European Journal of Vascular and Endovascular Surgery 44 (2012) 432–441

Contents lists available at SciVerse ScienceDirect

European Journal of Vascular and Endovascular Surgery

journal homepage: www.ejves.com

# One-year Clinical Outcome after Primary Stenting for Trans-Atlantic Inter-Society Consensus (TASC) C and D Femoropopliteal Lesions (The STELLA "STEnting Long de L'Artère fémorale superficielle" Cohort)

J.-M. Davaine [a,d], L. Azéma [a,c], B. Guyomarch [b,d], P. Chaillou [a,d], A. Costargent [a,d], P. Patra [a,c,d], G. Lambert [c,d], Y. Gouëffic [a,c,*]

[a] CHU Nantes, l'Institut du thorax, Service de Chirurgie Vasculaire, Nantes F-44000, France
[b] CHU Nantes, l'Institut du thorax, Centre d'Investigation Clinique, Nantes F-44000, France
[c] Université de Nantes, Nantes F-4400, France
[d] INSERM, U957, Nantes F-44000, France

**WHAT THIS PAPER ADDS?**

- Currently, endovascular treatment of long femoropopliteal lesions as a first-choice treatment remains controversial. Despite a high technical success rate, little data are available on the clinical benefit for patients over time. In the present study we prospectively assessed the safety and the efficacy of primary stenting for TASC C and D femoropopliteal lesions. We found that sustained clinical improvement at mid-term was high. Nevertheless, the necessity of secondary procedures due to in-stent restenosis and thrombosis makes narrow surveillance mandatory. Therefore, our results contribute to further support the use of primary stenting for TASC C and D femoropopliteal lesions.

ARTICLE INFO

*Article history:*
Received 30 March 2012
Accepted 23 July 2012
Available online 21 August 2012

*Keywords:*
Peripheral artery disease
Femoropopliteal
Angioplasty
Stent
TASC C and D
Critical ischaemia

ABSTRACT

*Objective:* The study aims to evaluate the safety and the efficacy of primary stenting for Trans-Atlantic Inter-Society Consensus Document II on Management of Peripheral Arterial Disease (TASC) C and D femoropopliteal lesions.
*Design:* Prospective cohort study.
*Methods:* Patients with TASC C and D *de novo* femoropopliteal lesions were treated with the same endovascular technique by implanting a primary nitinol self-expanding stent (LifeStent®, Bard Peripheral Vascular, Tempe, AZ, USA). Patients were included in a single-centre registry and prospectively followed up. The primary end point was primary sustained clinical improvement after 12 months. Secondary end points were secondary sustained clinical improvement, primary and secondary patency rates, freedom from target lesion revascularisation (TLR), freedom from target extremity revascularisation (TER) and stent fracture rate.
*Results:* We enrolled 58 patients (62 limbs) suffering from either claudication (40.3%) or critical limb ischaemia (59.7%). Lesions were either TASC C (62.9%) or TASC D (37.1%). Median length of the treated segment was 220 ± 160 mm. The mean number of stents was 2.2. Mean follow-up was 17 months, with one patient lost to follow-up. At 1 year, the primary end point was 68.6% while secondary sustained clinical improvement was 82.6%. Freedom from TLR and TER rates were 81.1% and 96.3%. Primary and secondary patencies were 66% and 80.9%. One-year primary and secondary sustained clinical improvement rates were 76.7% ± 7.2 for TASC C and 46.3% ± 11.1 for TASC D ($p = 0.03$) and 87.6% ± 5.9 for TASC C and 67.3% ± 11.3 for TASC D ($p = 0.09$), respectively. The ankle–brachial pressure index increased from

*Abbreviations:* ABI, ankle–brachial index; CLI, critical limb ischaemia; DSA, digital subtraction angiography; IC, intermittent claudication; ISR, in-stent restenosis; MACE, major adverse clinical event; PAD, peripheral arterial disease; PSV, peak systolic velocity; TASC, Trans-Atlantic Inter-Society Consensus Document II on Management of Peripheral Arterial Disease; TER, target extremity revascularisation; TLR, target lesion revascularisation.

* Corresponding author. Y. Gouëffic, CHU Nantes, l'Institut du thorax, Service de Chirurgie Vasculaire, Boulevard Jean Monod, Nantes F-44000, France. Tel.: +33 2 40 16 50 93; fax: +33 2 40 16 50 81.
*E-mail address:* yann.goueffic@chu-nantes.fr (Y. Gouëffic).

1078-5884/$ – see front matter 
http://dx.doi.org/10.1016/j.ejvs.2012.07.015

0.58 to 0.94 ($p = 0.001$) at 1 year and the incidence of in-stent restenosis (ISR) was 19.3%. Stent fracture and disconnection rate was 17.7%.
*Conclusions:* Primary stenting of TASC C and D lesions appears to be safe and efficient given the high-sustained clinical improvement and the low rate of ISR observed in our study. Endovascular treatment of such long and severe lesions exposes to high rate of stent fractures, which should not be a concern given their low clinical impact.


The Trans-Atlantic Inter-Society Consensus Document II on Management of Peripheral Arterial Disease (TASC) was published in 2007.[1] In its revised stratification for femoropopliteal lesions, TASC II included more severe disease levels than TASC I and recommended endovascular repair for type A, B and C (with qualifications). However, endovascular repair remains commonly indicated in limited lesions shorter than 150 cm whereas bypass surgery is recommended to treat extensive disease with long lesions and critical limb ischaemia (CLI).

Recent advances in endovascular techniques have led to widespread applicability of endovascular repair for more severe femoropopliteal lesions. Even though lesions are more distal and longer, the technical success does not seem to be altered. Successful recanalisation of TASC C and D lesions exceeds 80%.[2,3] In addition, the use of new techniques and devices such as retrograde approach and re-entry catheters improves the technical success rates following failed initial procedure.[2] According to some authors, failure of endovascular repair does not preclude the possibility of infrainguinal bypass.[4] Thus, the use of primary stenting to treat femoropopliteal occlusive lesions has shown the most promising outcomes.[5] However, primary stenting for longer femoropopliteal lesions is controversial because of the high risk of stent fracture.

Newer generations of longer nitinol self-expanding stents could allow endovascular treatment of longer femoropopliteal lesions thanks to their resistance to compression and fracture in this tortuous physical environment.[6] The purpose of the Stenting long de l'artère fémorale superficielle (STELLA) study was to evaluate prospectively the safety and the efficacy of primary stenting using LifeStent® (Bard Peripheral Vascular, Tempe, AZ, USA) to treat femoropopliteal TASC C and D lesions.

## Methods

### *Experimental design*

STELLA is a follow-up single-centre study cohort in which patients were referred for peripheral arterial disease (PAD) and presented with *de novo* femoropopliteal TASC C and D lesions longer than 15 cm. Patients were enrolled between November 2008 and October 2009. Endovascular therapy was considered a first intention treatment. Inclusion and exclusion criteria are summarised in Table 1. Patients had either one or two limbs treated. The protocol was approved by the local ethics committee and all patients gave informed consent.

