Results of heparin-bonded ePTFE-covered stents for chronic occlusive superficial femoral artery disease

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Objective: **The purpose of this study was to assess the 1-year patency rates of heparin-bonded covered stents in the treatment of chronic occlusive disease of the superficial femoral artery (SFA).**

Methods: **All patients treated with a heparin-bonded endograft between April 2009 and October 2010 for chronic occlusive disease of the SFA were prospectively gathered in a database and retrospectively analyzed. Primary, primary-assisted, and secondary patency rates, assessed by ultrasound scanning, were analyzed at 1-year, as were the complication rates and mortality.**

Results: **A total of 56 limbs were treated with a heparin-bonded covered stent in 53 patients for chronic ischemia Rutherford category 3 (n = 36), 4 (n = 5), 5 (n = 11), and 6 (n = 1). Lesions were classified as TransAtlantic Inter-Society Consensus (TASC)-2-B (n = 9), C (n = 14), and D (n = 33), and the mean treated lesion length was 18.5 ± 7.7 cm. Postoperative complications occurred in 7.5%, including hematoma (n = 1), edema (n = 1), pneumonia (n = 1), and urinary retention (n = 1), and the 30-day mortality rate was 0%. The mean follow-up was 413 ± 208 days. At 1 year, the primary patency was 76%, the primary-assisted patency 82%, and the secondary patency 89%. The limb salvage rate was 100%.**

Conclusions: **Heparin-bonded covered stents seem to provide a valid alternative to surgical treatment of long occlusive lesions in the SFA. Randomized trials and long-term data are required before considering the technique as a new standard of care. (J Vasc Surg 2012;56:118-25.)**

Peripheral arterial disease (PAD) is a widespread problem with a prevalence of 3% to 10%, increasing to 15% to 20% over the age of 70 years.[1-3] The prevalence of intermittent claudication is estimated at 3% in patients aged 40 and 6% in patients aged 60.[4,5] One percent of patients with PAD will eventually develop critical limb ischemia annually. The TransAtlantic Inter-Society Consensus (TASC) has given recommendations for treatment strategies based on morphologic stratification of the lesions.[5] Surgery is considered the gold standard for lesions with a length of >15 cm. Endovascular alternatives and results, however, are evolving continuously.

The introduction of nitinol stents has improved results of endovascular treatment of chronic occlusive lesions of the superficial femoral artery (SFA). One-year primary patency rates have been reported between 63% and 80% in lesions with a length of 5 cm to 11 cm.[6-8] The major limitation of endovascular treatment is the occurrence of (in-stent) re-stenosis due to intimal neo-hyperplasia. To reduce the incidence of in-stent re-stenosis, covered stents have been introduced. We have recently shown that these may reduce re-stenosis to edge stenosis only.[9] Case series have shown 1-year primary patency rates between 44% and 93% for lesions from 8 cm up to 26 cm.[10-12] McQuade et al[13] have recently published the 4-year results of a randomized trial comparing an above-knee prosthetic femoropopliteal bypass with covered stents. There were no differences in primary or secondary patency rates between both treatment modalities, and limb salvage rates were also comparable, indicating that covered stents may be a viable alternative for bypass surgery. The venous femoropopliteal bypass, however, is associated with higher patency rates when compared to prosthetic bypasses.[14]

The introduction of the heparin-bonded technology has significantly improved patency rates of peripheral surgical bypasses.[15,16] Because endograft failure is often due to acute thrombosis rather than in-stent re-stenosis, the heparin-bonding technology has also been integrated with endografts. It is believed that the irreversible bonded heparin-molecules in the inner surface of the graft may prevent thrombosis, thus further increasing their performance. To date, no clinical studies have been published using heparin-bonded endografts. The purpose of the present study was to assess the 1-year results of heparin-bonded

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covered stents in the treatment of chronic occlusive disease of the SFA.

METHODS

Patients. All patients treated with a heparin-bonded expanded polytetrafluoroethylene (ePTFE)-covered stent between April 2009 and October 2010 in the Alysis Hospital, located at Rijnstate in Arnhem and the Isala Clinics in Zwolle, The Netherlands, were prospectively gathered in a database. Two dedicated vascular surgeons (M.R. and W.F.) and one interventional radiologist (J.O.) performed all the procedures.

