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Case Series

Femoropopliteal bypass for chronic lower limb ischemia: A prospective cohort study and single center cases series

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ABSTRACT

Background: Peripheral occlusive arterial disease (POAD) is a steadily increasing global epidemic. Femoropopliteal bypass (FPB) is the traditional therapeutic option whenever endovascular treatments failed or not indicated. We present our experience in lower limb revascularization.
Patients and methods: Prospective observational cohort single center study included 158 patients with intermittent claudication (IC) or critical limb ischemia (CLI). The patients were placed in 7 Rutherford categories & their angiographic findings were graded according to Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) criteria. The ipsilateral great saphenous vein was used for revascularization.
Results: male patients were 113 (71.5%); female were 45 (28.5%). Age ranged from 39 to 77 years, with a mean of 60.7 ± 7.8 years. About 79.1% of patients were in the 6th & 7th decades. Only 26 patients (16.5%) had severe IC & 83.5% had CLI. Almost all patients with Rutherford category 3–6 had an ankle brachial index (ABI) less than 0.70. Most Femoropopliteal lesions (n = 115, 72.8%)near half infrapopliteal lesions (n = 74, 46.8%) were of TASC II B & C types. Majority of patients received a vein graft. Distally, 100 grafts (66.7%) were sutured below the knees whereas the remainder were either behind (n = 31) or above the knees (n = 8). The follow up ranged from 1 month to 11 years. One & 5 year patency rates of vein grafts were 88.7% & 70.2% respectively.
Conclusions: FPB using saphenous graft yield a very good graft patency, low rates of amputation, morbidity and mortality. Long-term patency is excellent.

1. Introduction

Peripheral occlusive arterial disease (POAD) is a global epidemic. Most patients are asymptomatic. However, one-fourth of patients present with intermittent claudication (IC) or critical limb ischemia (CLI). Each has a different natural history. Intermittent claudication has mostly a good prognosis while only a minority of these patients ultimately losing their extremities. Critical limb ischemia, on the other hand, is a serious condition with a high rate of limb loss unless timely intervention is done [1–4]. A practical and simple definition of CLI is that proposed by the European Working Group on CLI. This group defined CLI as the presence of ischemic rest pain requiring analgesia for more than two weeks, or ulceration, or gangrene of the lower extremity with an ankle systolic blood pressure ≤50 mm Hg and/or toe systolic pressure ≤30 mmHg [5]. The first step in the management of PAD is modification of risk factors. Thereafter, medical therapy plays an important role in the management of the majority of patients with IC. Severe or disabling IC and CLI need urgent revascularization beside conservative therapy to avoid a potential limb loss. Femoropopliteal bypass (FPB) is the commonest open revascularization procedure with good results in the properly selected patients. Other methods of limb salvage such as endovascular intervention has recently emerged and gained an increasing popularity with relatively high coast and

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limited to certain TASC types. The optimal therapy of lower limb chronic ischemia is best tailored to the individual patient and should be provided by a team [6–10]. In this paper, the single center surgical revascularization of chronic lower limb ischemia using FPB is presented and evaluated in light of published relevant literature.