### *Endovascular procedures*

All procedures were performed by vascular surgeons. Patients were examined preoperatively by an anaesthesiologist. Local anaesthesia with conscious sedation was indicated unless general anaesthesia was required. Access to the culprit lesion was achieved either by way of an over-the-aortic-bifurcation approach with the use of a dedicated 6F-long sheath (45 cm) (Destination®, Terumo, St Quentin, France) or via antegrade approach with the use of a 6F sheath (Destination®, Terumo, St Quentin, France). After sheath placement, an intravenous bolus of 50 UI $kg^{-1}$ of heparin was administered. Stenotic lesions were crossed in an intraluminal fashion and occlusions were recanalised with a hydrophilic 0.035-inch guide wire and a balloon catheter (Optapro®, Cordis, Issy, France). An intentional plane was created in the proximal patent artery by forming a loop at the end of the guide wire. The looped guide wire and the balloon catheter were then forcefully advanced across the occlusion. The true lumen re-entry was indicated by a subtle release of wire resistance near the distal portion of arterial occlusion. Distal re-entry was ensured after withdrawal of the guide wire by contrast media injection through the balloon lumen catheter. No re-entry device was used. Primary stenting was preferably performed unless predilation with a 3-mm balloon was necessary because of highly calcified lesions. The stent dimensions were chosen by visual estimation to fit vessel diameter at best with a length exceeding the lesion length by 5–10 mm proximally and distally. The maximal available length of stent was 170 mm. Lesions were treated with as few stents as possible. Adjacent stents overlapped by 1 cm. We used the self-expandable LifeStents® (Bard Peripheral Vascular, Tempe, AZ, USA) of either 6 or 7 mm in diameter. Stents were routinely post-dilated to ensure optimal extension and apposition. The balloon dimension (Optapro®, Cordis, Issy, France) was chosen so that the nominal diameter is 1 mm narrower than the vessel diameter to reduce medial damage[7] and so that the balloon length does not exceed that of the stent. The technical result of the procedure was assessed by digital subtraction angiography (DSA). Every associated inflow or outflow lesions suspected to be involved in the disease were treated during the same procedure. Significant aspect of the lesion was assessed by the surgical team according to preoperative findings (magnetic resonance imaging (MRI), angio-computed tomography (CT) scan and duplex ultrasonography (US)), clinical stage of the disease (CLI vs. intermittent claudication (IC)) as well as to intra-operative findings (DSA). Groin closure was accomplished via manual compression

**Table 1**
Inclusion and exclusion criteria.

| Inclusion criteria | Exclusion criteria |
|---|---|
| • Age ≥ 50-years<br>• Symtomatic patients according Rutherford stages 3, 4, 5 and 6<br>• *De novo* atheromatous femoropopliteal occlusive disease >15 cm in length<br>• TASC C–D femoro-popliteal lesions according the TASC II guidelines<br>• Adequate femoro-popliteal inflow and outflow either pre-existing or successfully re-established (outflow defined as patency of at least one infragenicular artery)<br>• Successful crossing of the target lesion, inflow and outflow lesions with a guide wire<br>• Written informed consent<br>• Patient belongs to the French health care system | • Restenosis<br>• No atheromatous disease<br>• Asymptomatic lesion<br>• Acute ischaemia or arterial thrombosis<br>• Lesion within or adjacent to an aneurysm<br>• Patient enrolled in another trial<br>• Refusing patient<br>• Pregnancy<br>• Known allergies to heparin, aspirin, other anti-coagulant/ antiplatelet therapies<br>• No written informed consent<br>• Life expectancy < 1 year |

and, for day-case procedures, using a vascular closure device (Angioseal®, St Jude Medical, France).

A prophylactic dose of low-molecular-weight heparin was given during hospitalisation to prevent venous thrombo-embolic events. Postoperatively, patients were prescribed aspirin (75–160 mg day$^{-1}$) and clopidogrel (75 mg day$^{-1}$) for 6 months and then patients were prescribed only clopidogrel.[5,8] When patients were under oral anti-coagulant treatment, aspirin was the only anti-platelet agent added. Observance to the medical treatment was ascertained at each clinical end point.

*Follow-up*

Patients were prospectively followed on an outpatient basis. Major adverse clinical events (MACEs) were intentionally sought. Follow-up included medical examination, ankle–brachial index (ABI) measurement and duplex scan at 1, 3, 6, 9, 12 and 18 months and yearly thereafter. Information collected on standardised forms filled during Doppler US examination was systematically ascertained by a surgeon in charge of the study. For this purpose, patients and general practitioners were contacted by telephone. The hospital database was systematically searched for any additional relevant information. Clinical examination was performed by the surgeon at 1 and 12 months postoperatively. Stent fractures were assessed by biplane X-rays at 12 months with two different projections separated by at least 45° using the highest available magnification. Data were recorded prospectively in a computerised database. Logistic organisation was provided by two clinical research officers. An independent core laboratory (CoreLab, Bad Krozingen, Germany) analysed X-rays for stent fractures. Magnification of the images was used in any case in which stent strut fracture was suspected using the QVA software (Medis medical imaging systems®, Leiden, the Netherlands). Stent fracture was finally assessed by a medical advisor according to the Jaff classification.[9]

*End points and definitions*[10]

The primary end point was primary sustained clinical improvement at 12 months.

Secondary end points were secondary sustained clinical improvement, primary and secondary patency, technical success, minor and major complications, major cardiovascular events (MACEs), limb salvage, target lesion revascularisation (TLR), target extremity revascularisation (TER), in-stent restenosis (ISR), in-stent thrombosis and stent fracture. Detailed definitions of outcome are:

Primary sustained clinical improvement was defined as a sustained upward shift of $\geq$1 category of the Rutherford classification for claudicants and by wound healing and rest pain resolution for patients in CLI, without the need for repeated TLR in surviving patients. Secondary sustained clinical improvement was defined as primary sustained clinical improvement including the need for repeated TLR. Primary patency was defined as patency without any percutaneous or surgical intervention in the treated segment or in the adjacent areas. Technical success was defined as achievement of a final residual diameter stenosis of <30% on the procedural completion angiogram. Minor complications are those following procedure (within the first month) and not requiring further treatment and not extending hospital stay. Major complications required re-intervention or delay (more than 24 h) in patient discharge. MACE included all deaths, major amputation, procedural-related serious adverse events and device failure or malfunction. TLR expresses the frequency of the need for repeated procedures (endovascular or surgical) due to a problem arising from the lesion (+1 cm proximally and distally to include edge phenomena) in surviving patients with preserved limb. TER expressed the frequency of the need for repeated procedures due to a problem arising remotely from the initial lesion. ISR were assessed by duplex ultrasound and was defined by restenosis of more than 50% and by a peak systolic velocity (PSV) index greater than 2.4 at the lesion site. The diagnosis of stent thrombosis was considered when occlusion was seen on duplex scan without any previous sign of restenosis. The occurrence of stent fracture was determined by biplane radiography at 12 months.[9]

*Statistical analysis*

Statistical analysis results were reported prospectively on an intention-to-treat basis. Continuous variables were presented as mean ± SD, categorical variables as count and percent. Demographic and co-morbidity data were recorded per patient and patency data were calculated on a per limb basis. Survival rate curves for TLR/TER were plotted and calculated using the Kaplan–Meier method. For patients who died before the final follow-up examination or for patients lost to follow-up, the status of the last follow-up examination was recorded. A $p$-value <0.05 was considered statistically significant. Data were analysed using the Statistical Package for the Social Sciences (SPSS) software (SPSS Inc., Chicago, IL, USA).

## Results

*Patients' characteristics and demographics*

A total of 58 patients (62 limbs) were enrolled. Over the same period, 302 patients were treated for femoropopliteal lesions (endovascular repair: 231; open repair: 71). The baseline characteristics of the study population are described in Table 2. Indications for intervention included 25 limbs (40.3%) for claudication and 37 limbs (59.7%) for CLI.