In all patients, secondary risk prevention was performed according to the national guidelines and all patients with intermittent claudication were initially treated with walking exercise. Only those with unsuccessful exercise training were indicated for intervention. The indication for endovascular treatment was based on anatomic suitability and the preference of both the patient and surgeon. Generally, covered stents were used in lesions with a length of more than 15 cm, whereas bare metal stents or plain balloon angioplasty were used in shorter lesions. Anatomic suitability consisted of an adequate inflow without a flow-limiting stenosis in the aortoiliac arteries, a patent popliteal artery above the P3 level with a luminal diameter of at least 4.2 mm, and at least one patent crural vessel.

Demographics, clinical status, and medical history were noted and retrospectively reviewed. Procedural aspects and follow-up data were retrieved. Lesions were reviewed and scored according to the TASC-2 criteria.[5] Additionally, the lesion length, luminal vessel diameters, and the number of patent run-off vessels were scored.

Patients with a lesion length of <5 cm were excluded from the analysis as were patients who had undergone a previous stent placement in the ipsilateral SFA or femoropopliteal bypass surgery.

Follow-up consisted of clinical assessment, including physical examination, ankle-brachial index (ABI) measurements, and duplex ultrasound scans at 1, 3, 6, and 12 months. The ABI was measured in a supine position using a Nicolet VasoGuard (CareFusion Corporation, San Diego, Calif) or a Basic 3 (Atys Medical, Soucieu en Jarrest, France). Complications and additional treatments were registered in the hospital files.

Definitions. Risk factors were scored according to the Society for Vascular Surgery medical comorbidity grading system. Re-stenosis was defined as a peak systolic velocity (PSV) ratio >2.5, as measured on ultrasound scanning. An occlusion was defined as absence of flow in the treated segment of the superficial femoral artery. Primary patency was defined as the absence of re-stenosis or occlusion in the target vessel. Primary-assisted patency was defined as patency achieved by secondary endovascular interventions to treat re-stenosis of the target vessel. Secondary patency was defined as patency achieved by all procedures aimed at recanalizing an occluded endograft, thereby preserving the endograft. Limb salvage was defined as the absence of an above-ankle amputation.

Treatment protocol. Procedures were performed using antibiotic prophylaxis. The common femoral artery was approached either percutaneously or surgically, as preferred by the treating surgeon. When there was a concomitant lesion in the common or profunda femoral artery, an endarterectomy was performed. Heparin (5000 IU) was administered. The diseased segment of the SFA was passed using a Terumo wire (Terumo Medical Corporation, Elkton, Md) and a catheter, either endoluminal or subintimal, and a re-entry was created distally. The segment was predilated with a regular angioplasty balloon and the endografts were positioned from distal to proximal with minimal oversizing. The entire diseased segment was covered with endografts and endografts were postdilated with an angioplasty balloon with the same size as the endograft. Control angiography of the bypass and outflow vessels was performed routinely. In case of a percutaneous approach, the access was closed using a closure device (Angio-Seal; St. Jude Medical, St. Paul, Minn, or Proglide; Abbott Vascular, Bruxelles, Belgium) or by manual compression.

The used endograft was the heparin-bonded Viabahn endoprosthesis (W. L. Gore, Flagstaff, Ariz), which is a self-expanding helical nitinol stent covered with a heparin-bonded thin ePTFE tube.

Postprocedural patients received statin treatment and dual antiplatelet inhibitors, unless oral anticoagulation was indicated for other reasons.

Statistical analysis. Patient characteristics and characteristics of the treated lesions are presented as mean and SD, unless otherwise stated. Patency rates were determined using the Kaplan-Meier life-table method using PASW statistics software, version 18.0 (SPSS, Chicago, Ill). Log-rank testing was used to determine possible differences in patency rates between different subgroups (ie, different TASC-2 lesions, level of distal anastomosis, lesion length, diabetes mellitus, smoking, stent diameter, and number of patent outflow vessels). A P value $< .05$ was considered statistically significant. Data are presented as mean and SD, unless otherwise stated.

RESULTS

Patient population. During the study period a total of 59 SFAs in 56 patients were scheduled for endovascular treatment, of which 56 SFAs were successfully treated (95%). In the remaining three patients, the procedure was converted to an open femoropopliteal bypass because of the inability to recanalize the diseased segment. The mean age was 69.6 ± 9.4 years and the male:female ratio was 40:13. Twenty-one patients (37.5%) were treated in the Isala Clinics in Zwolle and the remaining 35 patients (62.5%) in the Rijnstate Hospital, Arnhem.

