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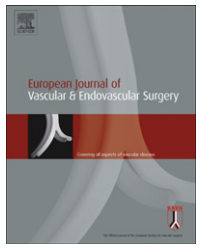

REVIEW

The Incidence of Arterial Stent Fractures with Exclusion of Coronary, Aortic, and Non-arterial Settings

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Abstract *Background:* This study aimed to review the literature regarding fracture of arterial stents, especially its relation to location of placement, clinical relevance, and type of stents.
Material and methods: We searched published articles in PubMed up to February 2008 by using the terms: stent fracture or stent breakage.
Results: Thirty-one articles met our inclusion and exclusion criteria. Most of the studies reported fractures in stents placed in the superficial femoral artery or popliteal arteries. The cumulative incidence of stent fractures ranged from 2% to 65%, i.e. 0.6 to 60 per 1000 person-months. Stent fractures occur more frequently in the superficial femoral artery and are common when multiple stents are deployed and overlap. Stent fractures are associated with a higher risk of in–stent restenosis and re-occlusion.
Conclusion: The incidence of stent fracture, its location of placement, and type of stent used were diverse across studies. Stent fracture may cause clinical deterioration especially in the femoropopliteal segment, and it should be detected before clinical manifestation appears. Further studies with larger study population involving new type of stents for a longer follow up period are warranted.

Introduction

Intravascular stents are frequently used to treat stenoses or occlusive disease in the vascular system. Percutaneous arterial therapy was developed in 1969 after Charles Dotter described the original technique.[1] In 1985, Palmaz reported

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results of stent placement in dog arteries.[2] The first stent was implanted into a human coronary artery in 1986.[3]

Currently commercially available stents can by divided into three major types: balloon—expandable, self—expanding, and shape-memory or nitinol stents. Since first clinical application of stents, many technical improvements have been developed. The technical parameters of the device, e.g. the rigidity, strength, elasticity and plasticity, should be taken into account when placing stents at particular vascular sites. It is still disputed whether primary stenting is necessary or if stenting should only be performed after an unsuccessful angioplasty.[4–12] Initial technical success rates are high for arterial stents, however, the durability of these devices in different peripheral vascular beds is diverse. Complications can arise, and stent fracture is one example. Stent fractures may cause a number of complications, such as restenosis, occlusion, pseudo-aneurysm, vessel perforation, and embolism.[4–8,13–26] The aim of this study was to review the literature regarding stent fractures.

Material and Methods

Data sources

We searched the published literatures in PubMed up to February 2008 by using the searching terms stent fracture or stent breakage. Our inclusion criteria were that a full original study was published in English, Dutch or German, and that the authors reported stent fracture in stenotic or occluded peripheral arteries. Articles reporting stent fractures in either aorta or coronary arteries, non-arterial settings and patency of stent grafts were excluded. Manual cross-check from the reference lists of all relevant articles identified additional papers, which were not found in Pubmed by our searching term.

Results

We initially identified 346 articles related to stent fracture in Pubmed. After assessing those studies and related articles from manual cross-check, 31 articles met our inclusion criteria, and were included in our review.[4–8,13–38] Most of the studies reported stent fractures in the femoropopliteal or superficial femoral artery segment. The baseline characteristics of the articles are presented in Table 1. The study design of the articles was heterogeneous. Six studies were performed in a prospective manner[6,27–31]; five studies[27–31] were randomized, whereas some of them were extension from the previous studies.[29,31] Nine studies were performed in a retrospective manner,[7,8,14,15,17,21,23,24,32] seventeen were case reports.[4,5,13,16,18–20,22,25,26,33–38] We found articles related to stent fractures in the tibioperional trunk,[4] popliteal artery,[5,13,33] femoropopliteal,[6,7] superficial femoral artery,[8,14,15,28–33] iliac,[16,17,34] renal,[18–21,35] superior mesenteric artery,[36] brachiocephalic trunk,[37] subclavian,[22] vertebral arteries,[23,24,38] carotid artery,[25] and pulmonary artery.[27]

