Randomized comparison of ePTFE/nitinol self-expanding stent graft vs prosthetic femoral-popliteal bypass in the treatment of superficial femoral artery occlusive disease

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Background: **A randomized prospective study comparing the treatment of superficial femoral artery occlusive disease percutaneously with an expanded polytetrafluoroethylene (ePTFE)/nitinol self-expanding stent graft (stent-graft) vs surgical femoral to above knee popliteal artery bypass with synthetic graft material.**

Methods: **One hundred limbs in 86 patients with superficial femoral artery occlusive disease were evaluated from March 2004 to May 2005. Patient symptoms included both claudication and limb threatening ischemia with or without tissue loss. The TransAtlantic InterSociety Consensus (TASC) II A (N = 18), B (N = 56), C (N = 11), and D (N = 15) lesions were included. Patients were randomized prospectively into one of two treatment groups; a percutaneous treatment group (group A; N = 50) with angioplasty and placement of one or more stent-grafts or a surgical treatment group (group B; N = 50) with a femoral to above knee popliteal artery bypass using synthetic conduit (Dacron graft or ePTFE). Patients were followed for a total of 24 months. Follow-up evaluation included clinical assessment and physical examination, ankle-brachial indices (ABI), and color flow duplex sonography at 3, 6, 9, 12, 18, and 24 months.**

Results: **The mean total lesion length of the treated arterial segment in the stent-graft group was 25.6 cm (SD ± 15 cm). The stent-graft group demonstrated a primary patency of 81%, 72%, and 63% with a secondary patency of 86%, 83%, and 74% at 6, 12, and 24 months, respectively. The surgical femoral-popliteal group demonstrated a primary patency of 84%, 77%, and 64% with a secondary patency of 89%, 86%, and 76% at 6, 12, and 24 months, respectively. No statistical difference was found between the two groups with respect to primary (P = .716) or secondary patency (P = .695). Grouping of less severe (TASC II A/B) vs more severe (TASC II C/D) lesions demonstrated patency at 24 months for the femoral-popliteal arm of 63% and 67%, respectively while that of the stent-graft arm was 64% and 47%, respectively. Secondary patency was 76% in both TASC classifications for the femoral-popliteal arm with 78% and 47% patency found respectively in the stent-graft group. These resulted in no significant difference for primary (P = .978) or secondary (P = .653) patency overall, although there is a trend for decreased patency with higher TASC II lesions.**

Conclusion: **Management of superficial femoral artery occlusive disease with percutaneous stent-grafts exhibits similar primary patency at 24-month follow-up when compared with conventional femoral-popliteal artery bypass grafting with synthetic conduit. This treatment method may offer an alternative to treatment of the superficial femoral artery segment for revascularization when prosthetic bypass is being considered or when autologous conduit is unavailable. (J Vasc Surg 2009;49:109-16.)**

The superficial femoral artery (SFA) is a common location for the origination of symptomatic lower extremity vascular disease. Advances in endovascular therapy have provided new options for treatment of disease in this arterial segment. Lesions previously thought amenable only to open surgical bypass can now be successfully managed percutaneously. In an early international trial study group, Lammer et al[1] deployed the Hemobahn endoprosthesis (W. L. Gore and Associates, Inc, Flagstaff, Ariz) in 80 limbs with occlusive femoral-popliteal lesions. A primary patency of 90% and 79%, at 6- and 12-month follow-up, respectively, was achieved. Subsequent to this report, the graft delivery system was modified (although the graft itself remained without change) and was renamed the Viabahn endoprosthesis. Ensuing studies of this stent- graft platform in the SFA have demonstrated similar results.[2-13] We have previously published a midterm report on the current series with a 12-month follow-up demonstrating primary and secondary patency rates of 74% and 84% respectively in both a stent-graft arm (n = 50) and surgical arm (n = 50).[14] While vein bypass is still considered the "gold standard" in surgical treatment of severe atherosclerotic disease, synthetic graft is often used in current practice for femoral-popliteal above knee bypass for various reasons including lack of acceptable venous conduit or for patients

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who are poor operative candidates. The purpose of our study was to compare the efficacy of the stent graft vs open surgical femoral to above-knee popliteal bypass in the treatment of SFA occlusive disease.