Patient characteristics and risk factors are shown in Table I. Four patients (7.1%) had previously undergone an angioplasty of the SFA without stent placement, and three others (5.4%) had undergone an angioplasty with (n = 2) or without (n = 1) stent placement of the iliac artery. One patient already had a patent aortoiliac bypass, and another patient had previously undergone an endarterectomy of the

Table I. Patient characteristics and risk factors

Risk factor	*No. of patients (%)*
Diabetes mellitus	
Yes	22 (41.6)
No	31 (58.4)
Smoking	
Never	16 (30.2)
Former	10 (18.9)
Current	27 (50.9)
Hypertension	
Yes	43 (81.1)
No	10 (18.9)
Hyperlipidemia	
Yes	41 (77.3)
No	12 (22.7)
History of cardiac disease	
No	33 (62.3)
>10 years ago	8 (15.1)
Stable AP, recent MI	9 (16.9)
Non-stable AP	3 (5.7)
Neurological status	
Asymptomatic	48 (90.6)
Asymptomatic CVA/TIA	4 (7.5)
Symptomatic CVA	1 (1.9)
Renal disease	
No disease	42 (79.2)
Renal disease	8 (15.1)
Dialysis dependent	3 (5.7)
Pulmonary disease	
Yes	13 (24.5)
No	40 (75.5)
ASA classification	
I	1 (1.9)
II	22 (41.5)
III	28 (52.8)
IV	2 (3.8)
Rutherford classification	
3	36 (67.9)
4	5 (9.4)
5	11 (20.8)
6	1 (1.9)

AP, Angina pectoris; *ASA,* American Society of Anesthesiologists; *CVA,* cerebrovascular accident; *MI,* myocardial infarction; *TIA,* transient ischemic attack.

Table II. Characteristics of the treated lesions

Anatomic character	*No. of patients (%)*
Level of distal end of endograft	
P1	36 (64.3)
P2	17 (30.3)
P3	3 (5.4)
Number of patent outflow vessels	
0	1 (1.8)
1	5 (8.9)
2	11 (19.6)
3	39 (69.7)
Lesion length (mm)	185 ± 77
Luminal diameter superficial femoral artery (mm)	5.4 ± 1.1
Luminal diameter popliteal artery (mm)	4.6 ± 0.75

Data are presented as mean and SD.
P1, Popliteal artery cranial of the upper border of the patella; *P2,* popliteal artery between the tibia plateau and upper border of the patella; *P3,* popliteal artery below the tibia plateau.

ipsilateral common femoral artery. Two patients (3.6%) had already undergone a minor amputation of the ipsilateral limb.

The mean preprocedural ABI was 0.49 ± 0.1 with a range of 0.19 to 0.74. Nine lesions (16.1%) were classified as TASC-2-B lesions, 14 (25%) as TASC-2-C lesions, and the remaining 33 (58.9%) were TASC-2-D lesions. The mean length of the lesions was 18.5 ± 7.7 cm. Other anatomic lesion characteristics are shown in Table II.

Procedure. Four patients were treated using local anesthesia only (7.5%), 26 patients were treated using spinal anesthetics (49.1%), and the remaining 23 patients had general anesthetics (43.4%). The use of spinal or general anesthetics enabled a conversion to a hybrid approach or a surgical bypass in case of a technical failure within the same session. A percutaneous approach was used in 34 procedures (60.7%). In most of these cases, access was acquired using ultrasound scan guidance. Endografts were inserted with an exposed common femoral artery, as preferred by one of the surgeons, using a longitudinal incision in 11 patients (19.6%) and a concomitant endarterectomy of the communal femoral artery was performed in 11 other patients (19.6%). An additional angioplasty of the iliac arteries, with bare metal stent placement in two of them, was performed in five patients in order to improve inflow, and angioplasty of the popliteal artery was performed in two patients to improve outflow. Three patients underwent a necrotectomy and a planned minor amputation was performed in two patients. In one patient, a bilateral procedure was combined with the treatment of an abdominal aortic aneurysm using endovascular aneurysm repair (EVAR). Postoperatively, one patient was treated with continuous thrombolytic therapy, because of thrombosis of the crural arteries that already existed before the intervention. This was also the only patient who stayed in the medium-care unit during the 2 days of receiving thrombolytic therapy.

