Stent fracture after provisional stenting using four brands of nitinol stents in trans-atlantic inter-society consensus c and d femoropopliteal lesions: in 1 year's follow-up

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Introduction
Stenting Trans-Atlantic Inter-Society Consensus C and D lesions of the femoral–popliteal segment is still controversial. There is a wide range of stent fractures ranging between 2 and 62% with different clinical outcomes. This study aimed to investigate the clinical impact and outcome of stent fracture of complex lesions of the femoral–popliteal territory using four brands of stents after 1 year.
Patient and methods
This was a retrospective study on 102 limbs that had Trans-Atlantic Inter-Society Consensus C and D femoral–popliteal lesions. All of them were treated with balloon angioplasty with bailout stenting (self-expandable nitinol stents, Portege EverFlex, E-Luminexx, and Absolute Pro). Patients were followed up by clinical assessment, and duplex and biplane radiography to detect stent fracture.
Results
After a mean 9±5.6 months' complete follow-up of 150 stents in 102 limbs, mean length of the stented segment being 16.5±9.9 cm, the following results were obtained. An overall 78% of stents were fractured. An overall 88.2% of the treated limbs were occluded and presented with critical limb ischemia. The patency rate was 0% for type III and type IV stent fractures, 50% for type II stent fracture, and 6.25% for type I stent fracture. There was no correlation between the type of stent fracture and either stent location (proximal, mid, distal superficial femoral artery and supragenicular popliteal artery) or stent design (brand).
Conclusion
The patency rate for the stented femoral–popliteal segment was very poor, despite great advances in the designs of stents to withstand the highly varied forces applied to this segment. Stenting this segment should be the last option, in which surgery has a great risk (drug-coated balloon and/or atherectomy devices, failed or unavailable).

Keywords:
femoral–popliteal stenting, in stent occlusion, stent design, stent fracture

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Introduction

Everyday, advances in endovascular technology have encouraged intervention in long complex lesions with a high success rate [1,2]. Despite endovascular interventions in the superficial femoral artery (SFA), which accounts for more than 50% of all endovascular interventions, maintaining long-term patency after these interventions is still a challenging issue [3]. Although the main stream in the literature mentions that it is better to stent SFA lesions than perform percutaneous transluminal angioplasty (PTA) [4–11], the incidence and the clinical impact of stent fracture were still a controversy; some of the literature reported a high incidence rate of in-stent stenosis, occlusion, and thrombosis, and deterioration of the patient's clinical presentation, whereas the others did not [12–17]. SFA is located in the most dynamic portion of the body, exposing it to great cyclic forces in the form of compression, bending, and torsion [18–21]. Stent conformability is defined as the degree to which a stent can bend around its longitudinal axis after deployment, and this is attributed to stent design, which is determined by numbers and arrangement of the interconnectors between the stent struts, strut length and strut cross-sectional shape, strut angles, stent material, and manufacturing process [22]. Recently many stent designs have been developed to meet the requirement of SFA stenting. The aim of this study was to compare the incidence and the clinical impact of stent fracture in four designs of nitinol stents after they had been inserted in long complex SFA lesions as bailout procedures.

Patients and methods

This retrospective study was carried out between November 2013 and October 2015. It was ethical committee approved by the Department of Vascular Surgery in 2013. All patients were informed of the risks and benefits of the procedure and gave written informed consent to participate before enrollment. 'Endovascular first' concept was the policy in the management of chronic lower limb ischemia. Preoperatively, all risk factors were determined, such as diabetes, hypertension, renal impairment or ischemic heart disease.

Inclusion criteria

Patients with criteria of chronic lower limb ischemia were classified according to the Rutherford classification as follows: class IV (rest pain), class V (minor gangrene), or class VI (major gangrene).

Lesions were classified according to Trans-Atlantic Inter-Society Consensus (TASC) II which are as follows: TASC II (C) lesions, which are de-novo stenotic, occlusive to more than 15 cm, or restenotic lesions in the SFA after performing angioplasty twice, or TASC II (D) lesions, which cause chronic total occlusion (CTO) of CFA or SFA (>20 cm involving the popliteal artery) or CTO of the popliteal artery and proximal trifurcation vessels. The presence of adequate inflow and outflow, either pre-existing or re-established was an important factor. Outflow being through at least one tibial vessel ending in the foot.

