Current efficacy of open and endovascular interventions for advanced superficial femoral artery occlusive disease

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Background: **There has been a marked paradigm shift in the treatment of symptomatic femoro-popliteal disease with a shift from open to endoluminal therapy. The consequence of this shift in therapy is poorly described. The aim of this study is to examine the clinical efficacy of this shift in treatment strategies.**

Methods: **A database of patients undergoing open (OPEN) and endoluminal (ENDO) intervention for TASC II C and D femoro-popliteal lesions between 1990 and 2010 was retrospectively queried. Kaplan-Meier survival analyses were performed to assess time-dependent outcomes. Factor analyses were performed using a multivariant Cox proportional hazard model for time-dependent variables.**

Results: **A total of 2593 limbs underwent either OPEN or ENDO treatment for symptomatic and anatomically advanced femoro-popliteal disease over a 20-year period. There was a two-fold rise in endovascular interventions between the first and second decade. In the first decade, 80% of the interventions were OPEN, while in the second decade, 61% of the interventions were ENDO. There were equivalent comorbidities in both groups, and survival was also equivalent. Endoluminal therapy was more commonly performed on claudicants. Thirty-day mortality was equivalent, but major morbidity was higher in OPEN compared with ENDO. Cumulative patency was equivalent in both groups with a similar reintervention rate. In contrast, clinical efficacy (freedom from recurrent symptoms, maintenance of ambulation, and avoidance of major amputation) was significantly higher in the OPEN group ($P = .002$). The presence of critical limb ischemia, diabetes, end-stage renal disease, and poor tibial runoff were predictors of poor anatomic and functional outcomes in both groups.**

Conclusions: **There has been a marked shift in treatment modality for advanced femoro-popliteal disease with a lowering of the symptomatic threshold for intervention over 2 decades, likely spurred by the ease of endoluminal interventions. Although peri-procedural and anatomic outcomes for both procedures are equivalent, it appears that open surgery carries a superior long-term clinical efficacy. This superiority is negatively influenced by poor preoperative ambulation status, high modified Cardiac Risk Score, worse presenting symptoms, the occurrence of major adverse cardiovascular events, poor tibial runoff, the absence of hemodynamic success, and occlusion of the original bypass. (J Vasc Surg 2013;58:1267-75.)**

Over half of all peripheral vascular disease involves the superficial femoral artery (SFA).[1] The first endovascular SFA interventions were reported over 40 years ago.[2] However, the past 20 to 30 years have seen the most rapid growth and change in this treatment field.[3] It is during this time that a paradigm shift in the treatment of symptomatic femoro-popliteal disease from open to endoluminal therapy has occurred.[4,5] Reports have suggested differences in anatomical and functional outcomes between these treatment modalities.[6] Objective performance goals have been sought and described for evaluating catheter-based treatment vs traditional surgical bypass in the treatment of critical limb ischemia.[7] However, the consequences of endovascular therapy are still evolving and still described via inconsistent reporting metrics.[8] We have previously demonstrated the impact of various factors on SFA interventions as well as the disparities in anatomic outcomes and objective performance goals in patients undergoing lower extremity endovascular interventions vs open bypasses.[9-11] This report examines the anatomic and clinical efficacy of this shift in treatment strategies over two decades of practice and the factors that drive functional outcomes.

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METHODS

Study design. A database of patients undergoing treatment of lower extremity arterial disease between 1990 and 2010 was retrospectively queried. The group receiving treatment of the SFA were identified and further stratified into those undergoing surgical revascularization and those receiving endoluminal therapy. Data utilization fell under the category of secondary use of pre-existing data as defined by the Institutional Review Board and Health Insurance Portability and Accountability Act.

Study setting. Academic Medical Center with 1000 beds in a catchment area of 5 million people. It is a tertiary and quaternary referral facility.

Methodology. For each patient captured, demographics, symptoms, existing comorbid conditions, and risk factors for atherosclerosis were identified. Therapy for individual patients was dictated by individual attending physician preference and was not regulated by unit guidelines. All patients received aspirin daily (81 mg or 325 mg) as a general cardiovascular protection agent. In the past 5 years, all patients received statins and beta-blockers in addition to aspirin for cardiovascular protection if no contraindications.

Noninvasive studies were performed initially on all patients receiving a work-up for peripheral arterial disease. Seventy-three percent of the OPEN group and 88% of the ENDO group had a duplex at last follow-up. Mean follow-up was 6.13 years (range, 0-19.4 years) and 4.56 years (range, 0-19.6 years) for the OPEN and ENDO groups, respectively. Patients with serious symptoms or signs of severe stenosis/occlusion based upon the initial noninvasive tests received angiograms. Angiograms and angiographic reports were reviewed; lesions were described by length, calcification, and patency and then categorized under the TransAtlantic Inter-Society Consensus II (TASC II) system.[12] Of note, those angiograms performed prior to TASC II publication were rescored according to TASC II criteria for consistency. The preoperative distal runoff was scored by the number of patent tibial vessels and according to a modification of Society for Vascular Surgery (SVS) criteria employed for determining bypass runoff (using the cumulative score for the distal popliteal from knee joint to first tibial branch; maximum 9+1) and each of the tibial vessels to the ankle (maximum 3 each), giving a maximum possible total score of 19.[13,14] This modification has been previously published by our group.[14]

Angioplasty was performed with a patient under systemic heparin administration (40-60 Units/kg), and completion angiography was performed to assess the technical result. Stents were utilized (at the discretion of the operator) primarily or as an adjunct for flow-limiting dissections, intimal flaps, or poor technical results (≥50% residual stenosis).

Patients underwent routine duplex ultrasound follow-up at 1, 3, and every 6 months following their procedure using criteria previously described by our group.[14] During follow-up, angiography was only performed if noninvasive studies suggested restenosis/occlusion (positive duplex scan with a drop in ankle-brachial index [ABI] of >0.15 and toe-brachial index of >0.1), and the patient had recurrent symptoms.