*Intra-operative and perioperative data*

Details of the 62 endovascular procedures are given in Table 3. According to the TASC II classification, 39 limbs (62.9%) were classified as TASC C and 23 limbs (37.1%) as TASC D. The over-the-bifurcation approach was realised for 38 limbs (61.3%) and an

**Table 2**
Baseline patients characteristics.

| Variables | |
|---|---|
| Age, yr (mean ± SD) | 71.4 ± 12 |
| Male sex, *n* (%) | 42 (72.4) |
| Smoking, *n* (%) | 34 (58.6) |
| Active | 13 (22.4) |
| Previous | 21 (36.2) |
| Hypertension, *n* (%) | 48 (82.8) |
| Hyperlipidaemia, *n* (%) | 29 (50) |
| Diabetes mellitus, *n* (%) | 25 (43.1) |
| Type I | 2 (3.4) |
| Type II | 23 (39.7) |
| Renal insufficiency | 13 (22.4) |
| On dialysis | 1 (1.7) |
| Obesity (BMI > 25), *n* (%) | 27 (46.6) |
| Coronary artery disease, *n* (%) | 28 (48.3) |
| Cerebrovascular disease, *n* (%) | 9 (15.5) |
| Rutherford stage of PAD, *n* (%) | |
| 3 | 25 (40.3) |
| 4 | 13 (21) |
| 5 | 20 (32.2) |
| 6 | 4 (6.5) |
| Clinical status | |
| Claudication, *n* (%) | 25 (40.3) |
| Critical limb ischaemia, *n* (%) | 37 (59.7) |

**Table 3**
Baseline intraoperative and perioperative data.

| Variables | |
|---|---|
| TASC II classification of the lesions, *n* (%) | |
| C | 39 (62.9) |
| D | 23 (37.1) |
| Approach, *n* (%) | |
| Crossover | 38 (61.3) |
| Antegrade | 24 (38.7) |
| Length of the treated lesions, mm (median, IQR) | 220 mm ± 160 mm |
| Length of stented segment, mm (median, IQR) | 260 mm ± 180 mm |
| Number of stent per patient, *n* (mean ± SD) | 2.2 ± 0.9 |
| Number of stents implanted, *n* (%) | 134 (100) |
| 1 | 16 (25.8) |
| 2 | 22 (35.5) |
| 3 | 22 (35.5) |
| 4 | 2 (3.2) |
| Diameter of implanted stent, *n* (%) | 134 (100) |
| 6-mm | 104 (77.6) |
| 7-mm | 30 (22.4) |
| Crural runoff vessels (ultrasound), *n* (%) | |
| 1 | 12 (19.4) |
| 2 | 18 (29) |
| 3 | 14 (22.6) |
| Not documented | 18 (29) |
| Associated procedures, *n* (%) | |
| Endovascular repair | 20 (32.2) |
| Aortic bifurcation | 1 (1.6) |
| Common iliac artery | 1 (1.6) |
| External iliac artery | 6 (9.7) |
| Internal iliac artery | 2 (3.2) |
| Common femoral artery | 2 (3.2) |
| Below the knee arteries | 7 (11.3) |
| Controlateral iliac artery | 1 (1.6) |
| Open repair | 4 (6.4) |
| Femoral edarteriectomy | 3 (4.8) |
| Controlateral femoro-popliteal bypass | 1 (1.6) |
| Minor amputations | 3 (4.8) |
| Major amputations | 0 (0) |
| Major adverse cardiovascular event, *n* (%) | 2 (3.4) |
| Day-case vascular procedure, *n* (%) | 5 (8.1) |
| Duration of fluoroscopyin, min (mean ± SD) | 18.9 ± 10 |
| Irradiation, mGy/m$^2$ (mean ± SD) | 3.3 ± 3 |
| Duration of procedure, min (mean ± SD) | 79 ± 36 |
| Amount of contrast agent, ml (mean ± SD) | 87 ± 36 |
| Duration of hospital stay, *d* (mean ± SD) | 3 ± 4 |
| Perioperative complications, *n* (%) | |
| Minor | 5 (8.1) |
| Major | 6 (9.7) |

TASC: Trans-Atlantic Inter-Society Consensus.

anterograde approach for 24 limbs (38.7%). Median length of the treated lesions was 220 ± 160 mm (150–480 mm). Forty-eight out of the 62 (77.4%) of the lesions involved the popliteal artery. Median stented segment was 260 ± 180 mm and the mean number of stents implanted per limbs was 2.2 ± 0.9 (1–4). In 77.6% of the cases, 6-mm diameter stents were implanted. Concomitant treatment was performed for 20 limbs (32.2%) by endovascular repair and for four limbs (6.4%) by open repair. During the perioperative period, no patient was lost to follow-up. One patient died within 1 month after the procedure from congestive heart failure. Six (9.7%) major complications led to an extent of hospitalisation and/or re-intervention – two puncture site haematomas, one post-revascularisation syndrome, one acute coronary syndrome, one congestive heart failure and one bowel obstructive syndrome. Three minor amputations (4.8%) were required but no major amputation. The average length of hospitalisation stay was 3 days (1–25). Five limbs (8.1%) were treated in the context of day-case vascular procedure. In these cases, an arterial femoral closure device (angioseal® 6F, St Jude Medical, France) was used to allow early discharge. Detailed information regarding both TASC and clinical status is given in Table 4. Patients presenting with CLI were older than patients presenting with claudication ($p = 0.004$) and were more frequently females ($p = 0.04$). The number of stents implanted, lesion and stenting lengths were higher in TASC D compared with TASC C patients ($p = 0.0001$). The procedure was also longer in TASC D vs. TASC C patients ($p = 0.003$).

*Follow-up*

The mean follow-up time (Table 5) was 17.2 months (1–30). One patient was lost to follow-up (follow-up time: 9th month). Five (8.0%) patients died during the follow-up period (one within 30 days and four within 1 year) (Table 5).

At 1 month, the clinical status was improved in 55 limbs and the primary sustained clinical improvement was 90.1 ± 2.2%. Six limbs did not improve and one remained unchanged. Five patients with CLI did not heal satisfactorily and were considered not improved. One-month primary sustained clinical improvement rates were 100% for TASC C, 95.5% ± 4.4 for TASC D, 100% for IC and 97.3% ± 2.7 for CLI, respectively. One-month secondary sustained clinical improvement rates were 100% for TASC C, 95.5% ± 4.4 for TASC D, 100% for IC and 97.3% ± 2.7 for CLI, respectively (Table 6). At 1 year, primary and secondary sustained clinical improvement was obtained in 37 (68.6% ± 6) and 48 (82.6% ± 5.1) limbs, respectively (Fig. 1). No patient developed clinical worsening compared to baseline. Thirty-five (64.8%) limbs were considered asymptomatic, claudication and CLI were observed in 16 (29.6%) and in three (5.6%) cases, respectively (Fig. 2). No improvement was achieved in six (11.1%) limbs. One-year primary sustained clinical improvement rates were 76.7% ± 7.2 for TASC C, 46.3% ± 11.1 for TASC D ($p = 0.03$), 74.1% ± 1.0 for IC and 60.1% ± 8.3 for CLI ($p = 0.23$), respectively. One-year secondary sustained clinical improvement rates were 87.6% ± 5.9 for TASC C, 67.3% ± 11.3 for TASC D ($p = 0.09$), 84% ± 8.5 for IC and 77.7% ± 7.5 for CLI ($p = 0.54$), respectively (Table 6). Mean Rutherford index at baseline and at 12 months were 4.1 ± 1.0 and 0.8 ± 1.3, respectively ($p < 0.001$) (Fig. 2). There was no limb loss in claudicants. The limb salvage rate at 1 year in patients with CLI was 97.3%. One patient, despite patent stent, required major amputation. Complete wound healing was achieved in 17 out of the 24 cases after 1 year. Additional procedures were necessary in two cases (one TER and one TLR).