Exclusion criteria

Patients who had sensitivity to contrast media, renal impairment (serum creatinine ≥2.0 mg/dl), extensive peripheral vascular disease that precluded safe insertion of an introducer sheath, lesions within or adjacent to an aneurysm, asymptomatic lesion, claudicating patients, and patients with acute ischemia or arterial thrombosis, or life expectancy less than 1 year were excluded from the study.

Intervention

All procedures were performed under local anesthesia, except in patients who had rest pain; the procedures were carried out under conscious sedation (midazolam 1–2.5 mg) and intravenous analgesia. Access was achieved by antegrade approach using a 6F sheath (Cordis Avanti; Johnson & Johnson), or contralateral crossover by the aortic bifurcation approach (8F 45 cm crossover sheath Cordis Avanti, Johnson & Johnson).

Retrograde access of popliteal or pedal vessels was obtained if antegrade attempt of crossing the lesion was unsuccessful. The choice of distal access depended on the extent of the lesion and the fitness of the patient; popliteal access was not preferred in obese patients. A micro puncture kit containing a 21 G needle and 0.018 in straight tipped wire was used to get access. After the distal access had been gained, a mixture of 100 μg of glyceryl trinitrates and 5000 IU of heparin (70–80 IU/kg) was administered. Lesions were crossed using the intraluminal method; angled hydrophilic Glide wire (Terumo Boston Scientific Corp, Natick, Mass/Vascular) was advanced to the level of occlusion under angiographic guidance. Other lesions were crossed using a subintimal method; the angled tip of the wire was directed to the wall, followed by advancing of the wire in the subintimal plan.

No re-entry device was used. Advanced techniques to cross CTO lesions were used when the previous conventional methods failed; subintimal arterial flossing with antegrade-retrograde intervention (SAFARI) technique or double balloon technique, in which two small balloons were inflated simultaneously with the intention to break the plaque and open the channel between the antegrade and retrograde wires, was used [17].

All the patients underwent PTA of the target lesions. Appropriate balloon sizes were determined on the basis of the diameter of the reference vessel adjacent to each lesion. Bailout stenting was used for residual stenosis of more than 30% or persistent dissection after prolonged inflation times (2–3 min). The stent dimensions were chosen by visual estimation to fit the vessel diameter. Adjacent stents were overlapped by 1 cm. Self-expandable Epic stent (Boston Scientific Corporation), E-LUMINEXX vascular stent (Bard Peripheral Vascular, Tempe, Ariz), and Absolute pro (Abbott; Abbott Vascular Inc, Menlo Park, CA) were used according to diameter and length availability. The used stent was of either 5, 6, or 7 mm in diameter. Stents were routinely postdilated to ensure optimal extension and apposition. The balloon (Wanda Boston Scientific Corp, Natick, Mass/Vascular) dimension and length were chosen not to exceed the length of the stent.

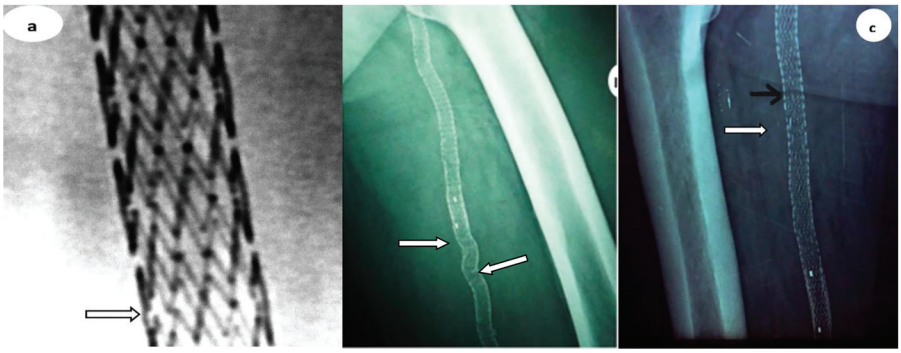
The technical results of the procedures were assessed by final angiography at the end of the procedures. Associated outflow lesions that were suspected to be involved in the disease were treated during the same procedure.

A prophylactic dose of low-molecular weight heparin was prescribed to the patients during hospitalization. Patients were continued on dual antiplatelet therapy with clopidogrel 75 mg once daily and aspirin of 75 mg once daily for at least 6 months.