Statistical analysis. All statistical analyses were performed on an "intention-to-treat" basis. Measured values are reported as percentages or means ± standard deviation (SD). Patency and limb salvage rates were calculated using

Table I. Characteristics of patients

	ENDO	*OPEN*	P *value*
Demographics			
Limbs treated, No.	1177	1416	
Male	64	58	.05[a]
Average age, years	67 ± 13	67 ± 14	1.00[b]
Symptoms			
Claudication	53	50	.0001[c]
Rest pain	20	28	
Tissue loss	28	22	
Comorbidities			
Cardiac risk index	3.4 ± 1.8	3.0 ± 1.6	.0001[b]
Smoking history	73	83	.0001[b]
Current smoker	20	13	.0001[b]
Coronary artery disease	62	66	.035[b]
Congestive heart failure	29	26	.093[b]
Hypertension	91	72	.0001[b]
Diabetes	54	42	.0001[b]
Hyperlipidemia	67	44	.0001[b]
Statin	63	33	.0001[b]
Metabolic syndrome	44	29	.0001[b]
Chronic kidney disease	28	25	.081[b]
On hemodialysis	10	8	.072[b]
Transient ischemic attack/ cerebrovascular accident	13	6	.0001[b]
Carotid endarterectomy	12	11	.46[b]
Hypothyroidism	12	7	.001[b]
Hypercoagulability	4	6	.025[b]
Preoperative ambulatory status			
Ambulatory	54	61	.0001[c]
Ambulatory/homebound	40	38	
Nonambulatory/transfer	4	1	
Nonambulatory/bedridden	2	0	

ENDO, Endoluminal intervention; *OPEN,* open intervention.
Data are presented as percentages or mean ± standard deviations.
[a]Mann Whitney test.
[b]Fisher exact test.
[c]χ^2 test.

Kaplan-Meier analyses and reported using current SVS criteria and objective performance goals.[7,13] Standard errors are reported in Kaplan-Meier analyses. Definitions of all outcome parameters used are shown in the appendix. The log rank test was used to determine differences between life tables. Nonparametric testing or χ^2 were used to analyses individual variables. Univariant and multivariant Cox regression analyses were performed for independent variables. Analyses were performed using JMP software, version 9.0 (SAS Institute, Cary, NC).

RESULTS

Patient population. A total of 2593 limbs underwent either surgical revascularization (OPEN cohort) or endovascular treatment (ENDO cohort) for symptomatic and anatomically advanced femoro-popliteal disease over the 20-year period. In the first decade studied, 80% of all procedures performed were OPEN, while in the second decade, 61% of all procedures were ENDO. In total, 1177 limbs underwent ENDO treatment, and 64% of these interventions were in males, while in the OPEN group, 58% of the interventions were in males ($P = .05$; Table I). One thousand four hundred sixteen limbs underwent surgical revascularization (OPEN) by femoral to popliteal bypass. Fifty-six percent were bypasses to the above-knee popliteal artery; 44% were to the below-knee popliteal artery. Sixty-nine percent of the bypasses were performed with prosthetic graft, while the remainder (31%) utilized vein conduit. Fifty-three percent of the revascularizations were for lifestyle-limiting claudication in the OPEN group and, similarly, 50% of the interventions were performed for this reason in the ENDO group. The remainder in each group was for treatment of rest pain and/or tissue loss, and there was no significant difference between OPEN and ENDO in either category. When the Project of Ex-vivo Vein Graft Engineering via Transfection III (PREVENT III) risk of amputation score is applied, the distribution of the low-, medium-, and high-risk groups was significant with the open group having lower risk amputation patients (Table II). Age was similar in both groups. Past smoking history and current smoking significantly different between the groups, though each in an opposing distribution (Table I). Initial ABI between groups was similar (0.49 ± 0.17 vs 0.53 ± 0.15; OPEN vs ENDO; $P = 1.0$). Existing disease at other levels, aorto-iliac or tibial disease, was treated concomitantly during the same admission and was equivalent between groups (18% vs 16%; OPEN vs ENDO; $P = .9$). There were not a significantly higher number of patients in either group with the following comorbidities: coronary artery disease, congestive heart failure, chronic kidney disease with or without dialysis, and hypercoagulability (Table I). However, there was a significant difference between the groups regarding hypertension, diabetes, hyperlipidemia, metabolic syndrome, cerebrovascular disease, transient ischemic attack/cerebrovascular accident, and hypothyroidism (Table I). Preoperative ambulatory status did not differ between groups (Table I). All patients treated in this study had either TASC II C or D lesions. Patients receiving OPEN therapy had a significantly higher percentage of patients with number of TASC II D lesions (Table II). Metrics used to grade the runoff showed a difference in the number of tibial runoff vessels between the groups as well as a difference in modified SVS runoff score, higher in the OPEN group (Table II).

Immediate outcomes. The technical failure rates (failed, incomplete, or suboptimal revascularization) were 4% for patients treated with ENDO. Eventual need for open bypass surgery in the ENDO group in the following 3 months was 14%. These bypasses were done for thrombosed or failed endovascular intervention. Thirty-day mortality was similar in the groups. Peri-operative morbidity, consisting of MI, stroke, reintervention on same leg, access site complications, and wound complications, was higher in the OPEN group (Table III). Thirty-day major adverse cardiac events (MACE), defined as MI, stroke, or death, were higher in the OPEN group. Thirty-day major adverse limb events (MALE), defined as amputation or endovascular or open re-intervention on same leg, were higher in the ENDO group (Table III). Hemodynamically, there was an increase in ABIs in both groups, with >75% of all treated patients having an ABI increase >0.15, no difference between groups. However, the mean change in ABI was significantly greater in the OPEN group (Table IV). Following intervention, a similar percentage of patients in each group achieved immediate symptom relief. Postoperative ambulatory status was also similar between the ENDO and OPEN groups. Status at discharge did differ between the groups, with a larger percentage of ENDO patients transferring to rehabilitation facilities (Table IV).