Mean ABI increased from baseline levels of 0.59 ± 0.1 to 0.94 ± 0.2 at 1 month and remained elevated at 0.94 ± 0.2 at 1 year ($p < 0.001$) (Fig. 3).

At 1 year, primary and secondary patency rates were 66% and 80.9%, respectively (Fig. 4). One-year primary patency rates were 82.1% ± 6.6 for TASC C, 44% ± 11.4 for TASC D ($p = 0.009$), 79.4% ± 9.2 for IC and 61.4% ± 8.4 for CLI ($p = 0.17$), respectively. One-year secondary patency rates were 84.9% ± 6.2 for TASC C, 63.9% ± 12.4 for TASC D ($p = 0.12$), 90% ± 6.7 for IC and 71% ± 8.3 for CLI ($p = 0.15$), respectively (Table 6). During follow-up, seven (11.3%) cases of stent thrombosis and 12 (19.3%) cases of ISR were observed. Patients with TASC D lesions displayed a higher rate of ISR compared with TASC C patients (35% vs. 10%, $p = 0.005$, Table 4). Of the seven cases of stent thrombosis, one occurred within 30 days, none occurred within 31 days to 3 months, three occurred within 3–6 months and three occurred within 6–12-months. Among seven patients with stent thrombosis, two patients underwent palliative treatment due to severe and life-threatening comorbidities, three patients underwent a walking programme in the absence of CLI and the last two patients underwent a re-intervention (one femoropopliteal bypass and one angioplasty) since they presented with CLI. Of the 12 (19.3%) cases of ISR, none occurred within 30 days, three occurred within 31 days to 3 months, five occurred within 3–6 months and four occurred within 6–12 months. Of the 12 cases of ISR, six patients presented with

**Table 4**
Main characteristics (demographic, clinical, procedural) according to TASC classification of lesions and clinical presentation of patients.

| | TASC C | TASC D | *p* value | IC | CLI | *p* value |
|---|---|---|---|---|---|---|
| Age (mean ± SD) | 72 ± 10 | 68 ± 15 | 0.215 | 66 ± 10 | 74 ± 12 | 0.004 |
| Male, Nb (%) | 27 (69) | 19 (83) | 0.25 | 22 (88) | 24 (65) | 0.04 |
| IC, Nb (%) | 18 (46) | 7 (30) | 0.22 | 25 (100) | 0 (0) | – |
| CLI, Nb (%) | 21 (54) | 16 (70) | 0.22 | 0 (0) | 37 (100) | – |
| TASC C, Nb (%) | 39 (100) | 0 (0) | – | 18 (72) | 21 (57) | 0.22 |
| TASC D, Nb (%) | 0 (0) | 23 (39) | – | 7 (28) | 16 (43) | 0.22 |
| Ruth. (baseline) | 4 ± 1 | 4 ± 1 | 0.31 | 3 ± 0 | 5 ± 1 | 0.0001 |
| Ruth. (1st month) | 1 ± 2 | 2 ± 2 | 0.061 | 1 ± 1 | 2 ± 2 | 0.001 |
| Ruth. (12th month) | 1 ± 1 | 1 ± 1 | 0.459 | 1 ± 1 | 1 ± 1 | 0.375 |
| ABI (baseline) | 0.5 ± 0.1 | 0.60 ± 0.1 | 0.054 | 0.6 ± 0.1 | 0.6 ± 0.1 | 0.112 |
| ABI (1st month) | 1 ± 0.2 | 0.9 ± 0.2 | 0.335 | 1 ± 0.2 | 0.9 ± 0.2 | 0.316 |
| ABI (12th month) | 1 ± 0.2 | 0.9 ± 0.2 | 0.028 | 1 ± 0.2 | 1 ± 0.2 | 0.529 |
| Nb of stent, (mean ± SD) | 2 ± 1 | 3 ± 1 | 0.0001 | 2 ± 1 | 2 ± 1 | 0.06 |
| Lesion length, (mean ± SD) | 183 ± 60 | 334 ± 79 | 0.0001 | 216.49 ± 1 | 254 ± 98 | 0.146 |
| Stenting length, (mean ± SD) | 213 ± 67 | 366 ± 79 | 0.0001 | 237 ± 96 | 289 ± 103 | 0.135 |
| Associated angioplasty, Nb (%) | 10 (26) | 10 (43) | 0.15 | 7 (28) | 13 (35) | 0.55 |
| Associated surgery, Nb (%) | 4 (10) | 0 (0) | 0.09 | 0 (0) | 4 (11) | 0.32 |
| Contrast agent, ml (mean ± SD) | 82 ± 39 | 96 ± 29 | 0.162 | 97 ± 42 | 80 ± 29 | 0.095 |
| Irradiation, ($mGy/m^2$) | 2.96 ± 3.12 | 4.07 ± 2.6 | 0.208 | 4.17 ± 3.34 | 3.71 ± 2.58 | 0.079 |
| Procedure length, min (mean ± SD) | 69 ± 30 | 97 ± 39 | 0.003 | 78 ± 43 | 80 ± 31 | 0.845 |
| Hospital stay, days (mean ± SD) | 3 ± 4 | 3 ± 4 | 0.601 | 2 ± 3 | 4 ± 3 | 0.064 |
| Minor complications, Nb (%) | 3 (8) | 4 (17) | 0.51 | 2 (8) | 5 (14) | 0.81 |
| Major complications, Nb (%) | 2 (5) | 4 (17) | 0.18 | 2 (8) | 4 (11) | 0.99 |
| ISR, Nb (%) | 4 (10) | 8 (35) | 0.005 | 4 (16) | 8 (22) | 0.44 |
| Thrombosis, Nb (%) | 4 (10) | 3 (13) | 0.62 | 1 (4) | 6 (16) | 0.19 |
| TLR, Nb (%) | 5 (13) | 6 (26) | 0.23 | 3 (12) | 8 (22) | 0.45 |
| TER, Nb (%) | 2 (5) | 0 (0) | 0.36 | 0 (0) | 2 (5) | 0.23 |

symptoms recurrence and five patients (six limbs) were asymptomatic. Symptomatic patients were treated. Asymptomatic ISR were considered to threaten vessel patency in three cases (for the three other asymptomatic ISR, surveillance was recommended). A total of nine redo procedures were performed. These procedures consisted of redo angioplasty in all cases but one, in which a vein femoropopliteal bypass was performed. All patients, but two, were clinically improved at 12 months. These two patients were claudicants and a conservative treatment was chosen.

At 1 year, TLR and TER-free cumulative survival rates were 80.3 ± 5.3% and 96.5 ± 2.4%, respectively (Fig. 5(a) and (b)). A total of 11 TLR and two TER were performed during follow-up. Of the 11 TLR procedures, endovascular repair was performed in nine cases to treat ISR ($n = 8$) and in one case to treat in-stent thrombosis ($n = 1$). Surgical repair was realised to treat one ISR and one in-stent thrombosis. The two TER procedures were angioplasties performed to maintain vessel patency.

The survey of medical treatment is represented in Table 7. All patients received at least one anti-platelet agent for the first 6 months and 67% of them were on both aspirin and clopidogrel. Occurrence of in-stent thrombosis was observed in five patients taking two anti-platelet agents, and in two patients taking only one anti-platelet agent.