Incidence

Table 2 presents the incidence of stent fractures. The cumulative incidence (frequency of stent fractures) ranged from 2% to 65%. This incidence rate is equivalent to 0.6—60/1000 person-months (Table 2). Scheinert *et al.*[6] investigated the occurrence and clinical impact of nitinol stent fracture after femoropoliteal stenting. By examining 121 legs after femoropopliteal artery stenting with a mean follow up of 10.7 months, they found that 37% (45/121) of legs treated had 64 stent fractures. Sabety *et al.*[7] reported 8 (15%) stent fractures in the femoropopliteal segment of 53 treated legs after 8 months follow-up. Iida *et al.*[8] reported data of superficial artery stenting with nitinol stents in 40 examined patients after mean follow-up of 13.6 months. Stent fractures occurred in 28% (11/40) of patients. They found that the incidence of stent fracture for patients who walked >5000 steps/day was higher than patients who did not. Duda *et al.*[27] reported results of a prospective study evaluating the effectiveness of shape memory alloy recoverable technology (SMART) nitinol self-expending stents coated with a polymer impregnated with serolimus (rapamicin) versus uncoated SMART stents in superficial femoral artery obstructions. The mean length of stented segment was 85 mm and the rate of nitinol stent fractures was 18% (6/33) after 6 months. Duda *et al.*[28] reported a series of stents placed in the superficial femoral artery. The mean length of stented segment was 81.5 mm and after 6 months the incidence of stent fractures was 8% (4/50). Subsequently the same authors[29] reported an incidence of stent fractures of 26% (17/65). Schlager *et al.*[14] compared stent fractures in nitinol stents versus Wallstents implanting for sub-optimal angioplasty in the superficial femoral artery. Radiographically, 11% (25/220) of the patients had stent fractures. Allie *et al.*[15] reported a 65% incidence of stent fractures in 110 patients treated with nitinol stents at 11 months. Ferreira *et al.*[32] reported one class II fracture (multiple single struts at different locations) using nitinol stents (Zilver, Cook, USA) in 59 treated patients after mean follow-up of 2.4 years. Schilinger *et al.*[31] reported 2 stent fractures after 12 month and there were no new stent fractures after 24 month for the same group of patients.

There were two case reports[16,34] and one retrospective study[17] regarding stent fractures in the iliac artery. Müller — Leise *et al.*[17] reported data of 23 patients with a mean length of iliac artery occlusion of 12 cm. One of 3 stented patients had early re-occlusion due to stent breakage. There were four case reports of renal artery stenting and stent fracture afterwards.[18–20,34] One clinical study described renal artery entrapment by the diaphragmatic crus. There was only one stent fracture in three stented patients.[21] Klepczyk *et al.*[36] presented two cases of fracture following stenting of the superior mesenteric artery. Periard *et al.*[37] described clinically significant stent rupture in the brachiocephalic trunk causing vertebral steal syndrome. One case report[22] described 3 cases of stent fracture in the subclavian artery and two cases of stent breakage in the subclavian vein. In 12 patients with symptomatic ostial vertebral artery stenosis who underwent stent implantation, Tsutsumi *et al.*[23] reported 3 stent fractures during a mean follow up of 31.5 months. Weber *et al.*[24] reported 2 stent fractures out of 26 patients with symptomatic atherosclerotic stenosis in the proximal vertebral artery treated with flexible balloon expandable stents after a mean follow—up of 11 months.

