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Original Studies

Endovascular Repair of Popliteal Artery Aneurysms With Anaconda Limbs: Technique and Early Results

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Objectives: The objective is to report the feasibility and technique of treating popliteal artery aneurysms (PAA) with a stent made of nitinol rings externally supported by thin polyester (Anaconda limbs). **Background:** PAA are the most common peripheral aneurysms. The main limitations of stents used in these settings are: short lengths, longitudinal and horizontal compliance mismatch; graft failure from angulation and movement at the joint level; and dislodgment. **Methods:** This is a prospective multicenter cohort study of consecutive symptomatic and asymptomatic PAA treated in tertiary vascular centers. Outcomes included patency of the stent and postoperative time-to-independent-ambulation and to-climb-a-flight-of-stairs. **Results:** Fourteen PAA were treated in 12 men, age 72 ± 3 years. The median ASA classification was 2.5. The length of artery covered was 147 ± 41 mm. The PAA diameter was 31 ± 5 mm, 6 were symptomatic. One stent was used in 6 aneurysms, two in 7, and three in 1. The average stent diameter was 10 ± 1 mm. The length of the proximal neck was 24 ± 6 mm with a diameter of 9.8 ± 1.9, and length of the distal neck 23 ± 3 mm with a diameter of 8.7 ± 1.2 mm. In 6 aneurysms, the stent crossed the knee joint. There was no mortality, and one stent occluded (primary patency 93% at 6 ± 3 months). The median hospital stay was 1.7 days, time to independent ambulation was 3 hr and the time to climbing a flight of stairs was 1 day. **Conclusions:** The use of Anaconda limbs for endovascular repair of PAA is feasible and safe.

Key words: peripheral vascular disease; popliteal aneurysm; computerized tomographic angiography

INTRODUCTION

Popliteal artery aneurysms (PAA) are the most common peripheral aneurysms (70–85%) [1,2], are bilateral in ~50% and associated with abdominal aortic aneurysms in 30–50% of patients [1–3]. Men with significant comorbidities are most often affected [4,5] and the etiology is usually atherosclerotic. The natural history is not well defined, but pooled estimates of complications and onset of new symptoms in asymptomatic PAA treated conservatively is 41.6% (95% CI 35.6–45.6) [1–3,6] over a period of 3–5 years [7–9]: this includes pain because of enlargement or compression of surrounding structures, claudication, embolization, rupture and amputation (2.6%, 95% CI 2.2–3.1). Surgery is suggested for aneurysms >20 mm or with diameter 1.5 times that of the normal artery. The presence of mural thrombus is considered to increase the risk of new symptoms and complications [1–3,6,10].

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Conflict of interest: Dr. CS Cinà is a consultant for Vascutek and Cook.

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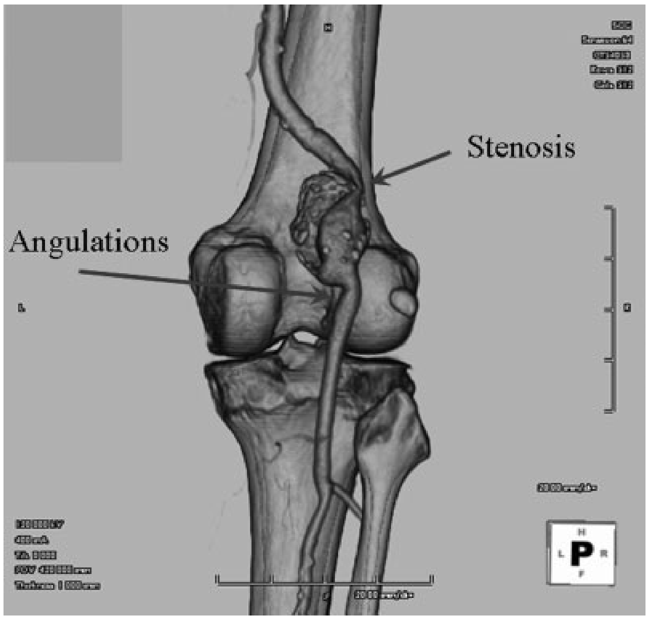

Fig. 1. Common anatomic-pathologic characteristics of popliteal artery aneurysms.