Long-term anatomic outcomes. There was a small but significant difference in the primary patency, as defined by SVS reporting standards, between groups at 5 years ($P = .04$), but there was no difference in assisted primary patency, as defined by SVS reporting standards (Fig 1, *A* and *B*). There was also no difference in secondary/cumulative patency, as defined by SVS reporting standards, at 5 years (Fig 1, *C*). Overall, the number of major amputations (below- or above-the-knee) was similar between

Table II. Runoff and lesion characteristics

	ENDO	*OPEN*	P *value*
Tibial runoff			
Tibial vessels, No.	2.0 ± 0.8	1.9 ± 0.8	.003[a]
Modified SVS runoff score	5.7 ± 3.4	6.8 ± 4.5	.0001[a]
TASC II category			
C	61	4	.0001[b]
D	39	96	
Amputation risk score	*ENDO*	*OPEN*	P *value*
PREVENT III	2.4 ± 2.3	2.1 ± 1.9	.0004[a]
Low (0-3)	73	78	.0005[b]
Medium (4-7)	22	20	
High (>7)	5	1	

ENDO, Endoluminal intervention; *OPEN,* open intervention; *PREVENT III,* Project of Ex-vivo Vein Graft Engineering via Transfection III; *SVS,* Society for Vascular Surgery; *TASC II,* TransAtlantic Inter-Society Consensus II.
Data are presented as percentages or mean ± standard deviations.
[a]Mann Whitney test.
[b]Fisher exact test.

Table III. Mortality, morbidity, and objective performance goals

	ENDO, %	*OPEN, %*	P *value*
Mortality and morbidity			
Mortality	1.5	2	.456[a]
Morbidity	3	8	.001[a]
Reintervention rate	27	22	.004[a]
OPG			
30-day MACE	3	7	.001[a]
30-day MALE	11	5	.001[a]
30-day major amputations	4	2	.001[a]

ENDO, Endoluminal intervention; *MACE,* major adverse cardiovascular event; *MALE,* major adverse limb event; *OPEN,* open intervention; *OPG,* objective performance goals.
[a]Fisher exact test.

Table IV. Hemodynamic changes and immediate symptom relief

	ENDO	*OPEN*	P *value*
Hemodynamic changes			
Change in ABI	0.3 ± 0.31	0.56 ± 0.23	.0001[a]
ABI increase >0.15	79	76	.073[b]
Immediate symptom relief			
Resolved	41	53	.001[c]
Improved	42	38	
No change	16	8	
Deterioration	1	1	
Postoperative ambulatory status			
Ambulatory	78	81	.0001[c]
Ambulatory/homebound	9	17	
Nonambulatory/transfer	6	6	
Nonambulatory/bedridden	7	6	
Discharge status			
Home	73	79	.0001[c]
Rehabilitation facility	17	11	
Skilled nursing facility	9	8	
Hospital	1	2	

ABI, Ankle-brachial index; *ENDO,* endoluminal intervention; *OPEN,* open intervention; *SD,* standard deviation.
Data are presented as percentages or mean ± standard deviations.
[a]Mann Whitney test.
[b]Fisher exact test.
[c]χ^2 test.

groups. However, there were significantly more above-knee amputations in the ENDO group (Table V).

Long-term functional outcomes. Limb salvage was greater in the OPEN group at 5 years (*P* = .02; Fig 2, *A*). There was no difference between the groups regarding amputation-free survival, or patient survival plus limb salvage, at 5 years (Fig 2, *B*). MALE, defined as above, at 5 years was significantly higher in the ENDO group (*P* = .01; Fig 2, *C*). Clinical efficacy, defined as absence of recurrent symptoms, maintenance of ambulation, and limb preservation, at 5 years was significantly higher in the OPEN group (*P* = .02; Fig 2, *D*). Overall mortality was greater in the OPEN group at 5 years (*P* = .04; Fig 2, *E*).

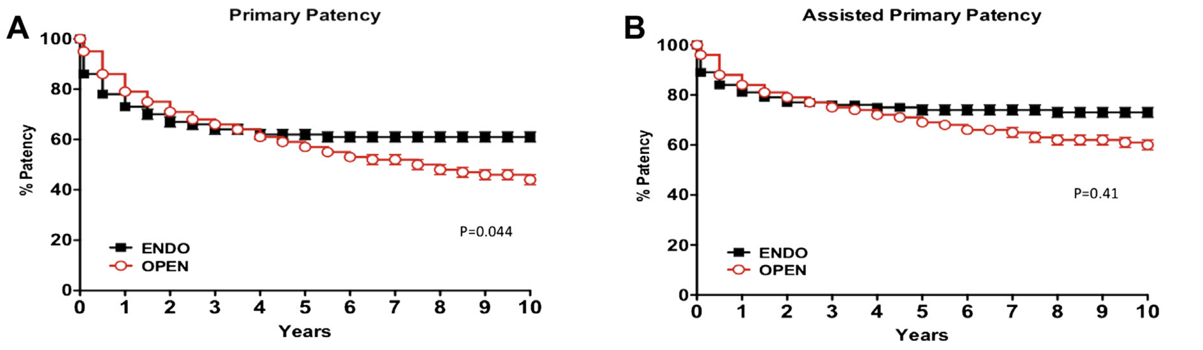
A Cox regression multivariant analysis was performed to examine factors that influenced the long term outcomes in both ENDO and OPEN groups.

ENDO group. The patient factors of creatinine >2 mg/dL, on hemodialysis, and the presence of diabetes, poor tibial runoff, and the absence of hemodynamic success had a negative influence on primary patency, assisted primary patency, and secondary patency (Table VI). Shorter survival was influenced by a high modified Cardiac Risk Score, presence of diabetes, presence of hemodialysis, worse presenting symptoms, and a MACE. Limb salvage was influenced negatively by presence of diabetes, creatinine >2 mg/dL, on hemodialysis, poor tibial runoff, the absence of hemodynamic success, and occlusion of the original site of intervention (Table VI). Clinical efficacy and amputation-free survival were effected by poor preoperative ambulation status, high modified Cardiac Risk Score, presence of diabetes, presence of hemodialysis, worse presenting symptoms, a MACE, poor tibial runoff, the absence of hemodynamic success, and occlusion of the original site of intervention (Table VI). Freedom from MALE was reduced by presence of diabetes, presence of hemodialysis, worse presenting symptoms, poor tibial runoff, and the absence of hemodynamic success (Table VI).