Complete X-ray follow up was obtained for 42 treated limbs. Ninety stents were analysed and 16 fractures were noted (17.7%). We observed one type I, seven type II, five type III and three type IV fractures. Loss of primary patency was associated with six cases of

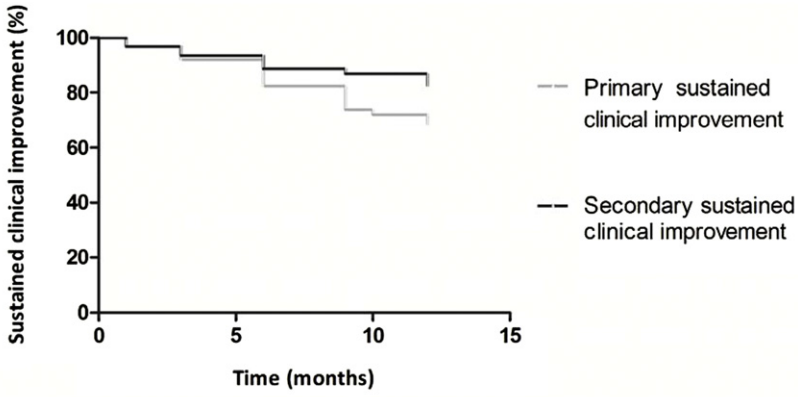
**Table 5**
Outcomes of the patients.

| Variables | |
|---|---|
| Death, *n* (%) | 5 (8.5) |
| Massive cardiac failure (on day 2) | 1 (1.7) |
| Cerebrovascular accident (3rd month) | 1 (1.7) |
| Myelodysplasia acutisation (3rd month) | 1 (1.7) |
| Pulmonary neoplasia (6th month) | 1 (1.7) |
| Unknown (11th month) | 1 (1.7) |
| Major adverse cardiovascular event, *n* (%) | 4 (6.8) |
| Pulmonary oedema(3rd month) | 1 (1.7) |
| ACBG (6th month) | 1 (1.7) |
| ACS (6th month) | 1 (1.7) |
| PMK implantation (6th month) | 1 (1.7) |
| Amputations, *n* (%) | 1 (1.7) |
| Minor | 0 (0) |
| Major | 1 (1.7) |
| Wound healing, *n* (%) | 17 (70.8) |
| Infection, *n* (%) | 2 (3.2) |
| Digestive bleeding, *n* (%) | 1 (1.7) |
| Intrastent restenosis, *n* (%) | 12 (19.3) |
| 1st month | 0 (0) |
| 3rd month | 3 (4.8) |
| 6th month | 5 (8.1) |
| 9th month | 2 (3.2) |
| 12th month | 2 (3.2) |
| Stent thrombosis, *n* (%) | 7 (11.3) |
| 1st month | 1 (1.6) |
| 3rd month | 0 (0) |
| 6th month | 3 (4.9) |
| 9th month | 1 (1.6) |
| 12th month | 2 (3.2) |

ACBG: acute coronary bypass grafting, ACS: acute coronary syndrome, PMK: pace maker.

**Table 6**
Primary and secondary sustained clinical improvement and patency according to TASC classification and clinical presentation (IC vs. CLI).

| | TASC C | TASC D | *p* | IC | CLI | *p* |
|---|---|---|---|---|---|---|
| Primary sustained clinical improvement, % ±SD | | | | | | |
| 1 month | 100 | 95.5 ± 4.4 | | 100 | 97.3 ± 2.7 | |
| 12 months | 76.7 ± 7.2 | 46.3 ± 11.1 | 0.03 | 74.1 ± 1.0 | 60.1 ± 8.3 | 0.23 |
| Secondary sustained clinical improvement, % ±SD | | | | | | |
| 1 month | 100 | 95.5 ± 4.4 | | 100 | 97.3 ± 2.7 | |
| 12 months | 87.6 ± 5.9 | 67.3 ± 11.3 | 0.09 | 84 ± 8.5 | 77.7 ± 7.5 | 0.54 |
| Primary patency, % ±SD | | | | | | |
| 1 month | 100 | 100 | | 100 | 100 | |
| 12 months | 82.1 ± 6.6 | 44 ± 11.4 | 0.009 | 79.4 ± 9.2 | 61.4 ± 8.4 | 0.17 |
| Secondary patency, % ±SD | | | | | | |
| 1 month | 100 | 100 | | 100 | 100 | |
| 12 months | 84.9 ± 6.2 | 63.9 ± 12.4 | 0.12 | 90 ± 6.7 | 71 ± 8.3 | 0.15 |




| | | Month 1 | Month 3 | Month 6 | Month 9 | Month 12 |
|---|---|---|---|---|---|---|
| Primary sustained clinical improvement | N | 60 | 57 | 51 | 44 | 39 |
| | % | 96.8 | 91.9 | 82.3 | 73,9 | 68.6 |
| | SE | 2.2 | 3.5 | 4.9 | 5.6 | 6 |
| Secondary sustained clinical improvement | N | 60 | 58 | 54 | 48 | 39 |
| | % | 96.8 | 93.5 | 88.6 | 86,8 | 82.6 |
| | SE | 2.2 | 3.1 | 4 | 4,4 | 5.1 |

**Figure 1.** Primary and secondary sustained clinical improvement. One year primary and secondary sustained clinical improvement rates were 68.6% and 82.6%, respectively.

stent fracture. Occurrence of in-stent thrombosis was associated with one case of stent fracture (type IV). Occurrence of ISR was related to five cases of stent fractures. Clinical impact and management of stent fractures are reported in Table 8.

## Discussion

In this single-centre cohort, we have evaluated prospectively the safety and the efficacy of primary stenting using LifeStent® (Bard Peripheral Vascular, Tempe, AZ, USA) to treat TASC C and D femoropopliteal lesions. Most of the procedures were performed to treat patients presenting with CLI. This strategy offered acceptable initial results at 1 year with high-sustained clinical improvements and low rate of re-intervention despite an elevated percentage of stent fracture.

Despite the absence of recommendations, primary stent implantation for TASC C and D femoropopliteal lesions has become routine practice. For instance, many manufacturers offer stents longer than 15 cm and up to 20 cm. However, evidence is lacking concerning the clinical outcome of such treatment. In our study, we observed that the rate of patients presenting with CLI was 60%

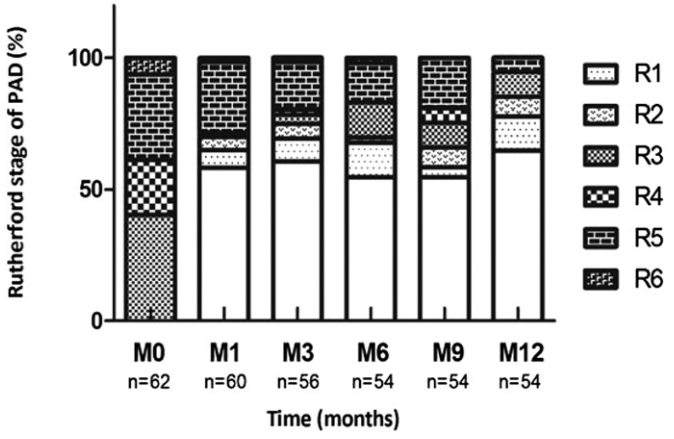



**Figure 2.** Clinical outcomes up to 12 months. At one year 35 (64.8%) limbs were asymptomatic, 16 (29.6%) presented with IC and 3 (5.6%) with CLI compared with 60% of patients presenting with CLI and 40% with IC at baseline. (R0 to R6: Rutherford stage 0 to Rutherford stage 6).