Pooled overall 5-year patency rates for open repair of PAA is 72% (95% CI 71–73) [7,8,11–15]. Mortality has been reported at 0–2% [9,12,16] and complications include: amputations (3.2%), occlusion of the graft (3.9%), wound infections (4.7%), foot drop (1.3%), deep venous thrombosis (1.6%), hematoma (3.4%), and mortality (2.0%) [4,5]. Although information regarding functional outcomes is limited, surgery is associated with considerable discomfort, prolonged rehabilitation and convalescence.

Endovascular repair of PAA appears to be a promising alternative to open repair. However, results appear to be inferior to open repair when considering only long term patency. Although PAA are typically limited arterial lesions for which endovascular repair may offer an ideal solution, there are specific anatomic, pathologic and functional characteristics which increase the complexity of this type of repair and potentially limit short and long-term success. These include the presence of stenosis because of associated atherosclerotic disease, impaired run-off due to distal embolization, angulation caused by the concomitant elongation of the artery, and repetitive stress caused by flexion and extension of the knee join (Fig. 1). In addition, no specific endograft device exists to treat PAA: home made covered stents, covered stents designed for tracheobronchial applications or limbs of endovascular grafts primarily designed to treat abdominal aortic aneurysms have been used. The main issues with these devices have been: limited flexibility, large delivery sheaths, short stent lengths, resulting in the need for multiple stents with consequent decrease in lumen and differential longitudinal compliance; graft failure from angulation and repeated movement at the joint level; and dislodgment of the stents at the landing and overlapping zones. In this setting, a stent often used is one made of PTFE and a continuous external exoskeleton made of nitinol (Viabahn and Hemobahn endoprosthesis, WL Gore, Flagstaff, AZ) [17,18]. Results appear to be acceptable, but inferior to those obtained with open repair. Finally, there are no studies reporting on an objective measure of improved early functional outcome after endovascular repair.

The purpose of this study is to report the feasibility, technique, and short-term patency and functional outcomes of PAA treated with a new endovascular stent made of thin polyester externally supported by separate nitinol rings (Anaconda limbs), which appears to have the ideal characteristics of length, flexibility and diameter.

MATERIALS AND METHODS

This is a prospective multicenter cohort study of consecutive PAA treated in three closely collaborating tertiary academic vascular referral centers from February 2007 to February 2008.

Inclusion

Symptomatic and asymptomatic patients were included if the PAA had a diameter >25 mm; a 20 mm proximal and distal landing zone; absent or treatable stenotic inflow disease; and at least one vessel run off extending to the foot. We excluded patients with acute ischemia or rupture at presentation.

Stent Graft

The Anaconda limb is a covered stents made of thin polyester externally supported by separate nitinol rings. It is available in 9 mm in diameter or greater and in length from 60 to 140 mm. The low profile and the flexibility render this endograft a seemingly ideal conduit for this application (Fig. 2).

Planning

All patients underwent ankle/brachial index (ABI) measurements before surgery, and volumetric contrast enhanced computerized tomography (CT) with a 64 slice scanner. Image post processing was done using the TeraRecon's Aquarius (TeraRecon) workstation (v.3.5). The length of the segment of artery to be covered and the diameter of the artery at the level of the anticipated landing zones was measured using 3-D rendering and center line reconstructions.

