Chapter 16
In the Patient with Profunda Artery Disease, Is Open Revascularization Superior to Endovascular Repair for Improving Rest Pain?

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Abstract The profunda femoris artery is the major collateral source of blood supply to the lower leg in patients with atherosclerotic obstruction of the superficial femoral artery. Open revascularization of the profunda is beneficial for patients with chronic limb ischemia, as technical success rates are high and durable patency has been demonstrated in a number of studies. However, there are strong advocates for increased use of endovascular techniques in the common femoral and profunda segments, reserving open surgery for patients who have failed catheter-based treatment. From currently available data, which consists almost entirely of retrospective analyses with the exception of one relatively small prospective randomized trial, we recommend that patients who are able to tolerate open surgery, do not have a hostile groin due to current or past infection or imbedded prosthetic material, and are not morbidly obese should preferably undergo open common femoral endarterectomy/profundaplasty as indicated. Endovascular therapy is a suitable option in those unable to tolerate open surgery, or in those with the aforementioned mitigating factors.

Keywords Femoral artery • Profunda femoris • Profundaplasty • Endovascular repair • Femoral endarterectomy • Femoral angioplasty • Rest pain • Critical limb • Ischemia

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Introduction

The profunda femoris artery (PFA) is the major collateral source of blood supply to the lower leg in patients with atherosclerotic obstruction of the superficial femoral artery (SFA). Atherosclerotic involvement of the PFA is usually limited to its ostium and proximal segment, and is almost invariably associated with extension of plaque into the common femoral artery (CFA) [1, 2]. Severe stenosis or occlusion of the CFA alone without extension into the PFA is less common, but in essence represents a functional obstruction to flow through the PFA. It has long been recognized that PFA revascularization can be beneficial in limb salvage for critical limb ischemia (CLI) and claudication [2–4]. However, technical considerations such as scarred groins and the presence of autogenous or prosthetic grafts originating near the femoral bifurcation can make the classic open profundaplasty a difficult and arduous procedure with increased potential for surgical site infection (SSI) [5]. Additionally, patients with severe peripheral arterial disease may have co-morbidities that increase the risk of open surgical repair.

With the widespread adoption of endovascular procedures for lower extremity arterial disease, there are strong advocates for increased use of these techniques in the common femoral and profunda segments, reserving open surgery for patients who have failed catheter-based treatment. Generally speaking, the PFA is well suited to endovascular revascularization, since the diseased portion is generally limited to the ostial segment and the adjacent CFA. However, this approach is not without its own set of challenges. A heavily calcified and stenotic femoral bifurcation can make selective catheterization of the PFA quite difficult. If the common femoral artery is occluded, the PFA may not be accessible by the standard approach from the contralateral leg or an arm. Furthermore, obstructions at the femoral bifurcation generally present with additional lesions involving the aorto-iliac inflow and/or the superficial femoral-popliteal outflow and tibial/pedal run-off. In these situations, management of the PFA may be dictated largely by the choice of technique to manage the other sites of disease [6].

For all of these reasons, the debate continues regarding the optimal management strategy for the profunda. Should endovascular profundaplasty be the first-line procedure for these patients and open profundaplasty be relegated to a historical footnote, playing only a limited role when endovascular procedures fail or are not feasible? Herein we aim to review the relevant literature, and make recommendations with regard to the appropriate use of both endovascular and open PFA revascularization techniques.

Search Strategy

In order to identify the pertinent data, PubMed, Medline and Google Scholar were queried for studies examining open and endovascular repair of occlusive disease of the common femoral and profunda femoris arteries according to the PICO outline (Table 16.1). All relevant studies examining open common femoral endarterectomy

Table 16.1 PICO table – endovascular vs. open intervention on the profunda femoris artery

P (patients)	I (intervention)	C (comparator group)	O (outcomes measured)
Patients with limb ischemia secondary to diseased profunda femoris or common femoral artery	Endovascular therapy	Open common femoral endarterectomy and/or profundaplasty	Technical success, primary patency, limb salvage

with or without profundaplasty were included without restriction on publication date since there has been no significant change in technique from the time of initial reports. With regard to endovascular interventions, however, only studies published after 2000 were included in order to more accurately reflect outcomes relating to current therapy in an era of rapidly advancing endovascular technology. Only two studies were identified that directly compared the two techniques [7, 8], one of which provided the only prospectively randomized, controlled data set [7]. The included studies were evaluated using the GRADE system [9, 10].