2. Patients and methods

Prospective single center cohort study conducted over an 11-year period (July 1st 2007 to July 1st 2018), 158 patients with symptoms and signs of IC or CLI were admitted to our department of vascular surgery affiliated to the public services of our university, for surgical revascularization of their chronically ischemic lower limbs. All patients were operated upon by one surgeon and team and received a FPB. This study was registered in the ResearchRegistry.com (registration number: researchregistry4932). This study was approved by the Institutional Review Board of for Medical Specializations (both scientific content and ethic committee). The work has been reported in accordance with the 2018 PROCESS criteria checklist [11]. Demographic characteristics were noted. Specific symptoms of POAD such as IC, rest pain, tissue loss, ulceration and gangrene as well as symptoms of atherosclerosis elsewhere in the body were recorded. Risk factors were identified besides details of preoperative medications. All cases who diagnosed as having revascularizable lower extremity POAD included in the study whenever the patient general condition was fit for a major surgery. All the followings conditions are excluded from the study: non-revascularizable lower extremity lesions, all patients had previous endovascular surgery and any patient had femoral-distal bypass. General physical and vascular examination of the affected and normal extremities was then performed. The Patients' clinical presentations were classified according to Rutherford classification (Seven categories). The diagnostic work up consisted of lipid and blood sugar measurement, Doppler ultrasonography (DUS) and peripheral angiography (conventional catheter angiography till 2011 and CT angiography thereafter) (Fig. 1). The patients were then grouped according to the anatomy of their lesions (TASC II). Smokers were strongly advised to quit. All patients received aspirin (100 mg/day) and statins whereas hypertensive patients prescribed antihypertensive medications and diabetics received hypoglycemic agents. B-blockers were given to patients with coronary heart disease. The selection of patients with CLI for surgery was based on angiographic findings. The preoperative preparation was standard. All operations were done under spinal anesthesia. The standard procedure of FPB by reversed autogenous ipsilateral great saphenous vein graft as described in operative textbooks was performed [10] (Fig. 2). The ipsilateral great saphenous vein (GSV) was harvested unless it was unavailable or unsuitable; in such a case a prosthetic graft (ePTFE or Dacron) were chosen. Vein grafts were always harvested through multiple skin incisions. Patients with gangrenous parts of the limbs (Rutherford category 6) received limited amputations in the same session. Very occasionally, an atheromatous CFA or popliteal artery received endarterectomy prior to graft anastomosis. Postoperative medications included aspirin (300 mg/day reduced to 100 mg/day after 3 months), statins (20 mg/day) and cilostazol (100 mg bid). Moreover, unfractionated heparin (UFH) was administered in a dose of 5000 IU 6 hourly via intravenous route for 7 days whenever the conduit was of bad quality, followed by Clopidogrel (75 mg/day). The patients were carefully monitored postoperatively for potential early complications and they were discharged home if there were no complications. Follow up visits were arranged to outpatient clinic. The complications and mortality were recorded. Graft patency was checked clinically and by DUS. In this study, the term "major amputation" was used to describe above- and below-knee amputations whereas forefoot or toe amputations were considered "minor."All information obtained by reviewing the medical records of the patients was entered into a Database created by Microsoft Access 2007 Software. The results were then collected by specifically designed queries and analyzed thereafter. Statistical analysis was performed using z test for 2 population proportions and T-test for 2 independent means.

Fig. 1. CT angiography of the lower limbs shows long segment left superficial femoral artery chronic occlusion.

Fig. 2. Proximal and distal site anastomosis for the saphenous vein graft.