In 16 cases (28.6%), one endograft was used, in 18 procedures (32.1%) two endografts were used, and in the remaining 22 cases (39.3%) three endografts were used. In three cases (5.4%), the used diameter of the endograft was 5 mm, in 45 patients (80.4%) it was 6 mm, in seven patients (12.5%) it was 7 mm, and in one patient (1.7%) it was 8 mm.

One procedure was complicated by a dissection of the popliteal artery that was treated in the same session with an additional endograft. Postoperative complications occurred in four of 53 patients (7.5%). One patient had a hematoma at the puncture site that was treated conservatively. One patient sustained urine retention that was conservatively treated with a urinary catheter for 24 hours. One patient developed pneumonia and was treated with antibiotics. One patient had an edema, without signs of deep venous thrombosis on duplex ultrasound scan. The swelling and redness, probably due to reperfusion, disappeared during the first postoperative month. The 30-day mortality rate was 0%.

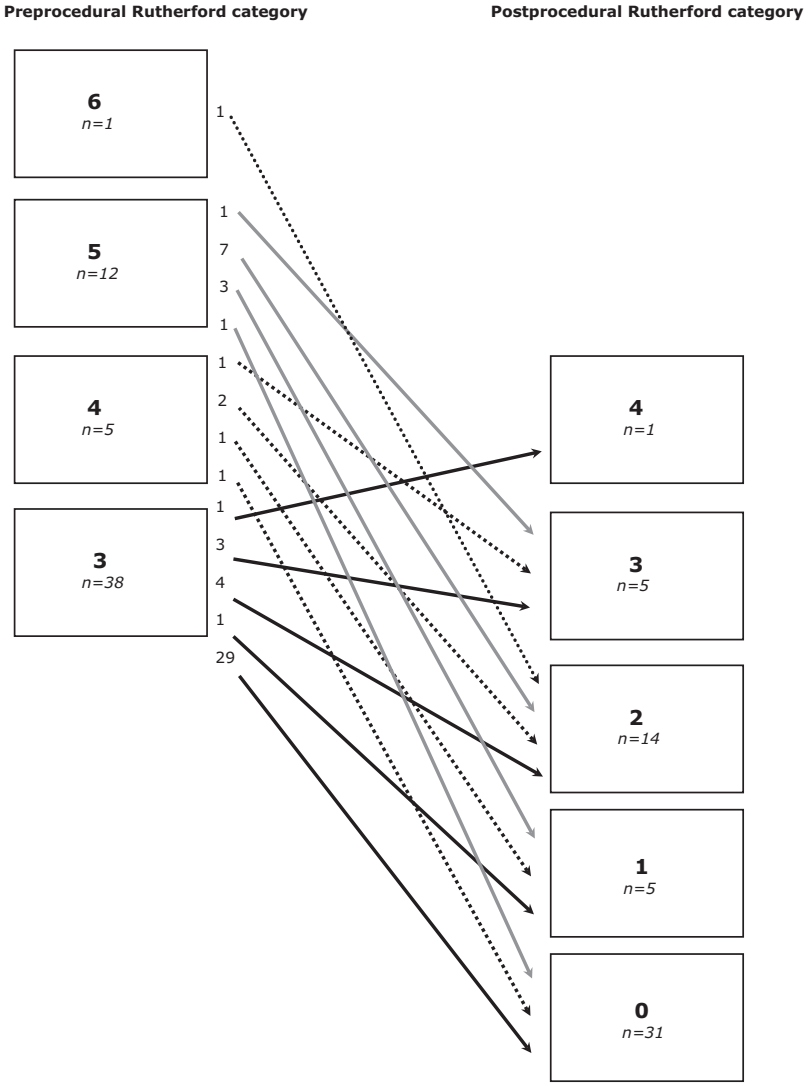


Fig 1. Individual changes in the Rutherford categories before and after the procedure.

