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Small Is Beautiful: Why Profundaplasty Should Not Be Forgotten

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Abstract
Background Surgical profundaplasty (SP)is used mainly as an adjunct to endovascular management of peripheral vascular disease (PAD) today. Results from earlier series of profundaplasty alone have been controversial, especially regarding its hemodynamic effect. The question is: Can profundaplasty alone still be useful? Our aim was to evaluate its role in the modern management of vascular patients.
Methods This was a retrospective outcome study. A consecutive series of 97 patients (106 legs) from January 2000 through December 2003 were included. In 55 (52%) legs, the superficial femoral artery was occluded. These patients were included in the current analysis. Of these patients 14 (25%) were female. Mean age was 71 ((11) years. Nineteen (35%) were diabetic. The indication for operation was claudication in 29 (53%), critical leg ischemia (CLI) in 26 (47%), either with rest pain in 17 (31%), or ulcer/gangrene in 9 (16%). Endarterectomy with patch angioplasty with bovine pericardium was performed in all cases. Mean follow-up was 33 (14 months. Mean preoperative ankle brachial index (ABI) was 0.6. Sustained clinical efficacy was defined as upward shift of 1 or greater on the Rutherford scale without repeat target limb revascularization (TLR) or amputation. Mortality, morbidity, need for TLR, or amputation were separate endpoints.
Results Postoperatively, ABI was significantly improved (mean = 0.7), in 24 (44%) by more than 0.15. At three years, cumulative clinical success rate was 80%. Overall, patients with claudication had a better outcome than those with CLI ($p = 0.04$). Two (4%) major amputations and 2 (4%) minor ones were performed, all in patients with CLI. None of the 9 (16%) ulcers healed.
Conclusion Profundaplasty is still a valuable option for patients with femoral PAD and claudication without tissue loss. It is a straightforward procedure that combines good efficacy with low complication rates. Further endovascular treatment may be facilitated. It is not useful for patients with the combination of critical ischemia and tissue loss.

Since the introduction of distal surgical revascularization and later catheter-based management, surgical profundaplasty is not commonly performed anymore. Results from earlier clinical series have been controversial. In a recent review, Earnshaw [1] concluded: "There is little literature and no science to provide clear recommendations for profunda disease. Indeed, the TransAtlantic Inter-Society Consensus has nothing to say on the subject." Calcified femoral arterial bifurcation is not readily accessible for the interventionalist either. A profundaplasty is a straightforward procedure with low morbidity and short hospital stay. Does it have any role at all in vascular surgery, or should it simply become part of medical history? The aim of our study was to clarify the outcome following open surgical profundaplasty in modern practice.

Methods

Between January 2000 and December 2003, 106 profundaplasties were performed in 97 patients at the Swiss Cardiovascular Center (SCVC) in Berne, Switzerland. Of the 97 patients, 14 (25%) were female. Mean age was 71

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(±11) years.The superficial femoral artery (SFA) was occluded in 55 (52%) cases. These patients were included in the study. Patient charts were retrospectively reviewed. Patient characteristics are seen in Table 1.

Indication for operation was lifestyle-limiting claudication in 29 (53%) and CLI in 26 (47%) patients, of which 9 (16%) had ulcer or tissue loss. Preoperative duplex scan and angiography were obtained. Mean preoperative ABI was 0.6.

Patient selection criteria included (1) severe stenosis of femoral bifurcation, especially of common and proximal profunda femoris artery with occlusion of the superficial femoral artery, (2) adequate proximal inflow or inflow to be improved by PTA/stenting, and (3) collaterals seen in angiography. Tibial runoff was not an exclusion criteria.

The operations were performed as primary surgical reconstruction. Previous PTA and/or stenting had been performed 27 times in 16 (29%) patients (iliac artery 6, common femoral 2, superficial femoral 14, profunda femoris 1, popliteal 4 times). Profundaplasty was performed as previously described by Martin et al. [2]. Arterial closure was done using bovine pericardial patch (Vascu-guard, Synovis Life Technologies Inc., St Paul, MN) in all cases. Mean (±SD) follow-up was 33 (±14.5) months. Sustained clinical treatment efficacy was defined as an upward shift of one or more on the Rutherford scale [3] without repeat target limb revascularization (TLR) or amputation. Mortality, need of amputation, or repeat TLR were solitary study endpoints. Cumulative freedom from surgical reintervention was defined as freedom from minor or major amputation or arterial reconstruction. Subgroup analysis was performed for Fontaine stages, for isolated (IP) or combined (IP with PTA or stenting) procedure, and diabetes mellitus. Ankle brachial pressure index (ABPI) was measured at baseline and postoperatively at intervals. All patients were followed up in the Department of Angiology at the SCVC.