Follow-up

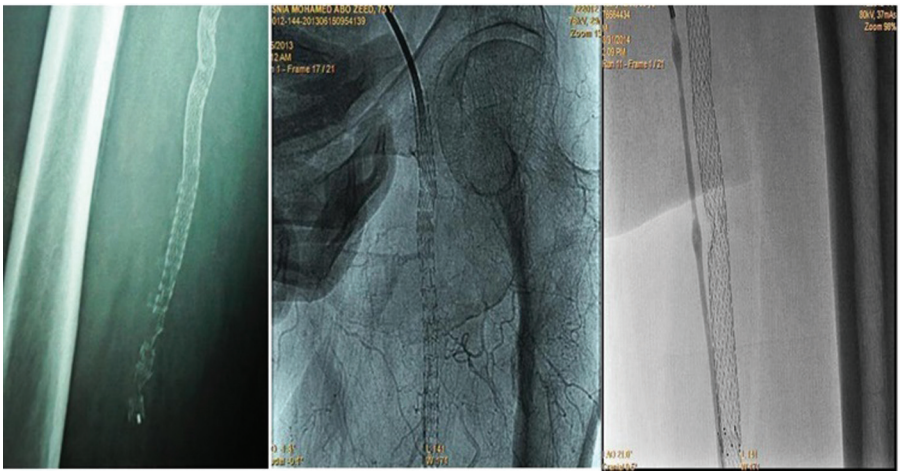
Clinical examination was performed by the surgeon at 1, 3, 6, and 12 months, postoperatively. Stent fractures were assessed by biplane radiography at 12 months with two different projections separated by at least 45° using the highest available magnification. Stent fracture was assessed and classified by a radiologist according to Poppa classification as type 1 (minor), type 2 (V-form), type 3 (complete separation without displacement), or type 4 (complete separation with displacement) (see Figs. 1 and 2). The exact site of each inserted stent was noted. The femoral–popliteal artery was divided into proximal femoral, midfemoral, distal femoral, supragenicular popliteal, and infragenicular popliteal parts. Length, diameter of each inserted stent, number of stents inserted, and total stented length per each patient were documented. In cases where stents fractured, the exact site of the fractured stent was noted – that is, proximal femoral, midfemoral, distal femoral, supragenicular popliteal, or infragenicular popliteal part. The type of stent fracture was noted; when several fractures were present on the same stent, only the most severe fracture was considered. Clinical impact evaluation including change of symptoms according to the Rutherford classification and duplex scan examination was performed at 1, 6, and 12 months and yearly. Duplex imaging of the revascularized vessel offers the best method of assuring the patency of the revascularization strategy and assessment of the degree of narrowing.The velocity criteria for determining stenosis vary; however, if the peak systolic velocity ratio was greater than 2.5, the degree of stenosis was considered significant enough to warrant further evaluation either with computed tomography angiography or magnetic resonance angiography or even direct angiography. Maintaining a close relationship with these patients was crucial, allowing the physician to identify and treat those patients who develop problems early, before the lesion progressed to a point where intervention became difficult.

Figure 1



Different types of fractured stent: (a) type I fracture, single struts fracture; (b) type II fracture, multiple stent fracture, V-shaped fracture; (c) type III fracture, transverse linear fracture.

Figure 2



Type IV fracture: type III with displacement.

Results

Over a period of 20 months, a total of 100 patients and 102 limbs were treated, in which 150 stents were inserted. They were retrospectively enrolled in the treatment of femoral–popliteal lesions. At 12 months' follow-up, radiography were obtained for all patients who attended the clinical follow-up.

Patients demographic, indication and comorbidity

Patients who were eligible for study and fitted the inclusion criteria were 100 in number [86 male individuals (85.3%) and 14 female individuals (14.7%)]. Their ages ranged from 42–80 years; the mean age was 58.8±9 years. Table 1 summarizes the demography and comorbidity of the patients. All treated patients presented with critical limb ischemia.

According to the TASC II classification, 79.4% patients presented with TASC II (C) lesions and 20.6% had TASC II (D) lesions. The median length for lesions in TASC II (C) and TASC II (D) was 143.45±97.6 and 220.6±55.7 mm, respectively. The mean stented length was 100.86 mm for TASC II (C) lesions and 170.96 mm for TASC II (D) lesions. The outflow tibial vessels for TASC II (C) and TASC II (D) were as shown in Table 2.

