Self-expanding nitinol stents in recanalisation of long-length superficial femoral artery occlusions in patients with critical limb ischaemia

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ABSTRACT

Introduction: This study aims to evaluate our experience with self-expanding nitinol stent-enabled recanalisation of long-length occlusions (30 cm or more) of the superficial femoral artery (SFA).

Methods: 573 patients underwent 842 lower limb interventions from August 2006 to December 2008. A retrospective review of patients undergoing recanalisation of long-length SFA occlusions with self-expanding nitinol stents and an evaluation of their patency and impact on limb salvage, were done.

Results: 22 patients (mean age 62.5 years, male: female ratio 11:11) underwent 22 long-length SFA stenting procedures. The spectrum of critical limb ischaemia included rest pain (five), ulcer (six) and gangrene (11). Length of occlusions varied from 30 cm to 45 cm (average length 36.4 cm). Five patients had stents placed through the ipsilateral popliteal artery approach, and the rest had stents placed through the femoral artery approach. All patients were followed up over an average duration of 12 months. One patient died due to associated medical conditions during this period. Six out of 21 (28.6 percent) of the stents thrombosed completely on one year follow-up. Of these, two patients underwent amputation, one patient had a bypass, and the stent in two patients were recanalised with balloon angioplasty. All remaining patent stents showed varying degrees of stenoses at one year. The overall limb salvage rate at one year following stent placement was 81 percent.

Conclusion: Our experience showed the beneficial result of long-length SFA stent placement with good limb salvage outcome. Repeat interventions may be required to maintain the patency of stents in these patients.

Keywords: critical limb ischaemia, long-length superficial femoral artery occlusions, self-expanding nitinol stents

INTRODUCTION

Peripheral vascular disease (PVD) is a significant problem affecting the elderly population in our society. Its incidence increases from about 4% in patients 40 years and older to 15% in patients over 70 years of age.[1] The spectrum of PVD ranges from an asymptomatic underlying condition in the early stages detected clinically with low ankle-brachial index, to intermittent claudication, rest pain and tissue loss/gangrene with disease progression. Limb loss as a result of amputation following severe PVD directly leads to poor overall survival in these patients.[2] The incidence of PVD in our local population in Singapore is estimated to be around 8%.[3] With life expectancy in our population being the same and even better than some of the other developed nations, we expect to encounter more patients with PVD in the future.

In our practice, a large majority of the patients present at an advanced stage of the disease with threatened limb/critical limb ischaemia. Only a small minority of the patients present at an earlier stage of intermittent claudication. This is further complicated by a relatively higher incidence of diabetes mellitus in our population, a disease known to place patients at high risk for PVD.[4] A large number of these patients have long segment occlusions in the infrainguinal arterial supply (about 30% of cases at our institute), making their management challenging. In this article, we reviewed our recent experience with recanalisation of long-length ($\geq$ 30 cm) occlusions of the superficial femoral artery (SFA) through a subintimal approach using long self-expanding nitinol stents.

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Table I. Distal run-off.

Patient no.	Anterior tibial artery	Posterior tibial artery	Peroneal artery
1	+		
2		+	+
3		+	+
4		+	+
5	+	+	+
6	+		
7			+
8		+	
9		+	
10	+		+
11	+		
12		+	+
13	+		+
14			+
15		+	+
16			+
17			+
18		+	+
19	+	+	+
20	+		+
21	+		
22			+
Total	9	10	16

+: present

METHODS

All patients underwent a preliminary assessment of the arterial supply to the diseased limb using Doppler ultrasonography or computed tomography angiogram. An initial diagnostic catheter angiogram was performed following access into the contralateral common femoral artery. Intervention was performed at the same session with the aim of establishing straight line flow of at least one vessel to the foot. After crossing the long-length occlusions through the subintimal approach, an angiogram was performed to confirm entry into the true lumen distal to the occlusion. All patients, except two, had the occlusions crossed using a combination of different wires and catheters. Assisted reentry into the distal true lumen was achieved in the other two patients using an Outback re-entry catheter (Cordis Corporation, Warren, NJ, USA) and a Frontrunner catheter (Cordis Corporation, Warren, NJ, USA). In cases where the occlusions could not be crossed or where it was not technically feasible to use the antegrade common femoral artery approach, an ipsilateral popliteal artery access was used for retrograde recanalisation of SFA. This combined approach enabled us to achieve an overall technical success rate of 98%.

