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Endovascular treatment of Angio-Seal-related limb ischemia-Primary results and long-term follow-up

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Endovascular Treatment of Angio-Seal™-Related Limb Ischemia – Primary Results and Long-term Follow-up

INAUGURAL-DISSERTATION
zur Erlangung der Doktorwürde der Medizinischen
Fakultät der Universität Zürich

vorgelegt von
Gian-Reto Jörg
von Domat/Ems

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Meinen lieben Eltern

In Dankbarkeit und Liebe

Inhaltsverzeichnis

	Seite
1. Abstract	4
2. Introduction	5
3. Materials and Methods	6
4. Results	7
5. Discussion	12
6. Conclusions	13
7. References	14
7. Verdankungen	16
8. Curriculum vitae	17

1. ABSTRACT

Objectives. To investigate primary success rates and long term follow-up of endovascular treatment of AngioSeal™–related limb ischemia.

Background. Current knowledge on optimal therapy of ischemic complications following application of AngioSeal™ is limited.

Methods. A single-center prospectively maintained data base was retrospectively interrogated and AngioSeal™ – related complications requiring endovascular treatment over an eight year time period were identified.

Results. Fifteen patients fulfilling the inclusion criteria were identified, resulting in an approximated incidence of 0.26% of all device implanted at our institution. In all cases, the complication was managed successfully in the absence of complications. 11 patients were treated with balloon angioplasty (PTA) and 4 with stent implantation because of suboptimal PTA results. Twelve patients were available for non-invasive vascular follow-up examination for a median time of 40 months postinterventionally. Only two patients needed a second intervention consisting of balloon angioplasty due to symptomatic restenosis. At final follow-up all patients were asymptomatic with no relevant restenosis.

Conclusion. Endovascular treatment for AngioSeal™–related limb ischemia with or without stent implantation results in an excellent immediate and long-term clinical and hemodynamic outcome.

2. INTRODUCTION

Femoral artery closure devices are widely used after cardiac and peripheral vascular interventions with the intention to decrease post-procedure manual compression time as well as bleeding complications (1). These devices have proven their efficacy in obtaining immediate haemostasis after sheath removal, allowing for early mobilization and hospital discharge, improving the patient's comfort. However, the risk of access-site-related complications for most femoral artery closure devices remains similar compared with manual compression (2). Device-related vascular injuries include pseudoaneurysm, arteriovenous fistula, hematoma, and femoral artery stenosis or thrombosis (2). The AngioSeal™ femoral artery closure device is a bioabsorbable, sheath-delivered device, which seals the puncture defect with a small collagen plug (1,3). Femoral artery stenosis and occlusions leading to severe limb ischemia or intermittent claudication following AngioSeal™ deployment have been described (4-6). Although ischemic complications after implantation of AngioSeal™ are rare, the resulting sequelae with intermittent claudication or severe limb ischemia are of clinical relevance. The treatment of choice of these device-related complications remains unknown. The decision to conservative, endovascular or surgical management depends on the severity of symptoms and anatomical localization of the obstruction. Small uncontrolled series have reported on successful surgical therapy with desobliteration and thrombectomy (4-5,7-11). Data on interventional therapy using percutaneous transluminal angioplasty (PTA) with or without stent implantation are limited to case reports and small series with a limited follow up period between three and six month (12-16). To our knowledge, the moist comprehensive study was reported by Steinkamp *et al.* using excimer laser-assisted recanalisation in 16 patients with clinical follow up at 6-month (15).

In summary, current knowledge on optimal therapy of ischemic complications following application of AngioSeal™ is limited, especially long term follow-up studies are currently lacking (Table I).

The aim of this study was to investigate success rate and long-term results of symptomatic AngioSeal™- related complications treated by an endovascular approach and to ascertain long-term outcome by means of clinical, duplex ultrasound, and ankle-brachial-index (ABI) at follow-up.

