CLINICAL RESEARCH

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Received: Accepted: Published:	2016.11.17 2016.12.08 2017.06.26	-	Mid-Term Outcomes of Total Occluded Lesions Artery	Stent Overla of Superficia	ap in Long al Femoral		
Authors' (Stu Data Statistic Data Inte Manuscript P Literat Funds	Contribution: Idy Design A Collection B al Analysis C rpretation D reparation E ure Search F Collection G	ABCDE 1 BG 2 DE 1 BDE 1	Ulas Bildirici Mujdat Aktas Emir Dervis Umut Çelikyurt	1 Department of Cardiology, Koc. 2 Department of Cardiology, Ereg	aeli University, Medical Faculty, Kocaeli, Turke ļi State Hospital, Zonguldak, Turkey		
Corresponding Author: Source of support:		g Author: f support:	Ulas Bildirici, e-mail: ihubildir@gmail.com Departmental sources				
Background: Material/Methods: Results: Conclusions:		xground: Aethods: Results: Clusions:	Superficial femoral artery chronic total occlusion (SCT Endovascular therapy is a treatment approach that I of this study was to compare the mid-term results of (>100 mm): the use of one long stent or two shorter Of 154 patients who underwent percutaneous infrai CTO lesions were selected for this retrospective stu 63.4±10.4 years (range 29–89 years); 71.8% of the p Patients were divided into two groups according to t stent were placed into group A and patients treated ture rate was significantly higher in group B compare were higher in group A, but type 3 and 5 fracture rat restenosis was significantly higher in group B compare Mid-term patency rate was low in patients with long Using a long single stent had an acceptable mid-ter Stent fracture seemed to be the main reason for in- gle stent strategy may be more appropriate and reas SFA lesions.	IO) is a common type of penas a poor long-term succe f two different uses of nitin stents. inguinal interventions from dy analysis. The mean age atients were male. the number of stents used. with two stents were place ed to group A (29.2% vs. 42 tes were significantly higher ared to group A (45.1% vs. g totally occluded superfici- m patency rate compared stent restenosis in cases o onable than a two stent st	Pripheral arterial disease (PAD). The aim for the server of the server of the study population was a patients treated with a single of the study population was a patients treated with a single of the study population was a patients treated with a single of the study population was a patient streated with a single of the study population was a patient streated with a single of the study population was a patient streated with a single of the study population was a patient streated with a single of the study population was a patient streated with a single of the study population was a patient streate of stent strates of the study population was a streat streate of the study population was a two stent strategy. I multiple stenting. A long sincategy in the treatment of long streated was a streated with a s		
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Background

Peripheral arterial disease (PAD) incidence rate ranges between 12–20% in the 65 year old and older population [1] and this percentage increases with age. Superficial femoral artery chronic total occlusion (SCTO) is a common type of PAD [2]. Superficial femoral artery atherosclerosis is a diffuse disease characterized by the presence of moderate to severe calcification [3] that can adversely affect treatment response. Open surgical revascularization is accepted as an appropriate treatment [4], however, endovascular therapy (EVT) is more widely used and has lower mortality and morbidity rates compared to surgery. The rate of procedure success and the rate of limbsaving are similar, and if necessary, surgery can be a last resort [5–7]. EVT has a reported success rate of 95% in SCTO [8], however, the long-term patency rate falls below 50% depending on the structure and location of the vessels [9]. Vessels exposed to mechanical factors (external forces, compression, torsion, and elongation) [10] have an increased frequency of restenosis and stent fracture. Nitinol stents are designed to be more flexible and resistant to mechanical stress in order to provide long-term patency and to reduce stent fracture [10]. Stent fracture is still a serious problem despite improvement in the structure of the nitinol stent aimed to reduce fractures. It is unclear whether the reported low success rates, especially in earlier studies involving long lesions, was due to the use of multiple stents or long stents since the nitinol stents used in older studies were shorter. Additional effects of multiple stenting on stent fracture and restenosis is unknown. The aim of this study was to compare the mid-term patency results of the use of a single long nitinol stent to the use of two shorter nitinol stents to treat long SCTO lesions (>100 mm).

