Results of the Protégé EverFlex 200-mm-long nitinol stent (ev3) in TASC C and D femoropopliteal lesions

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Objectives: **This study investigated the results with primary stenting using the Protégé EverFlex 200-mm-long self-expanding nitinol stent (ev3 Endovascular Inc, Plymouth, Minn) in femoropopliteal TransAtlantic Inter-Society Consensus (TASC) C and D lesions of at least 150 mm in length.**

Methods: **Between March 2008 and June 2009, 100 patients (66 men) presenting with 100 symptomatic TASC C and D femoropopliteal lesions were treated with at least one 200-mm-long Protégé EverFlex stent. The intention of this study was to treat all lesions with as few stents as possible. The primary study end point was primary patency at 12 months, defined as the absence of hemodynamically significant stenosis on duplex ultrasound imaging (systolic velocity ratio <2.4) at the target lesion and without target lesion revascularization (TLR) ≤12 months. Stent fracture occurrence was assessed at the 12-month follow-up by conventional x-ray imaging.**

Results: **Average patient age was 70 years. Preoperative symptom assessment reported 71 patients (71%) had claudication vs 29 (29%) with critical limb ischemia. Average lesion length was 242 mm (range, 160-450 mm), and 27 patients (27%) presented with popliteal involvement. A total of 158 Protégé EverFlex stents were used to treat 100 lesions. Kaplan-Meier estimation reported a 12-month freedom from target lesion revascularization of 68.2% and a primary patency rate of 64.8%. Stent fractures occurred in six patients (6.0%) when x-ray images taken immediately after the procedure were compared with those taken after 1 year.**

Conclusions: **The results of our Durability-200 study show an acceptable primary patency rate after 1 year was obtained in this patient cohort with TASC C and D femoropopliteal lesions. (J Vasc Surg 2011;54:1042-50.)**

Surgical bypass for severe lower extremity atherosclerosis is an effective treatment in patients presenting with claudication or critical limb ischemia. To date, autologous vein bypass is considered the gold standard.[1,2] In patients without a suitable long saphenous vein, the implantation of prosthetic grafts, either expanded polytetrafluoroethylene (ePTFE) or Dacron, is also associated with favorable long-term results.[3-7]

Open surgery is not always possible, however, due to prohibitive comorbidities, unsuitable conduit, or lack of an adequate distal target for revascularization. Moreover, the recent technologic advances in endovascular therapy have extended the applicability of minimally invasive treatment for challenging superficial femoral artery lesions that were previously deemed unsuitable for endovascular repair. Current infrainguinal endovascular options include balloon angioplasty, subintimal angioplasty, angioplasty with selective stenting, and primary stenting. Several trials have been published; however, the debate continues about which endovascular treatment is preferable.

The introduction of long and flexible stent designs has opened new perspectives for long-lasting endovascular treatment of challenging femoropopliteal lesions. The Durability-200 study is the first trial investigating the results with primary stenting using Protégé EverFlex 200-mm-long self-expanding nitinol stents (ev3 Endovascular Inc, Plymouth, Minn) in femoropopliteal TransAtlantic Inter-Society Consensus (TASC) C and D lesions at least 150 mm in length.

MATERIALS AND METHODS

The Durability-200 was a prospective, nonrandomized, dual-center, controlled trial performed at the Department Vascular Surgery at the Algemeen Ziekenhuis Sint-Blasius (Dendermonde, Belgium) and at the Department of CardioVascular and Thoracic Surgery at Imelda Hospital (Bonheiden, Belgium). It was registered with http://ClinicalTrials.gov Identifier NCT00637741.

The investigational device tested in the Durability-200 was the 200-mm-long self-expanding Protégé EverFlex nitinol stent. The Protégé EverFlex nitinol stent system is Conformité Européene-approved and indicated for use in

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patients with atherosclerotic disease of peripheral arteries. Patients eligible for Durability-200 had to present with TASC C or D femoropopliteal lesions, according to the TASC II (2007) recommendations.[8] The target lesion had to be located in the native femoropopliteal artery, with its most distal point maximally 3 cm proximal to the knee joint. The target vessel diameter had to be minimally 4 mm and maximally 6.5 mm, by visual estimation.

Every patient enrolled in this study had to receive at least one 200-mm-long Protégé EverFlex stent. The study intention was to treat all lesions with as few stents as possible. Additional stent placement was allowed whenever the investigators deemed this was necessary to obtain complete target lesion coverage. Stent lengths <200 mm could be used as second and third stents, provided that only Protégé Everflex stents were used and that the entire lesion length was covered by as few stents as possible.

The initial study sample size was 60 patients, as set by protocol v1.00 dd 080211, which was submitted to the Local Ethics Committee of the Algemeen Ziekenhuis Sint-Blasius and the Central Ethics Committee of Imelda Hospital. After submission of protocol amendment v2.00 dd 081105 to the Ethics Committees, this number was raised to 100 patients.