Table 1 Baseline characteristics of the articles

No	Author	Year	Type of study	No of cases	Vascular bed
1	Schwarzmaier - D'Assie[4]	2007	Case report	1	Tibioperioneal trunk
2	Furuichi S[33]	2007	Case report	1	Popliteal artery
3	Solis J[5]	2006	Case report	1	Popliteal artery
4	Babalik E[13]	2003	Case report	1	Popliteal artery
5	Scheinert D[6]	2005	Prospective cohort	121	Femoropopliteal
6	Sabety S[7]	2005	Retrospective cohort	65	Femoropopliteal
7	Iida O[8]	2006	Retrospective cohort	40	SFA
8	Duda SH[27]	2002	Randomized, multicenter, double-blind	36	SFA
9	Duda SH[28]	2005	Randomized, multicenter, double-blind	57	SFA
10	Duda SH[29]	2006	Randomized, multicenter, double-blind	93	SFA
11	Schlager O[14]	2005	Retrospective cohort	220	SFA
12	Allie DE[15]	2004	Retrospective cohort	110	SFA
13	Ferreira M[32]	2007	Retrospective cohort	59	SFA
14	Schillinger M[30]	2006	Randomized, single-institution	51	SFA
15	Schillinger M[31]	2007	Randomised, single-institution	46	SFA
16	Higashiura W[34]	2008	Case report	1	Iliac artery
17	Sacks BA[16]	1996	Case report	1	Iliac artery
18	Muller — Leisse C[17]	2001	Retrospective cohort	23	Iliac artery
19	Robertson SW[35]	2008	Case report	1	Renal artery
20	Sahins S[18]	2005	Case report	1	Renal artery
21	Bessias N[19]	2005	Case report	1	Renal artery
22	Bauget JP[20]	2003	Case report	1	Renal artery
23	Thony E[21]	2005	Retrospective cohort	3	Renal artery
24	Klepczyk L[36]	2008	Case report	2	SMA
25	Periard D[37]	2008	Case report	1	BCT
26	Phipp LH[22]	1999	Case report	3	Subclavian artery & vein
27	KIM SR[38]	2007	Case report	2	Vertebral artery
28	Tsutsumi M[23]	2006	Retrospective cohort	12	Vertebral artery
29	Weber W[24]	2005	Retrospective cohort	26	Vertebral artery
30	Valibhoy AR[25]	2007	Case report	1	Carotid artery
31	Knirsch W[26]	2003	Case report	1	Pulmonary artery

SFA = superficial femoral artery, SMA = superior mesenteric artery, BCT = brachiocephalic trunck.

Table 2 Incidence of stent fractures

No	Author/year	Vascular bed	No of Tx	No of #	CI of # (%)	Follow-up		IR (/1,000)
						Mean (m)	Total (pm)	
1	Scheinert D, 2005	FPA	121	45	37	11	1.295	35
2	Sabety S, 2005	FPA	53	8	15	8	424	19
3	Iida O, 2006	SFA	40	11	28	14	544	20
4	Duda SH, 2002	SFA	33	6	18	6	198	30
5	Duda SH, 2005	SFA	50	4	8	6	300	13
6	Duda SH, 2006	SFA	65	17	26	18	1.170	15
7	Schlager O, 2005	SFA	220	25	11	29	6.380	4
8	Allie DE, 2004	SFA	110	72	65	11	1.210	60
9	Ferreira M, 2007	SFA	59	1	2	29	1711	0.6
10	Schillinger M, 2006	SFA	51	2	4	12	612	3
11	Schilinger M, 2007	SFA	46	2	4	24	1104	2
12	Müller-Leisse C, 2001	IA	3	1	33	?	?	?
13	Thony F, 2005	RA	3	1	33	24	72	14
14	Tsutsumi M, 2006	VA	12	3	25	32	378	8
15	Weber W, 2005	VA	26	2	8	11	286	7

FPA = femoropopliteal artery, SFA = superficial femoral artery, IA = iliac artery, RA = renal artery, VA = vertebral artery, CI = cumulative incidence, IR = incidence rate, m = months, pm = person-months, Tx = treatment, # = fracture.