Material and Methods

Of 154 patients who underwent percutaneous infrainguinal interventions, a total of 170 CTO lesions were selected for the retrospective study analysis; 111 consecutive limbs from 97 patients with severe SCTO treated with EVT between July 2011 and June 2014 were included in this study. Patients with acute ischemia requiring urgent intervention and patients who had symptoms for the last three months were excluded. Informed consent was obtained from all patients and the ethics committee of the hospital approved this study.

Enrolment criteria

The criteria for enrolling patients in this study were as follows: (1) lifestyle-limiting claudication (for more than three months) or critical limb ischemia (CLI) defined as rest pain or tissue loss; (2) a long lesion with a total occlusion of >10 cm; (3) inoperable condition due to comorbid disease (i.e., severe heart failure, renal failure, chronic pulmonary disease such as chronic obstructive pulmonary disease), patients who might not survive major surgery, or patients who refused bypass surgery. The major exclusion criteria were: a target lesion that extended into the popliteal artery, and a previous implantation of a stent in the targeted superficial femoral artery (SFA). The degree of calcification was evaluated visually from angiographic views as we did not use intravascular ultrasound (IVUS) in our patient population. The patients were divided into two groups: group A was treated with a single long stent, and group B was treated with a double stent. Patients with incomplete recanalization and missing follow-up data were excluded from the study.

Treatment protocols

Once-daily dose of 325 mg aspirin, before and after the procedure, and 75 mg clopidogrel daily for 7 days before the procedure, 300 mg for 3 days before the procedure, or 600 mg within 24 hours before or immediately after the procedure, (aspirin 100 mg/day, clopidogrel 75 mg/day) were given to all the patients. Arterial access was gained through an ipsilateral or contralateral common femoral artery puncture. Contralateral puncture was applied in patients with ostial SFA occlusion. Intentional subintimal access was achieved using either a hydrophilic 0.035 inch wire or a 0.018 inch guidewire. Intravenous heparin (100 Ul/kg) was administered at the start of all the procedures. Primary angioplasty was performed with appropriately sized noncompliant balloons with inflation times ranging from 60-180 seconds after the SFA recanalization. We implanted a nitinol stent in accordance with the American College of Cardiology/American Heart Association guidelines [11] to patients who had a residual pressure gradient >10 mm Hg, residual stenosis >30%, and/or flow-limiting dissection after balloon therapy. The stents were self-expandable and had the diameter approximately 2-mm larger than the reference diameter. Selective stenting with self-expanding nitinol stents (the Protégé EverFlex Self-Expanding Peripheral Stent System, Plymouth, MN, USA) was performed. Overlapping segment was approximately 5-10 mm in patients treated with a double stent. Stent implantation was never performed in the middle or distal third of the popliteal artery.

Follow-up

All patients were discharged with oral antiplatelet therapy consisting of aspirin indefinitely, and clopidogrel 75 mg per day for at least one month after the procedure. Anticoagulant therapy was initiated in select patients. Clinical evaluations, such as symptom changes, ankle brachial index measurement, ultrasonographic evaluation of lesion patency, and stent fracture follow-up with x-ray were performed at baseline, 3, 6, 12, 18, and 24 months. Primary patency was defined as detection of peak systolic velocity ratio <2.4 on duplex ultrasound [12]. Angiography was performed in patients with peak velocity ratio above 2.4 on duplex ultrasound, no-flow in stent, or clinical suspicion of restenosis (decrement in the ankle-brachial index (ABI) or worsening symptoms reflected by changes in the Rutherford category). The in-lesion segment was defined as the in-stent segment plus 5 mm proximal and distal to the stent. A >50% stenosis on angiography was defined as in-stent restenosis. A stent fracture was defined as the complete/incomplete separation of the stent strut (>1 to 2 mm) identified by x-ray from four projections that lead to kink or misalignment along the axial length of the stent. Stent fracture classification published by Rocha-Singh et al. was used [13]. In summary, we classified stent fracture into the following five types: Type I, a single-tine strut fracture only; type II, multiple strut fractures at different sites; type III, stent fracture(s) with preserved alignment of the components; type IV, stent fracture(s) with malalignment of the components; type V, stent fracture(s) in a trans-axial spiral configuration. We performed an x-ray for four projections on every visit to evaluate the stent fracture. Overall primary patency, patency associated with and without stent fracture, patency according to the types of nitinol stents, and the morphology of the stent fracture were the outcomes of this study. Angiography was performed on the patients who had clinical and ultrasonographic findings supporting in-stent restenosis.