End points. The primary end point of the study was primary patency at 12 months, defined as the absence of hemodynamically significant stenosis on duplex ultrasound imaging at the target lesion and without target lesion revascularization (TLR) ≤12 months. Peak systolic velocities (PSV) were recorded 1 cm proximal to and 1 cm distal to the stented area, together with the highest PSV measurement inside the stented area. The grading of a stenosis was determined by the ratio with the normal PSV waveform as the denominator and the PSV in the stented portion as the numerator, which was defined as proximal peak velocity ratio. A peak systolic velocity ratio of ≥2.4 was considered hemodynamically significant.

Secondary end points of Durability-200 were:

1. technical success, defined as the ability to cross and dilate the lesion to achieve residual angiographic stenosis of ≤30% and residual stenosis of <50% by duplex imaging;
2. primary patency rate at 6- and 12-months of follow-up;
3. clinical success at follow-up, defined as an improvement of Rutherford classification at 6- and 12-month follow-up of one class or more compared with the preprocedure Rutherford classification;
4. stent fracture rate at the 12-month follow-up by x-ray imaging, categorized as mild (fracture of 1 strut), moderate (fracture of ≥1 strut but without complete separation), or severe (complete separation); and
5. serious adverse events, defined as any clinical event that was fatal, life-threatening, or judged to be severe by the investigator; resulted in persistent or significant disability; necessitated surgical or percutaneous intervention; or required prolonged hospitalization.

Table I. Inclusion criteria

General inclusion criteria
- De novo, restenotic, or reoccluded lesion located in the femoropopliteal arteries suitable for stenting
- Patient presents a score of 2 to 5 after Rutherford classification
- Patient is willing to comply with specified follow-up evaluations at the specified times
- Patient is aged >18 years
- Patient (or his or her legal representative) understands the nature of the procedure and provides written informed consent before enrollment in the study
- Before enrollment, the guidewire has crossed target lesion
- Patient is eligible for treatment with the self-expanding nitinol EverFlex (ev3) stent

Angiographic inclusion criteria
- The target lesion is located within the native femoropopliteal artery until maximally 3 cm proximal of the knee joint
- The target lesion has angiographic evidence of stenosis or restenosis >50% or occlusion, which can be passed with standard guidewire manipulation
- The target lesion, visually estimated, has a minimal length of 15 cm and can be categorized as either a type C or D lesions according the TASC II guidelines
- Target vessel diameter visually estimated is >4 mm and <6.5 mm
- There is angiographic evidence of at least one vessel runoff to the foot

TASC, TransAtlantic Inter-Society Consensus.

Patients were eligible for enrollment in Durability-200 when they complied with all general inclusion criteria and all angiographic inclusion criteria, as specified in Table I, and when none of the exclusion criteria were met, as specified in Table II. After verification of the inclusion and exclusion criteria, written informed consent for the collection of personal medical data was obtained for each patient before enrollment in the trial.

Procedure and hospitalization. All eligible patients underwent a baseline clinical examination to collect clinical data before the procedure. This consisted of medical history, medication record, physical examination, clinical category of critical limb ischemia according to the Rutherford classification[9] by means of a Walking Impairment Questionnaire (WIQ), and ankle-brachial index (ABI) at rest. The baseline vascular risk factors collected were history of nicotine abuse, presence of arterial hypertension, diabetes mellitus, renal insufficiency (serum creatinine >1.2 mg/dL in men or >0.9 mg/dL in women), hypercholesterolemia (total cholesterol >190 mg/dL), and obesity, defined as a body mass index (BMI) >25 kg/m^2. To be included, patients needed to have an abnormal ABI at rest. Evidence of disease was assessed by color-flow Doppler ultrasound (CFDU) imaging and duplex scanning, when performed. Final assessment of the lesion severity had to be confirmed by procedural angiography.

Vascular access was achieved, and all inflow-limiting lesions were treated according to the investigator's standard clinical practice. Lesion crossing with an approved conventional guidewire was obtained up to the distal vessel beyond the target lesion. Whenever free movement of the