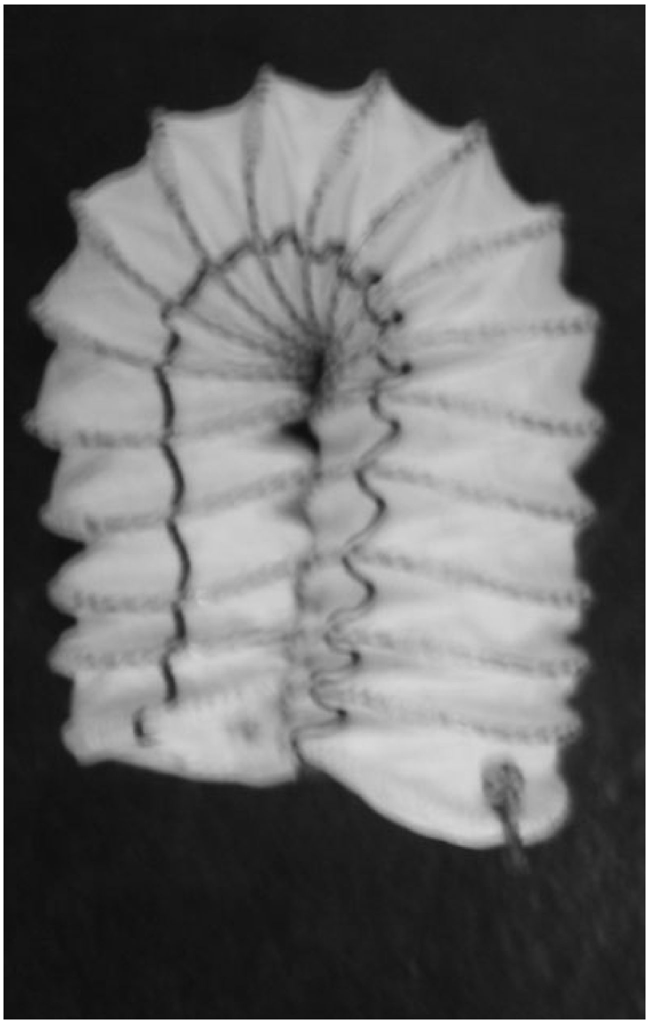

Fig. 2. The Anaconda limb is a flexible stent that can accommodated extreme degreed of angulation.

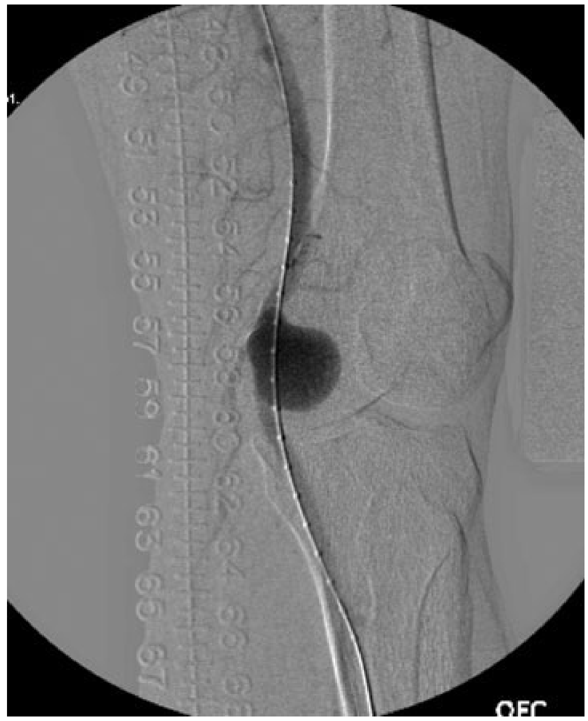

Fig. 3. The straight graduated catheter is in place.

In planning the stent graft the following principles were followed: avoid crossing of the knee joint when possible (to minimize angulation and buckling of the prosthesis); place the distal landing zone at least 35 mm proximal to the anterior tibial artery if possible (or if this were absent, 50 mm proximal to the tibioperoneal artery bifurcation); and use the least number of stents to cover a specific length or artery. We oversized the stent of 5–10% of the arterial diameter measured adventitia to adventitia. If more than one stent was required, we used an overlap of 20 mm. Data for planning were collated in a specifically designed form (see Appendix).