Results

A critical review of the literature did not provide data for either technique that clearly separated results for patients with rest pain from those with claudication, ulcer or tissue loss. In order to determine the most appropriate procedure for patients with rest pain alone, we have assessed the available published data regarding technical success, safety, immediate hemodynamic and clinical improvement, durability, the need for re-intervention, and limb salvage and with this information attempt to infer the best approach for varying patient circumstances.

Open Surgery: The Gold Standard

The first profundaplasty was performed in 1953 by Norman Freeman, but was not reported until 1961 [11]. Since then, open common femoral endarterectomy with or without profundaplasty has become a well-established approach for restoring the collateral function of the PFA to relieve claudication and limb-threatening ischemia, and to improve the healing potential for a below the knee amputation when limb salvage is not feasible. Success is dependent upon iliac inflow and tibial/pedal run-off as well as the quality of arterial collaterals across the knee. The latter can be estimated by calculating the profunda-popliteal collateral index (PPCI) derived from pre-operative segmental limb pressure measurements using the formula: $PPCI = ((AK\ Pressure - BK\ Pressure)/AK\ Pressure)$ [12]. An index greater than 0.5 predicts high resistance due to poor collaterals and is a strong indicator of failure, whereas an index of less than 0.25 has been associated with a 67 % success rate [12].

The outcomes for PFA/CFA endarterectomy are presented in Table 16.2. Data from the early 1970s showed that profundaplasty could be performed safely and with good results [2–4]. Towne et al. [4] presented a series of 237 profundaplasties in 209 patients, 69 (29 %) performed as an isolated procedure and 169 (71 %) in combination with some form of inflow augmentation. Operative mortality was 2 % and immediate technical success was achieved in 99 % of claudicants and 89 % of CLI. The patency rate for claudicants was 77 % at 5 years but only 23 % for CLI, with only an insignificantly lower success for isolated repairs versus those with associated inflow procedures. However, since patency was not assessed by direct visualization in many of the patients, failure may have been the result of progression of disease in the tibial/pedal run off bed rather than the profundaplasty itself. Amputation was required in 43 limbs, all but one in the limb salvage group. All 24 with below-knee amputations had patent profunda repairs whereas the profunda was occluded in 17 of 19 requiring above-knee amputation. Lawson et al. [3] demonstrated a 100 % technical success rate with no perioperative mortality for profundaplasty as a limb salvage procedure. Limb salvage was 87 % and 77 % and patency was 80 % and 60 % at 1- and 2.5-years, respectively. In 1987, Fugger et al. [13] described their experience with profundaplasty as a standalone procedure from a prospectively maintained database of 168 patients treated for SFA occlusion. 68 % of patients had clinical improvement, more commonly in those with better tibial runoff and without ischemic ulceration. The limb salvage rate was 68 %, and of those amputated only 41 % were above-knee. More contemporary data has consistently shown good outcomes as well. In 2001 Cardon et al. [18] published their experience with 110 limbs undergoing endarterectomy of the femoral bifurcation for claudication or CLI. Although only 84 % of procedures were technically successful, perioperative mortality was 1 %. Local morbidity was 22 %, but complications were mostly of a minor nature not requiring re-operation. Patency at 3- and 5-years was 95 % and 88 %. Clinical improvement was sustained in 80 % and 71 % of patients over the same intervals. Kang et al. (2008) [21] retrospectively reviewed 58 patients (65 limbs) from their prospectively maintained database who underwent common femoral endarterectomy (CFE). Two-thirds of these patients were claudicants and one-third had CLI. All cases were technically successful. 1-year and 5-year patency was 93 % and 91 % respectively, and there were no amputations. Concomitant endovascular inflow and outflow (hybrid) procedures were performed in 37 (57 %) limbs. Recurrent stenosis occurred in the CFA in only 1 of 28 isolated CFEs but in 4 of 37 of the hybrid procedures. In the same year, Kechagias et al. [23] published a similar retrospective series of CFE, with 15-year follow-up data. Endarterectomy extended into the proximal PFA in 39 % of these patients. Freedom from ipsilateral re-intervention was 68 %, 51 % and 42 % over 5-, 10- and 15-year intervals. However, only one re-intervention was required at the original endarterectomy site. Limb salvage was 94 % at 5 and 10 years, and 85 % at 15 years. Independent predictors of major amputation were current smoking status and critical limb ischemia. Al-Koury et al. [24], Ballotta et al. [26] and Desai et al. [27] have recorded similar results. Each of these studies achieved 100 % technical success with CFE, and primary patency rates of greater than 90 % at up to 7 years [26]. Limb salvage rates were high, 87 % in the Desai study and 100 % in both the Al-Koury and Ballotta series.

