the 0.035-inch guide wire was reinserted and the diagnostic catheter removed, the 5-F sheath was exchanged for a 10-cm-long, 7-F sheath (Terumo). The selected stent device with a self-expanding stent (Dynalink, Boston Scientific, Natick, Mass [$n = 5$]; Luminexx, Bard, Murray Hill, NJ [$n = 8$]) was advanced toward the stenosis under fluoroscopic guidance. When the stent was in position, it was carefully unfolded under fluoroscopic control according to the manufacturer's recommendation. Then, balloon dilation (Wanda; Boston Scientific) was performed. The balloon diameter was chosen on the basis of the suprastenotic aortic diameter. Dilation was performed under manometric (Encore 26; Boston Scientific) and fluoroscopic control. The goal was to achieve a residual stenosis of less than 30%. Success was verified by measuring the postinterventional mean pressure gradient across the treated segment without previous injection of a vasodilator. The Dynalink stent was 14 mm in diameter and 38 mm long ($n = 5$). The sizes of the Luminexx stents used were as follows: 12-mm diameter and 40 mm long, 14-mm diameter and 30 mm long, 14-mm diameter and 40 mm long, and 14-mm diameter and 60 mm long ($n = 2$ each). For final angiographic control, documentation of technical success, and exclusion of distal embolization, angiography was performed by using a 5-F pigtail catheter.

Follow-up and Statistical Analysis

After initial regular follow-up examinations at 3, 6, and 12 months, all patients were contacted by telephone soon thereafter and urged to visit for clinical examination, including measurement of the ankle-brachial index and duplex US of the infrarenal aorta with the stent.

Technical success was defined as a residual stenosis of less than 30% reduction in diameter and a mean pressure gradient not greater than 5 mm Hg. Resolution of symptoms within 30 days after the intervention was considered to be an indication of early clinical success, and the absence of symptom recurrence was considered to be an indication of primary late clinical success. The patency of the targeted aortic segment was assessed with duplex US. The peak systolic velocity (PSV) ratio was defined by the PSV of the treated aortic segment to that of the nonaffected aortic segment above. A PSV ratio of 4.0 was used as the cut-off level for hemodynamically relevant restenosis of at least 70%. Primary patency was defined as maintainence of the patency of the stented vessel segment with no need for repeat intervention. A Kaplan-Meier graph was calculated for the analysis of freedom from recurrent symptoms. Statistical software (MedCalc, version 9.3.0.0; MedCalc Software, Mariakerke, Belgium) was used.



a. **b.**

Figure 2. Images in a 65-year-old woman with a severe stenosis of the infrarenal aorta. **(a)** Anteroposterior angiogram shows a stenosis of more than 90% due to extended calcification causing bright subtraction artifact. The mean pressure gradient before stent placement was 40 mm Hg. A 14-mm-diameter, 40-mm-long stent was deployed and balloon dilation performed with a 10-mm-diameter, 40-mm-long balloon. **(b)** Final right anterior oblique angiogram demonstrates a remaining eccentric 50%–60% stenosis delineated by the bright subtraction artifact. The mean pressure gradient after the intervention was 10 mm Hg.

RESULTS

General Findings

Primary stent placement was performed in the infrarenal aorta in all 13 patients. The initial technical success rate was 92% (12 of 13 patients). In one patient, a stenosis of 50% and a mean pressure gradient of 10 mm Hg were remaining because of strong and extended semicircumferential calcification (**Table 1**, **Fig 2**). The mean pressure gradient across the stenosis before intervention was 17.5 mm Hg ± 7.1 (range, 11–40 mm Hg). The mean pressure gradient after intervention was 2.5 mm Hg ± 3.0 (range, 0–10 mm Hg).

The mean follow-up period was 26

months (range, 5–53 months). None of the patients died during the observation period. No complications, as defined by the quality improvement guidelines of the SIR Standards of Practice Committee (15), were observed.

Patency and Clinical Success Rates

Two restenoses among the 13 targeted aortic segments were observed, one immediate due to extended calcifications and one after 7 months. The primary patency rate was 85% (11 of 13 patients).

Four patients had continuous (n = 1) or recurrent (n = 3) symptoms at a mean of 10 months (range, 0–21 months) after stent placement. Thus, the primary late clinical success rate was 69% (nine of 13 patients). According to the Kaplan-Meier table, the freedom-from-symptom rate was 84% at 7 months and 63% at 21 months (**Table 2**, **Fig 3**).