Concomitant tibial angioplasty was performed in 88% of the patients (88/100). The average number of stents was 1.5 stents inserted per patient. The number of stents inserted per limb (see Fig. 3) and the location of stents are shown in Fig. 4.

Table 1 Summarizes demography and comorbidity of patients

Age (years)	58.8±9
Sex (male : female) (%)	85.3 : 14.7
Diabetic (%)	61.8
Hypertensive (%)	38.2
Renal impairment (%)	14.7
Cardiac (%)	47.6
Previous iliac stent (%)	0
Rutherford classification (%)	
Class IV	38.1
Class V	26.5
Class VI	35.3

Table 2 Summarizes anatomic characteristics of the distal runoff of patients

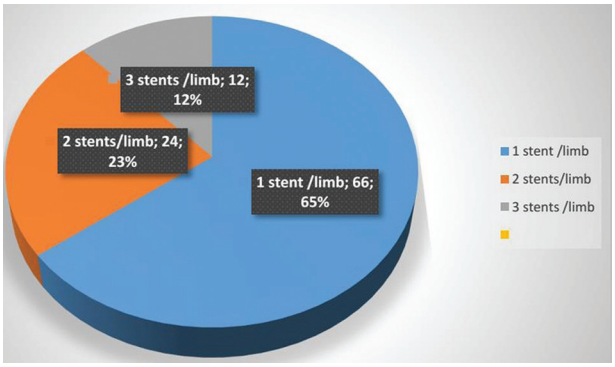
	TASC II C (%)	TASC II D (%)	*P*
Number of vessel runoff			
One vessel runoff	50.0	51.4	0.990
Two vessel runoff	41.7	40	
Three vessel runoff	8.3	8.6	
ATA	55.6	48.6	0.556
PTA	61.1	54.3	0.561
Peroneal	41.7	54.3	0.287

ATA, anterior tibial artery; PTA, percutaneous transluminal angioplasty; TASC, Trans-Atlantic Inter-Society Consensus.

Stent fracture

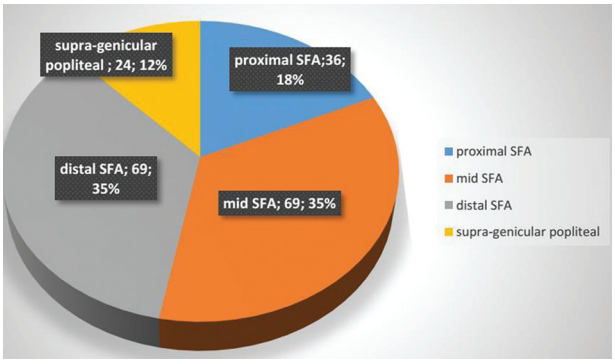
- An overall 78% of the stents (117/150) were fractured. Multiple stent fracture was seen in 40% of the stents (60/150).
- An overall 65% of the limbs (66/102) had one stent inserted, of which 89.3% of the stents (59/66) were fractured, and 53% of inserted stents were short stents less than or equal to 100 mm.
- An overall 23% of the limbs (24/102) had two stents inserted, of which 87.5% of stents (21/24) were fractured; in 11 limbs both stents were fractured and in ten limbs one stent only was fractured; 50% of the inserted stents were less than or equal to 100 mm long.
- An overall 11.8% of the limbs (12/102) had three stents inserted, of which 83.3% of the stents (10/12) were fractured; all the three stents were fractured in six limbs, whereas in four limbs only two stents were fractured. All stents inserted in those patients were more than or equal to 100 mm long.

Figure 3



The percentage of limbs according to number of stents inserted in each limb.

Figure 4



The percentage of stents according to their location.