Table 16.2 Open common femoral and/or profunda femoris revascularization series

Author (year)	N (limbs)	Indication (%CLI) [a]	Technical success (%)	Primary patency	Limb savage	Peri-op mortality (%)	Complication rate
Towne (1981) [4]	209 (239)	60 %	100	77 % claudication, 23 % CLI (5 years)	80 % IP, 36 % PA (6 years)	2	17 %
Lawson (1983) [3]	11 (15)	100 %	100	80 % (1 year)	87 %	0	–
Fugger (1987) [13]	163	SFA occlusion	100	96 % (1 month)	68 % (Fontaine III,IV)	8.6	–
Mukherjee (1989) [14]	29	41 %	100	100 %	100 %	0	0 %
Springhorn (1991) [15]	22 (29)	69 %	96	96 %	–	0	31 %
Jacobs (1995) [16]	51 (68)	69 %	100	81 % (1 year), 54 % (4 years)	96 %	0	29 %
Hoch (1999) [17]	51 (53)	79 %	100	95 % (1 year), 88 % (3 years)	90 %	3.9	31 %
Cardon (2001) [18]	101 (110)	52 %	84	95 % (3 years), 88 % (5 years)	93 %	1	2.7 %
Nelson (2002) [19]	34	59 %	100	85 % (1 year)	100 %	0	15 %
Salvolainen (2007) [20]	97 (106)	47 %	100	–	96 %	3.6	9 %
Kang (2008) [21]	58 (65)	32 %	100	93 % (1 year), 91 % (5 years)	100 %	0	9 % (5 % major)
Chang (2008) [22]	171 (193)	54 %	98	97 %	95 %	2.3	22 %
Kechagias (2008) [23]	90 (111)	31 %	100	–	93 %	1.8	17.1 %
Al-Koury (2009) [24]	95 (105)	35 %	100	100 % (11 month)	95 %	1	7.6 %
Derksen (2009) [25]	140	25 %	–	–	–	0.7	14.3 %
Ballotta (2010) [26]	117 (121)	40 %	100	100 % (1 year), 96 % (7 years)	100 %	0	6.6 %
Desai (2010) [27]	81 (87)	48 %	100	93 % (3 years)	87 %	1	5 %

[a] *CLI* ischemic rest pain and/or tissue loss, Fontaine III-IV/Rutherford 4–6; *IP* inflow and profundaplasty; *PA* profundaplasty alone; dash (–) denotes no information available

Open surgery to address occlusive disease of the femoral bifurcation has stood the test of time and is both safe and durable. However, less invasive endovascular therapies are being applied with increasing frequency based on concerns regarding tolerance for open surgery in high risk patients, technical difficulties with re-operative groins, operating time, length of hospital stay and local wound complications. In an investigation centered on surgical site infections (SSI) following CFE, Derksen et al. [25] noted a 14 % SSI rate with 75 % of those requiring re-operation. Independent risk factors for development of SSI were re-operative groins and placement of drains at the initial procedure. Although similar incidences of SSI have been reported in other studies, most have been minor problems responding to non-operative therapy [21, 23, 24, 26].