Table II. Exclusion criteria

- Presence of another stent in the target vessel that was placed during a previous procedure
- Presence of aortic thrombosis or significant common femoral ipsilateral stenosis
- Previous bypass surgery in the same limb
- Patients for whom antiplatelet therapy, anticoagulants, or thrombolytic drugs are contraindicated
- Patients who exhibit persistent acute intraluminal thrombus of the proposed lesion site
- Perforation at the angioplasty site evidenced by extravasation of contrast medium
- Patients with known hypersensitivity to nickel-titanium
- Patients with uncorrected bleeding disorders
- Aneurysm located at the level of the superficial femoral artery
- Female patient with child-bearing potential not taking adequate contraceptives or currently breastfeeding
- Life expectancy of <12 months
- Ipsilateral iliac treatment before the target lesion procedure with a residual stenosis >30% or ipsilateral iliac treatment conducted after the target lesion procedure
- Use of thrombectomy, arthrectomy, or laser devices during the procedure
- Any planned surgical intervention or procedure within 30 days of the study procedure
- Any patient considered to be hemodynamically unstable at onset of the procedure
- Patient is currently participating in another investigational drug or device study that has not completed the entire follow-up period

wire tip within the distal vessel lumen was not observed, the guidewire was withdrawn and redirected. To ensure intraluminal position of the guidewire, a low-profile infusion catheter could be advanced over the guidewire distal to the target lesion. Distal runoff was ensured after withdrawal of the guidewire and contrast media injection through the infusion catheter. After successful lesion passage, diagnostic angiography of the lesion area and distal runoff was performed, and upon confirmation of the angiographic inclusion criteria, the patient was enrolled in the study.

Stent implantation was performed according to the standard procedures stipulated in the instructions for use available for the Protégé EverFlex stent. Each patient received at least one 200-mm-long stent, and the investigator used as few stents as possible to obtain complete lesion coverage. Predilation and postdilation were performed according to the physician's discretion. Finalization of the endovascular intervention was performed by acquiring hemostasis through manual compression or the application of a closure device.

Immediately after the procedure, conventional x-ray imaging was performed in two planes with at least a 45° difference in inclination between both angles, with maximal opacification and zoom. This served as a reference to be used for comparison with the images obtained at the 12-month follow-up, which had to be captured in the same two planes, to assess stent fracture occurrence.

The study protocol did not mandate any scheme for concomitant medication during the hospital stay and follow-up. However, it was recommended that patients be given clopidogrel (75 mg/d) for 1 month, assurance of clopidogrel saturation before the procedure, and lifelong administration of aspirin (75 to 300 mg/d). In case of possible thrombosis, thrombolytic or antiplatelet therapy could be used in conjunction with the intervention, according to institutional protocols.

Tests required immediately after the procedure were angiography and high-intensity cine-run. Tests before discharge included CFDU and duplex scanning, Rutherford categorization, and ABI.

Follow-up. Clinical follow-up data were collected at 1, 6, and 12 months. Other follow-up data collected consisted of data from unplanned or interim follow-up visits and reports of patient deaths. Regular follow-up visits ensured monitoring the patient's condition and the stent or procedure, or both. Patients were to adhere to a follow-up visit time restriction of ±7 days for the 1-month follow-up and ±30 days for the 6- and 12-month follow-up visits.

After 1 month, medication registration, physical examination, ABI measurements, and clinical categorization of critical limb ischemia according to the Rutherford categorization was required. After 6 months, all 1-month investigations were repeated and supplemented with a CFDU imaging (duplex scanning) at the treated vessel. After 1 year, all 6-month investigations were performed, together with a biplanar x-ray examination, which was compared with the x-ray images taken immediately postoperatively. To be able to adequately interpret the x-ray images, separate images were taken for every stent implanted in two planes with maximal opacification and zoom.

Data collection and statistical analysis. Double-data entry was performed in an electronic database to generate descriptive data summaries. Categoric variables were rendered by frequency distributions and cross tabulations. Continuous variables were reported by calculation of mean (range) and median (standard deviation). For all variables, a 95% confidence interval for the relevant parameters of the underlying distribution were used. Kaplan-Meier estimations were calculated for life-tables of all time-dependent events, for the period starting on the date of the procedure up to and including the 12-month follow-up visit, with the use of MedCalc software (MedCalc Software, Mariakerke, Belgium). Stratification to preprocedural risk factors, Rutherford classification, and lesion criteria were performed and compared by the log-rank test, reporting differences in outcomes. Associated values of $P < .05$ were considered significant. All periprocedural and postprocedural complications (<24 hours) were evaluated and documented.

RESULTS

Between March 2008 and June 2009, 131 patients with symptomatic femoropopliteal arterial obstructive lesions of at least 150 mm met the inclusion criteria. Of them, 27 refused to sign informed consent, and the wire crossing was not successful in four patients. Technical success was achieved in the remaining 100 patients (66 men), and no patients had a residual stenosis after treatment of >30% (angiographic control) or >50% (duplex control). Average

age was 70 years (range, 46-87 years). Baseline vascular risk factors reported a history of nicotine abuse in 56 patients (56%), of which 37 (66%) were still current smokers; 61 (61%) had arterial hypertension, with 50 (82%) controlled by medical therapy; diabetes mellitus was present in 27 (27%), of which 11 (37.9%) were insulin-dependent; and renal insufficiency was present in 21 (21%), hypercholesterolemia in 41 (41%), and obesity in 23 (23%).