OPEN group. In the OPEN group, the presence of creatinine >2 mg/dL, and presence of diabetes, poor tibial runoff, use of prosthetic, and the absence of hemodynamic success had a negative influence on primary patency, assisted primary patency, secondary patency, survival, limb salvage, amputation-free survival, MALE, and clinical efficacy (Table VI). Worse presenting symptoms did not influence outcomes, and the presence of hemodialysis only influenced assisted primary patency. Lower survival was influenced by a high modified Cardiac Risk Score, presence of diabetes, presence of hemodialysis, worse presenting symptoms, and a MACE (Table VI). Decreased limb salvage was found in the presence of diabetes, on hemodialysis, worse presenting symptoms, poor tibial runoff, the absence of hemodynamic success, and occlusion of the original bypass (Table VI). Clinical efficacy and amputation-free survival, defined as any above-ankle amputation of the index limb or death (any cause), perioperative death, or any major adverse limb event (MALE), were effected by poor preoperative ambulation status, high modified Cardiac Risk Score, worse presenting symptoms, a MACE, poor tibial runoff, the absence of hemodynamic success, and occlusion of the original bypass (Table VI). The presence of diabetes decreased clinical efficacy while the presence of hemodialysis decreased amputation-free survival. Freedom from MALE was reduced by presence of diabetes, worse presenting symptoms, poor tibial runoff, and the use of prosthetic material (Table VI).

DISCUSSION

In this study, we analyzed the short- and long-term outcomes between groups of patients undergoing either SFA endovascular intervention or surgical revascularization for symptomatic disease in TASC II C and D lesions. The key differences between the groups in the 30 days postprocedure were MALE and 30-day major amputations, which were higher in the ENDO group, and all-cause morbidity and MACE, which were higher in the OPEN group. Immediate postprocedural hemodynamic/symptom improvement and restoration of impaired ambulation were equivalent in both groups over time. However, the long-term differences between the groups were mostly related to clinical efficacy rather than anatomic patency, with clinical efficacy significantly greater in the OPEN group compared with the ENDO group. This was despite the fact that the factors identified (poor preoperative ambulation status, high modified Cardiac Risk Score, worse presenting symptoms, the occurrence of MACE, poor tibial runoff, the absence of hemodynamic success, and occlusion of the original site of intervention or bypass) to contribute to poor outcomes were similar in each group. This improvement in clinical efficacy was



# at Risk	0	1	2	3	4	5	6	7	8	9	10
Endo	962	612	507	428	311	234	188	124	77	53	39
Open	1381	938	783	684	561	473	397	340	275	229	175

# at Risk	0	1	2	3	4	5	6	7	8	9	10
Endo	962	664	562	484	362	271	213	144	90	59	43
Open	1381	996	860	771	647	545	466	399	334	279	224

# at Risk	0	1	2	3	4	5	6	7	8	9	10
Endo	962	673	569	492	369	274	215	145	91	60	44
Open	1381	1005	866	778	657	553	472	405	339	283	227

Fig 1. Anatomic outcomes. Kaplan-Meier analysis of patients with open (*OPEN*) or endovascular (*ENDO*) interventions. Data are the mean ± standard error of the mean and number of limbs at risk shown in the table. No error bars are shown if the standard error of the mean is >10%, and the data set terminates if the number at risk is <10. Log rank sum test was performed for statistical analysis. **A,** Primary patency. **B,** Assisted primary patency. **C,** Secondary patency.

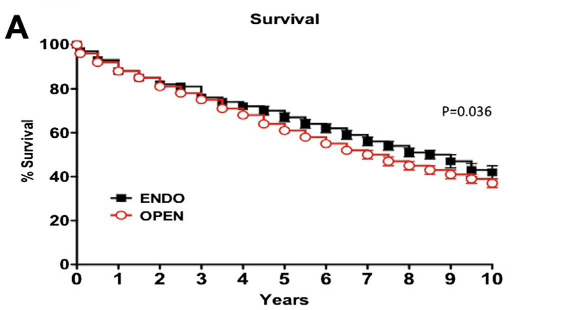
Table V. Minor and major amputations

	ENDO, %	*OPEN, %*	P *value*
Amputation			
No amputation	81	78	.001[a]
Toe and/or forefoot	6	10	
Major amputation	13	12	
Below-knee amputation	31	50	.0001[b]
Above-knee amputation	69	50	

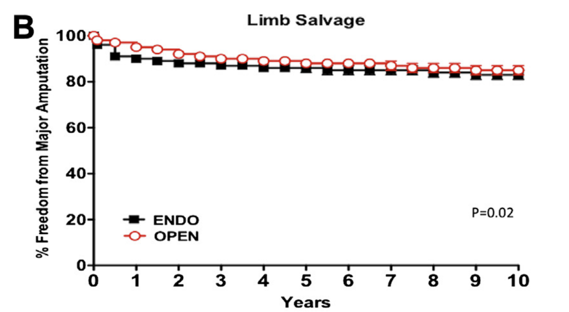
ENDO, Endoluminal intervention; *OPEN,* open intervention.
[a]χ^2 test.
[b]Fisher exact test.

not driven by survival, as there was a lower long-term survival in the OPEN group, but rather by the defined elements of absence of recurrent symptoms, maintenance of ambulation, and limb preservation. The factors we identified as important in this regard because of their negative impact on the superiority of OPEN bypass were poor preoperative ambulation status, high modified Cardiac Risk Score at presentation, worse presenting symptoms at presentation, the occurrence of MACE, poor tibial runoff, the absence of hemodynamic success, and occlusion of the original bypass. These are consistent with the literature.