Endovascular Intervention: The Alternative

Angioplasty of the PFA has been performed since the 1970s [28]. The results of this early data noted both clinical and hemodynamic improvement as well as limb salvage in the majority of patients with femoral-popliteal obstruction. Endovascular surgery has advanced significantly since that time, and has become the favored modality for many complex lesions of the lower extremity on the basis of low morbidity, shorter hospital stay and faster recovery [5]. Since outcomes will presumably improve along with rapidly advancing technology, only recent data (since 2000) is included in this review. The relevant studies are summarized in Table 16.3.

Both Silva et al. [29] and Dick et al. [32] reviewed patients treated by isolated balloon angioplasty of the PFA. 62 % of 32 limbs evaluated in the Silva study and all of the 55 in the Dick study had SFA occlusions. In the Silva study, technical success was achieved in 94 %, and procedural success (defined as technical success plus an ABI increase > 0.1) was 91 %. Freedom from amputation at 34 months was 94 % and ipsilateral freedom from re-intervention was 90 %. Those patients who underwent profundaplasty alone (31 %) demonstrated a significant improvement in ABI from 0.4 to 0.72 and none required major amputation. The data from Dick et al. is somewhat less convincing. Technical success was 85 % and there was no significant increase in ABI. Primary patency was 61 % and 48 % at 1 and 3 years respectively, leading the authors to conclude that there is only modest sustained benefit from this approach and it should be reserved for limb salvage in patients without a surgical alternative.

To specifically address the role of endovascular surgery in complex patients, Donas et al. (2009) [6] retrospectively reviewed a small group of 15 patients with critical limb ischemia (i.e. Rutherford class 4–6) at high risk for surgery and 2 or more prior groin procedures. These patients showed significant hemodynamic improvement with an average ABI increase from 0.3 at baseline to 0.66 at 30 days, 0.7 at18 months and 0.6 at 3 years. Rest pain was relieved and ischemic ulcers resolved within one month in all patients. Primary patency at 3

Table 16.3 Endovascular CFA/profunda interventions (published series since 2000)

Author (Year)	N (limbs)	Location	Indication (%CLI)[a]	Technical success (%)	Primary patency	Limb savage	Peri-op mortality (%)	Complication rate
Silva (2001) [29]	31 (32)	PFA	59	94	90 % (34 months)	94 % (34 months)	3	9 %
Stricker (2004) [30]	27 (33)	CFA/PFA	18	100	87 % (1 year)	96 % (30 month)	0	0 %
Silva (2004) [31]	20 (21)	CFA	43	100	90 % (1 year)	90 % (1 year)	5	0 %
Dick (2006) [32]	55	PFA	31	85	61 % (1 year), 48 % (3 years)	100 % (3 years)	0	1.8 %
Donas (2009) [6]	15	PFA	100	100	80 % (3 years) (2^{o} patency 86 % 3 years)	93 % (3 years)	0	0 %
Azema (2011) [33]	36 (40)	CFA	30	100	95 % (1 year)	97 % (1 year)	0	5.5 %
Bauman (2011) [34]	98 (104)	CFA	19	98	27 % CLI, 32 % claud (2 years)	94 % CLI 100 % claud (1 year)	0	2 %
Bonvini (2011) [35]	321 (360)	CFA/PFA	22	93	81 (1 year)	99 %	1.2	6.4 % (1.4 % major)
Paris (2011) [36]	26	CFA	39	96	88 % (14 months)	96 % (14 months)	0	–
Ahn (2012) [37]	61 (69)	CFA	45	81	67 % (1 year)	–	0	1.4 %
Bonvini (2013) [38]	94 (97)	CFA	20	91	86 % (1 year)	100 %	1	7.2 %
Datillo (2013) [39]	30 (31)	CFA	40	90	88 % (1 year)	96 % (1 year)	0	13 % (7 % major)