The preoperative symptom assessment reported 40 patients (40%) with a walking distance of 100 to 250 meters (Rutherford category 2); 31 (31%) had a limited walking distance <100 meters (Rutherford category 3); 14 (14%) had rest pain (Rutherford category 4), and 15 (15%) had nonhealing arterial ulcers (Rutherford 5). This brought the total number of claudicant patients to 71 (71%) vs 29 critical limb ischemia patients (29%).

Looking at the lesion allocation and configuration, 50 right limbs (50%) were treated. Average lesion length was 242 mm (range, 160-450 mm), and 49 lesions (49%) were between 150 and 200 mm in length. Popliteal involvement was present in 27 patients (27%). Calcified lesions were reported in 79 (79%). There were 75 patients (75%) with three patent outflow vessels, 16 (16%) with two outflow arteries, and nine (9%) with only one outflow vessel.

Technical success was achieved in all 100 patients (100%), and 158 Protégé EverFlex stents were used to treat the 100 lesions. Placement of one stent was reported in 49 patients (49%), which corresponded with the number of lesions between 150 and 200 mm in length. Dual stents were used in 44 patients (44%), and three stents were deployed in seven (7%). When multiple stents were used, the observed overlap zone was between 10 and 30 mm in length.

Five patients experienced a complication before being discharged from the hospital. One patient had postprocedural blood loss and went into a hemorrhagic shock with ischemia of the left leg caused by an in-stent occlusion in the study lesion. He had a reintervention by means of endovascular thrombectomy, followed by dilation and stent placement at the occluded segment. This patient was considered to have a loss of primary patency. In two patients, a stenosis of the common femoral artery occurred at the puncture site on the contralateral limb before discharge from the hospital. Immediate dilation of this stenotic segment was performed. Two patients with distal embolization were successfully treated by endovascular aspiration in the below-knee arteries.

The 30-day mortality rate was 1%, with one patient who died on the day after the procedure of septic shock induced by methicillinresistant *Staphyloncus aureus.* Other 30-day complications occurred in four other patients. Blood loss in one patient after the procedure resulted in hemorrhagic shock and an in-stent reocclusion causing ischemia of the left leg. Endovascular thrombectomy was successfully performed to restore the blood flow. Another patient had acute ischemia 5 days after the index procedure, which was successfully treated with thrombolysis. An in-stent thrombosis occurred in one patient on day 12 after the index procedure. Revascularization was achieved by placement of a femoropopliteal below the knee prosthetic bypass. One patient complained of recidivating claudication on day 14 due to an in-stent restenosis in the study stent, which was successfully treated with thrombolysis, followed by percutaneous transluminal angioplasty with stent placement.

Compared with baseline, a significant improvement in ABI was found at the 1-month (0.97 ± 0.09, $P < .0001$), 6-month, (0.92 ± 0.14, $P < .0001$), and 12-month (0.92 ± 0.14, $P < .0001$) follow-up visits. The mean Rutherford class decreased from 3.04 ± 1.07 at baseline to 0.68 ± 1.13 at 1 year ($P < .0001$). During the 12-month follow-up period, stent occlusion occurred in 24 patients and stent restenosis in 10. Thirty of these patients received a repeat intervention.

Freedom from TLR after 12 months was 68.2% (Fig 1). The 12-month primary patency rate for the total population by Kaplan-Meier estimate was 64.8% (Fig 2). Stents with loss of patency were associated with a worsening in Rutherford class and ABI. Fig 3 shows the primary patency at 12 months in patients with a decrease in ABI of at least 0.15. Stratification between lesions located in the superficial femoral artery only and those with popliteal artery involvement showed a nonsignificant difference ($P = .86$) for the 1-year primary patency rates of 65.6% for the former and 63.9% for the latter. Stratification between patients with and without diabetes mellitus showed 66.8% and 59.3% primary patency after 12 months, respectively, which was not a statistically significant difference ($P = .67$). No statistically significant difference ($P = .50$) in 1-year primary patency rates was found in stratification between TASC C (68.5%) and TASC D lesions (63.9%). Stratifications on the number of stents used did not show any statistical difference in 12-month primary patency rates, whether one or multiple stents were implanted (Fig 4). The patient survival rate for the entire population after 12 months was 85.0% (Fig 5).

Stent fractures occurred in six patients (6.0%) when the x-ray images taken immediately after the procedure and after 1 year were compared. Mild stent fractures (fractures of one strut) occurred in four patients (4.0%), and moderate fractures (fracture of >one strut but without complete separation) were present in two (2.0%). No severe fractures (complete separation) were found. The occurrence of stent fractures could not be linked to the number of stents implanted: two of the mild fractures occurred in patients with one stent implanted, and another two fractures occurred in patients with two stents. Loss of primary patency was reported in one patient with a moderate stent fracture. The remaining five fractured stents were not associated with a loss of primary patency within the 1-year follow-up period.