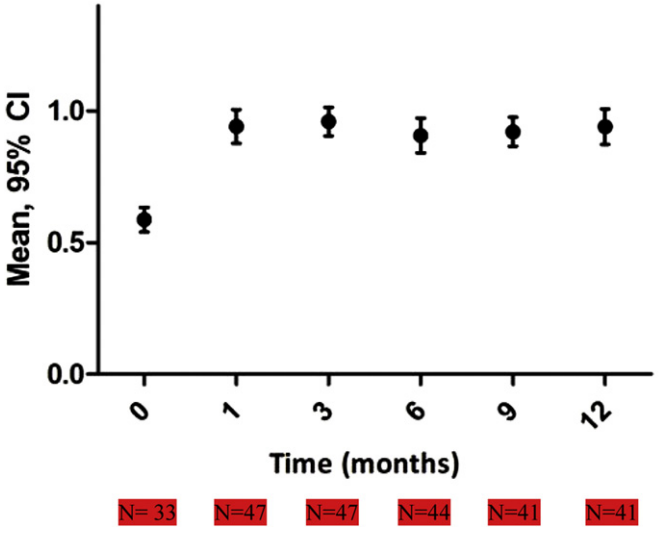
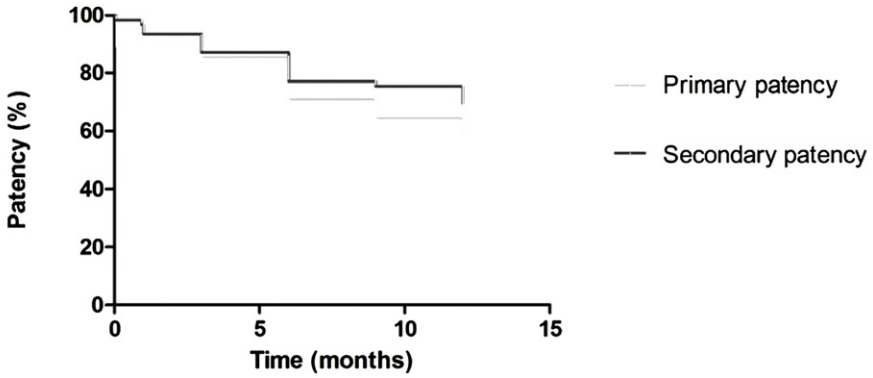



**Figure 3.** Sustained haemodynamic improvement at 1 year. Mean ankle brachial index increased from baseline levels of 0.59 ± 0.1 to 0.94 ± 0.2 at 1-month and 0.94 ± 0.2 at 1-year ($p < 0.001$). ABI: ankle brachial index; CI: confidence interval.



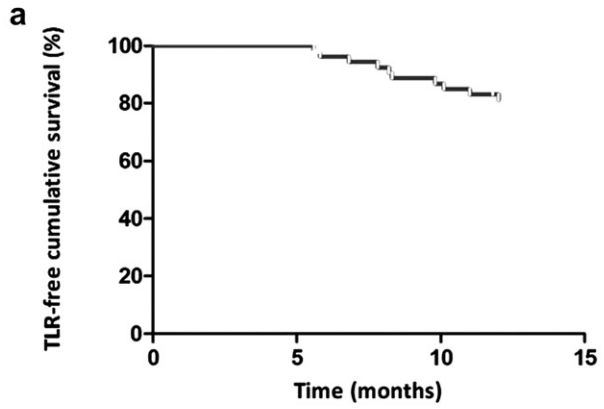

| | | Month 1 | Month 3 | Month 6 | Month 9 | Month 12 |
|---|---|---|---|---|---|---|
| Primary patency | N | 62 | 60 | 52 | 46 | 38 |
| | % | 100 | 98.4 | 91.7 | 81,1 | 66 |
| | SE | | 1.6 | 3.6 | 5,1 | 6.4 |
| Secondary patency | N | 62 | 60 | 52 | 47 | 38 |
| | % | 100 | 98.4 | 95.1 | 87,7 | 80.9 |
| | SE | | 1.6 | 2.8 | 4,4 | 5.5 |

**Figure 4.** Primary and secondary patency. One-year primary and secondary patency rates were 66% and 80.9%, respectively.

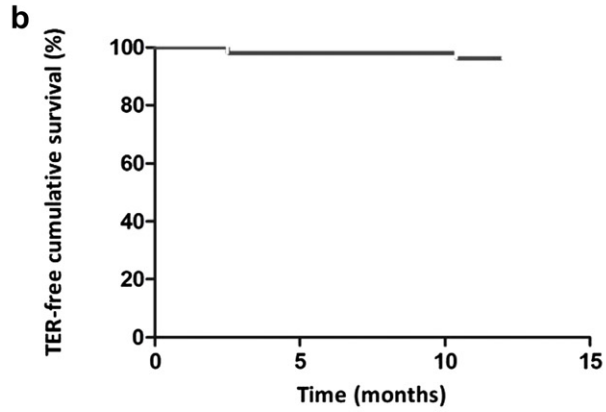
compared with previous landmark studies in which 12.5% and 2.9% of CLI patients were reported.[5,11] Others have recently investigated the results with primary stenting in femoropopliteal lesions longer than 15 cm.[12] The mean lesion length was 242 mm, lesions extended to the popliteal artery in 27% of the cases and the rate of CLI was 29%. By contrast, the popliteal artery was involved in 77.4% of our patients. This high rate of popliteal artery involvement could explain the differences in CLI rates between both studies since lesions extending to the popliteal artery may preclude the collateral circulation from the deep femoral artery.

*Clinical improvement*

After 1-year follow-up, primary sustained clinical improvement was 68.6% while secondary sustained clinical improvement was 82.6%. No patient has experienced clinical worsening following endovascular procedure. Six percent of our patients presented with CLI at 1 year vs. 59.7% at baseline. Only one patient required major amputation. Clinical improvement was also correlated with a haemodynamic parameter since mean ABI was normalised at 1 year. In two cases, a femoropopliteal bypass was realised during follow-up with no difficulty related to prior endovascular procedure. In contrast to our findings as well as those of Bosiers, lower rates of clinical improvement have been reported in the past.[2] Statistically significant differences were noted between TASC C and D lesions in terms of primary sustained clinical improvement and primary patency (76.7% vs. 46.3%, $p = 0.03$ and 82.1% vs. 44%, $p = 0.009$). Interestingly, no statistical difference was noted between secondary rates (87.6% vs. 67.3%, $p = 0.09$ for secondary sustained clinical improvement and 84.9% vs. 63.9%, $p = 0.12$ for secondary patency, respectively). Furthermore, patients with TASC D lesions experienced ISR more frequently than patients with TASC C lesions (35% vs. 10%, $p = 0.005$). These results suggest that, provided strict follow-up is observed, not only TASC C but also TASC D patients benefit from this endovascular strategy. In our study, stent thrombosis and restenosis were the causative factors associated with a lack of clinical improvement. Thrombosis results from the influence of various factors such as cardiac insufficiency, hypercoagulability, pro-inflammatory states, severity of initial clinical presentation or poor runoff,[13] whereas ISR is related to intimal hyperplasia. At 1 year, in-stent thrombosis and ISR rates were 11.3% and 19.3% in our study, compared with 24% and 10% in that of Bosiers.[12] Taken together, these results represent a cumulated rate of events at 1-year follow-up of 30.6% compared with 34%, respectively. Both studies are similar regarding the definition of ISR, which was considered significant by a PSV ratio $\geq$2.4. However, considering the long time interval between two successive ultrasound exams in their follow-up schedule (6 months vs. 3 months in the STELLA trial), some ISR events might have been considered as stent thrombosis. Consequently, we cannot rule out that their stent thrombosis rate might have been overestimated and their ISR rates underestimated, which could explain this discrepancy. Nevertheless, the 1-year rate of ISR seems particularly low ($<$20%) in both studies considering the severity of the lesions. This might be related to the sub-intimal recanalisation technique used to treat occluded lesions. The looped guide wire tip is crossing the lesion in the sub-intimal space, hence splitting apart a considerable amount of smooth muscle cells in the media. This could reduce significantly the pool of smooth muscle cells available to induce intimal hyperplasia compared with the transluminal technique. We also have noticed that most of the restenosis events (eight out of 12) have been detected during the first 6 months. This contrasts with the delay of 12 months usually observed by most authors[14] suggesting that narrow US surveillance is preferable. In some cases, ISR and thrombosis were left untreated due to the lack of consecutive symptoms or due to a degradation of the general condition of patients.