Valibhoy *et al.*[25] presented a case of stent fracture using a self−expanding stent in a patient who underwent carotid artery stenting for stenosis. Knirsch *et al.*[26] presented the only case report about longitudinal stent fracture 11 months after implantation in the left pulmonary artery.

Clinical relevance

Table 3 presents the clinical implication of stent fracture. Scheinert *et al.*[6] reported 64 stent fractures in 45 treated legs after 11 months. 67% of 64 stent fractures in the femoropopliteal segment were associated with stent occlusion or restenosis, and concluded that there was a considerable risk of stent fractures after long segment femoral artery stenting, which is associated with a higher in-stent restenosis and re-occlusion. Sabety *et al.*[7] reported 8 stent fractures in the femoropopliteal segment of 53 treated legs after 8 months. Restenosis was found in 75% (6/8) of cases. They found that mid-term restenosis after long-segment femoropopliteal stenting using nitinol stents remained a major problem, particularly in patients with diabetes mellitus. However, mid-term results in nondiabetic patients were encouraging. Duda *et al.*[27] reported results of a prospective study where all 6 (18%) nitinol stent fractures after 6 months were asymptomatic. In a subsequent study,[28] they reported 8% (4/50) stent fractures without symptom after 6 months. Later on, Duda *et al.*[29] extended both previous studies[27,28] with follow-up up to 18 months. They did not find any clinical symptoms in patients with stent fracture. Schlager *et al.*[14] demonstrated that the length of the stented segment was significantly associated with stent fractures ($p = 0.046$). In patients with Wallstents (Boston Scientific, Natik, MA, USA), they did not find significant association between fractures and restenosis ($p = 0.56$); whereas in patients with SMART stents (Cordis, Miami, Florida, USA), fractures were significantly associated with restenosis ($p = 0.008$). No complications other than restenosis were associated with stent fractures in this study. Unfortunately they did not report the number of patients with restenosis due to stent fracture. Allie *et al.*[15] found that stent fractures were associated with angiographic stenosis (>50%) or occlusion in 76% (55/72) patients, where 60% (33/55) patients were clinically symptomatic. In this study, the average lesion length was 17.5 cm (range: 6−34 cm). Significant clinical implications of stent fracture were not clearly mentioned in some studies.[30−32] Müller − Leise *et al.*[17] reported one early re-occlusion of 3 stented iliac arteries due to stent breakage. Thony *et al.*[21] reported one renal artery restenosis due to stent fracture 24 months after deployment. Tsutsumi *et al.*[23] reported 25% (3/12) asymptomatic stent fractures after a mean follow up of 32 months. Weber *et al.*[24] reported 8% (2/26) asymptomatic stent fractures after a mean follow−up time of 11 months.

The overall mean follow-up time of the studies included in our review ranged from 6 to 32 months. Clinical complications were more frequently found in studies with longer follow up time (Table 3).

Type of stent

Table 4 shows the type of stent used in different vascular beds. Scheinert *et al.*[6] analyzed the performance of different nitinol stents. They reported fracture rates of 27% (14/52) for SMART, 29% (7/24) for SelfX (Abbot Medical Devices, Beringen, Switzerland), and 53% (24/45) for Luminex (BARD, Murray Hill, New Jersey). There were no initial differences between groups. Iida *et al.*[8] reported 28% (11/40) stent fractures using Luminex stents in the superficial femoral artery. In patients with stent fractures, the lesion length was longer (215 vs. 114 mm) and the number of stents used per case was greater (2.4 vs. 1.4). Duda *et al.*[27] reported 3 nitinol stent fractures in SMART serolimus eluting and 3 nitinol stent fractures in the uncoated SMART group. In 2005, Duda *et al.*[28] reported 2 nitinol stent fractures in SMART serolimus eluting (Cordis, Miami, FL, USA) and 2 nitinol stent fractures in uncoated SMART