- It was found that 56% of the stents were less than or equal to 100 mm in length (see Fig. 5).
- The location and distribution of fractured stents in different parts of the femoral–popliteal territory are shown in Fig. 6. The types of stent fracture are shown in Fig. 7.
- The patency rate of the fractured stent after 1 year's follow-up was 0% for type IV and III stent fractures, 50% for type II stent fracture, and 6.25% for type I stent fractures.
- Type II stent fracture was represented in 53% of all types of stent fracture. The mean stented length associated with type II stent fracture was 16.88±11.22 cm and 26.5% of type II fractures were located in the mid SFA (see Fig. 6). There was no significant difference between the locations where type II stent fractures occurred (P=0.118) or in the time elapsed for the type II stent fractures to be occluded (P=0.246) (see Table 3).
- Type III stent fracture was represented in 26% of all types of stent fracture. The mean stented length associated with type III stent fracture was 17.12 ±9.56 cm (see Fig. 6). There was no significant difference between the locations where type III stent fractures occurred (P=0.415) or in the time elapsed for the type III stent fractures to be occluded (P=0.168) (see Table 3).

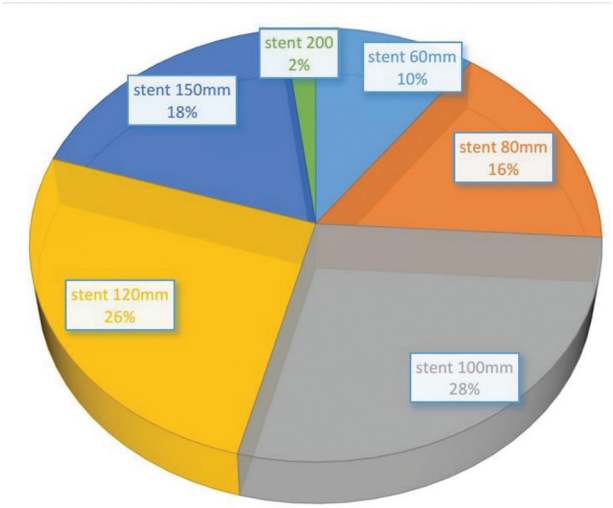
and

- There was no significant difference in stent fracture in the different stent brands (see Fig. 8). The incidence of stent fracture in the different stent brands Absolute pro, Portege EverFlex, E-Luminexx, and Epic was 8.8% (8/90), 26.6% (24/90), 22.2% (20/90), and 42.86% (38/90), respectively (P=0.258. 0.031, 0.191, and 0.034, respectively).
- The incidence of type II fracture in the different locations, that is, proximal, mid, distal, and supragenicular parts of the popliteal artery was insignificant (P=0.504, 0.124, 0.065, and 0.003, respectively).

Clinical impact of stent fracture

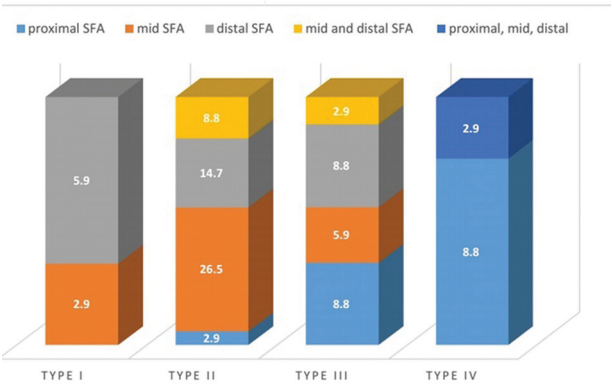
- An overall 88.2% of the limbs (90/102) were occluded and presented with critical limb ischemia, which ranged from rest pain to major gangrene.
- An overall 11.8% of the limbs (12/102) were patent; a total of 9/102 limbs had fractured stent and 3/102 limbs had no stent fracture.
- Of the patients in whom the stents were fractured, five patients had type I stent fracture and the patients were symptom free; three patients had type II stent fracture, and, despite the stented segment being patent, the patients presented with gangrene in their toes for which tibial angioplasty was performed.

Figure 5



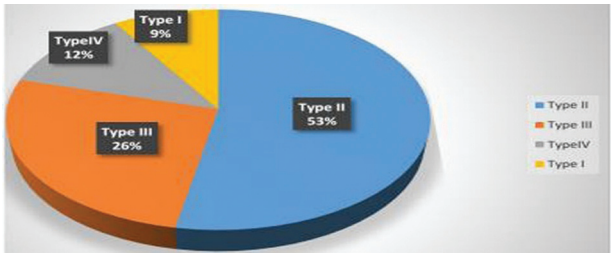
Length, number, and percentages of each inserted stent.

Figure 6



Distribution of different fracture types according to different segments of the femoral popliteal territory.

Figure 7



Percentages of different fracture types.