| Months | 0 | 1 | 3 | 6 | 9 | 12 |
|---|---|---|---|---|---|---|
| N | 62 | 62 | 62 | 57 | 50 | 43 |
| % | 100 | 100 | 100 | 96,6+/-2,4 | 89,6+/-4,0 | 80,3+/-5,3 |




| Months | 0 | 1 | 3 | 6 | 9 | 12 |
|---|---|---|---|---|---|---|
| N | 62 | 62 | 59 | 57 | 55 | 51 |
| % | 100 | 100 | 98,4+/-1,6 | 98,4+/-1,6 | 98,4+/-1,6 | 96,5+/-2,4 |

**Figure 5.** (a) Freedom from target lesion revascularisation. One-year TLR-free cumulative survival rate was 81.1%. (b) Freedom from target extremity revascularisation. One year TER-free cumulative survival rate was 96.3%. TLR: target lesion revascularisation. TER: target extremity revascularisation.

We do not report on our technical success rate. This work was rather focussed on the clinical outcome of a specific subset of patients requiring challenging endovascular procedures. Moreover, even for longest TASC and D lesions, recent studies have reported a success rate of recanalisation of about 80–85% of the cases.[3]

For comparison purposes, after 2 years, the primary patency rates of venous and polytetrafluoroethylene (PTFE) above-the-knee femoropopliteal bypass are estimated to be 80% and 69%, respectively.[14] Patency rates of below-the-knee femoropopliteal bypass have been reported to be up to 71% at 3 years.[15] Patency rates following sub-intimal angioplasty vary widely between 56% and 70% at 1 year.[3] Studies usually do not differentiate between IC and CLI patients when reporting patency rates. We report a 1-year primary patency rate of 79.4% in IC patients and 61.4% in CLI patients with secondary patency rates of 90% and 71%, respectively. These results compare favourably with other data given the high proportion of CLI patients in our cohort. Important differences between primary and secondary rates emphasise the need for narrow surveillance and repeated TLR when patency is threatened.

**Table 7**
Medical treatment survey.

| | Baseline | 1 mo | 3 mo | 6 mo | 9 mo | 12 mo |
|---|---|---|---|---|---|---|
| Antiplatelet agents | | | | | | |
| 0 agent | 0 | 0 | 0 | 0 | 0 | 0 |
| 1 agent | 20 | 11 | 11 | 25 | 32 | 34 |
| 2 agents | 38 | 46 | 40 | 23 | 13 | 12 |
| Vitamin K antagonists | 12 | 12 | 8 | 9 | 11 | 11 |
| Statin | 41 | 45 | 44 | 42 | 40 | 40 |
| Angiotensin-converting enzyme inhibitors | 43 | 45 | 42 | 40 | 36 | 37 |

**Table 8**
Clinical impact and management of stent fractures.

| Stent fracture | Type of fracture | ISR | Thrombosis | Clinical impact | Additional procedure and outcome |
|---|---|---|---|---|---|
| 1 | 2 | + | 0 | Return to IC | TLR asymptomatic |
| 2 | 2 | 0 | 0 | 0 | 0 |
| 3 | 1 | 0 | 0 | 0 | 0 |
| 4 | 2 | + | 0 | CLI vs. IC at baseline | TLR asymptomatic |
| 5 | 4 | + | 0 | IC vs. CLI at baseline | TLR asymptomatic |
| 6 | 3 | + | 0 | Asymptomatic | 0 |
| 7 | 3 | + | 0 | Asymptomatic | 0 |
| 8 | 3 | 0 | 0 | 0 | 0 |
| 9 | 3 | 0 | 0 | 0 | 0 |
| 10 | 2 | 0 | 0 | 0 | 0 |
| 11 | 2 | 0 | 0 | 0 | 0 |
| 12 | 4 | 0 | 0 | 0 | 0 |
| 13 | 2 | 0 | 0 | 0 | 0 |
| 14 | 3 | 0 | 0 | 0 | 0 |
| 15 | 4 | 0 | + | IC vs. CLI at baseline | Considered not improved |
| 16 | 2 | 0 | 0 | 0 | 0 |

0: no event, ISR: in-stent restenosis, IC: intermittent claudication, CLI: critical limb ischaemia, TLR: target lesion revascularisation., +: presence of in-stent restenosis.

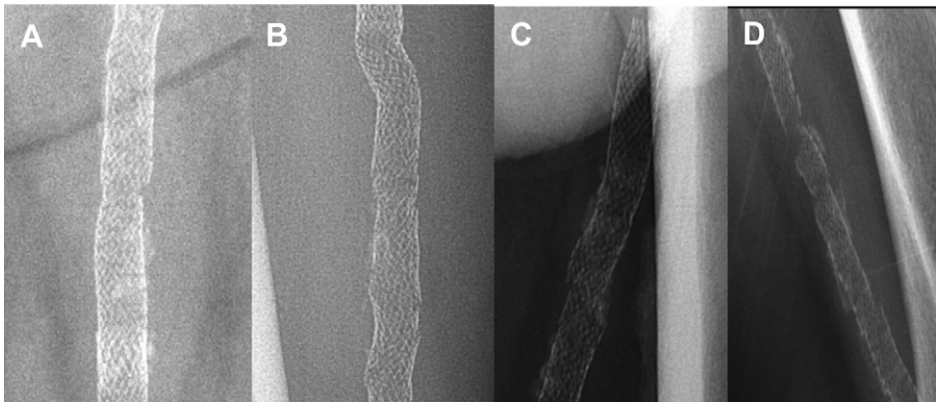



**Figure 6.** X-rays showing different types of stent fractures according to the Jaff et al. Classification: type 1 (panel A), type 2 (panel B), type 3 (panel C) and type 4 (panel D) stent fractures.

*Stent fracture*

Stent fracture rate was particularly elevated. Incidence of stent fracture in the literature ranges from 2% to 65%.[16,17] In 77.4% of the cases, stents were placed in the popliteal artery. Consequently, stenting crossed the Hunter region and the knee joint, both zones identified as vascular bending segments subjected to high mechanical axial stress.[18–20] This might explain the high fracture rate. Interestingly, no fracture has been noted in stent overlap zones (Fig. 6). Implanted stents were of 6- and 7-mm diameters. These diameters allow treatment of the majority of superficial femoral artery (SFA) lesions. For patients with small vessel diameter, stents larger than the nominal vessel diameter could damage the arterial wall. However, the correlation between the metallic coverage and the risk of ISR is not established.[21]

Most importantly, the clinical impact of stent fracture is still a matter of controversy in the literature. Some suggest that stent fractures are associated with a higher incidence of ISR, thrombosis or embolism.[16,17,19] Others do not report a significant association between stent fracture and clinical deterioration.[12,22,23] In our hands, despite the high number of fractures observed, impact on clinical deterioration remained very limited.