DISCUSSION

The main limitation of this prospective, multicenter, single-arm, controlled study was the lack of a control group. Consequently, this study is not powered to report any relationships at a statistically significant level. Further-

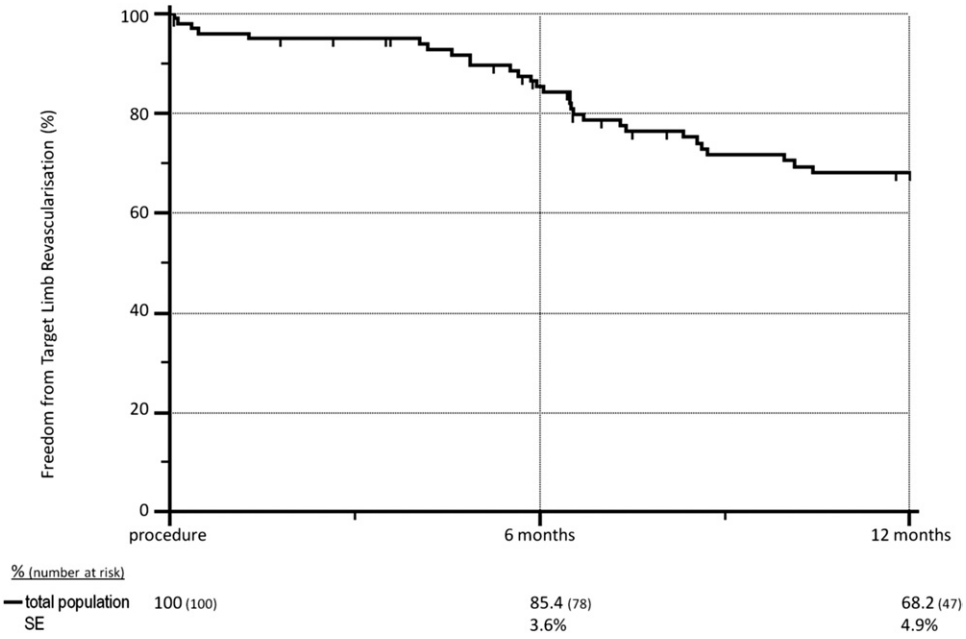

Fig 1. Kaplan-Meier estimate shows freedom from target lesion revascularization at 12 months for the total population.

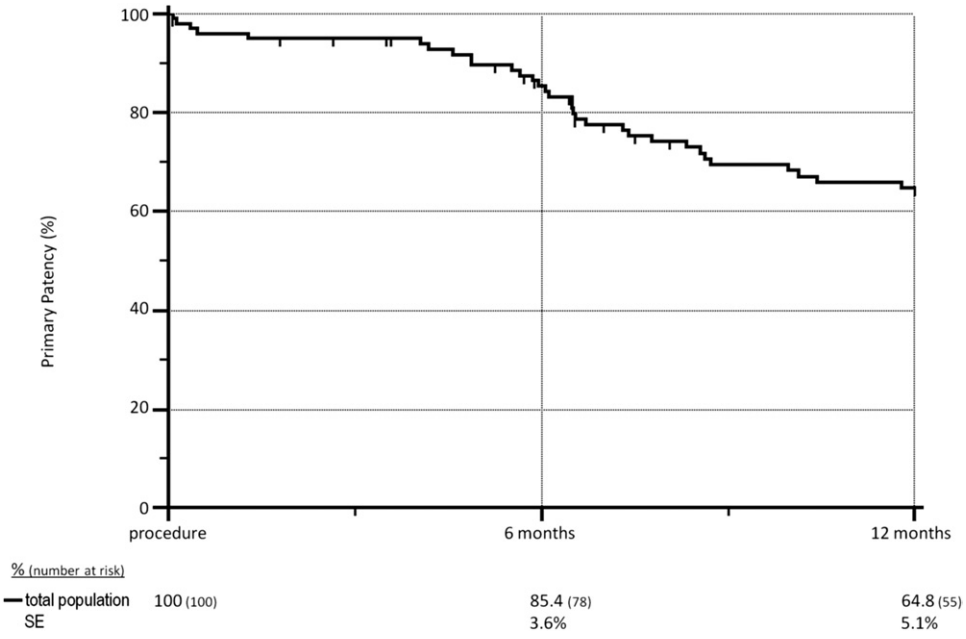

Fig 2. Kaplan-Meier estimate shows primary patency at 12 months for the total population.

more, patients were eligible only when they had a good runoff and when the target lesion could be crossed.