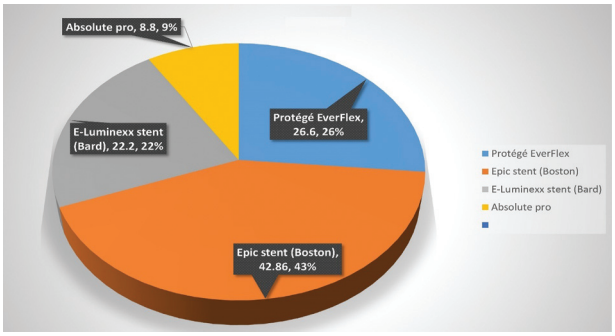
Table 3 Illustrates types II and III fracture to different stent locations and time elapsed for stent occlusion

	Mean stent length (*P* value)	Time elapsed for stent occlusion
Type II fracture		
P	0.415	0.168
Proximal SFA	20 cm	3 cm
Mid SFA	12.67 cm	7.67 months
Distal SFA	16.6 cm	7 months
Distal and upper pop	24.67 cm	14.76 months
Type III fracture		
P	0.118	0.246
Proximal SFA	9.33±3 cm	11.33±4 months
Mid SFA	19.33±15.56	7.5±7 months
Distal SFA	9.33±1.15 cm	9±2.65 months
Distal and upper pop	39 cm	28 months

SFA, superficial femoral artery.

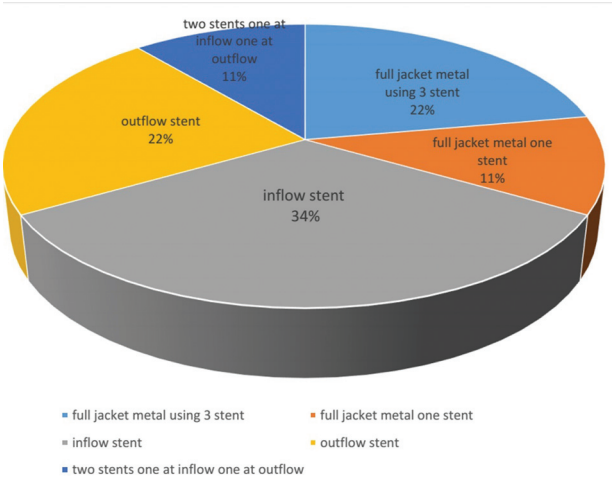
- One patient had type II stent fracture, and this patient presented with incapacitating claudication, which was associated with external iliac artery occlusion, as the patient improved after PTA to the external iliac artery lesion.
- In comparing the fractured stent group to the nonfractured stent group, there was no significant difference related to the age of the patients. The mean age of patients in the fractured stent group and nonfractured stent group was 57.89±8.66 and 62.83±10.57 years, respectively (*P*=0.23).
- The mean stented length in the fractured stent group and nonfractured stent group was 17.6±10.5 and 11.33±4.5 cm, respectively (*P*=0.139).
- An overall 84% of the limbs (75/90) underwent angioplasty; 51 limbs improved on PTA alone using a drug-eluted balloon, and 24 limbs underwent bailout stenting for residual lesions. In patients who needed bailout stenting, six limbs had full metal jacket (three limbs had three stents per limb to cover inflow, outflow, and in-stent lesions, and the other three limbs had a long stent covering inflow, outflow, and in-stent lesions). Three limbs had two stents inserted; one stent was at inflow and the other was at outflow of the lesion. Fifteen limbs had only one stent reinserted per limb, either at the inflow lesion or at the outflow lesion (see Fig. 9).
- An overall 13% of limbs (12/90) were transferred to surgery (see Fig. 10). Patients who were transferred to surgery had a relatively fair risk for surgery.
- An overall 3% of limbs (3/90) underwent above knee amputation, in which presentation was acute thrombotic ischemia. These patients' conditions were documented from the previous angioplasty they had undergone, which showed that they had a poor distal runoff and their presentation was late.

Figure 8



Percentage of stent fracture related to different manufacturers' stents.