Statistical analysis

All statistical analyses were performed using SPSS (SPSS Inc., Chicago, IL, USA). Data were presented as mean \pm standard deviation. We used unpaired *t*-test to compare the continuous variables between the groups, and chi-square test was used to compare ratios. The Kaplan-Meier method of survival analysis was used in order to determine primary patency, and primary patency was compared by log-rank testing. A *p* value <0.05 was accepted as statistically significant.

Results

Patient characteristics

From 2011 to 2014, 187 limbs from 169 patients were treated. The revascularization attempt failed in seven patients with SFA lesions. After excluding nine patients (10 SCTOs) who did not have follow-up data available (due to myocardial infarction, cerebral infarction, and infection), 154 patients (170 CTOs) were included in the study: the mean patient age 63.4 ± 10.4 years (range 29–89 years); and 71.8% were males. Patient characteristics were consistent with the intended study population and are summarized in Table 1. The most common pre-existing risk factors were: smoking defined as current or recent smoking (less than one year since cessation), 89.4% (152 patients); hypertension, 80% (136 patients); hyperlipidemia, 64.1% (109 patients); and coronary artery disease, 61.1% (104 patients). Demographics, comorbid conditions, symptom status, and lesion morphology are listed in Tables 1 and 2. Medication, body mass index, and biochemical parameters were similar between the two groups. The average Rutherford classification score was 3.6 ± 0.9 on admission; 35 patients (20.5%) had critical limb ischemia (CLI), and the average ABI was 0.41 ± 0.14 .

Procedural results

Our success rate was 96.3% for the totally occluded SFA process. Recanalization could not be achieved in seven of the 187 limbs. The mean lesion length was 154.5±35.9 mm. Severe calcification was observed in 38 patients (22.3%), and was significantly more common in group B than group A (31.8% vs. 12.2%). The average vessel diameter was 6.9±0.7 mm, and there was no difference between the two groups. Details of pre-procedural lesion characteristics are summarized in Table 2. Stent fracture rates after the follow-up are given Table 3. Fracture rate was significantly higher in group B (29.2% vs. 42%). Type 1 and 2 fracture was higher in group A, but type 3 and 5 fractures were significantly higher in group B (Table 3). There was a significant correlation between the presence of restenosis and stent fracture (70.4%, 43/61 patients). The effect of stent fracture morphology on restenosis was also evaluated. Restenosis occurred in almost all patients with type 5 fractures (92.8%, 13/14 patients). Although type 1 and 2 stent fractures (38%, 8/21 patients) revealed similar outcomes compared with those without stent fractures (38.5%, 42/109 patients), higher rates of restenosis were detected in patients with type 3 and 4 fractures (84.6%, 11/13 patients). Also, higher restenosis rates were seen in patients with multiple stent fractures (70%, 14/20 patients) (Table 3). Primary patency was 92%, 76%, 63%, and 50% at 6, 12, 18, and 24 months, respectively and fracture rate was 9.2%, 17.8%, 23.5%, and 35.8% at 6, 12, 18, and 24 months, respectively. The overall restenosis rate was 50% in the study population, although group B had a higher restenosis rate than group A (45.1% vs. 54.5% p=0.05) (Table 4). In all, 90 patients underwent coronary angiography, in which restenosis was determined according to duplex ultrasound. Restenosis was detected in 85 patients.