(continued)

Table 16.3 (continued)

Author (Year)	N (limbs)	Location	Indication (%CLI)[a]	Technical success (%)	Primary patency	Limb savage	Peri-op mortality (%)	Complication rate
Davies (2013) [40]	42 (44)	PFA +/– Fem-pop segment	73	94	81 % (1 year)	78 % (1 year)	0	2.3 %
Davies (2013) [41]	115 (121)	CFA	62	90	77 % (1 year)	84 % (1 year)	2.5	6 %
Yamawaki (2013) [42]	87 (104)	CFA	45	100	52 % (1 year)	95 % (1 year)	3.4	1 %
Mehta (2014) [43]	167	CFA	45	–	83 % (17 months)	95 % (17 months) All in CLI pts	0.6	2.4 %

[a]*CLI* ischemic rest pain and/or tissue loss, Fontaine III-IV/Rutherford 4–6; dash (–) denotes no information available

years was 80 %, secondary patency was 86 %. There was one amputation, a conversion from below-knee to above-knee, yielding an overall limb salvage rate of 94 % at 3 years.

Davies et al. [40] compared those patients undergoing balloon angioplasty on the PFA alone to those undergoing both PFA and femoral-popliteal (FP) segment interventions. Technical success (defined as post-procedural stenosis < 30 %) was achieved in 94 % of PFA alone and 85 % of PFA + FP cases. There was no significant difference in limb salvage (72 PFA vs. 78 % PFA + FP) and freedom from re-intervention (81 PFA vs. 96 % PFA + FP) between the two groups, and the authors concluded that endovascular PFA revascularization alone is a reasonable option even if the FP segment cannot be addressed.

Additional studies addressing endovascular interventions on the CFA and PFA are outlined in Table 16.3. Results have been relatively consistent over the reference time period, with high technical success rates of 81–100 %. For those studies reporting this metric, limb salvage rates of greater than 90 % were routinely seen at follow-up intervals of 1–3 years. Primary patency has been somewhat more variable, with reported rates varying from 52 to 95 %.

For those patients unsuitable for open repair and facing amputation, an endovascular approach may be the only option for limb salvage. Taylor et al. [44] specifically addressed this population in a retrospective review of 314 patients with CLI who had significant functional limitations or medical co-morbidities that prohibited open revascularization. Of these, 131 (42 %) patients underwent PTA and 183 patients (58 %) underwent major limb amputation. Perioperative mortality was not significantly different but was relatively high overall (4.4 % for amputees and 3.8 % for PTA), consistent with the high-risk nature of these patients. At 2 years, however, there was a significant survival advantage for amputees (48 % vs. 29 %). On life-table analysis there was unsurprisingly an ambulation difference favoring PTA in the short-term, but this difference became non-significant by 12 months. Maintenance of independent living status was also short-lived, with the advantage for the PTA group lasting only 3 months. This study included all lower extremity lesions and no subgroup analysis was performed on CFA and/or PFA lesions, but the suggestion is that PTA may not impart any significant benefit over primary amputation for these very debilitated patients.

Head to Head Comparison

The study by Diehm et al. [8] presented a retrospective review of 21 limbs with CFA/PFA obstruction and occluded femoral-popliteal segments with critical limb ischemia (57 % ischemic rest pain, 43 % ulceration and tissue loss). Patients underwent either PFA balloon angioplasty with or without stenting (67 %), or open profundaplasty (33 %). Both groups had 100 % technical success and in-hospital limb salvage, however there were 2 perioperative deaths (29 %) in the group of 7 patients subjected to endarterectomy. The results of these two cohorts together demonstrated a 55 %

mortality rate, 36% need for major amputation, and 49% ipsilateral re-intervention rate at 12 months. Ischemic rest pain resolved in 67% while ulcerations healed in only 11%, which is consistent with the findings of others that CFE/profundaplasty is significantly more likely to relieve rest pain than heal ischemic ulcers. A direct comparison of safety and efficacy between groups was not possible due to small sample size.