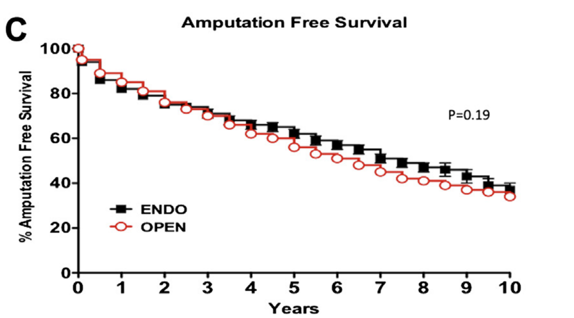
Presentation. This study focused on advanced TASC II lesions (C and D); however, compared with the ENDO group, the OPEN group had a greater percentage of D lesions. This would reflect the preference to treat these advanced lesions open, which was the recommendation of both TASC I and TASC II. We did not find that the patients in either group were more likely to present with more advanced symptoms of rest pain or tissue loss as, in this study, presenting symptoms were equivalent, suggesting that there was no bias in this particular regard. However, the PREVENT III risk of amputation was lower in the OPEN group compared with the ENDO group. This is also supported by the findings that the OPEN group had better runoff as evidenced by the statistically significant number of patent tibial runoff vessels as well as a lower modified SVS runoff score compared with the ENDO group. This must be understood to reflect appropriate selection bias and may have influenced the



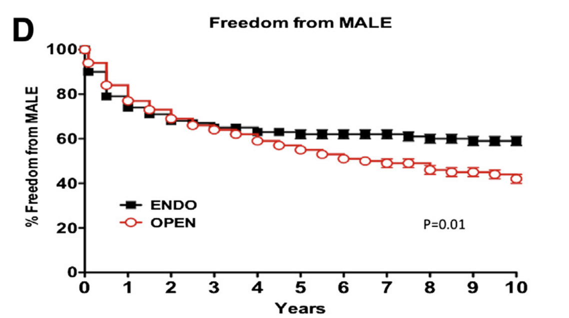
# at Risk	0	1	2	3	4	5	6	7	8	9	10
Endo	962	830	740	649	503	373	286	191	112	69	51
Open	1381	1167	1036	944	813	694	607	525	446	364	301



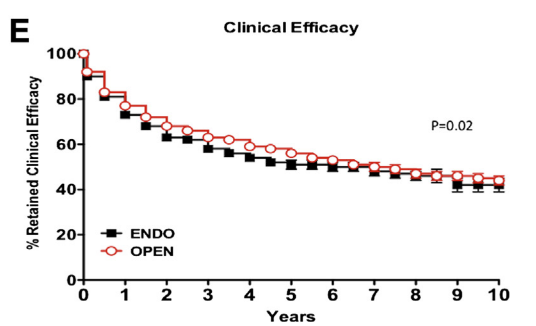
# at Risk	0	1	2	3	4	5	6	7	8	9	10
Endo	962	765	674	595	465	341	262	174	102	61	45
Open	1381	1090	951	849	717	607	524	447	374	300	240



# at Risk	0	1	2	3	4	5	6	7	8	9	10
Endo	962	743	634	555	439	340	260	173	102	45	28
Open	1381	1126	983	879	753	646	559	481	406	333	274



# at Risk	0	1	2	3	4	5	6	7	8	9	10
Endo	962	591	482	400	294	221	179	120	75	75	38
Open	1381	930	769	669	547	459	385	329	267	220	167



# at Risk	0	1	2	3	4	5	6	7	8	9	10
Endo	962	629	502	410	299	215	169	117	74	46	32
Open	1381	939	767	667	555	474	404	344	282	234	184

Fig 2. Functional outcomes: Kaplan-Meier analysis of patients with open (*OPEN*) or endovascular (*ENDO*) interventions. Data are the mean ± standard error of the mean and number of patients or limbs at risk shown in the table. No error bars are shown if the standard error of the mean is >10% and the data set terminates if the number at risk is <10. Log rank sum test was performed for statistical analysis. **A,** Survival. **B,** Limb salvage. **C,** Amputation-free survival. **D,** Freedom from MALE. **E,** Clinical efficacy. *MALE,* Major adverse limb event.

subsequent differences in clinical efficacy. Consistent with the literature, this study demonstrated that patients presenting with worse symptoms in both ENDO and OPEN had poorer short-term and long-term outcomes. We have previously shown that the presence of metabolic syndrome, diabetes alone, chronic kidney disease, and dialysis will negatively affect outcomes after SFA intervention.[9-11,15,16] The ENDO group has a greater percentage of patients with diabetes and metabolic syndrome, which is a reflection of the changes in demographics in the vascular population over time, linked to the shift to more endovascular procedures. Furthermore, several other authors have