Table 1 Patient characteristics

Age (mean, yr)	71 ± 11
Female	14 (25%)
Male	41 (75%)
Fontaine II	29 (53%)
Fontaine III	17 (31%)
Fontaine IV	9 (16%)
Smoking	41 (75%)
Diabetes mellitus	19 (35%)
Renal insufficiency	11 (20%)
Obesity	14 (25%)
Dyslipidemia	23 (42%)
Hypertension	38 (69%)
COPD	12 (22%)

COPD = chronic obstructive pulmonary disease, renal insufficiency = creatinine > 140 mg/ml, dyslipidemia = under treatment with statins, obesity = body mass index > 30 kg/m^2

Statistical analysis

Statistical analysis was performed using SPSS software (SPSS Inc., Chicago, IL). Preoperative factors predicting successful outcome were analyzed using Fischer's exact test. Kaplan–Meier survival analysis was used to estimate the rates of cumulative freedom from surgical reintervention and sustained clinical treatment efficacy. Statistical significance of observed differences were evaluated by the log-rank test. Wilcoxon signed-rank test was used to compare ABPI before and after revascularization.

Results

Patients were followed at the Swiss Cardiovascular Centre at three and six months and then annually by clinical examination, ABPI measurement, and duplex scan to ensure the patency of the profunda femoris artery. There was no 30-day mortality in the group of claudicants, but two patients (4%) with extreme critical ischemia died postoperatively from myocardial infarction. Perioperative complications are seen in Table 2. Minor surgical complications occurred in five (9%) cases: one (2%) superficial infection and three (4%) postoperative hematomas were surgically evacuated under local anesthesia. One (2%) developed postoperative pneumonia. Mean postoperative ABPI was 0.7. in 24 (44%) patients; it improved significantly (>0.15) after profundaplasty. The difference in pre- versus postoperative ABPI was less than 0.05.

Sustained clinical treatment efficacy according to Rutherford [3] was 80% at three years (Fig. 1). In five (9%) legs, a femoropopliteal reconstruction was performed during follow-up (2 in claudicants, 3 for critical limb ischemia). In five (9%) legs, an occlusion of SFA was postoperatively treated by PTA at an average of five months after the initial procedure. Two (4%) iliac arteries were stented to improve inflow. TLRs included two (4%) PTAs of the distal profunda. The overall TLR rate was 10 (18%), with some arteries undergoing more than one PTA.

Cumulative freedom from surgical reintervention was 84% at three years. There was a difference between clau-

Table 2 Perioperative morbidity

Hematoma	3 (6%)
Wound infection	1 (2%)
Myocardial infarction	2 (4%)
Pneumonia	1 (1%)

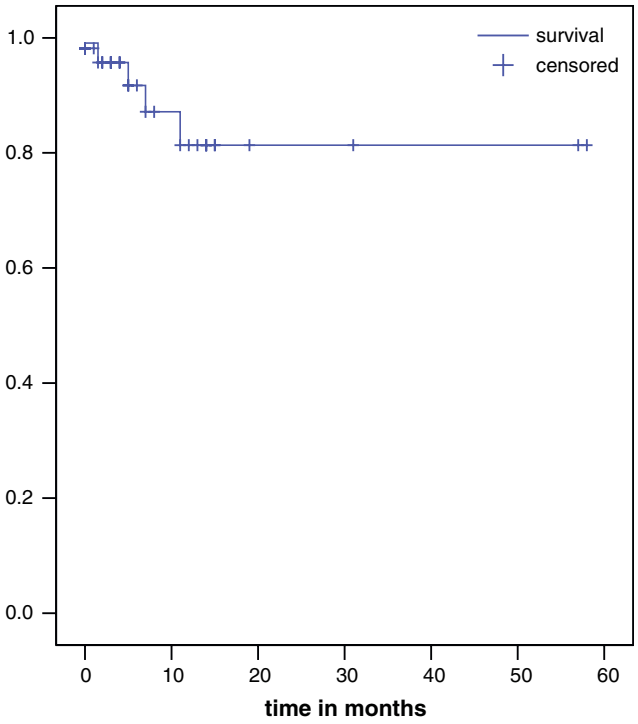

Fig. 1 Kaplan–Meier analysis for sustained clinical efficacy according to Rutherford et al. [3]

dicants (2, 7%) and patients with CLI (5, 19%). Clinically, subgroup analysis showed an upward shift in the Rutherford classification in claudicants versus CLI. Healing of ischemic lesions was not seen in any of the nine (17%) legs. In the remaining ones, two (4%) major and two (4%) minor amputations were performed.