Discussion

During the follow-up period, the patency rate decreased in both groups and the restenosis rate was found to be 50% at two years. Restenosis was significantly associated with stent fracture. Also, risk of restenosis increased with increasing severity of fractures. Restenosis developed in almost all patients

	Overall (170 p)	Group A (82 p)	Group B (88 p)	P Value
Age	63.4±10.4	61.9±11.6	64.8±9.1	Ν
Men	71.8% (122)	73.2% (60)	70.5% (62)	Ν
Hypertansion	80% (136)	70% (64)	81.8% (72)	Ν
Hyperlipidemia	64.1% (109)	62.1% (51)	65.9% (58)	
Diabetes mellitus	48.2% (82)	51.2% (42)	45.4% (40)	Ν
Smoking (current)	89.4% (152)	90% (74)	88.6% (78)	Ν
Renal failure	17.6% (30)	14.6% (12)	20.5% (18)	Ν
Cerebrovascular disease	3.5% (6)	2.4% (2)	4.5% (4)	Ν
Coronary artery diseas	61.1% (104)	56.1 (46)	65.9% (58)	Ν

 Table 1. Baseline demographic characteristics of patients.

P – patients; N – non-significant.

Table 2. Lower limb and lesion characteristics.

	Overall	Group A	Group B	p Value
ABI	0.41±0.14	0.39±0.1	0.42±0.1	Ν
Rutherford classification	3.6±0.9	3.5±0.8	3.6±0.9	Ν
Critical limb ischemia	20.5% (35)	18.3% (15)	22.7% (20)	Ν
TASC II	2.6±0.5	2.4±0.5	2.8±0.4	Ν
Vessel diameter	6.9±0.7	6.8±0.8	7.0±0.7	Ν
Lesion lenght, mm	154.5±35.9	147±34.9	163.2±32.9	Ν
Lesion calcification				
Moderate/severe	22.3% (38)	12.2% (10)	31.8% (28)	0.05
Mild/none	77.7% (132)	87.8% (72)	68.2% (70)	Ν

Critical limb ischemia; Rutherford stages 4-6. N - non-significant.

Table 3. Stent fracture and restenosis rates in groups.

	Ove	rall	Grou	A qu	Gro	up B	P value
Fracture rate	35.8%	(61)	29.2%	(24)	42%	(37)	0,001
Type 1/restenosis rate	8.9%	(15)	11%	(9)	6.8%	(6)	0.005
Type 2/restenosis rate	3.5%	(6)	4.9%	(4)	2%	(2)	Ν
Type 3/restenosis rate	7.6%	(13)	3.6%	(3)	11.3%	(10)	0.001
Type 4/restenosis rate	7.6%	(13)	6.1%	(5)	9%	(8)	Ν
Type 5/restenosis rate	8.2%	(14)	3.6%	(3)	12.5%	(11)	<0.001
Multi fracture/restenosis rate	11.1%	(19)	8.5%	(7)	13.6%	(12)	0.002

N – non-significant.

	Overall	Group A	Group B	p value
Restenosis	50% (85p)	45.1% (37p)	54.5% (48)	0.05
Amputation	7% (12p)	7% (6p)	7% (6p)	Ν
Changes in ABI	0.36±0.28	0.42±0.25	0.29±0.29	0.05

Table 4. Adverse event rates at 24 months.

P – patients; N – non-significant; ABI – ankle-brachial index.

with stent distortion (type V stent fracture). In addition, stent fracture and restenosis was significantly more common in the group treated with multiple stents. Demographic features and lesion length were similar between the groups. However, heavily calcified lesions were higher in group B.