After crossing the occlusions, all patients initially underwent balloon angioplasty with long-length (5 mm/6 mm × 10 cm) balloons, depending on the estimated diameter of the native SFA. Stents were used only if the result of the balloon angioplasty was suboptimal, or the occlusions were elastic with no patency after the initial angioplasty. Stents were placed only if there was at least one vessel run-off below the knee (anterior or posterior tibial artery preferentially) into the foot. In cases with concomitant infrapopliteal arterial occlusions, the disease below the knee was treated and recanalised prior to stent placement in SFA. All stents were then post-dilated at nominal pressure with the same-size balloon after deployment.

There was a deliberate attempt to use long SFA stents in all cases to keep the number of stent overlaps to the minimum. The stents used in our series included Smart (Cordis Corporation, Warren, NJ, USA), Protégé Everflex (ev3 Endovascular Inc, Plymouth, MN, USA) and Lifestent Flexstar (Edwards Lifesciences, Irvine, CA, USA). At least two stents were required in all patients, as the minimum length of occlusions recanalised was 30 cm. All patients were placed on dual antiplatelet therapy following the procedure (clopidogrel and aspirin). Clopidogrel was discontinued three months after the procedure, with aspirin continued long-term. All patients were followed up clinically and on Doppler ultrasonography for a period of at least one year after the procedure. Catheter angiogram and re-intervention were performed in patients with recurrent stenosis or in those with new lesions elsewhere in the same limb. The overall limb salvage rates were evaluated in all patients.

RESULTS

A total of 842 lower limb peripheral vascular interventions in 573 patients were performed at our institute over a period of 30 months from August 2006 to December 2008. 96% of these interventions were performed on patients with critical limb ischaemia. 65% of the patients had concomitant supra- and infrapopliteal stenotic/occlusive disease requiring treatment. 22 patients underwent stent placement for at least full-length SFA occlusions (30 cm or more in length) using the subintimal approach. The group comprised 11 male and 11 female patients, with a mean age of 63.2 years. The presenting complaint was gangrene (n = 11), ulcer (n = 6) and rest pain (n = 5). The significant associated comorbidities included diabetes mellitus (n = 19, 86.4%), and end-stage renal failure (n = 3, 13.6%). The distal run-off comprised one vessel (n = 11), two vessels (n = 9) and three vessels (n = 2) (Table I). The length of occlusion was 30–45 cm (average 36.4 cm). The total number of stents used was 61, and the average stent length and diameter was 15 cm and 6 cm, respectively.

Five patients underwent stent placement through the

Figs. 1 & 2 Right leg angiograms through a catheter placed from a contralateral left common femoral artery approach show a full length superficial femoral artery occlusion. Multiple collaterals reform the proximal popliteal artery at the adductor hiatus.

Figs. 3 & 4 Post-stent placement completion angiograms in the same patient show completely revascularised superficial femoral artery occlusion with good distal flow.

ipsilateral popliteal artery approach, and the remaining 17 patients underwent stent placement through the femoral artery approach (Figs.1–4). No procedure-related mortality was encountered. Two patients had distal embolisation following stent placement, which was treated with overnight thrombolytic therapy with normal flow established eventually. One patient had concomitant mid-popliteal artery flow limiting dissection related to guidewire tip, and was treated adequately with balloon tamponade. One patient with a significant popliteal artery to vein fistula related to popliteal artery access was treated with covered stent placement.

One patient died during the follow-up period due to unrelated causes. Six cases per limb (28.6%) occluded completely on follow-up within three months. None of these six cases had a three-vessel run-off. One was associated with severe stent fracture. One patient with occluded stents was recanalised with balloon angioplasty through the stents. One patient had a femoropopliteal bypass, while the other four underwent below/above knee amputations (BKA/AKA). Two patients had forefoot amputation. All patients who underwent either BKA or AKA were diabetics, whereas all the patients who were non-diabetics had patent stents (Table II). The primary patency at one year was 44.4% and the assisted primary patency was 66.7%. The overall limb salvage rate at one year post-intervention was 81%.

