Original Article

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Investigating the Frequency of Stent Fracture and its Impact on in-Stent Restenosis in Patients Undergoing Carotid Artery Stenting

Karotis Arterine Stent Uygulanan Hastalarda Stent Kırığı Sıklığının ve Stent İçi Restenoz Üzerine Etkisinin Araştırılması

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ABSTRACT

Objective: This single-center study aimed to assess the incidence and predictors of carotid artery Xact stent fractures (SF) and their impact on in-stent restenosis (ISR) during long-term follow-up.

Methods: A cohort of 108 patients (97 males, median age 69.4±8 months) who underwent Xact stent placement for internal carotid artery stenosis between 2013 and 2021 and were diagnosed with SFs through fluoroscopy in 2022 were included. SFs were categorized as types I-V based on fracture characteristics. Follow-up included duplex ultrasound examinations to assess stent patency.

Results: The average follow-up duration was 49.2±24.3 months, with ISR observed in 10 patients. Twenty-three SFs (21.3%) were identified: type I (5 patients), type II (7 patients), type III (3 patients), type IV (6 patients), and type V (2 patients). Calcification and stent length significantly predicted SFs ($p<0.001$; $p<0.028$).

Conclusion: Calcification and stent length are associated with Xact SFs, but SFs do not impact ISR during long-term follow-up.

ÖZ

Amaç: Bu tek merkezli çalışmanın amacı, uzun süreli izlem sırasında karotis arter Xact stent kırıklarının (SF) görülme sıklığını ve öngörücülerini değerlendirmek ve bunların stent içi restenoz (ISR) üzerindeki etkisini değerlendirmektir.

Yöntemler: 2013-2021 yılları arasında iç karotis arter darlığı için Xact stent yerleştirilen ve 2022'de floroskopi ile SF tanısı konan 108 hasta (97 erkek, ortanca yaş 69,4±8 ay) kohortuna dahil edildi. SF'ler kırık özelliklerine göre I-V tiplerine ayrıldı. İzlem, stent geçirgenliğini değerlendirmek için dubleks ultrason muayenelerini içeriyordu.

Bulgular: Ortalama izlem süresi 49,2±24,3 aydı ve ISR 10 hastada gözlemlendi. Yirmi üç stent kırığı (%21,3) tanımlandı: Tip I (5 hasta), tip II (7 hasta), tip III (3 hasta), tip IV (6 hasta) ve tip V (2 hasta). Kalsifikasyon ve stent uzunluğu SF'leri anlamlı olarak öngördü ($p<0,001$; $p<0,028$).

Sonuç: Kalsifikasyon ve stent uzunluğu, Xact stent kırıkları ile ilişkilidir, ancak SF'ler uzun süreli izlem sırasında ISR'yi etkilememektedir.

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ABSTRACT

Keywords: Internal carotid artery, Xact stents, stent fracture, in-stent restenosis

ÖZ

Anahtar Sözcükler: İç karotis arter, karotis stentler, stent kırığı, stent içi restenoz

Introduction

In selected patient groups, carotid artery stenting (CAS) is an increasingly common endovascular treatment method for The carotid artery stenosis (CAS). Developing techniques for access and devices in CAS provide patients with better procedural outcomes through a minimally invasive procedure (1). In cases where surgical access is challenging, CAS may offer advantages over carotid endarterectomy (CEA), resulting in fewer cranial nerve injuries and wound complications (2). Due to repeated motion of the head and neck, the carotid arteries experience daily movements, including flexion, extension, and rotation. Following CAS, these carotid arteries are subjected to constant mechanical stress caused by these movements, which can lead to stent fractures (SF) occurring at the rates ranging from 0% to 39% (3,4). It has been previously shown that SF may be associated with in-stent restenosis (ISR) or other significant adverse clinical events in coronary and peripheral arteries (5). However, the relationship between SF and ISR in patients with carotid stents remains a subject of ongoing debate (6).

The aim of this study is to investigate the frequency of SF in Xact stents, which are the most commonly used type of stent in our clinic for the treatment of internal carotid artery (ICA) stenosis, and to examine their impact on the development of ISR during long-term follow-up. Additionally, it aims to assess potential factors associated with the development of SF in ICA and determine the need for treatment in such cases.