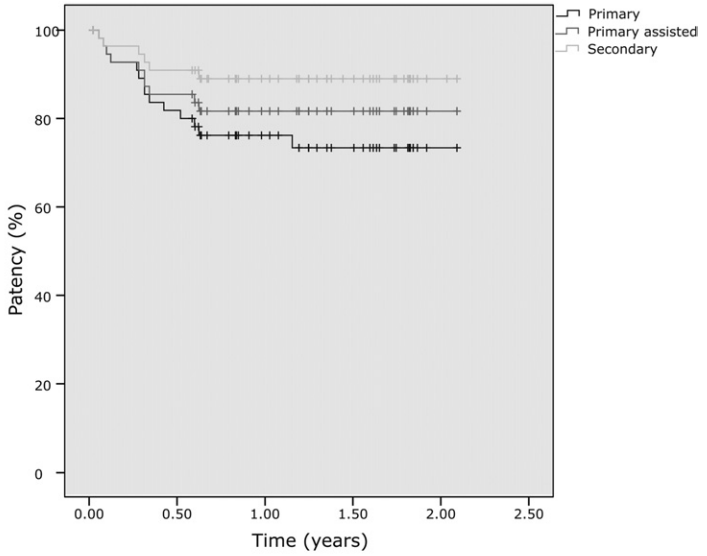
Patients were admitted to the hospital for a mean of 3.0 ± 2.6 days. Most patients were admitted the day before the intervention. Patients who underwent a percutaneous procedure had a mean length of stay of 2.4 ± 1.2 days, and patients with an open approach were admitted for 3.6 ± 2.5 days. The mean postoperative ABI was 1.00, with a range of 0.74 to 1.17.

Postoperatively, 37 patients (69.8%) were treated with the combination of acetylsalicylic acid 80 mg and clopidogrel 75 mg, eight patients (15.1%) received acetylsalicylic acid 80 mg with dipyridamol 400 mg, and four patients (7.5%) were treated by acetylsalicylic acid 80 mg only. Four patients (7.5%) were treated by Coumadin derivates because of other indications. All patients were treated with statins.

Clinical outcome. All but one patient were clinically improved after placement of the endograft(s) (Fig 1). The median Rutherford category improved from category 3 (range, 3-6) preoperatively to category 0 (range, 0-4) postoperatively ($P < .001$). There was one patient that did not improve clinically having an early endograft failure and she was treated with a surgical femoropopliteal bypass. The subset of patients that were treated for critical limb ischemia (n = 18) had all improved. Sixteen patients (88.9%) improved from critical ischemia to claudication (Rutherford category 1-3) and the others were asymptomatic. At 1-year follow-up, the freedom from target lesion revascularization was 92.6%.

Patency. The mean follow-up was 413 ± 208 days. The 1-year primary patency was 76.2%, the 1-year primary-assisted patency was 81.7%, and the secondary patency rate was 89.0% (Fig 2). During follow-up, no major amputations were performed.

A univariate analysis of risk factors, commonly associated with failure, showed no significant difference between



Limbs at risk					
Primary patency	56	45	29	19	2
Primary assisted patency	56	47	31	20	2
Secondary patency	56	50	34	21	3
Patency (%)					
Primary patency	100	81.8	76.2	73.4	73.4
Primary assisted patency	100	85.5	81.7	81.7	81.7
Secondary patency	100	90.9	89.0	89.0	89.0
SE (%)					
Primary patency	0	5.2	5.8	6.2	6.2
Primary assisted patency	0	4.8	5.2	5.2	5.2
Secondary patency	0	3.9	4.2	4.2	4.2

Fig 2. Kaplan-Meier survival curve showing primary patency, primary-assisted patency, and secondary patency of the heparin-bonded endografts.

subgroups, as defined in the statistical analysis (Table III). The number of endografts used seemed to have an effect on the patency rate, although not statistically significant ($P = .097$). The use of three endografts decreased the primary patency rate by 28% and 24%, respectively, when compared with the use of one and two endografts (Fig 3). Moreover, patients with a single vessel run-off (n = 5) tended to have a lower, but not statistically significant, patency rate compared with patients with two or three vessel run-offs.

Outcome of failures. During follow-up, the endograft failed in six patients (10.1%). In all but 1 patient, the Rutherford category at time of failure was similar or lower when compared to the preoperative Rutherford category. The other patient went from Rutherford category 3 to category 4.

In two patients with a preprocedural Rutherford classification of 3 and 4, respectively, the occlusion was found during routine duplex scan surveillance without having clinical symptoms. The other four patients returned with symptoms and were all initially treated by chemical thrombolysis. In one patient, the endograft then remained patent for another 9 months before it finally failed. This patient was treated with a below-knee ePTFE bypass due to the absence of usable vein conduit. In the other three patients, thrombolysis failed and they were treated with a venous above-knee femoropopliteal bypass. The distal runoff did not change after failure of the endograft, when compared to the preoperative state.