SCTO lesions are a common type of PAD and are difficult to treat. EVT has three basic problems in the treatment of totally occluded lesions: (1) challenges in wire passage, (2) entry into the lumen, and (3) ensuring long-term patency. The technical success rate for EVT for stenotic and occlusive lesions in SCTO lesions has been shown to reach over 95% [14], and this ratio was 96.3% in our study. However, long-term patency is a major problem in lesions which have severe calcification [14,15]. In addition, atherosclerotic tissue with intense calcification induces a strong inflammatory response [15]. Similarly, in our study, severe calcification was observed in 22.8% of lesions. However, SFA is uniquely one of the longest and most dynamically active vessels [16]. SFA demonstrates bending, elongation, kinking movement other than the flexion and compressed due to muscle mass surrounding it. These movements increase the risk of in-stent restenosis by activating smooth muscle cell proliferation and inflammation [16-18]. Neointimal hyperplasia that evolves due to repetitive biomechanical forces is highly effective in the development of stent restenosis of SFA [16-18]. Moreover, this movement causes stent fracture. All these factors reduce the long-term success of EVT in SFA stenting. Although, intermediate-term restenosis rates are variable, it is usually nearly 50% [19-21], as observed in our results.

Stent fracture is considered an important obstacle to ensure long-term patency in SFA lesions. Also, stent fracture is one of the main reasons for lower success rates of balloon-expandable endovascular stents compared to balloon angioplasty alone [22]. Although fracture rates were lower with first generation nitinol stents, patency rates remained low in the longterm. The second-generation stent designs have tried to reduce the fracture rate. However, new generation nitinol stents degrades over time despite their elasticity. In addition, fractures have been observed in stents implanted for relatively immobile abdominal and thoracic aorta due to device fatigue [23]. Second-generation flexible nitinol stents were used in our study and the stent fracture rate was 35.8%. The stent fracture rate varied in other trials (2–53%) [24–26]. Variability of stent fracture rates may be related to stented segment length, stent design, stent location, and process technique. Increasing the stent length outside the size of the SFA is also a reason for stent fracture [26]. The mean lesion length in our study was 154.5 ± 35.9 mm, and it was quite long compared to other studies. This may be a reason for our higher fracture rate.

Restenosis rate was 70.4% in patients with stent fractures. Restenosis rate increased with the severity of the fracture and restenosis reached 92.8% with type V fractures. According to several recent studies, stent fractures are associated with stent restenosis or reocclusions in about two-thirds of the cases. Particularly when stent fractures were categorized as type V, restenosis was observed in almost all cases [27]. As a result, preventing distortion of the stents seems to be an important step in the development of stent restenosis.

When the two groups were compared, fracture and restenosis rates were significantly higher in the group treated with two stents (Table 4) and may be related to higher fracture rates in this group (Table 3). In addition, multiple fractures were also higher in this group apart from severe stent fracture (type IV and V). Although mild (type I and II) stent fractures may be a benign condition in some patients, severe (type IV and V) stent fractures are associated with stent restenosis or reocclusion in the majority of the cases [28]. Our study also showed the similar results. While mild stent fracture (type I and II) was higher in patients treated with a single stent, severe fracture (type III-V) was higher in patients treated with two stents, with 78.5% of type V stent fractures occurring in this group. All of these factors may have contributed to higher restenosis rates. However, overlapping between stents may be the main reason for higher fracture and distortion in patients treated with two stents. In general, multiple stents are required to cover the lesion segment, and they should overlap by a minimum of 5-10 mm (5-20 mm). Although, this approach is applied in all vessels, it may not be suitable for SFA. Overlapping critically increases the axial stiffness of the stented segment [27]. Circular flexion between the hip and knee causes axial compression because of the anatomical position of the SFA. SFA is located in adductor canal and stents are exposed to axial and bending

stress during the exercise and eventually stent distortion and fracture occur [29,30]. Overlapping reduces the flexibility of stents (special mechanical influences) and the physical stress response that leads to stent distortion and multiple fractures.

Conclusions

As a result, despite the quite higher success rate in long totally occluded SFA lesions, mid-term patency rate was still low. However, a long single stent had an acceptable patency rate

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at mid-term compared to a two stent strategy. Overlapping and stent fracture seemed to be the basic reason for restenosis in the multiple stent procedure. Perhaps, using long single stent in SFA lesions may be more appropriate to avoid fracture and distortion. If a multiple stent strategy has to be selected, stents could be implanted sequentially without overlapping.

Conflicts of interest

None.

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