3. Results

There were 113 males (71.5%) and 45 females (28.5%) with a male: female ratio of 2.5: 1. The age ranged from 39 to 77 years with a mean of 60.7 ± 7.8.8. The majority of patients (79.1%) were in the 6th and 7th decades. Obesity and smoking were the top co-morbidities as they were reported in three quarters of the patients. More than half of the patients (53.2%) were diabetics (Table 1). Severe IC (Rutherford Category 3) was reported in 26 patients (16.5%) while the remaining 83.5% of patients had CLI (Rutherford Category 4–6). Near half the patients (47.4%) were in Rutherford category 6 (having ulceration or gangrene). Worthy to note that all patients with Rutherford category 6 had underwent a minor amputation of the gangrenous tissues concurrent with bypass surgery. The majority of patients (132, 83.5%) had absent popliteal and pedal pulses but preserved femoral pulse. A minority (Four patients) had absent femoral, popliteal and pedal pulses. In 21 patients (13.3%), the pulse status was not documented in the medical records. The left side exceeded the right, however the difference was not statistically significant (p value <0.05). All patients had measurement of ABI prior to surgery. ABI values consistent with severe ischemia (p value <0.40) were reported in more than half of the patients (89, 56.3%) while values consistent with moderate ischemia (0.40–0.69) was reported in 66 patients (41.8%). Only a few patients (3, 1.9%) had ABI indices of mild ischemia. The difference between the moderate and severe ischemia groups in their ABI values was statistically significant at p value <0.05. Comparing the number of patients who were considered to have moderate to severe ischemia by ABI measurements preoperatively to Rutherford Class (155 vs. 158), the difference was not statistically significant at $p < 0.05$. Table four nicely demonstrates how preoperative ABI value correlated very well with Rutherford category. Almost all patients with Rutherford category 3–6 had ABI less than 0.70 (consistent with moderate to severe ischemia). Only 3 patients (mostly claudicants) had ABI above 0.7 (Table 2). The vast majority of CFAs (146, 92.4%) were patient. In regard to the popliteal arteries, although the Doppler findings were not recorded in 71 cases (45%), almost a similar number of patients (69) had mildly narrowed or patient arteries. The SFAs were either occluded (55, 34.8%) or moderately to severely stenosed (98, 62%). Most DFAs were mildly to moderately narrow (137, 86.7%). Most of the leg arteries (143, 90.5%) had no reported Doppler findings. In regard to angiography, conventional catheter angiography was performed in 53 (33.5%) patients who were received in the period 2007–2011. CT angiography was routinely done thereafter (in 105 patients, 66.5%). According to the angiographic findings, the stenotic and/or occlusive arterial lesions were classified using TASC II criteria, Table 3 shows this classification. We observe that only 43 patients (27.2%) had type C and D femoropopliteal lesions and only 84 patients (53.2%) had type C and D Infra-popliteal Lesions. All grafts were proximally sutured to the CFA. Four patients had endarterectomy of CFA prior to the procedure of FPB. Types of grafts and their sites of distal anastomoses are shown in Table 4. The vast majority of our patients (n = 150, 94.9%) received a vein graft while prosthetic grafts were occasionally used (Dacron 5 and ePTFE 3). Two thirds of the vein grafts were distally placed below the knees (n = 100, 66.7%) whereas grafts behind and above the knees came next (31 and 8 respectively). It is of interest to note that 1-year patency rates of vein grafts differed according to their distal site of anastomosis. Retrogenicular grafts achieved 100% patency (31/31). In contrast, above-knee grafts were 87.5% patient (7/8) very close to below-knee grafts (86/100, 86%). In other words, retrogenicular grafts were superior to either above-knee or below-knee grafts in term of 1-year patency rates. The difference was statistically significant ($p < 0.05$). The hospitalization period ranged from 2 to 45 days with a mean of 6.9 day. Most patients (n = 123, 77.8%) stayed for ≤ 7 days while 29 patients (18.4%) stayed for 8–14 days. A few patients (n = 5) stayed for 15–21 days and a single patient stayed for 45 days. Table 5 displays the postoperative complications. The commonest postoperative complication was SSI (n = 39, 24.7%). Other less frequent complications were managed conservatively. Very few postoperative interventions were necessary such as wound debridement (n = 9), evacuation of wound hematoma (n = 4) and graft thrombectomy (n = 2). Three patients (1.9%) had major amputations (2 above-knees and one below-knee) performed 9 weeks, 3 months and 4 years postoperatively. One above-knee amputee died on the 9th postoperative week. Seven patients (4.4%) had minor (forefoot or toes) amputations. Four patients (2.5%) died in the first 9 weeks postoperatively. They were 3 women and one man aged 60–75 yrs with a mean age of 67. All had multiple co-morbidities with an ABI < 0.40 and Rutherford category 5–6. Three received BK-RSVG while one received a Dacron graft. SSI complicated 3 while early graft occlusion and AK-amputation recorded in one patient. The patients succumbed in 1st, 2nd and 9th postoperative weeks due to AMI, septic shock and CVA. Four other patients (2.5%) died 2–4 years after operation due to CVA and HF. Worthy to mention that all these patients had their grafts patent until their death. The follow up ranged from 1 month to 11 years with an average of 4.5 years. Table 6 displays the patency rates of vein grafts over time. There is a gradual decline in the graft patency over time (from 88.7% at 1 year to 70.2% at 5 years). The 1-year patency of all prosthetic grafts in this study was 87.5%. It was 100% for ePTFE and 80% for Dacron grafts. When these patency rates of Dacron or ePTFE grafts were compared with vein graft patency, the difference was not statistically significant ($p < 0.05$).

Table 1
Displays the risk factors or co-morbidities.

Co-morbidities			
Co-morbidity	Gender		Total, no. (%)
	Male	Female	
Obesity	87	33	120 (76)
Smoking	103	16	119 (75)
DM	44	40	84 (53.2)
HTN	43	19	62 (39.2)
IHD	40	16	56 (35.4)
Hyperlipidemia	33	12	45 (28.5)

Table 2
Correlation between preoperative ABI values and Rutherford categories.