3. MATERIALS AND METHODS

Our single-center prospectively maintained data base was retrospectively interrogated for the time period between 2000 and 2007 for endovascular management of AngioSeal^{TM}–related complications. Only patients presenting with clinical symptoms such as rest pain or intermittent claudication were referred to the vascular clinic and had therefore been included in the analysis. Ultrasound exams of all patients treated with AngioSeal^{TM} was not routinely done. Non-invasive vascular examination including pulse wave recordings and measurement of the ankle-brachial index (ABI) had been performed at baseline and one day, 3, 6 and 12 months after the procedure and annually thereafter. At baseline and when restenosis was suspected the degree of the obstruction was determined by color coded duplex sonography (CCDS). Endovascular treatment was performed in the routine manner from a contralateral approach using a 4 to 6 Fr sheath inserted into the common femoral artery (CFA). After diagnostic angiography confirming the obstruction, a bolus of 5000 units of unfractionated heparin was injected intra-arterially. The lesion was crossed with a 0.018 wire (Boston Scientific, Natik, MA, USA) and angioplasty was done with over-the-wire balloon catheters with a long inflation time up to three minutes (Figure I). In cases with insufficient angiographic results self-expandable nitinol stents (6/30mm – 9/30mm) had been implanted (Figure II). Successful angioplasty was defined by a final angiogram with residual stenosis of less than 50% since some regression of the obstruction by healing of the dissection was expected and stent placement therefore when ever possible avoided. Post-interventional therapy consisted of aspirin 100mg/day combined with clopidogrel 75mg/day for four weeks after stent implantation. In case of clinical relevant restenosis or reocclusion a second endovascular treatment was performed using the same technique.

Clinical information were obtained from the prospective clinical data base and collected in an anonymized form. Descriptive data were expressed as median values and ranges.

4. RESULTS

In the time period of eight years (2000 to 2007) 15 patients fulfilling the inclusion criteria were identified. Over this period estimated 5800 closure devices of the type AngioSeal^{TM} were used at our hospital, resulting in an approximated incidence of device related complications of 0.26%.

Patient's characteristics are given in Table II. Median age was 55 (45 – 82) years, gender was uniformly distributed (8 men/7 women). Critical limb ischemia had occurred in five patients immediate after insertion of the AngioSeal^{TM} device, while all others presented with limiting claudication after placement of the device. The CFA was affected in 10, the superficial femoral artery (SFA) in five patients. In six patients an occlusion and in nine a high grade stenosis of the vessel was diagnosed by CCDS and confirmed by angiography. In all patients crossing the lesion from the contralateral approach and balloon angioplasty (PTA) was possible without further complication as distal embolization or bleeding at the puncture site. In four patients stent implantation was necessary due to insufficient result after PTA.

In two patients initially treated with plain angioplasty a second PTA without stent implantation was necessary due to a symptomatic restenosis of the common and proximal superficial femoral artery after 3 and 6 month, respectively. The final follow-up after 41 and 17 months of these two patients was unremarkable (Table II).

Three patients died during follow up unrelated to critical limb ischemia. The median follow-up time of the remaining 12 patients was 41 (4 – 79) months. At final follow up all patients were asymptomatic and no relevant restenosis was detected by CCDS.

Table I:

Reported therapy of lower limb ischemic complications after the use of AngioSeal™

Author (Reference)	Year	Patients [n]	Localisation	Therapy	Follow-up [month]
Stein (14)	2000	1	CFA	endovascular	n.a.
Goyen (12)	2000	5	CFA, PA	endovascular	0 - 4
Steinkamp (15)	2001	16	CFA, PFA, SFA	endovascular	0 - 6
Kirchhof (5)	2002	10	CFA, SFA	surgery (most)	2 - 3
Shaw (13)	2003	1	CFA	endovascular	3
Thalhammer (4)	2004	14	CFA, SFA, PFA, EIA, CIA	surgery (most)	n.a.
Abando (11)	2004	1	CFA	surgery	n.a.
Mukhopadhyay (17)	2005	1	n.a.	conservative	0
Biancari (9)	2006	3	CFA	surgery	0 - 3
Dregelid (8)	2006	4	CFA, SFA	surgery	0 - 1
Castelli (10)	2006	4	CFA, SFA	surgery	1 - 12
Lee (16)	2007	1	CFA	endovascular	1
Kadner (7)	2008	7	CFA	surgery	1 - 12

CFA: common femoral artery; PA: popliteal artery; SFA: superficial femoral artery; EIA: external iliac artery; CIA: common iliac artery; n.a.: not available

Table II:

Patients' characteristics

Age [years]	Sex [m/f]	Symptoms	Localisation	Lesion	Therapy	Follow-up [month]	Re-intervention
78	f	CLI	SFA	Occlusion	Stent	┼	-
46	m	CLI	CFA	Occlusion	Stent	┼	-
81	f	CLI	CFA	Occlusion	Stent	29	-
58	m	Claudication	CFA	Occlusion	Stent	42	-
65	f	Claudication	CFA	Stenosis	PTA	29	-
66	f	Claudication	CFA	Stenosis	PTA	45	-
55	m	CLI	CFA	Stenosis	PTA	41	CFA stenosis
69	m	CLI	SFA	Stenosis	PTA	41	-
54	f	Claudication	CFA	Stenosis	PTA	40	-
45	m	Claudication	SFA	Stenosis	PTA	58	-
54	f	Claudication	CFA	Stenosis	PTA	4	-
53	m	Claudication	SFA	Occlusion	PTA	17	SFA stenosis
82	f	Claudication	CFA	Occlusion	PTA	┼	-
54	m	Claudication	SFA	Stenosis	PTA	79	-
51	m	Claudication	CFA	Stenosis	PTA	37	-

m: male; f: females; CLI: critical limb ischemia; SFA: superficial femoral artery; CFA: common femoral artery; PTA: percutaneous transluminal angioplasty; ┼ dead during follow up.

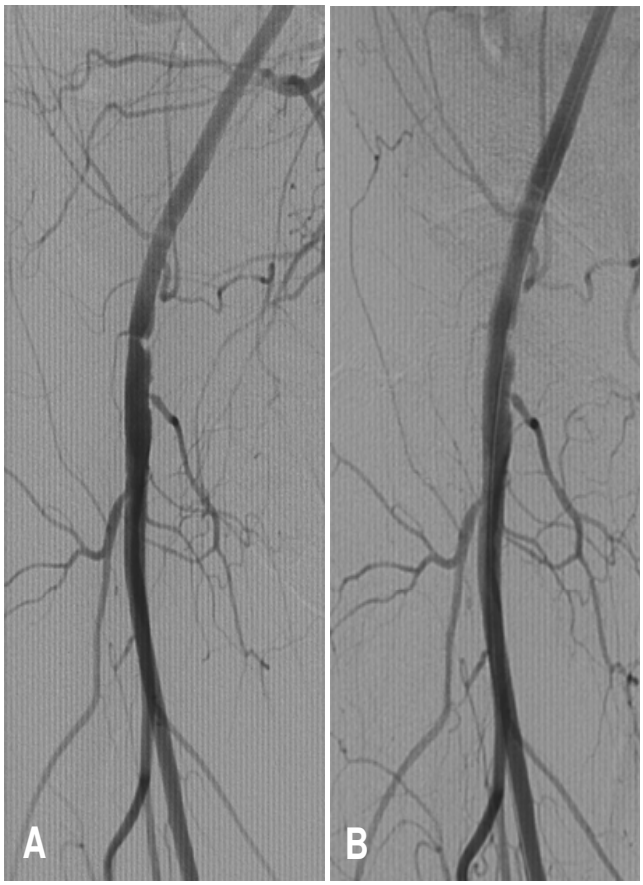

Figure 1: Angiogram of a 51 years old male patient with severe claudication of the right leg after AngioSeal™ implantation (A) The right common femoral artery shows a short circumscribed high grad stenosis, which was successfully treated with balloon angioplasty (B)