Table VI. Multivariant proportional hazards analysis

		ENDO	
Patency	*Primary*	*Assisted primary*	*Secondary*
Diabetes	0.68 (0.53-0.88); *P* = .004	0.35 (0.25-0.66); *P* = .003	0.42 (0.22-0.42); *P* = .01
Creatinine >2 mg/dL	0.34 (0.32-0.67); *P* = .01	0.44 (0.34,0.55); *P* = .002	0.62 (0.43-0.84); *P* = .02
Hemodialysis	0.32 (0.22-0.45); *P* = .001	0.42 (0.26-0.65); *P* = .001	0.77 (0.65-0.94); *P* = .007
Worse pre-procedure symptom	0.42 (0.32-0.54); *P* = .001	0.31 (0.29-0.56); *P* = .001	0.31 (0.22-0.42); *P* = .001
Poor tibial runoff	0.44 (0.22-0.87); *P* = .01	0.32 (0.22-0.45); *P* = .001	0.72 (0.53-0.94); *P* = .02
No hemodynamic success	0.54 (0.43-0.69); *P* = .001	0.88 (0.32-0.66); *P* = .001	0.59 (0.46-0.87); *P* = .001
Life and limb	*Survival*	*Limb salvage*	
High modified cardiac risk score	0.52 (0.33-0.8); *P* = .002		
Diabetes	0.72 (0.52-0.99); *P* = .04	0.52 (0.33-0.8); *P* = .002	
Creatinine >2 mg/dL		0.60 (0.39-0.92); *P* = .023	
Hemodialysis	0.30 (0.05-0.96); *P* = .025	0.61 (0.23-0.97); *P* = .04	
Worse pre-procedure symptom	0.52 (0.41-0.66); *P* = .001	0.29 (0.17-0.49); *P* = .0001	
Poor tibial runoff		0.67 (0.49-0.91); *P* = .01	
MACE	0.04 (0.08-0.02); *P* = .001		
No hemodynamic success		0.35 (0.16-0.72); *P* = .034	
Occlusion at site of intervention		0.31 (0.21-0.39); *P* = .005	
Patient-centered outcomes	*Clinical efficacy*	*Amputation-free survival*	*Freedom from MALE*
Poor preoperative ambulation status	0.34 (0.15-0.66); *P* = .005	0.59 (0.43-0.75); *P* = .02	
High modified cardiac risk score	0.41 (0.23-0.68); *P* = .007	0.86 (0.77-0.98); *P* = .017	
Diabetes	0.61 (0.49-0.77); *P* = .006	0.55 (0.32-0.77); *P* = .001	0.56 (0.41-0.78); *P* = .004
Hemodialysis	0.32 (0.22-0.45); *P* = .001	0.42 (0.26-0.65); *P* = .001	0.77 (0.65-0.94); *P* = .007
Worse pre-procedure symptom	0.76 (0.60-0.97); *P* = .03	0.50 (0.38-0.67); *P* = .001	0.53 (0.41-0.67); *P* = .001
Poor tibial runoff	0.69 (0.56-1.67); *P* = .03	0.77 (0.65-0.93); *P* = .004	0.92 (0.75-1.15); *P* = .044
MACE	0.49 (0.27-0.95); *P* = .037	0.40 (0.18-0.82); *P* = .02	
No hemodynamic success	0.54 (0.43-0.69); *P* = .001	0.67 (0.52-0.88); *P* = .004	0.58 (0.44-0.88); *P* = .019
Occlusion at site of intervention	0.62 (0.32-0.74); *P* = .001	0.43 (0.32-0.65); *P* = .005	
		OPEN	
Patency	*Primary*	*Assisted primary*	*Secondary*
Diabetes	0.77 (0.67-0.92); *P* = .003	0.78 (0.65-0.95); *P* = .012	0.78 (0.78-0.94); *P* = .013
Creatinine >2 mg/dL	0.78 (0.78-0.99); *P* = .046	0.74 (0.67-0.99); *P* = .048	0.73 (0.55-0.98); *P* = .032
Hemodialysis		0.64 (0.45-0.98); *P* = .039	
Worse pre-procedure symptom			
Poor tibial runoff	0.73 (0.59-0.91); *P* = .002	0.62 (0.48-0.78); *P* = .005	0.69 (0.49-0.95); *P* = .023
Use of prosthetic	0.64 (0.50-0.80); *P* = .02	0.74 (0.60-0.90); *P* = .002	0.73 (0.59-0.90); *P* = .002
No hemodynamic success	0.81 (0.42-0.92); *P* = .01	0.69 (0.45-0.86); *P* = .012	0.57 (0.38-0.75); *P* = .001
Life and limb	*Survival*	*Limb salvage*	
High modified cardiac risk score	0.81 (0.70-0.94); *P* = .006		
Diabetes	0.82 (0.72-0.94); *P* = .003	0.77 (0.67-0.88); *P* = .004	
Creatinine >2 mg/dL			
Hemodialysis	0.57 (0.48-0.71); *P* = .001	0.61 (0.46-0.82); *P* = .001	
Worse pre-procedure symptom	0.69 (0.61-0.80); *P* = .001	0.75 (0.66-0.85); *P* = .001	
Poor tibial runoff		0.22 (0.09-0.72); *P* = .001	
MACE	0.41 (0.29-0.61); *P* = .001		
No hemodynamic success		0.88 (0.78-1.01); *P* = .04	
Bypass occlusion		0.85 (0.75-0.98); *P* = .012	
Patient-centered outcomes	*Clinical efficacy*	*Amputation-free survival*	*Freedom from MALE*
Poor preoperative ambulation status	0.34 (0.32-0.37); *P* = .001	0.55 (0.44-0.61); *P* = .001	
High modified cardiac risk score	0.94 (0.90-0.99); *P* = .0001	0.95 (0.92-0.99); *P* = .02	
Diabetes	0.74 (0.63-0.87); *P* = .0002		0.77 (0.67-0.91); *P* = .0014
Hemodialysis		0.65 (0.48-0.97); *P* = .005	
Worse pre-procedure symptom	0.76 (0.65-0.91); *P* = .001	0.64 (0.56-0.74); *P* = .03	0.74 (0.55-0.94); *P* = .04
Poor tibial runoff	0.62 (0.51-0.77); *P* = .001	0.74 (0.62-0.86); *P* = .0002	0.70 (0.57-0.86); *P* = .002
Use of prosthetic	0.86 (0.75-0.99); *P* = .04	0.52 (0.01-0.29); *P* = .007	0.56 (0.29-0.95); *P* = .03
MACE	0.51 (0.34-0.81); *P* = .006	0.62 (0.41-0.92); *P* = .04	
No hemodynamic success	0.46 (0.23-0.84); *P* = .008	0.72 (0.51-0.90); *P* = .02	
Bypass occlusion	0.24 (0.21-0.28); *P* = .001	0.71 (0.62-0.82); *P* = .001	

ENDO, Endoluminal intervention; *MACE,* major adverse cardiovascular event; *MALE,* major adverse limb event; *OPEN,* open intervention.
Values are risk ratio (95% confidence intervals).

demonstrated that the severity of presenting symptoms,[17] lesion severity,[18,19] and poor tibial runoff will affect the outcomes of SFA endovascular interventions.[14]

Anatomic outcomes. The 5-year primary patency was greater in the OPEN group compared with the ENDO group, which is consistent with previous reports.[6,8] While the study did have a large number of prosthetic bypasses, reflecting the environment we work in, it is clear from the analysis that vein bypasses performed better than prosthetic bypasses. As a result of the greater number of prosthetic bypasses, the secondary patency was similar between the ENDO and OPEN groups with an equal number of reinterventions. Patency was dependent on the quality of tibial runoff and was influenced by the presence of diabetes and chronic renal insufficiency. Occlusion of the site of intervention or occlusion of the bypass did affect functional outcomes and the likelihood of amputation.