In a 65-year-old woman, a stenosis of 50%–60% remained after stent placement because of extended calcification in the infrarenal aorta (**Fig 2**). Because the patient had abdominal pain while postdilating, further widening of the targeted aortic segment was not performed to avoid the potential risk of aortic rupture. At discharge after stent placement, the clinical stage was Fontaine IIa. The patient reported worsening symptoms (Fontaine stage IIb) at the latest follow-up. Duplex US showed a PSV ratio of 3.0, which corresponded to the known stenosis, but also revealed hemodynamically relevant stenoses in the iliac arteries, which were successfully treated endovascularly with PTA.

A 67-year-old man with restenosis after 7 months underwent surgery with bypass grafting in another hospital. More detailed information with regard to preoperative duplex US and other imaging techniques could not be obtained.

Table 2
Freedom-of-Symptom Rates

Time of Follow-up (mo)	No. of Patients at Risk	No. of Events (Continuous or Recurrent)	Freedom-of-Symptom Rate	Standard Error
0	13	1	0.923	0.074
7	11	1	0.839	0.104
12	8	1	0.734	0.134
21	7	1	0.629	0.150

Note.—Freedom-of-symptom rates were determined with Kaplan-Meier tables; a corresponding graph with 95% confidence intervals is shown in Figure 3.

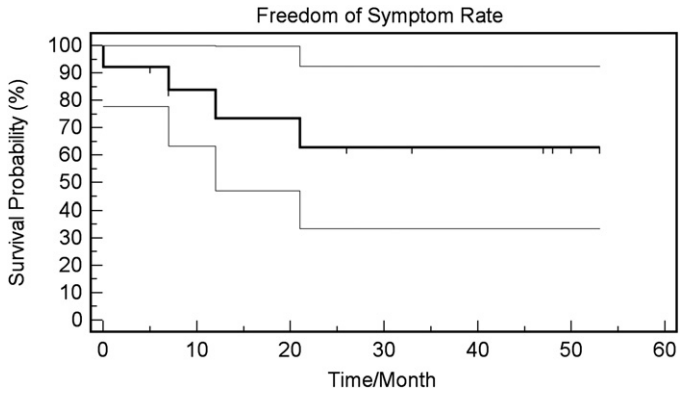


Figure 3. Graph shows the cumulative freedom-of-symptom rate (abscissa) in months (ordinate) with the 95% confidence interval. Vertical lines indicate drop-outs.

DISCUSSION

With encouraging results for primary (85%; range, 70%–100%) and secondary (90%; range, 85%–100%) patency rates, PTA has evolved as a powerful treatment option for distal aortic stenosis (6,14,16,17). Focal infrarenal aortic stenoses not extending to the aortic bifurcation and iliac arteries, however, are rare. Until today, no randomized trials were available offering data about which endovascular technique is the most durable with regard to long-term patency: PTA alone, PTA with secondary stent placement after PTA failure, or primary stent placement (8,13,16–18). The literature for the endovascular treatment of complex eccentric calcified, ulcerated aortic stenoses is limited (8,12,14).

PTA alone of ulcerated calcified lesions may be associated with embolization that may be potentially preventable with stent placement (13). PTA of these lesions may also cause early thrombus formation, acute thromboembolism, and late myointimal hyperplasia (19,20). Thus, we performed primary stent placement in our study to avoid immediate and late distal embolization of plaque or thrombus and to provide an even surface of the targeted aortic segment that would enable laminar blood flow. It is doubtful, however, that stent placement would prevent myointimal hyperplasia. The presented results with primary patency of 85% are comparable to those recently reported in the literature. Schedel et al (14) found a primary hemodynamic patency rate of 85% with two recurrent stenoses during the follow-up, and a secondary hemodynamic patency rate of 100% after repeat intervention. In our study, one patient remained with a hemodynamically relevant residual stenosis because extended calcifications did not allow for sufficient widening of the stenosed aortic segment. Another patient with restenosis underwent surgical bypass grafting. Unfortunately, no more detailed clinical information and imaging data could be obtained for the patient who underwent surgery in another hospital. Another similar primary patency rate of 83% at a mean follow-up of 27 months was obtained by Simons et al (16) in 2006. Ruppert et al (8) reported a patency rate of 100% for 10 patients—of 14 patients initially enrolled—who were available for the last follow-up; it remains unclear what happened to three patients who had a

residual stenosis greater than 30% after stent placement. If those patients had been included in the analysis as done in our study, the patency rate would have been 79%. Stoeckelhuber et al reported an excellent patency rate of 100% in nine patients after a midterm follow-up of 2 years (9); the information provided for the long-term follow-up of 9 years (12) seems vague, with only four patients showing up to a final examination. Therasse et al (13) reported a comparatively low primary patency of 69% at 3 years for aortic stent placement and a higher primary patency rate of 85% for aortic PTA alone; they attributed the lower patency rate of stent placement to the size of the abdominal aorta, whereas a smaller aortic diameter seems to tend toward restenosis.