Methods

Study Population

Our research constitutes a retrospective observational cohort study conducted at a single center. Ethical approval was granted by the University of Health Sciences Türkiye, Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital, and the study adhered to the principles outlined in the Helsinki Declaration (decision no: 2023.08-84, date: 24.10.2023). Over the period spanning January 2013 to December 2021, we enrolled a total of 134 consecutive patients who underwent endovascular intervention using Xact stents for ICA stenosis at our institution. The inclusion criterion was as follows: Availability of all medical records for retrospective analysis and patients who underwent CAS using Xact stents. The exclusion criterions were as follows: Patients with a history of systemic inflammation (n=5), familial hyperlipidemia (n=3), vasculitis (n=2), Burger's disease (n=1), and those with inadequate clinical and preoperative parameters (n=11) were excluded from the study. Additionally, patients who underwent emergency CEA after the procedure (n=4) were not included in the study. After the inclusion and exclusion criteria, a total of 108 patients were included in the study.

Demographic data, laboratory findings, and outcomes were collected from hospital records, file reviews, and telephone interviews. The CAS was routinely evaluated bilaterally using two-sided carotid duplex ultrasonography (DUS), and afterward, patients were verified through computed tomography angiography (CTA) or digital subtraction angiography (DSA). Our vascular team, consisting of an experienced interventional cardiologist, a consulting neurologist, and a cardiovascular surgeon, determined the indication for CAS. CAS was performed on patients with high surgical risk who had asymptomatic CAS of 70-99%, with procedure-related death and stroke rates of less than 3%, and a life expectancy of more than 5 years. Additionally, CAS was performed on patients with symptomatic CAS of 50-69% and procedure-related death and stroke rates of less than 6%. Symptomatic carotid stenosis was defined as the occurrence of symptoms of stroke or transient ischemic attack within the last 6 months. Asymptomatic carotid stenosis was defined as the absence of previously identified symptoms or symptoms occurring more than 6 months ago. Coronary artery disease was defined as having a history of angina pectoris, myocardial infarction, or coronary revascularization. Diagnosis of chronic heart failure required a left ventricular ejection fraction of less than 50% and the presence of one or more of the following: symptoms, clinical signs, radiographic abnormalities, and hospitalization. Chronic kidney disease is defined as a glomerular filtration rate of less than 60 mL/min/1.73 m^2 that persists for more than 3 months. Peripheral artery disease is defined as the presence of arterial lesions in the lower extremities detected by imaging methods along with the presence of claudication, or a history of peripheral revascularization. Stenosis of the contralateral ICA was defined as 50 percent or greater. The distal tortuosity index (TI) was calculated by referencing the course of the ICA from the carotid bulb, where it enters, to the base of the skull, where the carotid canal is located (7). The total length of the ICA's natural anatomical course, which is curved or angled between these two reference points, is considered as the "arch length" when measured. The straight distance measured between the carotid bulb and the base of the skull is referred to as the "cord length". Therefore, the distal TI is expressed with the following formula: TI = [(arch length/cord length - 1) × 100]. TI was calculated by two independent observers from DSA images of patients in the PACS system. Intra-observer and inter-observer differences for SF were less than 5%.

Grading of Calcification

The assessment of ICA calcification was conducted as follows: Circularity (continuous and discontinuous) and thickness (thick ≥1.5 mm and thin <1.5 mm); none (no calcification), mild (thin and discontinuous calcification), moderate (thin and continuous

calcification or thick and discontinuous calcification), and severe (thick and continuous calcification) (8).

Figure 1 shows calculation of TI. In this example, with a total arch length of 86.3 mm and a cord length of 74.9 mm, TI for this patient was calculated as 15.22. TI was calculated with the following formulation:

TI = [(86.3 / 74.9 - 1) × 100] = [(1.1522 - 1) × 100] = [0.1522 × 100] = 15.22

Procedural Data and The Stenting Method

All procedures were performed by two experienced interventional cardiologists. All procedures were performed via femoral access. Prior to obtaining percutaneous femoral artery access, all patients received local anesthesia. Systemic fractionated heparinization (70-100 U/kg) was administered to all patients. To assess the severity of lesions and treatment methods, all patients underwent preoperative conventional angiography and DSA cerebral embolism protection devices (Spider FX - Emboshield NAV6 and Filterwire EZ) were used in all cases, depending on availability. In this study, Xact stents (Abbott Vascular, Santa Clara, CA) were used. In general, pre-dilatation was carried out using balloons ranging from 2 to 5 mm. Post-dilatation was predominantly conducted using a 5 mm balloon, with a range of 4 to 6 mm. To assess stent patency and any residual stenosis, intracranial and extra cranial angiograms were routinely performed at the end of the procedure. The technical success of the procedure was defined as achieving a residual stenosis of 30% or less without any occurrence of dissection or extravasation. All patients were initiated on acetylsalicylic acid (100 mg/day) and clopidogrel (75 mg/day) at least 1 week before the procedure, unless the patient was already using these antiplatelet medications. Patients