DISCUSSION

The present study shows the results of the first prospective cohort of patients treated in our centers with a heparin-bonded covered stent for chronic occlusive disease of the SFA. Based on our data, we conclude that the use of heparin-bonded covered stents for this indication is feasible, safe, and related with a good clinical outcome. This indicates that the use of heparin-bonded endografts might be a valid alternative for surgery in this specific group of patients. The technique, however, may also be considered as an extra treatment option before even considering a surgical reconstruction. In our series, failure of the endoluminal bypass did not lead to any major amputations or worsening of the clinical status, which confirms the observation of McQuade et al[13] that the use of covered stents in SFA occlusive disease is not related to an increased amputation rate due to covering collaterals in case of failure.

Femoropopliteal bypass surgery is related to morbidity, including early postoperative complications such as wound healing problems in 5% to 44% and edema in up to 40% to 100%.[17-20] The minimally invasive character of an endovascular reconstruction may well decrease morbidity in these often frail patients. The overall complication rate in our

Table III. Primary patency rates of the heparin-bonded endografts in relation to risk factors for failure

Risk factor	*No. of patients*	*Patency (%)*	P *value*
TASC-2 classification			.575
B	9	77.8	
C	14	85.7	
D	33	69.7	
Level distal anastomosis			.598
P1	36	72.2	
P2	17	82.4	
P3	3	66.7	
Lesion length			.790
<15 cm	17	76.5	
>15 cm	39	74.4	
Diabetes mellitus			.528
Yes	24	78.1	
No	32	70.8	
Smoking			.758
No	16	81.3	
Former	13	76.9	
Current	27	70.4	
Endograft diameter			.562
5	3	100	
6	45	71.1	
7	7	85.7	
8	1	100	
Number of used endografts			
1	16	87.5	.09
2	18	83.3	
3	22	59.1	
Number of patent outflow vessels			.513
0	1	100	
1	5	40	
2	11	72.7	
3	39	79.5	

P1, Popliteal artery cranial of the upper border of the patella; *P2,* popliteal artery between the tibia plateau and upper border of the patella; *P3,* popliteal artery below the tibia plateau; *TASC,* TransAtlantic Inter-Society Consensus.

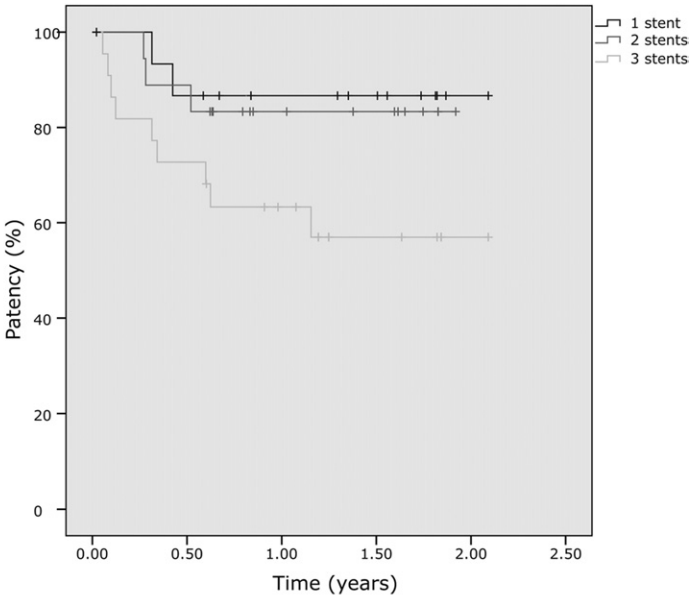
study was only 7.5%, which then again may seem high for an endovascular procedure, emphasizing the vulnerability of this patient group. There were no wound healing disturbances and only one patient had a self-limiting postoperative edema. Comparative studies with either bare metal stents and surgical bypass, assessing both patency rates and quality of life, such as the SUrgical versus PERcutaneous Bypass (SUPERB) and the Viabahn vs Bare Nitinol Stent (VIBRANT) in the treatment of long lesion (≥8 cm) superficial femoral artery occlusive disease trials, are essential in defining the role of heparin-covered endografts in the treatment algorithm of chronic occlusive SFA disease.[21]