Surgical Technique

All procedures were performed in the operating theater using a 12-inch image intensifier C-arm fluoroscopy unit (OEM 9900, GE Health Care Technologies, Salt Lake City, UT). A radio-opaque ruler (Infant measuring tape, Allegiance Healthcare Corporation) was placed medial to the limb requiring surgical intervention. With the patient in supine position, under local anesthesia the leg was prepped and draped. We surgically exposed the common femoral artery (CFA) through a 4–5 cm horizontal incision centered on the artery and ~3 cm above the inguinal crease. Access to the artery was achieved using a technique described elsewhere [19]. After administration of heparin (100U/Kg), the CFA was punctured in a prograde fashion. A 9-French (Fr) sheath was then placed with the tip in the SFA and an angiogram performed through the side port of the sheath.

Under fluoroscopy, a straight graduated catheter (Cook Medical) and an angle tip 0.035 inch glide wire (Terumo Medical Corporation) was then used to cannulate the popliteal artery distal to the aneurysm. The glide wire was advanced into the posteotibial artery and the straight graduated catheter ultimately parked in the distal popliteal artery or tibioperineal trunk. The glide wire was exchanged for a semi-stiff guide wire with a platinum soft tip (Sorin Group). Another angiogram was performed at this point through the side arm of the 9Fr sheath to confirm the length of the artery that needed to be covered, and to define the distal end of the aneurysm and its relation with the anterior tibial artery or tibio-peroneal trunk (Fig. 3). The 9Fr Sheath was exchanged for the 14Fr delivery system of the An-

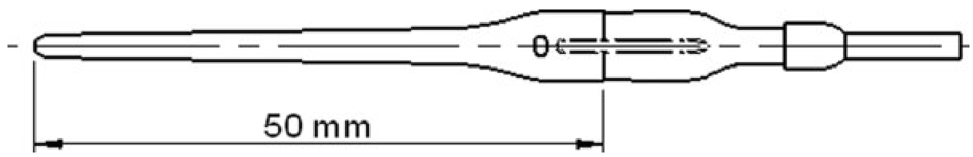

Fig. 4. Image of the tip of the Anaconda limb.

aconda limb which was advanced into the SFA and popliteal artery. The cone of the Anaconda system has a thinner distal component (20 mm in length and 1.5 mm in diameter) (Fig. 4). The tip of the tapered nosecone was advanced into the tibio-peroneal trunk as required in order to allow for distal deployment in the desired landing zone. Once the Anaconda stent was unsheathed a confirmatory angiogram was obtained either through the delivery system of the stent graft or thorough the 9Fr sheath repositioned in the CFA (Fig. 5). If necessary a second stent was inserted. Completion angiograms included inflow and tibial outflow to rule out distal embolization or dissections. Once all hardware was removed closure of the artery was achieved tightening the purse-string sutures and the wound was close in a routine fashion.

Postoperative Care

At the end of the procedure we applied a flexible stabilizing knee splint (Zimmer) which was kept in place for 7 days. We feel that this may be an adjunct to prevent early thrombosis by limiting the possibility of sluggish flow caused by forced knee bending at a time of high susceptibility of the stent to thrombosis. All patients received preoperative aspirin 325 mg and clopidogrel 75 mg which were continued daily after surgery indefinitely.

Follow Up

Follow up included ultrasound, plain X-rays and ABI at discharge; CT angiography within 4 weeks and every 6 months thereafter. A clinical assessment and ABI at 3 months was done in all patients. Functional results were assessed evaluating the time-to-independent-ambulation and the time-to-climb-a-flight-of-stairs after discharge from the postanesthetic care unit.