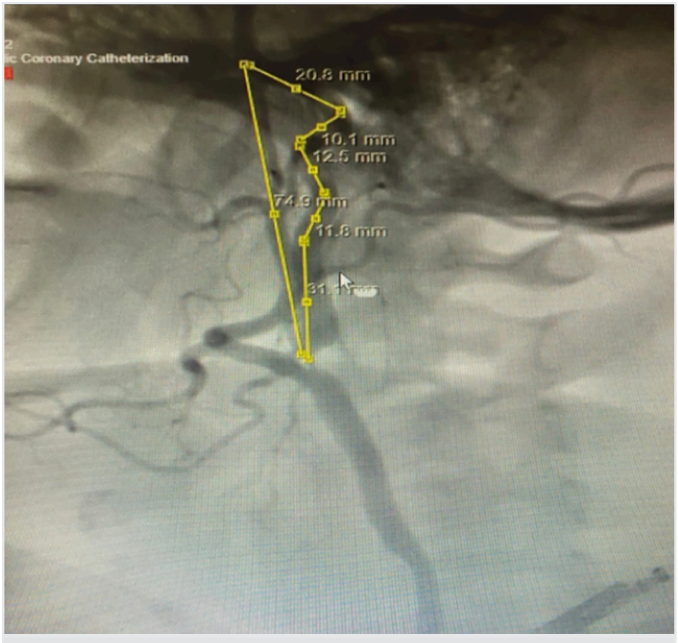

Figure 1. The formula for the distal tortuosity index is indeed as follows: distal tortuosity index = [(arch length/ cord length-1) × 100]

received dual antiplatelet therapy (DAPT) for 3 months, followed by lifelong monotherapy unless there was a cardiac indication for prolonged DAPT. All patients were hospitalized for a minimum of 24 hours of neurological observation. Patients were independently examined by a neurologist before and after the procedure. Patients without any complications were discharged from the hospital one day after the intervention.

Follow-Up

Follow-up examinations were conducted at intervals of 1, 6, and 12 months following the endovascular procedure, followed by annual assessments thereafter.

During the follow-up visits, their clinical status, demographic information, and medical history were re-documented. To evaluate the carotid flows, ISR or carotid stenosis and presence of any SF, bilateral carotid DUS examinations were conducted. In addition to ultrasound, some patients underwent anteroposterior and lateral cervical radiographs to assess SF. Information from these patients' ultrasounds and radiographs were obtained from the hospital records system. ISR was defined as the presence of ≥70% stenosis within the stent. The presence of significant ISR was confirmed using CTA or DSA. Primary patency was defined as an open stent without the need for intervention.

Assessment of SFs

After evaluation of symptoms and DUS, patients were taken to the DSA laboratory to detect SFs, and fluoroscopic images of the ipsilateral neck area were obtained. The images were recorded in standard and neurodevice modes. Close-up high-resolution images were obtained from anterior-posterior, oblique, and lateral angles to examine the integrity of the stent citrate in detail. The fluoroscopic image evaluation was carried out by consensus of two experienced interventional cardiologists. The detected SFs were classified according to the classification proposed by Nakazawa et al. (9) This classification consists of a total of 5 grades: Type I (single strut fracture), type II (multiple strut fractures without stent deformity), type III (multiple strut fractures with stent deformity), type IV (complete stent separation without gap), and type V (stent tearing, complete SFs) (Figure 2). Patients were classified as SF (+) and SF (-) based on the presence of SFs. Intra-observer and inter-observer differences for SF were less than 5%.