In addition to the assessment of the patency of the treated aortic segment, it is essential to evaluate the clinical findings. Even though only patients with relevant focal stenosis in the infrarenal aorta were included in our study, additional relevant stenoses may occur in the pelvic and femoral arteries of patients with atherosclerosis. In our study, the primary late clinical success, which was defined as maintaining relief of symptoms, was achieved in 69% of patients, and the cumulative freedom-of-symptom rate was 63% at 21 months. One patient had recurrent symptoms due to aortic restenosis. Two patients with progressive generalized atherosclerosis had symptoms that could be related to relevant stenoses in iliac and femoral arteries (**Table 1**). One patient's symptoms were definitely not caused by restenosis but originated most probably from the lumbar spine. Simons et al (16) and Ruppert et al (8) reported similar late clinical success rates (68% and 70%, respectively); both authors had patients with symptoms caused by arterial stenoses distal to the stented aorta.

In our study of primary aortic stent placement, low-profile stent devices were used continuously; the maximum sheath size required was only 7 F. Other published studies reported the use of high-profile stent devices, most often the Wallstent (Boston Scientific) or Palmaz stent (Cordis), requiring sheath sizes of 10–14-F (8,9,12–14,18,21–23). With use of smaller introducer sheaths, the complication rate should be kept to a minimum; major complications such as puncture site dissection, pseudoaneurysm, or thromboembolic adverse events may be avoided. In our study, we did not observe any peri-interventional procedure-related complication. In recently published studies, several major complications that were considered to be related to the procedure have been reported (8,13,14,16). Thus, we believe the use of low-profile stent devices combined with a peri-interventional antiplatelet and antithrombosis regimen reduces the complication rate to a minimum and enables safe stent placement in calcified aortic lesions (**Fig 1**). Furthermore, primary stent placement with a self-expanding stent and careful, manometric-controlled poststent dilation should prevent plaque fragmentation, severe dissection, and distal embolization in calcified and ulcerated lesions. If the calcification is too extended, however, stent placement with poststent dilation may fail (**Fig 2**).

Our results with the minimally invasive endovascular approach appear comparable to those with surgical bypass grafting. In a large meta-analysis of results of aortic bifurcation grafts (24), 5-year patency rates of 80%–85% were found. The mortality and morbidity rates associated with surgical bypass grafting were 3% and 8%, respectively. Considering the limited study population of 13 patients and the strict exclusion criteria in our series, the complication rate of 0% cannot easily be generalized and regarded as superior to that obtained in the study of aortic bifurcation grafts. Larger patient numbers would certainly produce a noticeable complication rate when using the minimally endovascular approach as presented.

Our study has several limitations that must be addressed. First, the inclusion criteria allow only calcified and/or ulcerated lesions that were treated with primary stent placement; conventional PTA had not been attempted in any patient. However, primary stent placement was performed to minimize the risk of severe dissection, plaque fragmentation, and distal embolization. Second, we used two types of stents that might have different outcomes with regard to patency rate. The limited number of patients did not allow for statistical tests for significant differences among the two stent types. Third, the small sample size and limited follow-up did not allow for generalizing statements and recommendations for patients at risk (12,13).

In summary, endovascular therapy of focal calcified and/or ulcerated stenosis in the infrarenal aorta with primary stent placement by using a low-profile technique is effective and safe in patients with aortic atherosclerotic disease, given that our study results for primary patency rate, primary clinical success rate, and complication rate are promising, with values of 85%, 69%, and 0%, respectively. We again emphasize that three of four patients with recurrent symptoms did not have restenosis in the treated aortic segment. With a high degree of procedural standardization and improvement of endovascular interventional equipment, primary stent placement with use of a low-profile technique seems to have evolved as a powerful and safe modality for the treatment of focal calcified stenosis in the infrarenal aorta.

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