RESULTS

Technical Results

Overall 14 PAA were treated in 12 patients. In all cases aneurysm exclusion was technically successful. The average length of artery covered was 147 ± 41 mm. A single stent was used in 6 aneurysms, two stents were used in 7, and three stents were used for the repair of one popliteal aneurysm with extensive atherosclerotic disease of the SFA. When more than one stent was used, the overlap was 25 ± 9 mm. The average stent diameter was 10 ± 1 mm. The length of the proximal neck was 24 ± 6 mm with a diameter of 9.8 ± 1.9, and length of the distal neck 23 ± 3 mm with a diameter of 8.7 ± 1.2 mm. In six aneurysms the stent crossed the knee joint with the distal end of the stent landing 20–30 mm below the tibial plateau and in 8 the stent landed at or above the tibial plateau (0–35 mm). The distance of the distal stent from the anterior tibial artery was 39 ± 5 mm. In two cases, an angioplasty of the superficial femoral artery with a 6–8 mm balloon was necessary to advance the delivery system of the Anaconda limb.

Demographics and General Features

All patients were men, age 72 ± 3 years (range, 69–76 years). Hypertension was present in 12 patients

Fig. 5. Angiogram after deployment of the Anaconda limb.

Fig. 6. Computerized tomography with surface rendering displays the stent in the popliteal artery with the knee in resting position.

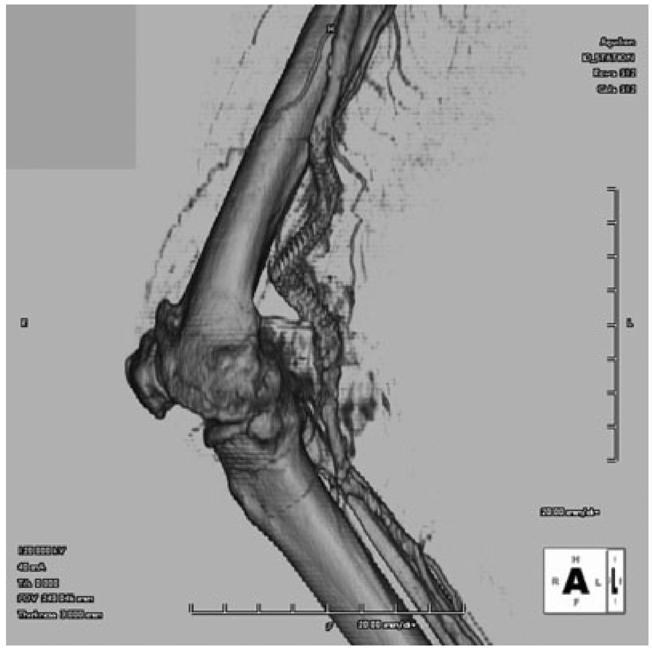

Fig. 7. Computerized tomography with surface rendering displays the stent in the popliteal artery with the knee in flexed position.

(100%), diabetes in 2 (17%), hypercholesteremia in 8 (67%), coronary artery disease in 10 (83%). The median ASA classification was 2.5 (2–3). Four had an associated AAA (33%), two of which had a previous endovascular repair. The average PAA diameter was 31 ± 5 mm (ranging 25–37 mm). Six (50%) were symptomatic (one had ischemia of the first toe requiring amputation; one claudication; two DVT secondary to compression; two localized pain). The number of tibial arteries patent was 3 in five cases, 2 in eight, and 1 in one (median 3).

Postoperative Outcomes

There was no mortality, and peri-operative technical success, defined as the procedural exclusion of the PAA without distal embolization, stent occlusion or ischemia within 30 days was 93%. There were no local complications at the access site including hematomas requiring explorations or lymph leaks. Overall, preoperative ABI was 0.95 ± 0.1 and postoperatively was 0.90 ± 0.2. One patient requiring 3 stent, with a combination of extensive superficial femoral artery stenosis requiring pre-emptive procedural angioplasty, and single vessel run-off (anterior tibial artery) developed acute stent occlusion before discharge and claudication but not threatening limb loss ischemia. At 3-month follow up his symptoms had improved to the point of walking 150–200 m, and he underwent successful endovascular repair of his contralateral PAA with the Anaconda limb device. Another patient with a small calcified femoral artery aneurysm required a patch arterioplasty of the access site due to dissection associated with insertion of the sheath. The median hospital stay was 1.7 days (ranging 1–3 days). The median time to independent ambulation was 3 hr (1–6 hr) from discharge from the postoperative care room and the time to climbing a flight of stairs was 1 day (1–2 days). At a mean follow up of 6 ± 3 months there were no graft-related complications or other graft occlusions, no endoleaks and no reinterventions. Computerized tomography displays the Anaconda limb in place 3 months after surgery with the knee in the extended position (Fig. 6) and with the knee flexed (Fig. 7).