Functional outcomes. While anatomic outcomes have been the focus of many reports in the literature, the unique aspect of this report is the focus on functional outcomes. Functional outcomes, namely reduction in symptoms, preservation of limb, and maintenance of ambulation, are the ultimate goal of all vascular interventions. There has been a decrease in major amputations reported in the Nationwide Inpatient Sample, associated with an increase in endoluminal interventions and a decrease in surgical procedures over the past few decades for a variety of reasons.[6] The ENDO group in this study had a greater number of 30-day major amputations as well as poorer long-term limb salvage. This was driven by presence of diabetes, creatinine >2 mg/dL, on hemodialysis, poor tibial runoff, the absence of hemodynamic success, and occlusion of the original site of intervention. The increased amputation rate contributed to poor amputation-free survival and poor clinical efficacy. The most significant finding in this study is that the group receiving OPEN therapy had greater long-term clinical efficacy despite long-term cumulative patency equal to that of ENDO. This occurred despite the fact that there were an equivalent number of patients showing an initial ABI/toe-brachial index rise >0.15 and a majority of the patients showing initial improvement or resolution of symptoms in both groups.

Study limitations. This study is retrospective in nature, and the clinical decision-making was individualized, not driven by a standard protocol. Similarly, it is acknowledged that this study is biased toward TASC D lesions being treated OPEN, likely as a result of the TASC I and II recommendations. In addition, this study was gathered from data over a 20-year period during which patterns and trends can change. Specific to this 20-year time period, ENDO interventions became increasingly more favored for SFA and popliteal disease for all ranges of clinical severity and anatomic complexity. Personnel as well as experience with both endovascular procedures and open surgery has changed over time, and this is acknowledged as a weakness of this paper. The high use of prosthetic conduit in the OPEN group is likely also a function of the time period as well as a majority of bypasses being above-the-knee.

CONCLUSIONS

There has been a marked shift in treatment modality for advanced femoro-popliteal disease with a lowering of the symptomatic threshold for intervention over two decades, likely spurred by the ease of endoluminal interventions. Although peri-procedural and anatomic outcomes for both procedures are equivalent, it appears that open surgery carries a superior long-term clinical efficacy. This superiority is negatively influenced by poor preoperative ambulation status, high modified Cardiac Risk Score, worse presenting symptoms, the occurrence of MACE, poor tibial runoff, the absence of hemodynamic success, and occlusion of the original bypass.

AUTHOR CONTRIBUTIONS

Conception and design: MD
Analysis and interpretation: MD, CS
Data collection: MD, CS, JA, YK, CB, MP, HE
Writing the article: MD, CS
Critical revision of the article: MD, CS
Final approval of the article: MD
Statistical analysis: MD, CS
Obtained funding: MD, AL
Overall responsibility: MD

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Additional material for this article may be found online at www.jvascsurg.org.

DISCUSSION

Michael C. Stoner (*Greenville, NC*). Good morning members and guests of the Society. Today, Dr Smolock and his colleges from Houston have presented their two-decade experience with open and endovascular revascularization for complex femoro-popliteal arterial occlusive disease. By the numbers, these data are impressive, and represent over 2500 interventions for severe claudication, rest pain, and tissue loss. The authors are to be lauded for the 20-year study time frame, thus presenting us with an evolving endovascular experience that mimics the national transition to an endovascular-weighted stance towards lower extremity arterial disease. In brief, the data, which likely represent the practice pattern for many in this room, showed that patients with systemic illness such diabetes or metabolic syndrome were more likely to have percutaneous therapy, and bypass was more commonly employed in TASC II D cases. While the surgeon-centric outcome of primary assisted patency was similar in the two groups, patient-centric outcomes involving limb salvage and the novel "clinical efficacy" favored patients undergoing bypass. However, the data as presented are difficult to draw meaningful conclusions from. A few questions I have for the authors:

1. The most glaring issue, which was appropriately acknowledged in the manuscript, is the selection bias. A large well-sized longitudinal database such as this would most appropriately be analyzed with a propensity score-weighted proportional hazard model. Without such an analysis, these data remain observational in nature, and the study fails to reach its potential. Have you considered such an analysis to correct for bias?
2. In your paper, there is a disconnect between assisted patency and clinical efficacy. This discordant finding highlights a major issue in the vascular literature today. For instance, consider the rather nebulous findings of the CLEVER trial. Do you think that this discordance was related to the robustness or ABI improvement following revascularization? It would be very informative to stratify your clinical efficacy endpoint by initial ABI gain.
3. As your group gained experience with endovascular therapy, did your selection criteria and outcomes change over time? What about utilization of endovascular adjuncts such as stents or atherectomy?

I'd like to specifically thank Dr Smolock for an advanced copy of the manuscript, and the Society for the privilege of starting the discussion.

Dr Christopher Smolock. Thank you for your questions, Dr Stoner. We acknowledge selection bias, and we look forward to conducting the analysis to correct for that bias in the paper. The disconnect between the patencies and the clinical efficacies is something that has been very interesting to us, and I think it does have to do with the patients being sicker in the endovascular group: more diabetes, more metabolic syndrome, probably worse small vessel disease even though tibial runoff scores were better in the endovascular group. However, those runoff scores only calculate to the ankle and do not include the foot arch or angiosomes, thus not accounting for small vessel disease in the foot. I believe this is probably tied together using the ABI/TBI data. Endovascular therapy results in a lower ABI/TBI than does open bypass. As the technology became available, the use of stents initially increased but then decreased and leveled off as our group approach became fairly conservative with minimal primary stenting, doing so for poor results or dissection with angioplasty alone. We do not do very much atherectomy.