Endovascular treatment of long femoropopliteal lesions and stent placement, in particular, remains a controversial issue, and results in TASC C and D femoropopliteal lesions are scarce. Percutaneous transluminal angioplasty in longer SFA lesions has poor outcomes.[10,11] The result with subintimal angioplasty (SIA), a technique in which a dissection is deliberately created, depends less on lesion length but depends rather on the presence of a healthy artery proximal distal to the lesion. High technical success rates of 80% to 90% are reported, but SIA remains controversial because primary patency rates at 12 months vary greatly between 22% and 79%.[12-16] To date, the only results with

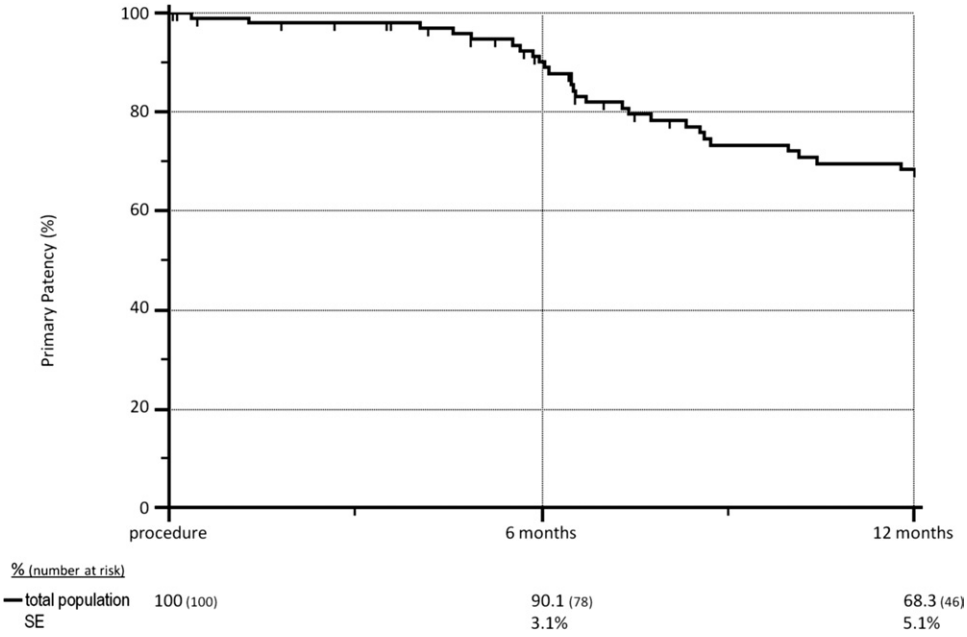

Fig 3. Kaplan-Meier estimate shows primary patency at 12 months in patients with a standard ankle-brachial index decrease of at least 0.15.

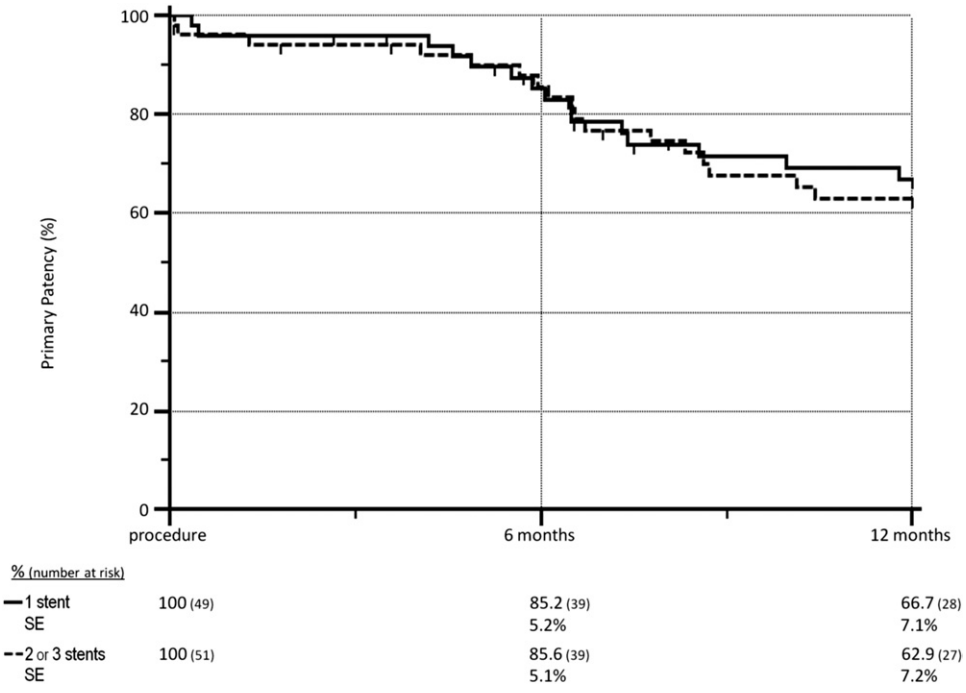

Fig 4. Kaplan-Meier estimate after stratification for implantation of one vs multiple stents.