Table 3 Clinical implication of stent fracture

No	Author/year	Vascular bed	No of #	No of Co	Follow-up mean (m)	Mean length SS (mm)	Clinical implication
1	Scheinert D, 2005	FPA	64	43	11	157	67.2% occlusion or retenosis
2	Sabety S, 2005	FPA	8	6	8	160	75% restenosis
3	Iida O, 2006	SFA	11	?	14	215	?%
4	Duda SH, 2002	SFA	6	0	6	85	no restenosis
5	Duda SH, 2005	SFA	4	0	6	82	no restenosis
6	Duda SH, 2006	SFA	17	0	18	83	no restenosis
7	Schlager O, 2005	SFA	25	?	29	107/139/125	?% restenosis
8	Allie DE, 2004	SFA	72	55	11	175	76% occlusion or retenosis
9	Ferreira M, 2007	SFA	1	?	29	192	?%
10	Schillinger M 2006	SFA	2	?	12	132	?%
11	Schilinger M 2007	SFA	2	?	24	132	?%
12	Muller - Leisse C 2006	IA	1	1	?	120	1 of 1 reocclusion
13	Thony F, 2005	RA	1	1	24	?	1 of 1 restenosis
14	Tsutsumi M, 2006	VA	3	0	32	?	no restenosis
15	Weber W, 2005	VA	2	0	11	?	no restenosis

FPA = femoropopliteal artery, SFA = superficial femoral artery, IA = iliac artery, RA = renal artery, VA = vertebral artery, # = fracture, Co = complications, (m) = month, SS = stented segment.

Table 4 Type of stents

No	Author/year	Vascular bed	Mean length SS (mm)	Type of stent			
1	Scheinert D, 2005	FPA	157	SMART	SelfiX	Luminex	
2	Sabety S, 2005	FPA	160	SMART	Dynalink		
3	Iida O, 2006	SFA	215	Luminexx			
4	Duda SH, 2002	SFA	85	SMART (se)	SMART (b)		
5	Duda SH, 2005	SFA	82	SMART (se)	SMART (b)		
6	Duda SH, 2006	SFA	83	SMART (se)	SMART (b)		
7	Schlager O, 2005	SFA	107/139/125	Wallstent	SMART	Dynalink/Absolute	
8	Allie DE, 2004	SFA	175	Nitinol stents?			
9	Ferreira M, 2007	SFA	192	Zilver			
10	Schillinger M, 2006	SFA	132	Dynalink	Absolute		
11	Schilinger M, 2007	SFA	132	Dynalink	Absolute		
12	Muller - Leisse C, 2006	IA	120	Palmaz			
13	Thony F, 2005	RA	?	Wallstent			
14	Tsutsumi M, 2006	VA	?	Palmaz	Bx Velocity	S670	Driver
15	Weber W, 2005	VA	?	S670	Velocity		

FPA = femoropopliteal artery, SFA = superficial femoral artery, IA = iliac artery, RA = renal artery, VA = vertebral artery, SS = stented segment, (se) = serolimus eluting, (b) = bare.

(Cordis, Miami, FL, USA) group. Duda *et al.*[29] reported results from both previous studies[27,28] up to 18 month and found 8 stent fractures in the bare stent group and 9 stent fractures in the serolimus eluting stent. Schlager *et al.*[14] reported 11% (25/220) stent fractures in the superficial femoral artery. The fracture rates were 19% (15/78) for Wallstent after a mean follow−up of 43 months (mean stented lesion length 107 ± 71 mm), 28% (8/29) for SMART stents after a mean follow-up of 32 ± 16 months (mean stented lesion length 139 ± 88 mm), and 2% (2/113) for Dynalin/Absolute stents after a mean follow-up of 15 months (mean stented lesion length 125 ± 84 mm). Allie *et al.*[15] reported 65% stent fractures. However, they did not describe what types of nitinol stents were used. Recent studies indicated that the occurrence of nitinol stent fractures are low in mid- to long-term follow-up.[30−32]

A wallstent (6×28 mm, Boston Scientific, Galway, Ireland) was used to treat renal artery stenosis due to entrapment by the diaphragmatic crus. Stent fracture was detected two years after deployment.[21] Weber *et al.*[24] reported 2 stent fractures in 26 patients with symptomatic atherosclerotic stenoses in the proximal vertebral artery treated with flexible balloon expandable stents S670 or Velocity (Cordis, Miami Lakes, FL, USA); however, type of stent was not described.