DISCUSSION

The use of covered stents to deal with PAA has been shown to be feasible in several studies [16,17,20–23]. A great variety of stents have been used from home made devices to commercially available stents such as the Wallgraft™ (Boston Scientific) a polyester covered self-expanding nickel-based super alloy stent; the Hemobahn™, the Viabahn™ (W.L. Gore & Associates), the Jostent® (Jomed® USA), and the Fluency™ (Bard) which are self-expanding nitinol (a titanium/nickel alloy) stents using an ultra-thin PTFE graft. However, long-term patency has been reported to be lower than traditional open repair. The limbs of the Anaconda system used for endovascular repair of abdominal aortic aneurysm seem to be ideal for PAA repair. They are low profile, allow precise deployment, have a reliable fixation system, low permeability of the graft fabric, a high degree of flexibility, and resistance to kinking and external compression. A visual inspection of the Anaconda prosthesis and a comparison with others PTFE-based nitinol covered stents demonstrates the difference in physical characteristics. From a construction standpoint the exoskeleton of the Viabahn is made of a continuous nitinol filament arranged in a helical manner which may appear as separate nitinol rings, but in fact they are interconnected and very closely placed. In the Anaconda limb the exoskeleton is made of independent rings of nitinol each made of multiple strands. This construction increases the flexibility and the radial force. Figure 7 shows how the stent tends to acquire a spiral configuration when the knee is bent rather than buckling as it occurs with other endostents. Because of these characteristics we believe that these stents may improve the results of endovascular repair of PAA. Our feasibility study shows that excellent perioperative and short-term patency and functional results can be achieved with this stent provided that accurate planning and meticulous technique is used. The one patient with acute stent occlusion did not develop limb-threatening ischemia, in contradistinction with the typical scenario observed with spontaneous acute PAA occlusion. Other investigators have reported similar findings [17]. Although the explanation for this is not clear we may postulate that this is secondary to a smaller burden of thrombotic material or the absence of embolization of atheromatous debris in the setting of stent failure. In addition, poor runoff and severe inflow diseases are associated with increased graft failure in both endovascular and traditional open repair of PAA.

The generalizability and applicability of our results are strengthened by the prospective design of the study and the participation of three different centers. There are however some limitations and pitfalls. The study has a small sample size with a non randomized design, the follow up is limited, the outcome assessor was not blinded or independent, and most patients had a good infragenicular run-off with limited inflow disease. Several authors have reported increased short-term graft patency in popliteal aneurysms with at least two vessel runoff [5,21,23–26]. From a technical point of view, the delivery system of the Anaconda limbs suffers from the fact that the design was specifically created for use in the iliac arteries: large profile (18 Fr), an outer sheet which does not have a smooth transition with the cone, and limited pushability due to its non braided construction.