Correlation between preoperative ABI values and Rutherford Category					
Preoperative ABI	Rutherford Category				Total
	3	4	5	6	
<0.40	7	11	17	54	89
0.40–0.69	17	13	15	21	66
0.70–0.90	2	0	1	0	3
Total	26	24	33	75	158

4. Discussion

Peripheral arterial disease is a steadily increasing global epidemic. It has a range of clinical manifestations. Symptomatic patients may present with IC or CLI [12]. Intermittent claudication mostly has a benign course responding very well to a conservative approach [13]. CLI, on the other hand, is a grave disease. Major lower extremity amputations at 1 year occur in approximately 20%–40% of untreated CLI patients [14]. Herein, we discuss the results of a single center one-surgeon experience in surgical

Table 3
TASC II Class in this case series.

Femoropopliteal Lesions		Infra-popliteal Lesions	
Grade	Number (%)	Grade	Number (%)
A1	14 (8.9)	A	26 (16.5)
A2	18 (11.4)	B1	12 (7.6)
B1	17 (10.8)	B2	21 (13.3)
B2	24 (15.2)	B3	15 (9.5)
B3	20 (12.7)	C1	16 (10.1)
B4	22 (13.9)	C2	26 (16.5)
C	22 (13.9)	C3	10 (6.3)
D1	18 (11.4)	D1	11 (7.0)
D2	3 (1.9)	D2	21 (13.3)
Total	158 (100)	Total	158 (100)

Table 4
Type of Graft vs. site of distal anastomosis.

Site of Distal Anastomosis	Type of Graft			
	RSVG	ePTFE	Dacron	Total
Supragenicular	8	1	1	10
Retrogenicular	31	0	1	32
Infragenicular	100	2	0	102
Not-mentioned	11	0	3	14
Total	150	3	5	158

revascularization of the chronically ischemic lower limb. PAD is becoming a major health problem in Western societies as the population continues to become more aged [15]. For instance, in Germany, the prevalence of PAD reached 20% among persons over 70 [16]. In the present series, the mean age was 60.7 years and most patients (79.1%) were in the 6th and 7th decades of their lives. However, 18 men (11.4%) were under 50. PAD is therefore not necessarily a disease of the elderly as young people can be affected as well. Males were predominant in this study with a male to female ratio of 2.5:1. According to Lawall et al., male predominance is noted among young people with PAD while sex distribution of the disease becomes equal among older people [16]. In the present study, males were predominant in both young and old age groups. It is of interest to note that women with PAD have earlier functional deterioration than men [1]. Moreover, the outcome of vascular surgical intervention is negatively influenced by female gender [16]. In PAD, there is an intimate association between the disease and medical co-morbidity particularly cardiovascular and cerebrovascular diseases. Hence, risk factor modification is essential to improve long-term survival [15,17]. The risk of CLI is amplified by the continued burden of atherosclerotic risk factors, especially diabetes and obesity [14]. Many patients in this study had multiple risk factors particularly obesity and smoking; each was observed in 75% of the patients. Patients with CLI who are medically undertreated have an eight-fold risk of major amputation and/or death. Unfortunately, less than one-third of patients with CLI present with optimal management of their risk factors. Accumulating evidence suggests that medical therapy particularly antiplatelet agents, statins, and beta-blockers improve graft patency and overall mortality of patients with PAD [13]. Based on this evidence, patients in this study were prescribed such medications before and after operation. Peripheral arterial disease is symptomatic in 25% of persons only while the remainder is usually asymptomatic [15]. All patients in the present series were, of course, symptomatic. Most of them (83.5%) had CLI while the minority (16.5%) had severe IC. Near half the patients (47.4%) were in Rutherford category 6 (having ulceration or gangrene). Intermittent claudication and CLI have different natural histories. While CLI is an absolute indication for limb revascularization, IC is not. Mild to moderate IC (Rutherford category 1 and 2) usually respond to conservative therapy unlike severe IC (Rutherford category 3) for which revascularization is a necessity [1]. Unfortunately, the state of peripheral pulses wasn't documented in 12 of our patients (13.3%). Four patients had absent femoral, popliteal and pedal pulses. These patients required endarterectomy of CFA to make FPB feasible.