Discussion

This review has identified great differences in the reported cumulative incidence of stent fractures. For example, the range of reported stent fracture in the superficial femoral artery is 2 to 65% (Table 2). Fracture was more commonly reported in studies specifically looking for stent fractures.[6,8,14,15] Stent fractures occur mostly in the bending vascular segments close to joints such as femoropopliteal and femoral segments.[4−8,13−15,28−33] From 31 articles reviewed, 15 were cohort and randomized studies. 73% (11/15) of the studies were reflecting stent fractures in the femoropopliteal or superficial femoral artery (SFA). Our review reveals that stent fractures occur more frequently after long segment femoral artery stenting, which is associated with a higher in−stent restenosis and reocclusion rates. A recent clinical trial (RESILIENT trial) reports no nitinol stent fracture in the SFA and popliteal segment after 12 month of follow up.[39] Stent fractures are more common with multiple stent deployment and overlap.[6−8,13−15] Only one paper reported the risk factors influencing nitinol stent fractures in the SFA, and walking habits was associated with stent fracture.[8] Unfortunately, the study had exclusively used stents with high potential of fracture (Luminexx, BARD, Murray Hill, New Jersey). However, we found that the number of patients with stent fractures was reported differently, and the correct incidence was unclear.

When stent fracture occurs, it commonly correlates with restenosis or re-occlusion in the stented artery and causes decline of clinical condition.[6−8,14,15,21,23,24,27−32]

We assessed stent fractures in relation to stent design. Only one study[14] compared stent fractures in nitinol stents versus Wallstents, implanted for sub-optimal angioplasty in the SFA. The incidence of stent fracture was lower in Dinalink/Absolute stents. However differences in length of targeted vessels (length of stent), number of stents used, type of stent, and follow-up time make conclusions difficult.[6,14,27−31] In other studies,[9−12] Palmaz and Absolute stent fractures were not demonstrated in the SFA. Schilinger *et al.*[30−32] reported low occurrence of stent fracture in the SFA despite multiple nitinol stent deployment after mid- to long-term follow-up.

Stainless steel stent fractures were reported in other vascular beds such as renal[21] and vertebral[23,24] arteries. We found single case reports regarding stent fractures in the subclavian artery,[22] brachiocephalic trunk,[37] carotid artery,[25] and superior mesenteric artery.[36]

Stent fractures in the vertebral artery segments occurred in balloon-expandable, coronary stainless steel stents, and were not associated with clinical adverse events.[23,24] For incidence calculation, we included only 15 studies (cohort and randomizes studies). There were 217 stent fractures in 850 procedures, giving an average cumulative incidence of stent

fractures of 26%. Approximately half of these patients had restenosis or occlusion of the stented segment. Mean follow-up time ranged from 6 to 32 months. Possibly more stent fractures might be detected if the follow-up time was longer, and studies were performed with the aim of searching for stent fractures by using X-ray and ultrasound screening. Ideally all diagnostic images should be analyzed and magnified if stent fracture is suspected.[40]

In conclusion, the incidence of stent fracture, its location of placement, and type of stent used were diverse across studies. If stent fracture occurs, it causes clinical deterioration especially in the femoropopliteal segment. Therefore, stent fracture should be detected before clinical manifestation appear. The implantation of stents should be well considered. Further studies with larger study population involving new type of stent for a longer follow up period are warranted.

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