SUPPLEMENTARY METHODS (online only). Definitions used in the text of the paper.

Definitions: Coronary artery disease was defined as a history of angina pectoris, myocardial infarction, congestive heart disease or prior coronary artery revascularizations. The Modified Lee Index was used to quantify cardiac risk.[1] Cerebrovascular disease was defined as a history of stroke, transient ischemic attack, or carotid artery revascularization. Chronic renal impairment was defined as an estimated glomular filtration rate <60 mL/min/1.73 m^2 or if the patient was on dialysis. Hypertension was defined as a systolic blood pressure >150 mm Hg or diastolic blood pressure >90 mm Hg on three occasions during a 6-month period. Hypercholesterolemia was defined as fasting serum concentrations of cholesterol >200 mg/dL, a low-density lipoprotein >130 mg/dL, or triglycerides >200 mg/dL. Diabetes was defined as a fasting plasma glucose >110 mg/dL or an HbA1c >7%. Noninsulin-dependent diabetes mellitus was defined as any patient with diabetes mellitus who did not routinely receive insulin therapy for their diabetes management. Insulin-dependent diabetes mellitus was defined as any patient with diabetes mellitus who routinely received insulin therapy. Metabolic syndrome was defined as previously described (insulin resistance or impaired glucose tolerance, hypertension, dyslipidemia, and abdominal obesity),[2] with the exception of abdominal circumference, which was not routinely recorded. We substituted a body mass index score ≥30.0 as a positive score instead of an abdominal circumference >102 cm or >88 cm for male or female patients, respectively. Functional status was determined preoperatively, at discharge, and again at 1 year postoperatively. Ambulation status was categorized as independently ambulatory, ambulatory with assistance such as a cane or a walker, wheelchair-bound, or bedridden. TASC II classification of disease severity for femoral lesions was used to define the categories of lesions.[3] The preoperative distal runoff was scored by the number of patent tibial vessels and according to a modification of Society for Vascular Surgery (SVS) criteria employed for determining bypass runoff (using the cumulative score for the distal popliteal from knee joint to first tibial branch; maximum 9+1) and each of the tibial vessels (maximum 3 each), giving a maximum possible total score of 19.[4] The modified PREVENT III amputation-free survival risk score allocated points (pts) to each patient for the presence of dialysis (4 pts), tissue loss (3 pts), age ≥75 (2 pts), and coronary artery disease (1 pt).[5] Total scores may then be used to stratify each patient into low-risk (≤3 pts), medium-risk (4-7 pts), and high-risk (≥8 pts) categories. In the FINNVasc Score system,[6] 1 point was allocated for the presence of diabetes, coronary artery disease, foot gangrene, and urgent operation, and the groups stratified into 5 categories (0,1,2,3,4), with categories 3 and 4 being considered high risk.

The SVS Objective performance goals (OPG) were defined at 30 days and 1 year.[7] To satisfy the OPG, the upper bound of the 95% confidence interval (CI) must be ≤ the OPG. Thirty-day OPG were major adverse limb event rate (MALE; amputation or major reintervention defined as endovascular reintervention on the same leg, placement of new bypass graft, use of thrombectomy or thrombolysis, or major surgical revision such as a jump or interposition graft), major adverse cardiovascular events rate (MACE; myocardial infarction, stroke, or death) and 30-day above-ankle amputation rate. The 1-year OPG used in this study were amputation-free survival: any above-ankle amputation of the index limb or death (any cause), perioperative death or any MALE. The SVS OPG investigators designated patients with several important characteristics to be "high-risk." These high-risk groups were designated as clinical high-risk (age over 80 and tissue loss), anatomic high-risk (infrapopliteal distal target), and conduit high-risk (absence of single-segment greater saphenous vein greater than 3 mm in diameter).[7] A death within 30 days of the procedure was considered procedure-related and a perioperative death. A major complication was defined as any event, regardless of how minimal, not routinely observed after endoluminal therapy that required treatment with a therapeutic intervention or re-hospitalization within 30 days of the procedure.

Supplementary Table (online only). Patient variables used for univariant and multivariant Cox proportional hazard analysis

Patient factors	*Procedural factors*	*Outcomes factors*
Gender	TASC II lesion category	Hemodynamic success
Body mass index >27	Recannulized	Postprocedure symptom outcome
Age >80 years	Tibial runoff	30-day MACE
Smoking status	Modified SVS runoff score	30-day MALE
Coronary artery disease	Complexity score	30-day amputation
Congestive heart failure		Ambulation status
Modified cardiac risk index		Postoperative discharge status
Hypertension		Postoperative ambulation status
Coagulation defect		Postoperative discharge status
Cerebrovascular		Occlusion of intervention
Diabetes		
Hypothyroidism		
Hyperlipidemia		
Statins		
Metabolic syndrome		
Hemodialysis		
Creatinine >2		
Pre-procedure symptom		
Preoperative ambulation status		

MACE, Major adverse cardiovascular event; *MALE,* major adverse limb event; *SVS,* Society for Vascular Surgery; *TASC II,* TransAtlantic Inter-Society Consensus II.

Systemic complications were those related to cardiac, pulmonary, renal, and sepsis. Local complications were those related to access site, surgical wounds, and the treated limb. Pre- and postprocedural symptoms were defined by SVS criteria,[8] and a drop in symptom score of 1 or greater in follow-up was considered as recurrent symptoms. Primary, assisted primary, and secondary patency rates were defined in accordance with the reporting standards of the SVS.[8] Clinical efficacy was defined as absence of recurrent symptoms, maintenance of ambulation, and limb preservation.

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