Table 5
Complications.

Complication	Number
SSI	39
Hematoma	15
Skin necrosis	3
Graft thrombosis	2
Chest infection	1
AK-amputation (at 3rd postoperative month)	2
BK-amputation (at 4th postoperative year)	1
Minor (Forefoot or toes amputation)	7
Nil	104

Table 6
Patency of vein grafts.

Patency of Vein Grafts[a]		
Graft patency	Number	Percentage
1st year	133/150	88.7
2nd year	117/139	84.2
3rd year	98/124	79
4th year	74/105	70.5
5th year	59/84	70.2
10 years	8/23	34.8

[a] x-year graft patency = patient grafts at x year/number of patients completed x year or more.

The majority of patients (n = 132,83.5%) had preserved femoral but absent popliteal and pedal pulses most probably due to an occlusive disease of SFAs. In such patients, DUS, angiography and surgical exploration were necessary to choose the optimum site for distal anastomosis. The diagnostic assessment of PAD is based on physical examination, measurement of the ankle-brachial index (ABI), and duplex ultrasonography [16]. Prior to revascularization, some sort of peripheral angiography would be necessary as well. In this series, preoperative ABI values correlated very well with Rutherford category and hence, disease severity. Almost all patients with Rutherford category 3–6 had ABI less than 0.70 (consistent with moderate to severe ischemia) while only 3 patients (mostly claudicants) had ABI above 0.70. DUS revealed mostly patient common femoral and popliteal arteries but occluded SFAs. These findings were consistent with the principles of arterial bypass surgery (patent inflow vessel, segmental arterial occlusion and good distal runoff). Most DFAs (n = 137, 86.7%) had mildly to moderately stenosis. Although DFA is an important artery for the nourishment of the thigh, the severity of its disease doesn't affect