*Study limitations*

The main limitations of this study are the absence of a control group and the relatively small sample size of patients, both limiting the statistical significance of our conclusions. In about one-third of the cases, adjunctive procedures were realised to improve outflow or inflow. These procedures had an impact on the outcome of the femoral stenting and, this constitutes a potential bias in the evaluation of the clinical improvement. The inclusion of patients in this study was influenced by some criteria such as the ability to cross the target lesion with a guide wire as well as the presence of inflow and outflow lesions. Consequently, conclusions of this study did not apply to these lesions subgroups and, in particular, to the highly calcified lesions. Indeed, arterial calcifications are particularly predictive of technical failure due to the inability to cross the lesion or to re-enter the true lumen.[3] However, presence of calcifications does not seem to influence primary-assisted patency.[24] To evaluate functional status outcomes, we have used a subjective clinical scale and we did not use a quality of life questionnaire.

## Conclusion

Primary stenting of TASC C and D lesions appears to be safe and efficient given the high-sustained clinical improvement and the

low rate of ISR observed in our study. Endovascular treatment of such long and severe lesions exposes to high rate of stent fractures, which should not be a concern given their low clinical impact. Early narrow clinical and duplex scan follow-up of long stents is mandatory to detect potential thrombosis and ISR events. Primary stenting of TASC C and D lesions needs ongoing surveillance and longer follow-up, given the high rate of CLI.

## Acknowledgments

We thank Carine Montagne and Brigitte Hauraix for their excellent logistical organisation.

## Funding Source

None.

## Conflict of Interest

None.

## References

1 Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *Eur J Vasc Endovasc Surg* 2007;**33**(Suppl. 1):S1–75.
2 Setacci C, Chisci E, de Donato G, Setacci F, Iacoponi F, Galzerano G. Subintimal angioplasty with the aid of a re-entry device for TASC C and D lesions of the SFA. *Eur J Vasc Endovasc Surg* 2009 Jul;**38**(1):76–87.
3 Markose G, Miller FN, Bolia A. Subintimal angioplasty for femoro-popliteal occlusive disease. *J Vasc Surg* 2010 Nov;**52**(5):1410–6.
4 Sandford RM, Bown MJ, Sayers RD, London JN, Naylor AR, McCarthy MJ. Is infrainguinal bypass grafting successful following failed angioplasty? *Eur J Vasc Endovasc Surg* 2007 Jul;**34**(1):29–34.
5 Schillinger M, Sabeti S, Loewe C, Dick P, Amighi J, Mlekusch W, et al. Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. *N Engl J Med* 2006 May 4;**354**(18):1879–88.
6 Rogers JH, Laird JR. Overview of new technologies for lower extremity revascularization. *Circulation* 2007 Oct 30;**116**(18):2072–85.
7 Farb A, Sangiorgi G, Carter AJ, Walley VM, Edwards WD, Schwartz RS, et al. Pathology of acute and chronic coronary stenting in humans. *Circulation* 1999 Jan 5–12;**99**(1):44–52.
8 CAPRIE Steering Committee. A randomised, blinded, trial of clopidogrel versus aspirin in patients at risk of ischaemic events (CAPRIE). *Lancet* 1996 Nov 16;**348**(9038):1329–39.
9 Jaff M, Dake M, Pompa J, Ansel G, Yoder T. Standardized evaluation and reporting of stent fractures in clinical trials of noncoronary devices. *Catheter Cardiovasc Interv* 2007 Sep;**70**(3):460–2.
10 Diehm N, Pattynama PM, Jaff MR, Cremonesi A, Becker GJ, Hopkins LN, et al. Clinical endpoints in peripheral endovascular revascularization trials: a case for standardized definitions. *Eur J Vasc Endovasc Surg* 2008 Oct;**36**(4):409–19.
11 Krankenberg H, Schluter M, Steinkamp HJ, Burgelin K, Scheinert D, Schulte KL, et al. Nitinol stent implantation versus percutaneous transluminal angioplasty in superficial femoral artery lesions up to 10 cm in length: the femoral artery stenting trial (FAST). *Circulation* 2007 Jul 17;**116**(3):285–92.
12 Bosiers M, Deloose K, Callaert J, Moreels N, Keirse K, Verbist J, et al. One-year results with the Protege EverFlex 200-mm-long nitinol stent (ev3) in Trans-Atlantic inter-society consensus C and D femoropopliteal lesions: durability-200 study. *J Vasc Surg* May 31.
13 Surowiec SM, Davies MG, Eberly SW, Rhodes JM, Illig KA, Shortell CK, et al. Percutaneous angioplasty and stenting of the superficial femoral artery. *J Vasc Surg* 2005 Feb;**41**(2):269–78.
14 Iida O, Uematsu M, Soga Y, Hirano K, Suzuki K, Yokoi H, et al. Timing of the restenosis following nitinol stenting in the superficial femoral artery and the factors associated with early and late restenoses. *Catheter Cardiovasc Interv* 2011 Oct 1;**78**(4):611–7.
15 Watelet J, Cheysson E, Poels D, Menard JF, Papion H, Saour N, et al. In situ versus reversed saphenous vein for femoropopliteal bypass: a prospective randomized study of 100 cases. *Ann Vasc Surg* 1987 May;**1**(4):441–52.
16 Rits J, van Herwaarden JA, Jahrome AK, Krievins D, Moll FL. The incidence of arterial stent fractures with exclusion of coronary, aortic, and non-arterial settings. *Eur J Vasc Endovasc Surg* 2008 Sep;**36**(3):339–45.
17 Adlakha S, Sheikh M, Wu J, Burket MW, Pandya U, Colyer W, et al. Stent fracture in the coronary and peripheral arteries. *J Interv Cardiol* 2010 Aug;**23**(4):411–9.
18 Schillinger M, Sabeti S, Dick P, Amighi J, Mlekusch W, Schlager O, et al. Sustained benefit at 2 years of primary femoropopliteal stenting compared with balloon angioplasty with optional stenting. *Circulation* 2007 May 29;**115**(21):2745–9.
19 Iida O, Nanto S, Uematsu M, Morozumi T, Kotani J, Awata M, et al. Effect of exercise on frequency of stent fracture in the superficial femoral artery. *Am J Cardiol* 2006 Jul 15;**98**(2):272–4.
20 Nikanorov A, Smouse HB, Osman K, Bialas M, Shrivastava S, Schwartz LB. Fracture of self-expanding nitinol stents stressed in vitro under simulated intravascular conditions. *J Vasc Surg* 2008 Aug;**48**(2):435–40.
21 Morton AC, Crossman D, Gunn J. The influence of physical stent parameters upon restenosis. *Pathol Biol (Paris)* 2004 May;**52**(4):196–205.
22 Bosiers M, Torsello G, Gissler HM, Ruef J, Muller-Hulsbeck S, Jahnke T, et al. Nitinol stent implantation in long superficial femoral artery lesions: 12-month results of the DURABILITY I study. *J Endovasc Ther* 2009 Jun;**16**(3):261–9.
23 Duda SH, Bosiers M, Lammer J, Scheinert D, Zeller T, Tielbeek A, et al. Sirolimus-eluting versus bare nitinol stent for obstructive superficial femoral artery disease: the SIROCCO II trial. *J Vasc Interv Radiol* 2005 Mar;**16**(3):331–8.
24 Antusevas A, Aleksynas N, Kaupas RS, Inciura D, Kinduris S. Comparison of results of subintimal angioplasty and percutaneous transluminal angioplasty in superficial femoral artery occlusions. *Eur J Vasc Endovasc Surg* 2008 Jul;**36**(1):101–6.