stent placement in SFA lesions >150 mm are those from a subgroup analysis of the Zilver PTX registry, which confirms that stenting of long SFA lesions with the Zilver PTX drug-eluting stent (DES; Cook, Bloomington, Ind) yields acceptable 12-month results. At the Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Congress in 2009, Sapoval[17] presented the results from a subgroup of 178 patients from the Zilver PTX Global Registry with 182 TASC C and D lesions that were an average length of 229 mm. He reported a freedom from

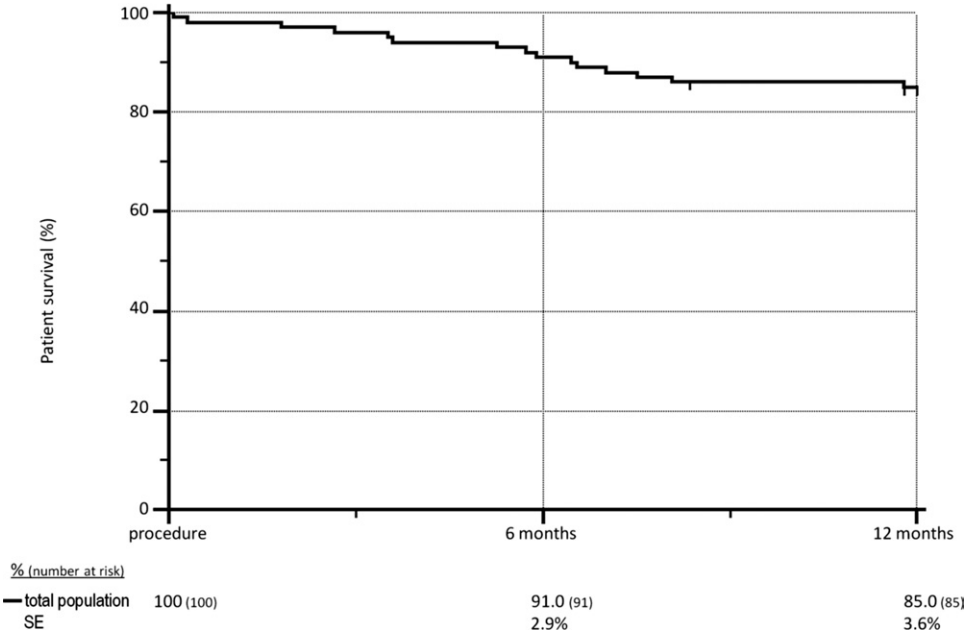

Fig 5. Kaplan-Meier estimate shows survival rate at 12 months for the total population.

target lesion revascularization rate of 79% after 12 months.[17] Primary patency rates were presented by Bosiers[18] at the 2010 CIRSE congress on a subgroup of 132 patients with 133 de novo lesions >150 mm, which had an average length of 226 mm. A 77.0% primary patency rate was reported in this subgroup after 12 months.[18]

The Durability-200 reports a 12-month primary patency rate of 64.8%, which means there is a 20% difference in results between endovascular stenting and surgical bypass. However, the success rates of surgical and endovascular procedures cannot be directly compared. Applying the term *patency* to the surgical definition would mean that vessel patency is maintained even in case of a high-grade stenosis. *Endovascular primary patency*, however, refers to an absence of binary restenosis.[19] Because the endovascular definition of primary patency is more strict, one could expect the resulting rates to be lower.

A second observation is the 10% difference in results between the Durability-200 results and those from the Zilver PTX subgroup analysis. Yet, it is important to notice that the price of a single DES is higher than that of a long flexible SFA stent and that a higher number of DES implantations are needed to treat TASC C and D femoropopliteal lesions. In the Zilver PTX Global Registry subgroup of lesions >150 mm, an average of 3.7 stents were implanted vs 1.6 stents in comparable lesions in our Durability-200 study. An elaborate discussion on the economic aspects of DES for the treatment of de novo lesions has been published.[20]

The stent fracture rate reported in the Durability-200 study was 6.0% after 12 months. Here also, the only data currently available on stent fractures in TASC C and D femoropopliteal lesions are those from the subgroup analysis of the Zilver PTX Global Registry, which reported a stent fracture rate of 2.6%.[17] However, this rate is based on the number of implanted stents instead of on the number of lesions, as is the case in Durability-200. Recalculating the stent fracture rate from the Zilver PTX TASC C and D groups on a lesion basis results in a fracture rate of 8.2%, which is more comparable to the Durability-200 fracture rate of 6.0%.