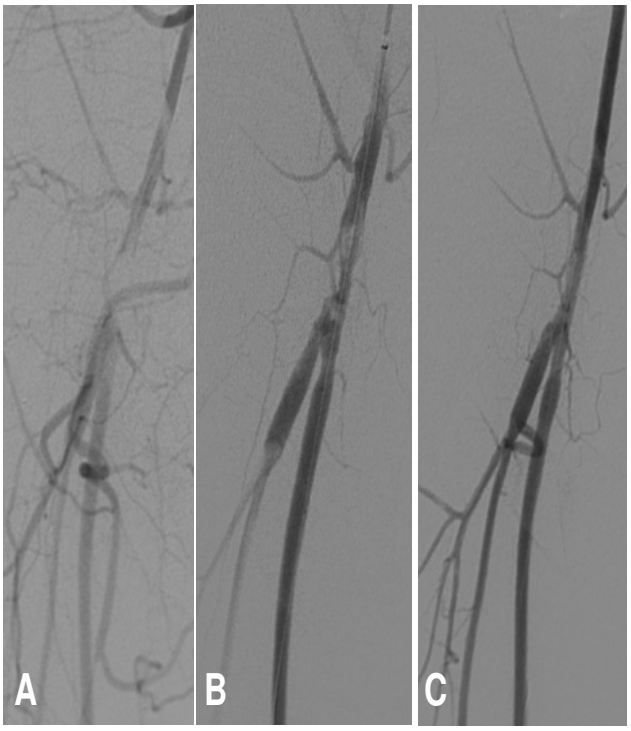

Figure 2: The angiogramm confirmed a short occlusion of the non-calcified right common femoral artery after AngioSeal™ application in a 58 years old patient (A). Due to dissection flow was still limited after angioplasty (B) and therefore a nitinol stent had been implanted (C)

5. DISCUSSION

This is the first report on long-term outcome of AngioSeal™–related vascular complications treated by an endovascular approach. Consistent with the current knowledge ischemic complications after the use of closure devices are rare with an estimated incidence in our series of 0.26% (2,4). Our data support the currently published data that PTA with and without Stent implantation in lesions due to AngioSeal™ is feasible and safe with good immediate results and excellent long-term outcome. Sole angioplasty is the preferred strategy in this setting; however in complete CFA occlusions or suboptimal PTA results stent implantation may become necessary. In our series, we did not find stent-related complications as kinking or intimal hyperplasia at follow up in the four patients treated. Arterial closure devices are increasingly used after percutaneous endovascular procedures and an absolute increase in ischemic complications may be expected in the future (2). Therefore, further data concerning the different therapeutic options and its outcome are needed. In cases with non-limiting claudication a conservative approach with “watchful waiting” is recommended since dissolving of the collagen plug may further reduce the obstruction (4,17). However, depending on the lesion characteristics (dissection, flow turbulences) short time anticoagulation might be discussed to avoid embolization. At our institution all clinical relevant complications had been successfully treated by balloon angioplasty and in some cases with stent implantation. From our experience surgical removal of the device with reconstruction of the vessel should be avoided since excellent long-term results after endovascular therapy can be achieved. In severe limb ischemia, immediate restoration of blood flow is mandatory and especially after coronary interventions open vascular surgery is associated with higher morbidity than the endovascular approach (18). In addition, the majority of patients are treated with dual antiplatelet therapy and this can increase the bleeding complications following surgical revision. Additional non-life threatening but disturbing complication include lymphatic fistulas, infections and delayed wound healing. Furthermore, possible complications of surgery in the groin area as lymphatic fistulas, infections and delayed wound healing might occur. Nevertheless, immediate and long term results after endarterectomy of the femoral bifurcation in case of heavily calcified lesions not related to AngioSeal™ are excellent (18-19). It is important to realize that the immediate result after PTA has not to be perfect, since healing of the dissection and dissolving of the AngioSeal™ plug will occur and regression of residual stenosis is common as we could document in our series by CCDS.

Our data support the currently published data that PTA with and without stent implantation in lesions due to AngioSeal™ is feasible and safe with good immediate results and excellent long-term outcome.

Sole angioplasty is the preferred strategy; however in complete occlusions with dissection stent implantation may become necessary. In our series, we did not find stent-related complications as kinking or intimal hyperplasia during follow-up. The incidence of restenosis up to five years was less than 20% due to the primarily non-atherosclerotic nature of the lesion.

The main limitation of the study is the small number of patients. Furthermore, no systematic ultrasound examinations after AngioSeal™ implantation had been performed which may result in an underestimation of asymptomatic AngioSeal™-related lesions. Finally, the estimation of the incidence of device-related complication was based on the number of devices used. However, we cannot exclude that patients with lower limb ischemic complication related to AngioSeal™ were not referred to our center for treatment despite the fact that the index endovascular procedure was performed at our institution.

5. CONCLUSIONS

Endovascular treatment with or without stent implantation for AngioSealTM–related limb ischemia can achieve excellent immediate and long-term clinical and hemodynamic outcome.

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8. Curriculum vitae

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