Linni et al. published the only prospective, randomized, controlled study in 2014 [7]. Of the 116 consecutive patients with atherosclerotic disease of the CFA, 80 met criteria for inclusion and analysis on an intent-to-treat basis. Patients were randomized to CFA balloon angioplasty and placement of a bio-absorbable stent or open endarterectomy. Interventions were technically successful in 97.5% of the endovascular patients and 100% of the open patients. There were 7 surgical site infections in the open group that were minor (not requiring intervention), and none in the endo group. Elevated body mass index appeared to be a promoting factor for SSI, consistent with the findings of others. Both operating time (68 vs.113 min) and length of hospital stay (1.6 vs. 6.8 days) were significantly longer in the open group. Six of the stent patients had early failures (5 of which were re-occlusions), versus none in the open group. At 1 year, primary patency was 80% for endo and 100% for open, and secondary patency was 84% vs. 100%. There was no significant difference between groups in post-operative rates of clinical improvement, ABI or limb salvage. Of the 6 stent failures, 5 required target lesion re-intervention whereas none were required in the open surgical group ($p = .023$). It is noteworthy that 57.5% of the endovascular treated limbs and 47.5% those managed by open endarterectomy had concomitant inflow and or infra-inguinal outflow procedures. The investigators did not stratify their results based on the presence or absence of adjunctive maneuvers or clinical presentation, probably because the number of patients in each group was insufficient for statistical analysis. Based on their demonstration of lower patency and the need for more interventions in the stent patients, despite the lower risk of surgical site infection, the investigators concluded that open CFA endarterectomy is superior to CFA stenting.

Recommendations

Open revascularization of the profunda has been shown to be beneficial for patients with critical limb ischemia. Technical success rates are high, and durable patency has been demonstrated in a number of studies [4, 21, 23, 24, 26] (evidence quality strong). For those with occluded femoral-popliteal segments, profundaplasty can provide limb salvage and clinical improvement in a majority of patients, or permit a lower level of amputation to below the knee when further revascularization is not feasible. This is especially true for patients with better tibial runoff and no ischemic tissue loss (evidence quality moderate). With regard to endovascular surgery, PTA of the femoral bifurcation appears to be a feasible and safe operation with high technical success rates (evidence quality strong). Operative mortality rates appear to be slightly lower for endovascular procedures although most recent studies demonstrate equivalence [21, 23, 24]. Immediate and long-term patency of endovascular repair generally appears to be less than that for

open surgery, which is confirmed by the limited amount of randomized data. However, in view of less frequent local wound complications, and shorter operating times and hospital stays it is difficult to establish a clear advantage for either approach. The addition of endovascular inflow and/or outflow procedures concurrent with the profunda/common femoral intervention appear to be readily accomplished regardless of the technique employed for relief of common femoral/profunda obstruction.

Recommendations

- For patients who are able to tolerate open surgery, do not have a hostile groin, and are not morbidly obese should preferably undergo common femoral endarterectomy and/or profundaplasty. (**evidence quality moderate, strong recommendation**).
- For those patients unsuitable for open repair and facing amputation, an endovascular approach may be the only option for limb salvage. (**evidence quality low, weak recommendation**).

A Personal View of the Data

There is no clear evidence to prefer the open surgical rather than the endovascular approach for rest pain versus the other Rutherford classes of ischemic severity. Comparison of outcomes is confounded by the retrospective nature of all but one report, the relatively small number of cases in most studies and the addition of varied ancillary maneuvers that may be the primary factor relating to immediate and long term outcomes. It is obvious that strong recommendations for the appropriate application of PTA/stent versus endarterectomy of the common femoral/profunda segment to maximize profunda collateral function will require a large multicenter, prospective study, preferably randomized.

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