Statistical Analysis

The statistical analysis of the study utilized the Statistical Package for the Social Sciences version 26.0 (SPSS Inc., Chicago, Illinois, USA). Various methods were employed to assess the distribution of variables, including visual techniques such as histograms and probability curves, as well as analytical methods like the Kolmogorov-Smirnov test. Numerical variables adhering to a normal distribution were summarized as mean ± standard deviation, whereas non-normally distributed numerical variables were presented as median (interquartile range). Categorical variables were expressed as percentages (%). To compare numerical variables between groups, we employed either Student's t-test or the Mann-Whitney U test, depending on

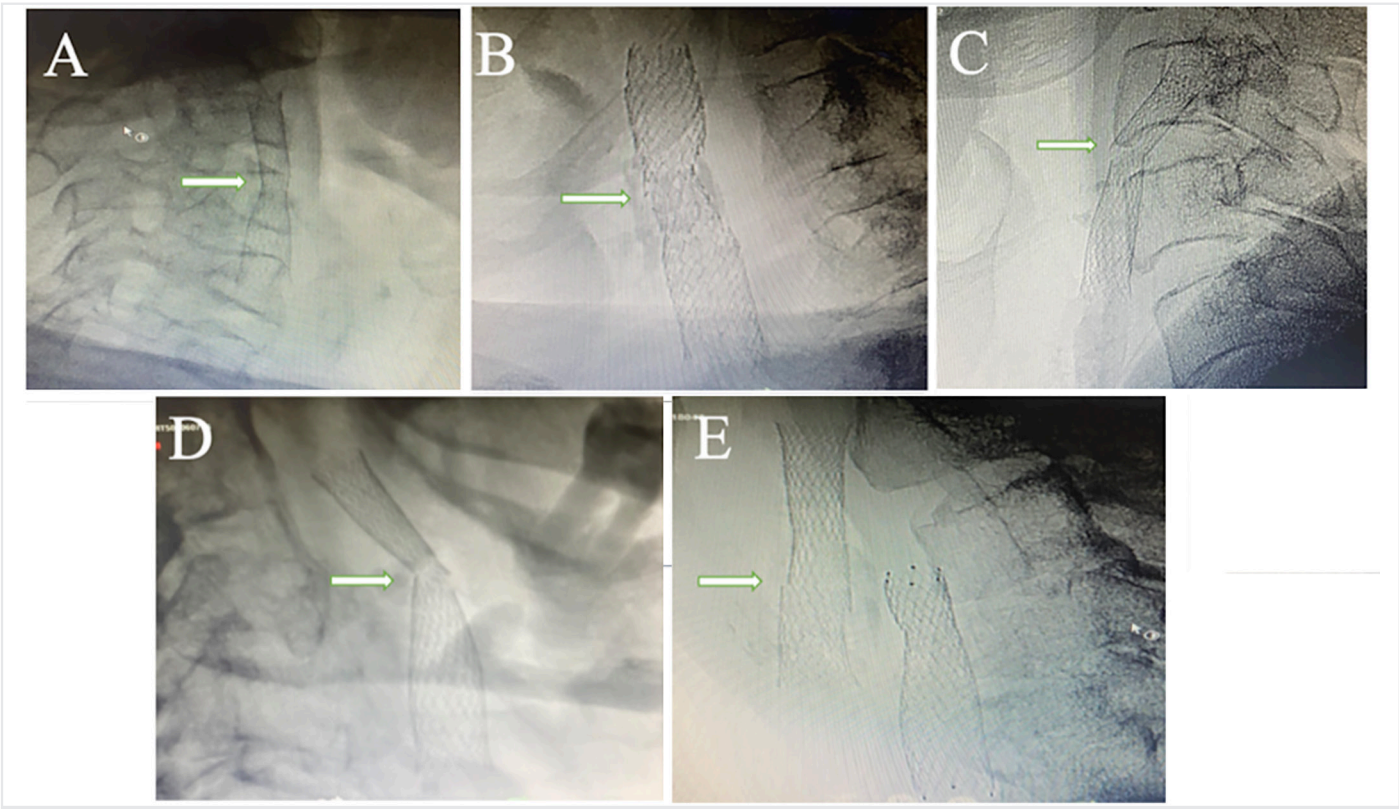

Figure 2. A) Type I (single strut fracture), B) Type II (multiple strut fractures without stent deformity), C) Type III (multiple strut fractures with stent deformity), D) Type IV (complete stent separation without gap), and E) Type V (stent tearing, complete stent fracture)

the distribution of the data. Categorical variables were assessed using either the chi-square test or Fisher's exact test. Event-free survival curves were generated using the Kaplan-Meier method and compared using the log-rank test. Additionally, a univariate and multivariate Cox proportional hazards model was utilized to estimate hazard ratios and 95% confidence intervals (95%) for clinical endpoints. Throughout the study, a significance level of less than 0.05 ($p<0.05$) was considered statistically significant.