selection of patients for arterial bypass procedure. The leg arteries Doppler studies were mostly not documented probably because the results of these studies were not very impressive. Doppler US has many advantages, like no radiation, repeatability, functional evaluation of blood flow, velocity quantification and direct measurement of thrombus, arterial dilatation or narrowing [18]. Despite these valuable information provided by DUS, we don't believe it is a substitute for angiography as there is a wide inter-observer variability and long examination time. Moreover, in multi-segmental and distal arterial disease, DUS overestimates the stenosis. Hence, CT angiography is preferred [18]. In our series CT angiography (CTA) performed in two thirds of patients. Based on angiographic findings, the arterial lesions of the studied patients were categorized into TASC II A to D types. CTA has many advantages over catheter angiography. The time needed to perform CTA is much less compared to conventional catheter angiography and it is possible to cover entire limbs within a few seconds. CTA using a single shot intravenous injection of non-ionic contrast medium reproduces the entire arterial anatomy within 2–3 min [18]. The time factor is very important for patients with severe rest pain and/or impending limb loss. Moreover, CTA is less invasive and less likely to produce contrast-induced nephropathy, yet its quality is very good and sufficient enough to make a surgical decision. Hence, CTA has replaced catheter-based angiography for clinical assessment of the aorta and its branches [18]. Surgical intervention is indicated for IC when a patient's quality of life remains unacceptable after a trial of best medical therapy. Endovascular revascularization and/or open reconstruction are cornerstones for limb salvage in patients with CLI. Recent advances in catheter-based technology have made endovascular intervention the preferred treatment approach for infra-inguinal diseases in many cases. Nevertheless, lower extremity bypass remains an important treatment strategy, especially for reasonable risk patients with a suitable bypass conduit [15]. All cases in this series were managed by open surgery (including TASC II A and B lesions) due to lack of endovascular facility in our center. If endovascular facility was available, then a high percentage of our patients particularly those with TASC II A and B lesions could benefit from it. According to TASC guidelines, type A and B lesions are better managed by percutaneous angioplasty [4,9]. However, we observe that although such lesions constituted a major bulk in the present study, they were managed surgically rather than by angioplasty. The reason for this fact is the lack of endovascular intervention in our center at the time of the study. Furthermore, according to BASIL clinical trial, patients expected to live more than 2 years are recommended to have bypass surgery first [4,9]. The mean age of our patients was 60.7 years and they were expected to live beyond 2 years. This might be another justification for the use of bypass surgery in the present cohort despite having type A and B lesions. Vein grafts were used in 150 patients (94.9%). Surgeons should make every effort to use vein and view prosthetic material as a last resort [4,19]. Lower extremity bypass grafting is most successful with a good quality, long, single-segment autogenous vein of at least 3.5 mm diameter [20]. The autogenous vein continues to be the best available conduit with the highest patency rate and the best treatment option. Compared to all other revascularization options for infra-inguinal disease, the vein bypass has the best limb salvage and long-term survival in patients appropriately selected for the procedure [4]. Prosthetic grafts were used very occasionally in this study (5 Dacron and 3 ePTFE grafts only). Despite the advantage of shorter operation time when prosthetic grafts are chosen, there are some disadvantages. Infection, graft thrombosis, the need for postoperative anticoagulant therapy and poor long-term patency are few to mention [5]. Prosthetic graft failure is generally acute with acute limb ischemia and carries a high risk of distal embolization into the outflow tract, in which case the price of graft occlusion is the risk of limb loss. In comparison, vein bypass failure is more chronic and much less likely to result in limb loss [4]. It is worthy to note that 1-year patency rates of vein and prosthetic grafts in this study were almost equal (88.7% and 87.5% respectively). Nevertheless, we share most authors their preference of vein grafts [1,3,4,6]. All grafts in the present series were proximally sutured to CFAs. However, the distal anastomoses were either below-knee (n = 102), behind-knee (n = 32) or above-knee (n = 10). The big number of below-knee grafts could be related to the high percentage (73%) of TASC II A and B lesions which favor below-knee anastomoses. Nevertheless, the intra-operative state of arteries often directs the surgeon to choose a particular site for distal anastomosis regardless the TASC II classification [4]. This study was characterized by a few postoperative complications and interventions, short hospitalization period (an average of 6.9 days) and an adequate follow up (an average of 4.5 years). The commonest complication was SSI (n = 39, 24.7%) which was higher than the previously reported rate of 11% [3]. Such infections are worrisome in the presence of prosthetic grafts. Fortunately, most grafts in this series were venous and all SSIs ultimately resolved. The best 1-year patency was achieved by grafts sutured behind the knee while above-knee and below-knee grafts did not differ in their patency rates. We think that adequacy of the distal run off vessels might explain this result. The overall 1-yr and 5-yr vein graft patency rates were 88.7% and 70.2% respectively. These rates were comparable to the international published rates of 77%–84% at one year [4] and 70% at 5-yreas [3]. In regard to amputation as a study endpoint, 3 patients in the present series had major amputations (1.9%) while the reported rate is 12% [13]. Four patients died within 9 weeks due to non-surgical causes (AMI, CVA and septic shock) making an early mortality of 2.5% within the reported rate of 0–6.3% [3]. If mortality and amputation were combined together, a composite endpoint would be obtained which is the amputation-free survival (AFS). It is the preferred outcome measure in CLI and is defined as the time to major amputation and/or death from any cause [21]. In Our study the AFS was present in about 78.45% of the cases (p value < 0.007). The major limitations of the study were as follows: small sample size, lack of comparison group, and single-centre experience. In conclusion, surgical revascularization of lower limbs with severe intermittent claudication or critical limb ischemia following an adequate medical therapy and risk factors modification is a very effective therapeutic strategy. The optimum workup should include ABI, DUS and angiography. FPB using RSVG yielded very good graft patency, low rates of amputation, morbidity and mortality matching the international standards. Larger, multi-centric, comparative study required for stronger conclusions and recommendations.

Ethical approval

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Author contribution

Aram Baram: Surgeon in charge, study design, follow-up, data collection, manuscript revision, statistical analysis.

Twana N Abdullah: assisted in surgeries, follow-up, study design, data collection, drafting.

Abdulsalm Y Taha: Study design, data base creation, manuscript revision, statistical analysis.

Conflict of interest statement

None.

Guarantor

Aram Baram.

Research registration number

researchregistry4932.

Consent to publish

Written consent obtained from all participants that their operation photos, images may be used for scientific publications only.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijso.2019.09.005.

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