In the last decade, multiple case series and few randomized trials have been published focusing on nonheparin-bonded endografts for SFA occlusive disease. Treatment strategies greatly varied, making comparisons inappropriate. The previous studies showed 1-year primary patency rate varying between 44% and 93% with large variation in treatment length (between 7 and 26 cm).[10-12] Moreover, there were large differences in the postinterventional antiplatelet strategy. In most series, patients were treated with acetylsalicylic acid, whereas in half of them, clopidogrel was added for 6 weeks to over 3 months. A study focusing on endovascular treatment of popliteal artery aneurysms showed that the use of clopidogrel was the only predictor of outcome.[22] In contrast to previous studies, patients were consequently treated with statins in our series, according to current guidelines on secondary risk prevention. Statins not only lower cholesterol but may also reduce the incidence of re-stenosis by their anti-inflammatory, antiproliferative, and antithrombogenic effects.[23]

In the study of McQuade et al,[13] 5 mm endografts seemed to perform worse compared 6- and 7-mm endografts at 2-year follow-up.[24] In the present study, we could not confirm this observation using heparin-bonded endografts, although our 5-mm group was very small. Further risk analysis did not reveal any significant predicting factor for failure. The use of three stents was associated with a nonsignificant 25% decrease in 1-year patency when compared to the use of one or two endografts. The numbers, however, were low and the lack of statistical significance may well represent a type II error. Multiple zones of overlap may decrease flexibility of the device, thereby possibly reducing performance, and have also been associated with an increased incidence of stent fractures after endovascular treatment of popliteal artery aneurysms.[25] Fortunately, with the introduction of a 25-cm endograft in 2010, the use of more than two stents is usually no longer necessary. Moreover, patients with a single vessel run-off seemed to be prone for failure in our series. However, the low number of patients with a single vessel run-off in this study renders any conclusion unreliable.

With the introduction of the heparin-bonded technology in the endograft, the design of the stent has also been changed in order to reduce edge stenosis. The proximal edge of the endograft no longer has a straight, but a contoured edge, that reduces infolding in case of oversizing, maintaining laminar blood flow and thus preventing intimal hyperplasia. The results of the present study may therefore not be attributed to the heparin-bonding technology only.

Whether the use of covered stents for long chronic occlusions of the SFA is cost-effective may not be concluded from the present data. The use of covered stents is likely to increase procedural costs. Additionally, endovascular techniques are often related to a higher incidence of reinterventions in order to maintain patency. In our series, only four patients required an additional angioplasty procedure to prevent failure. On the other hand, the mean hospital stay and complication rate is usually lower due to its minimal invasive character. Further studies focusing on cost-effectiveness are indicated. Prospective randomized trials are needed to compare the current gold standards, bare metal stents, and venous bypass vs heparin-bonded ePTFE-covered stent grafts, which should also include cost-effective analyses. Moreover, comparative studies with the newly developed drug-eluting stents are essential before considering the use of endografts as a routine treatment.



Limbs at risk					
1 stent	16	13	9	7	1
2 stents	18	16	9	7	0
3 stents	22	16	11	5	0
Patency (%)					
1 stent	100	86.7	86.7	86.7	86.7
2 stents	100	88.9	83.3	83.3	83.3
3 stents	100	72.7	63.3	57.0	57.0
SE (%)					
1 stent	0	8.8	8.8	8.8	8.8
2 stents	0	7.4	8.8	8.8	8.8
3 stents	0	9.5	10.3	11.1	11.1

Fig 3. Kaplan-Meier survival curve showing primary patency in relation to the number of endografts used.

In conclusion, the heparin-bonded endoluminal bypass is associated with acceptable patency rates and is related to a low morbidity and mortality rate. Furthermore, it does not exclude the later placement of a venous bypass. Randomized trials are indicated before considering the technique as a new standard of care and to elucidate the place of the technique in the treatment algorithm of chronic SFA occlusive disease.

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AUTHOR CONTRIBUTIONS

Conception and design: ML, MR
Analysis and interpretation: ML, WF, MR
Data collection: ML
Writing the article: ML, MR
Critical revision of the article: WF, SH, JO, CZ
Final approval of the article: RP, CZ, SS, MR
Statistical analysis: ML, ER
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Overall responsibility: MR

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