Results

The study comprised 108 patients, with a mean age of 69.4±8 years, of whom 97 (74.1%) were male. Patients were categorized into two groups according to the presence or absence of SF. Table 1 displays the fundamental demographic, clinical, and laboratory data of the study cohort. The groups with and without SF exhibited similar demographic, clinical, and laboratory characteristics. However, the presence of stenosis in the contralateral carotid artery [12 (52) vs. 24 (28.2), p=0.031] and the ISR rate [5 (21.7) vs. 5 (5.9), p=0.020] were significantly higher in the group of patients who developed SF. The lesion characteristics and DUS data of the study group are summarized in Table 2. The groups with and without SFs showed similarities in terms of lesion characteristics. However, heavy calcification was significantly higher in the group with SF [17 (73.9) vs. 14 (16.5), p<0.001], whereas less than heavy calcification grades were higher in the SF (-) group [0 (0) vs. 6 (7.1), 0 (0) vs. 25 (29.4), 6 (26.1) vs. 40 (47.1), p<0.001] (Figure 3). Furthermore, based on DUS, ICA/CCA [(1.7±1) vs. (1.1±0.3), p<0.001], peak systolic velocity (PSV) [78 (65-138) vs. 68 (58-85.5), p=0.007], and end-diastolic velocity (EDV) [29 (22-45) vs. 25 (18-30.5), p=0.013] were significantly higher in the SF (+) group.

The outcomes of procedural variables and stent characteristics are presented in Table 3. The groups with and without SF exhibited similarities in relation to these variables. However, the stent length (37.8±4.2 vs. 35.2±5.3, p=0.028) was found to be longer in the group of patients who had SF.

Univariate and multivariate Cox regression analyses were conducted to identify long-term predictors of ISR. Among these parameters, proximal diameter of the stent (p=0.008), post-dilatation (p=0.041), smoking status (p=0.048), and white blood cell count (p=0.039) demonstrated significant associations. A multivariate Cox regression analysis was performed using these variables. As a result of the multivariate Cox regression analysis, there was not any independent predictor for long-term ISR among these variables (Table 4).

The Kaplan-Meier method revealed no significant difference (log-rank p=0.164 between the groups) (Figure 4), indicating that the presence of SFs could not be linked to the development of long-term ISR.

Table 1. Basic demographic, clinical, and laboratory data of study patients

Variables	SF (+) group (n = 23)	SF (-) group (n = 85)	p-value
Male sex, n (%)	18 (78.3)	62 (72.9)	0.606
Age, year, mean (SD)	69.1±8.1	69.4±8	0.871
Diabetes mellitus, n (%)	15 (65.2)	38 (44.7)	0.081
Hypertension, n (%)	14 (60.9)	39 (46.4)	0.220
Dyslipidemia, n (%)	7 (30.4)	23 (27.1)	0.748
Coronary artery disease, n (%)	9 (39.1)	39 (45.9)	0.563
Congestive heart failure, n (%)	2 (8.7)	10 (11.8)	0.678
Chronic kidney disease, n (%)	9 (39.1)	28 (32.9)	0.579
Peripheral artery disease, n (%)	5 (21.7)	12 (14.1)	0.373
History of stroke, n (%)	7 (30.4)	37 (43.5)	0.257
History of TIA, n (%)	3 (13)	8 (9.4)	0.609
History of CEA, n (%)	3 (13)	8 (9.4)	0.609
Current smoking status, n (%)	9 (39.1)	30 (35.3)	0.734
Periprocedural stroke, n (%)	2 (8.7)	11 (12.9)	0.731
Postprocedural stroke, n (%)	2 (8.7)	7 (8.2)	1
SCCA, n (%)	12 (52.2)	24 (28.2)	**0.031**
Contralateral stroke, n (%)	1 (4.5)	5 (6.2)	0.773
Symptomatic related to stroke, n (%)	7 (30.4)	34 (40)	0.402
White blood cells, 10^6/L, mean (SD)	8±1.7	8.1±1.9	0.787
Hemoglobin, g/dL, mean (SD)	12.4±1.5	12.8±1.8	0.398
Serum creatinine, mg/dL, median (IQR)	0.9 (0.7-1.2)	1 (0.8-1.2)	0.615
LDL cholesterol, mg/dL, mean (SD)	92±40.6	92.2±33.8	0.975
CRP, median (IQR)	2.6 (1.3-5.1)	2.6 (1.1-6.3)	0.976
Follow-up time, months	57.3±22.1	47±24.6	0.073
Instent restenosis, n (%)	5 (21.7)	5 (5.9)	**0.020**