Discussion

Profundaplasty alone is not commonly performed anymore. It has been replaced by vascular reconstructions and catheter-based interventions. The inevitable question today is: Does surgical profundaplasty have any role in the modern management of peripheral vascular disease?

The surgical importance of the profunda femoris artery was discussed by Morris et al. [4] and Leeds et al. [5] in the early 1960s. The revascularization of the deep femoral artery to treat peripheral arterial occlusive disease was introduced by Natali in 1962 [6]. Cotton and Roberts [7] popularized the deep extended profundaplasty in the 1960s. Martin and Bouhoutsos [8] favored a patch over a short length. The first series was published by Martin and Bouhoutsos [8], but it dealt mainly with proximal inflow procedures. Jamieson [9] declared that profundaplasty should be used to treat only critical ischemia and was not indicated when the superficial femoral artery is patent. In our unit, we knowingly apply it to patients with claudication, thinking of it rather as part of general management than as a last resort prior to amputation. In our unit, profundaplasty is performed in patients with a patent superficial femoral artery (47%) and in patients with an occluded superficial femoral artery (53%). It has been compared to femoropopliteal reconstructions as well [10]. To clarify the effect of profundaplasty alone, we excluded patients with a patent SFA from the analysis.

Many opponents of profundaplasty think it has a very limited hemodynamic effect [11–13]. However, in our study there was a significant postoperative increase in ABI (mean = 0.6–0.7). Of the 97 patients, 44% had an improvement of greater than 0.15 compared with their preoperative values.

Clinical improvement after profundaplasty has been reported [14–16], but generally the results have been controversial: Rollins et al. [17] reported healing of ulcers in 53% in a small series. Cotton and Roberts [7] reported success in 59%, treating 68 patients with severe claudication, rest pain, and ulcers. Fugger et al. [11] reported improvement in 38% in Fontaine stage III ischemia and 28% in IV. Amputations could not be avoided. Our group has compared the results of surgical profundaplasty to those of PTA [18]. In our study profunda revascularization was not sufficient in Fontaine class IV ischemia (healing in none of the of 9 cases), but it was beneficial in patients with rest pain.

In our series, nine (17%) PTAs were performed within one year of the operation. Interestingly, five (9%) of our patients had a PTA of their SFA, probably due to the introduction of modern advanced guidewires that started appearing during the study period. In this situation the patch may well facilitate access for the intervention. In our series, bovine pericardial patch was used in all cases, leaving the vein intact for further options. One (2%) superficial infection was seen. Miksic and Novak [19] reported impaired results in connection with PTA/stenting of the iliac artery. In our series, PTA/stenting of the iliac artery was performed in 18% to improve inflow.

In our series, profundaplasty showed a cumulative rate of freedom from any surgical revascularization in 80% at three years, which can be compared to the results of Sutter et al. [15], who showed a 75% rate at five years in patients with Fontaine stage II. Sustained clinical treatment efficacy was 80% at three years, which compares favorably with the results of Jamil et al. [12], who found a 35% success rate in a mixed series of patients.

Patients with critical ischemia may benefit from profundaplasty as well. However, in the nine patients with CLI and tissue loss, none of the ulcers healed. Conceivably, all amputations were performed in this group. Similar results have been reported by Miksic and Novak [19]. CLI with

tissue loss can be seen as an indication for femoropoliteal reconstruction, as reported by Martin and Bouhoutsos [8].

Remote superficial artery endarterectomy and distal stenting have been reported by Rosenthal et al. [20] with a primary patency rate of 60% at 33 months. The procedure includes femoral endarterectomy if needed. We have no experience with the technique described by Moll et al. [21], but obviously it is technically more demanding than profundaplasty alone.

In our study, a short hospital stay and a low rate of complications (no mortality or major morbidity in patients with claudication) were seen. Amputations and mortality were restricted to patients with catastrophic critical ischemia without any possibility of surgical revascularization. As such, profundaplasty does not mean difficulties in case vascular reconstruction is later needed, and the vein is left intact. The bovine pericardial patch is easy to access surgically, and it can readily be punctured for endovascular interventions.

Limitations of our study include its retrospective nature and its relatively small number of patients. However, our follow-up coverage was good and the results present proof of concept for the procedure.

In conclusion, profundaplasty, either alone or combined with proximal or distal endovascular intervention, can be used in selected patients suffering from claudication or critical ischemia. It brings good relief of symptoms and objectively improves distal circulation. The operation is straightforward and can be performed with short hospitalization and low complication rates. Profundaplasty is useful in critical ischemia with rest pain, but it should not be performed in patients with ischemic tissue loss.

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