DISCUSSION

There are various endovascular techniques in practice for recanalisation of SFA occlusions. These include balloon angioplasty,[5] stent-enabled recanalisation,[6] endografts,[7] cryoplasty,[8] endovascular laser[9] amd silverhawk atherectomy.[10] Balloon angioplasty and stents are still
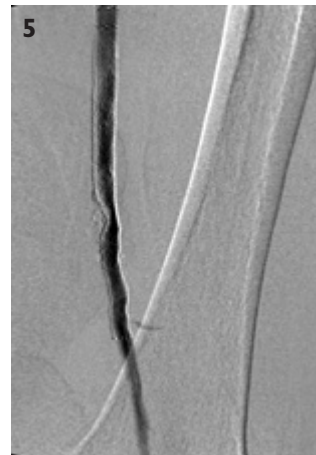

Fig. 5 Angiogram shows a calcified plaque in the distal superficial femoral artery causing an incomplete expansion of the stent with persisting significant residual stenosis.

the major techniques for recanalisation, with multiple studies demonstrating their benefits.[11,12] Some studies have demonstrated the superiority of stents over balloon angioplasty as far as patency is concerned.[13,14] At our institution, balloon angioplasty-enabled recanalisation is still the preferred first-line endovascular therapy due to its lower cost. Stents are used only if the balloon angioplasty result is suboptimal or if the occlusion is elastic. There have been studies demonstrating the superior patency of endografts such as Viabahn (Gore, Flagstaff, AZ, USA) in long-segment SFA occlusions.[15] However, endografts are not used as the first-line therapy in our institution due to the much higher cost of the combined length of endografts required for recanalisation. We routinely place these patients on surveillance after stent placement using Doppler ultrasonography. If required, these patients are brought back for repeat intervention, which includes endograft placement as second-line treatment.

Table II. Outcome post superficial femoral artery stenting upon follow-up.

Patient no.	Deceased	Occlusion of stents	Re-angioplasty	BKA/AKA amputation	Bypass	Limb salvaged
1	+					Not applicable
2			+			+
3						+
4		+			+	+
5						+
6				+		
7		+	+			+
8			+			+
9		+		+		
10		+				+
11		+	+	+		
12		+	+			+
13						+
14			+	+		
15						+
16						+
17			+			+
18						+
19						+
20						+
21						+
22						+
Total	1	6	7	4	1	17

+: present; BKA: below knee amputation; AKA: above knee amputation

Traditionally, surgical venous bypass graft is considered to be the gold standard in the management of these patients. However, a significant number of our patients either do not have adequate veins for bypass or the veins have been used elsewhere. The long-term patency of synthetic surgical bypass grafts is lower and is comparable to endografts in some studies.[15,16] The bypass grafts are also associated with stenoses in the long term, eventually leading to occlusion. In two patients in our series, the surgical bypass grafts placed earlier had occluded by the time they presented for SFA stent placement through the native artery.

There seem to be various factors involved in continued patency of SFA stents. SFA is subjected to a complex range of movements which directly affect the stents placed.[17] The earlier stents were prone to fractures, but the latest stents are less prone to this outcome. We encountered one severe stent fracture and two minor fractures, with the patient with the severe fracture eventually requiring a major amputation. The fractures were not related to the type of stent used. The arteries were significantly hard and chronically calcified in these patients. This suggests that stent fractures could still be an issue in the subgroup of patients with severely-calcified occlusions and it may be better not to place stents in this subgroup of patients.

The other unique problem we have encountered with nitinol stents in hard calcified arteries is the inability of the stent to open adequately in the presence of calcification. In two of these patients (Fig. 5), this contributed eventually to poor long-term patency and subsequent restenosis, requiring repeat intervention. This re-emphasises the difficulty in placing stents in patients with calcified arteries, as described above. Another factor which may affect patency could be the duration of antiplatelet therapy, especially the initial few weeks of clopidogrel therapy. There are no studies to document adequate dose and duration of antiplatelet therapy to enable long-term patency of stents in SFA. Further studies will be helpful in establishing standard dosage/duration to standardise therapy to keep these stents patent.

The patency of long stents could also be affected by the nature of underlying disease and distal run-off. The degree of in-stent stenosis appears to be less, with patients also being less symptomatic, in patients with three-vessel run-off distally. Also, patients with diabetes mellitus or end-stage renal failure have concomitant significant infrapopliteal disease which seems to adversely affect the stent patency. The final outcome that affects the patient is not stent patency but limb salvage. As long as the patients' limbs are salvaged and they have an adequate quality of life, we feel it is acceptable to recanalise their long occlusions with stents. Our limb salvage rate of 81% supports this opinion.

There were limitations in our study. The study was retrospective, with a small sample size. However, it provided useful evidence and guidelines in treating patients with SFA occlusive disease, which is very useful in our practice. A randomised control trial comparing

stents and endografts for long segment occlusions in our local Asian population will be extremely useful. This will not only establish standardised guidelines for managing these patients, but will also provide the long-term outcome of nitinol stents in a larger group of patients. In conclusion, our experience suggests a useful role of SFA stents for long-segment occlusive disease for limb salvage in the medium term. These patients, however, require routine follow-up and further interventions to ensure their stent patency.

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