Data are presented as percentage, mean ± standard deviation or median (interquartile range). CEA: Carotid endarterectomy, CT: Computed tomography, SCCA: Stenosis of the contralateral carotid artery, TIA: Transient ischemic attack, LDL: Low-density lipoprotein, CRP: C-reactive protein, SD: Standard deviation, SF: Stent fractures, IQR: Interquartile range

Table 2. Lesion characteristics and Doppler ultrasonography data of the study group

Variables	SF (+) group (n=23)	SF (-) group (n=85)	p-value
Lesion length, mm	11.1±5	10±4.9	0.324
DLFCB, mm	7.5±4.2	7±3.7	0.582
Percentage of stenosis, %	83±10.7	80.7±12	0.238
DSFCB, mm	25±8.2	24.4±7.2	0.751
Tortuosity index	13 (10-22)	13 (6.5-20)	0.327
ICA/CCA	1.7±1	1.1±0.3	**<0.001**
Calcification			
No	0 (0)	6 (7.1)	
Mild	0 (0)	25 (29.4)	**<0.001**
Moderate	6 (26.1)	40 (47.1)	
Heavy	17 (73.9)	14 (16.5)	
PSV	78 (65-138)	68 (58-85.5)	**0.007**
EDV	29 (22-45)	25 (18-30.5)	**0.013**
PSV/EDV	3±0.9	3.2±1.3	0.645

Data are presented as percentage, mean ± standard deviation or median (interquartile range). CCA: Common carotid artery, DLFCB: Distance of the lesion from the carotid bulb, DSFCB: Distance of the stent from the carotid bulb, EDV: End diastolic velocity, ICA: Internal carotid artery, PSV: Peak systolic velocity, SF: Stent fractures

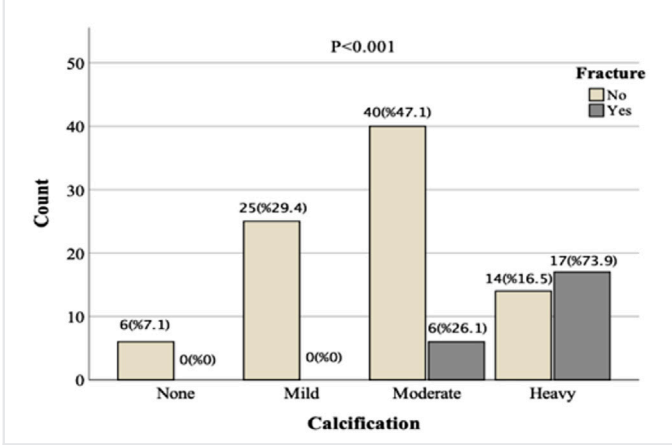

Figure 3. The degree of calcifications according to stent fractures

Discussion

In this study, we investigated and analyzed our clinical experience and results concerning SFs those might be associated with the development of ISR in long-term follow-ups after the implantation of Xact stents for CAS. In this study, among 108

patients who underwent CAS, SFs were detected in 23 (21.9%) patients during long-term follow-up. When patients were divided into two groups based on the presence or absence of SFs, a significantly higher rate of ISR development was found in the group with SFs (p=0.020). In DUS examination, it was observed that in patients with SFs, the lesion causing stenosis in the ICA was more frequently classified as severely calcified (p<0.001). Additionally, in patients with SFs, at the time of SFs detection, PSV and EDV were significantly higher compared to patients without SFs (p=0.007 and p=0.013, respectively). When examining procedural characteristics, it was observed that in patients with SFs, stent length was significantly longer (p=0.028). Regarding the development of ISR, when investigating risk factors, none of the parameters was identified as an independent predictor, moreover SFs did not emerge as a significant factor. Additionally, when Kaplan-Meier analysis was applied, no significant difference was found in terms of the time to ISR development between patients with and without SFs.