Figure 9

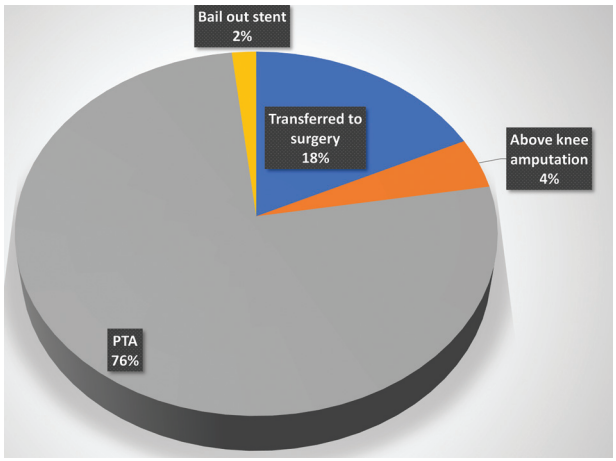


Different position of restenting.

Discussion

The stent fracture rate ranged between 2 and 65% in the literature with various factors influencing stent fracture rate [18,23]. Most studies report their stent fracture rate according to the number of treated limbs; in our opinion, the stent-based analysis seems more

Figure 10



Different modalities and their percentage in the management of occluded stented lesions.

relevant, particularly in long lesions with several implanted stents, in order to reflect the result of each implanted device.

This retrospective study reported the incidence of stent fracture and its clinical impact in four different designs of stents in patients with TASC II C and TASC II D lesions. In stent-based analysis, the incidence of stent fracture rate was 78%. In limb-based analysis, the incidence of stent fracture was 88.24%, and the incidence of symptoms recurrence was 79.4%.

Primary stenting was the protocol of management of long complete total occlusion in most reports in the literature [11,18,24], but the protocol for this study was provisional stenting for residual stenosis or dissection. As the length of the stent was directly proportional to the length of the lesion, [11,13,18,24,25] provisional stenting [for residual stenosis more than 30% or persistent dissection after many attempts of prolonged PTA (2–3 min)] was the protocol in this study to shorten the total stented length and provide a good prepared arterial segment for stenting.

The lesions in this sample were not long complete total occlusions, but they were hard, and sometimes calcified, needing nonconventional methods for recanalization. SAFARI technique and double balloon technique were the methods of recanalization in many lesions, which was contrary to what was reported in the literature [16,17,26]. It is thought that regions of high artery stress are the most susceptible to an adverse biological response. Thus, any chance to minimize such stresses while still maintaining arterial patency should be considered [19].

The high incidence of stent fracture rate observed in this study may be attributed to many factors such as the heterogeneity of stents (in design) being inserted in the same lesion, the use of multiple short stents with area of overlap in-between, and the patients recruited in the study being young.

Each stent brand possesses a unique stent design; strut cross-section shape, thickness of the struts, angle, number, length, and arrangement of interconnectors between these struts are all factors that affect the flexibility of each stent and its suitability for a certain lesion, which were improving overtime as the manufacturing process progressed. It was assumed that the evolution of design of E-Luminexx stent (first generation of self-expandable stent) to EverFlex, the second generation of slotted tube nitinol stents better flexibility; reducing the number of connections between cells or crowns and by plough configuring spiral orientation of these interconnections, decrease the incidence of stent fracture [27].The overlap of heterogeneous stents may exert an extra stress more than the localized rigidity and hinge point effect of the overlapped stent with the same design.

The mean age of the population in the published studies was 70, which was higher than that in this study population (58±9 years) [17,26]. Inserting stents in young active people subjected those stents to more bending, compression, torsion, and stretch forces [28].

The distal segment of the SFA (at the adductor hiatus) was considered to be the segment of the femoral–popliteal artery subjected to the most bending and tortuosity forces than other segments in the same territory [28–30], but, from this study, the incidence of the stent fracture was insignificantly related to the location where the stent was inserted.

The poor clinical outcome of this study population cannot be attributed to the incidence of stent fracture only but it may also be attributable to the high Rutherford grade at presentation; 50% had a patent single tibial vessel, and 50% of that single vessel was a peroneal artery that indirectly provided blood supply to the foot.

Conclusion

The incidence of stent fracture is high among different stent brands (design) and associated with worse clinical outcome. SFA and popliteal artery stenting should not be the first option for intervention except in those whose general health is at high risk for open surgical

bypasses. The new growing technology of drug-covered balloon or biodegradable stents should be compared with conventional stenting in its long-term patency rate and cost effectiveness.

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Conflicts of interest
There are no conflicts of interest.

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