Kudelko et al. were among the first to describe the treatment of a PAA using a Wallgraft endoprosthesis with good short-term results [24]. Lagan et al. [26], however, in a series of nine patients treated with the same stent documented a patency rate of 56% at 18 months. They postulated that a good peripheral runoff with patency of at least two vessels was necessary to achieve good results. A systematic review of the literature reported an average 1-year patency rate of 90% for surgical treatment and 75% for endovascular treatment [5]. Although the link between runoff and patency is robust, we also believe that the lower patency of endovascular repair of PAA is linked to devices with suboptimal design characteristics. The use of PTFE covered stents with a continuous nitinol exoskeleton (Hemobahn and Viabahn, WL Gore, Flagstaff, AZ) has shown encouraging results in the management of PAAs. In addition to some case reports [27,28], two studies reported on the exclusive use of Viabahn endoprosthesis as the only device [17,18] with an overall patency at 1 year of 92% (95% CI 78–98%); one study reported on the use of a combination of Viabahn and Hemobahn with a patency at 1 year of 80% (95% CI 76–89) [30]; three studies reported on the exclusive use of the hemoban [17,20,29] with a an overall 1-year patency 87%, 95% CI 76–94%); and finally three studies reported the results on the use of a combination of several types of stents (including some Hemobahn and Viabahn) with an overall patency 1 year patency of 75% (95% CI 62–86%) [16,22,26]. If all these studies are considered together the overall 1 year patency is 82% (95% CI 76–89%). Although these results are certainly encouraging and support the concept that endovascular treatment for popliteal aneurysms is a reasonable option, the search for better devices needs to continue. We feel that the ANACONDA limbs are potentially an ideal device for the endovascular management of PAA. Further research, however, is necessary to ascertain the long term results and to improve the size and profile of delivery systems. Finally the availability of smaller caliber or stents with a tapered configuration may increase the number of patients in whom this device may be used.

CONCLUSIONS

Based on theoretical constructs and the results of our preliminary study we believe that use of Anaconda limbs for endovascular repair of PAA is feasible and safe. A large sample size and a longer follow up than the present study offers is necessary to define the true role of this innovative approach to the treatment of PAA.

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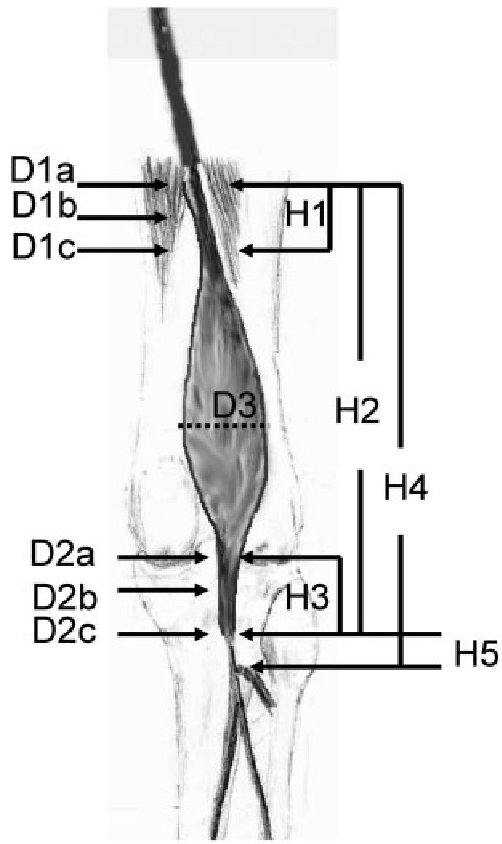
APPENDIX

Patient Name: ______________ DOB ____________ Study Number □□□ - □

POPLITEAL ANEURYSM WORKSHEET

	Diameters (mm) Three different levels over 20mm
Proximal landing (D1a,b,c)	/ /
Distal landing (D2a,b,c)	/ /
Aneurysm (D3)	
	Lengths (mm)
Proximal neck (H1)	
Distal neck (H3)	
Total length (H2)	
Graft to graft overlap	
D1a to anterotibial artery	
D2c to anterotibial artery	



	Patent	
	Yes	***No***
Antero-tibial artery		
Postero-tibial artery		
Peroneal artery		

Type of Prosthesis ______________________

Single component ______________________

Two components

Proximal ______________________

Distal ______________________

Logistics:

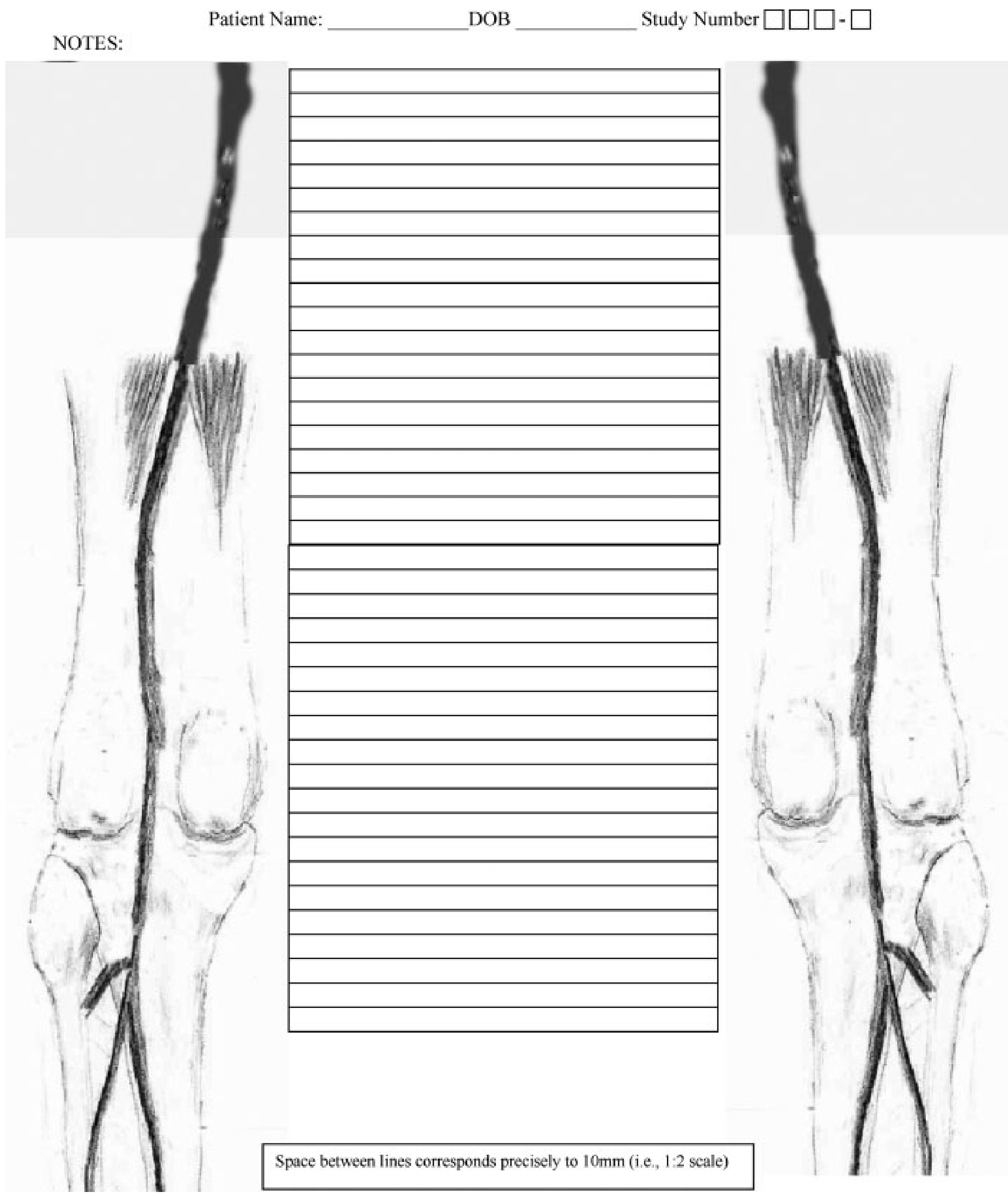
Measurement Date: ______________

Prosthesis Ordered ❑

Special Access Faxed ❑

Special Access Received ❑

OR Booked: ❑


Patient Name: ______________DOB ____________ Study Number □□□-□
NOTES:
Space between lines corresponds precisely to 10mm (i.e., 1:2 scale)