Table 3. Procedural variables and informational data of the stent

Variables	SF (+) group (n = 23)	SF (-) group (n = 85)	p-value
Predilation performed, n (%)	8 (34.8)	32 (37.6)	0.801
Postdilation performed, n (%)	16 (69.6)	53 (62.4)	0.523
Stent proximal diameter, mm	8.2±0.9	8.3±0.6	0.585
Stent distal diameter, mm	6.5±0.7	6.5±0.6	0.609
Stent length, mm	37.8±4.2	35.2±5.3	**0.028**
Side of the stent implantation Right ICA Left ICA	 16 (69.6) 7 (30.4)	 41 (48.2) 44 (51.8)	0.069
Predilation balloon size, mm	3.1±0.9	3.6±0.8	0.182
Postdilation balloon size, mm	4.9±0.6	4.8±0.5	0.376
Predilation balloon length, mm	17.6±2.5	19±3.7	0.334
Postdilation balloon length, mm	19.6±12.3	19.6±1.5	0.925

Data are presented as percentage, mean ± standard deviation or median (interquartile range). ICA: Internal carotid artery, SF: Stent fractures

In various studies, the incidence of SF in patients undergoing CAS has been reported to range between 0% and 39% (3,4). While many of these studies employed different stent types, the ACT 1 multicenter randomized trial (8), sponsored by Abbott Vascular, exclusively used the Xact stent, and the SF rate was determined to be 5.4%. In our patient cohort, all patients received the same stent (Xact, Abbott Vascular, Santa Clara, CA). We observed a proportionate rate of SF development (21.9%), consistent with the literature, however, our SF rate was higher compared to the findings of the ACT 1 Multicenter Randomized Trial.

The association between SFs and ISR were studied previously. Sfyroeras et al. (6) analyzed 13 studies examining SFs that developed after CAS (10 case reports and 3 clinical studies). A total of 55 SFs were identified, with the most commonly used stent associated with SFs being the Xact stent [22 SFs (40%)]. In 55% of cases, SFs were linked to ISR. SFs were frequently connected to ISR and generally remained asymptomatic. In our study, similar findings to the study by Sfyroeras et al. (6) were obtained, where the rate of ISR in patients with SFs was higher compared to patients without SFs (21.7% vs. 5.9%, p=0.020). In another study conducted by Weinberg al. (10), they evaluated 1091 CAS procedures, and SFs were identified in 51 patients (5.4%). Xact stents were used in all patients. Weinberg et al. (10) did not find a relationship between CAS - related SFs and adverse events. Additionally, contrary to our study, SFs were not identified as a risk factor for ISR. Moreover, Garcia-Toca et al. (11) evaluated 106 CAS procedures and identified SFs in 8 patients (7.5%). Both open and closed-cell stents were used

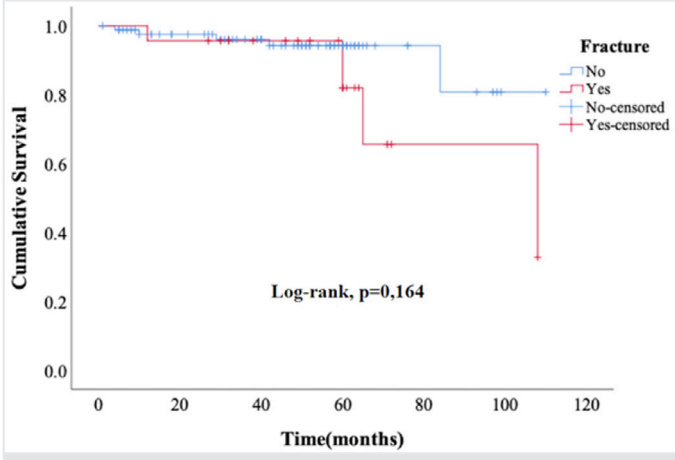

Figure 4. Kaplan-Meier survival curves for stent fractures in long-term stent restenosis

Table 4. Univariate and multivariate Cox regression analyses to identify long-term predictors of restenosis

	Univariate analyses			Multivariate analyses		
	HR	95%CI (lower-upper)	p-value	HR	95%CI (lower-upper)	p-value
Proximal diameter of stent	0.444	0.244-0.807	0.008	0.676	0.339-1.350	0.267
Postdilation	0.242	0.062-0.944	0.041	0.278	0.059-1.302	0.104
Current smoking	3.618	1.012-12.933	0.048	2.700	0.634-11.502	0.179
WBC	1.405	1.017-1.941	0.039	1.399	0.990-1.976	0.057

WBC: White blood cells, CI: Confidence intervals, HR: Hazard ratio; others, see Table 1, Table 2 and, Table 3

in this study, and similar frequencies of SFs were observed in both groups [7 (87.5%) vs. 1 (38.5%), p=0.067)]. Garcia-Toca et al. (11) did not find a relationship between SFs and the development of adverse events. While the rate of ISR was higher in patients with SFs, univariate and multivariate analyses did not identify SFs as a risk factor for ISR. Furthermore, when evaluating the duration of ISR development in long-term follow-ups, no significant difference was found between patients with and without SFs. On the other hand, case reports in the literature indicate that severe cases with SF (Type 3-5) can lead to adverse events and symptoms, necessitating treatment (12,13). Based on these findings, presence of SFs and its association with adverse events lack clinical significance.