Remarkably, there is a discrepancy between fracture rates reported in Durability I and Durability-200, even though both studies were conducted with the Protégé EverFlex. Moreover, only one stent implantation was allowed in the Durability I study in contrast to Durability-200, where multiple stent implantations were allowed. One could have expected a higher stent fracture rate in Durability-200. However, the Durability I investigators identified the implantation technique as an influential factor of subsequent stent fracture. A ≥10% stent elongation occurred during implantation in 90% of all fractured stents within this study.[21] Elongated stent placement increases the amount of continuous strain exerted on the stent struts, resulting in more fractures. Because no elongated stent placement occurred in the Durability-200 study, the resulting lower fracture rate seems to confirm this thesis.

The Durability-200 study did not find any relationship between stent fractures and primary patency. Of the six stent fractures found, five did not result in a loss of primary patency. Also, the number of stents implanted did not influence the occurrence of fractures. However, when fracture severity is taken into consideration, we can see that none of the mild fractures led to a loss of primary patency, whereas one of the two moderate fractures was related. A similar pattern was described by Durability I, where only

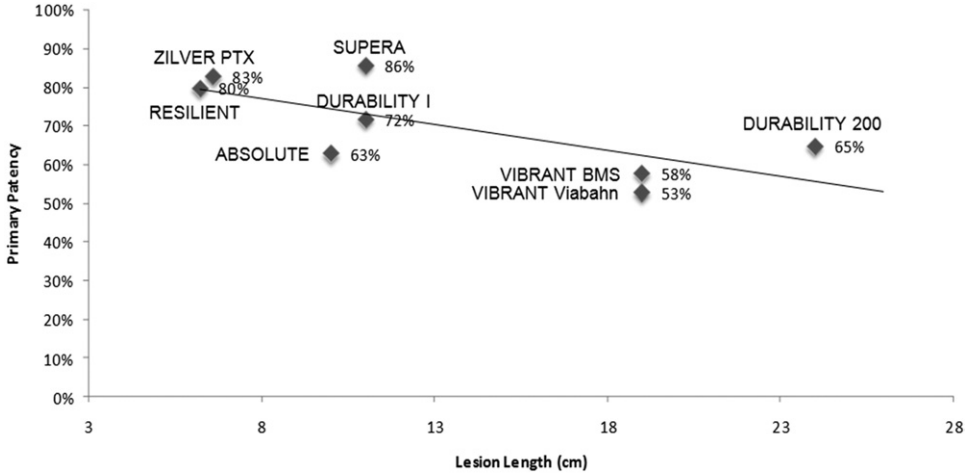

Fig 6. Positioning of the Durability-200 results compared with other studies of superficial femoral artery stenting.

two of five severe fractures had no restenosis, hinting that fracture severity may be an important factor to consider when assessing the correlation between stent fractures and loss of patency.

It is interesting to position the Durability-200 results within the array of other current SFA studies. The FemPac, Zilver PTX, RESILIENT (Randomized Study Comparing the Edwards Self-Expanding LifeStent vs. Angioplasty-alone in Lesions Involving the Superficial Femoral Artery or Proximal Popliteal Artery), and THUNDER (Local Taxan With Short Time and Exposure for Reduction of Restenosis in Distal Arteries) studies have an average primary patency rate of 80% (ranging between 76% and 83%) for lesions <8 cm. The Durability I, Absolute (Abbott, Abbott Park, Ill), and SUPERA stent studies (IDEV Technologies Inc, Webster Tex) showed an average primary patency rate of 72% (ranging, 63%-86%) for lesion lengths between 8 and 13 cm. The VIBRANT (VIABAHN Endoprosthesis Versus Bare Nitinol Stent) study reported lesions with an average length of 19 cm, treated with Viabahn implantation (W. L. Gore and Associates, Flagstaff, Ariz) or stent placement. The 12-month primary patency was 53% for the patients treated with the Viabahn endoprosthesis and 58% for the patients treated with a bare-metal stent. With these data in mind, a primary patency 50% after 12 months of lesions with an average length of 24 cm would follow the general trend. This is schematically reported in Fig 6.

CONCLUSIONS

Our Durability-200 results show an acceptable primary patency rate in this patient cohort with TASC C and D femoropopliteal lesions after 1 year. Our findings definitely warrant further investigation, preferably by means of randomized trials. The release of more SFA stent data will increase our understanding of the effect of stent design, fracture occurrence, and its potential relationship with patency outcome.

AUTHOR CONTRIBUTIONS

Conception and design: MB
Analysis and interpretation: MB
Data collection: MB, KD, JC, NM, KK, JV, PP
Writing the article: MB
Critical revision of the article: MB, KD, JC, NM, KK, JV, PP
Final approval of the article: MB, KD, JC, NM, KK, JV, PP
Statistical analysis: MB
Obtained funding: MB
Overall responsibility: MB

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