In the literature, it has been observed that as the length of the stent placed in the carotid artery and the TI (angle of deviation) between the internal/common carotid arteries increase, the risk of SF also increases (14). Consistent with the literature, in this study, patients who developed SFs after CAS were found to have longer stents (p=0.028). However, there was no significant difference in TI between the group with SF and the group without SF (p=0.327). The head and neck region, similar to the femoropopliteal region, is a highly mobile area. Around the central axis of the cervical vertebra, it undergoes 3-dimensional flexion, extension, and rotational movements. Although these movements are not entirely uniform, they affect the main carotid artery and ICA, exhibiting similar motion mechanisms in these vascular structures. However, studies have shown that the vascular segment undergoing stent placement after CAS loses some of this mobility, while other vascular segments without stent intervention maintain partial mobility (14). Consequently, this lack of alignment results in shear stress and compression on the stent. As the stent length and tortuosity increase, the stent's ability to accommodate this motion mismatch decreases.

The association between the severity of calcification and SF has been studied previously. The study by Chang et al. (3) examined the results of 219 CAS procedures and found that the presence of calcified plaques on direct radiography increased the rate of SF compared to the absence of calcified plaques (62% vs. 15%, p=0.001). Particularly severe calcification of the carotid artery has been identified as a risk factor for complications after CAS. Calcification affects the complete expansion of the stent in the artery. Calcified plaque exerts an external force on the stent, and rigidity increases in calcified vessels. This situation leads to SF and ISR (3,15). In our study, consistent with the literature, the rate of SF in severely calcified plaques was found significantly higher (p<0.001).

Type of SF is another point of view to discuss. In their study, Garcia-Toca et al. (11) classified patients with SFs based on the type of SF and found that the most commonly observed type was Type I-II. As the follow-up duration increases, it is likely that the proportion of more severe Type III-V might increase. As far as we are aware, there is currently no existing literature addressing this particular issue.

The type of SF is another perspective to discuss. Garcia-Toca et al. (11) classified patients with SF based on the SF type and found that the most common type was Type I-II. In our study, 52.1% of cases were Type I-II. It's possible that our longer follow-up period led to an increase in the prevalence of more severe Type III-V SF. However, to the best of our knowledge, there is no study in the literature that addresses this issue.

Study Limitations

This study had several limitations. Firstly, it was retrospective in nature and involved a relatively small sample size. Secondly, only a single type of stent was used for the CAS procedure, and the significance and role of SFs in other open and closed-cell stents were not investigated. Third, the exact date of SF occurrence was not known. Forth, approximately half of the patients had pre-existing computerized tomographic angiography; therefore, fluoroscopic images were used in half of the patient group to assess the presence and degree of calcification. Fifth, some important plaque features, especially those found in vulnerable plaques, were unknown: the presence of lipid core, parietal thrombus, ulceration, intraplaque bleeding, etc. Lastly, lesions with different etiologies resulted in a heterogeneous group of patients.

Conclusion

SFs is a common complication after CAS and the diagnosis of SFs requires careful and regular radiological assessment. SF was found associated with calcification and stent length as these factors increased the occurrence of SF. Additionally, ISR was found associated with SF however none of the parameters analyzed in our study was found as independent predictor. While mild SFs might lack clinical significance, evaluation of larger patient groups is necessary for advanced SF types.

Ethics

Ethics Committee Approval: Ethical approval was granted by the University of Health Sciences Türkiye, Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital, and the study adhered to the principles outlined in the Helsinki Declaration (decision no: 2023.08-84, date: 24.10.2023).

Informed Consent: Retrospective observational cohort study.

Authorship Contributions

Surgical and Medical Practices: M.A., A.A.Y., M.E., Concept: M.A., A.A.Y., A.I., Y.D., M.E., Design: M.A., F.C.P., A.Ş., Data Collection or Processing: M.A., A.I., S.A., G.D., Analysis or Interpretation: M.A., N.U., Literature Search: M.A., A.A.Y., F.C.P., A.Ş., Writing: M.A.

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