MATERIALS AND METHODS

Study design. Our study design has been previously published.[14] Briefly, the study is a prospective, randomized trial carried out at a single institution between March 2004 and May 2005. The study was approved by the FDA with an investigational device exemption (IDE) and was approved and monitored by the hospital institutional review board. All study participants signed an informed consent agreement as part of the initial enrollment. Patients with symptoms of lifestyle-altering claudication or rest pain with or without tissue loss were evaluated for treatment. Clinical examination and noninvasive studies (ankle-brachial indices and color-flow duplex ultrasonography) were used to confirm infrainguinal disease. All patients considered for treatment subsequently underwent digital subtraction angiography or computed tomography angiography to evaluate the location and extent of atherosclerotic disease.

Inclusion criteria consisted of patients that had atherosclerotic stenotic or occlusive lesions of the superficial femoral artery with no significant aorto-iliac disease. The infrapopliteal segment had to be patent with at least single vessel run-off to the ankle. Patients had to be acceptable surgical candidates in the event they were randomized to the surgical arm.

Enrolled patients were prospectively randomized by limb prior to intervention into one of two treatment groups: percutaneous endovascular treatment with the stent-graft or open surgical femoral to above-knee popliteal artery bypass with synthetic graft.

Study population. Between March 2004 and May 2005, a total of 100 limbs in 86 patients met the inclusion criteria as described. Forty patients (50 limbs) were randomized to treatment with the stent-graft and 46 patients (50 limbs) were randomized to treatment with femoral to above-knee popliteal artery bypass. The demographic data and associated comorbidities are summarized in Table I. While there was a statistical difference in patient age between the two treatment groups, there was no significant difference found in the patient comorbidities.

Technique. Stent graft design with our open surgical and endovascular technique have been previously published.[14] Briefly, all patients were accessed percutaneously in the common femoral artery via standard Seldinger technique and were fully anticoagulated with heparin (100 units/kg). Subintimal dissection was used to cross occlusive lesions with predilatation angioplasty of the lesion to be treated then being performed. Lesion length was recorded by in-plane technique using a marking catheter. Stent-graft deployment was accomplished with stents being sized to vessel diameter. Post deployment angioplasty molding was then performed. After stent-graft placement, patients were immediately started on aspirin (81-325 mg/d) and clopidogrel (75 mg/d) for a minimum of 3 months. Patients receiving warfarin therapy for other associated conditions prior to treatment were continued on the drug in addition to aspirin 81 mg/d. Clopidogrel was not used in these cases. After 3 months of treatment, antiplatelet therapy was left to the discretion of the treating physician. The choice of surgical conduit was also left to the discretion of the operating surgeon and was either ePTFE or Dacron graft. An identical antiplatelet regimen as previously described was instituted postoperatively for the surgical arm.

Table I. Patient demographics

	Stent-graft group (N = 40)	*Surgical bypass group (N = 46)*	P *value*
Mean age	72 (SD = 9.9; range 40-84)	67 (SD = 10.7; range 40-86)	.0333[a]
Smoking history	22	27	.8280[b]
Diabetes	14	20	.5090[b]
CAD	13	22	.1886[b]
HTN	30	42	.0763[b]
Hyperlipidemia	23	21	.2862[b]
COPD	2	8	.0973[b]

CAD, Coronary artery disease; *HTN,* hypertension; *COPD,* chronic obstructive pulmonary disease.
Four patients randomized one limb to both treatment groups.
[a]Two-tailed *t* test with pooled variances.
[b]Two-tailed Fisher exact test.

Postoperative assessment and follow-up examination. After discharge, follow-up included clinical examination, color flow Doppler ultrasound, and ankle-brachial indices at 3, 6, 9, 12, 18, and 24 months. Color flow Doppler ultrasound was performed at an approved ICAVL laboratory and used to assess patency of grafts and to detect recurrent arterial or graft stenosis. Primary and secondary patency rates and graft failure rates were defined with the criteria previously described by Ahn[15] and Rutherford.[16] Graft failure was defined as stent-graft/bypass thrombosis, restenosis of >50% of the treated arterial segment immediately above or below the stent-graft/bypass graft (anastamotic or stent landing zone sites), intra-stent/intra-graft restenosis >50%, or a decrease in the ankle-brachial index of 0.15 or greater.

Statistical analysis. An independent statistician reviewed all submitted data and performed the corresponding statistical calculations. The Kaplan-Meier method was used to calculate primary and secondary patency rates vs time of follow-up. The log-rank test was used to determine the statistical difference in patency rates and amputation rates between the two treatment groups. A two-tailed *t* test with pooled variances and two-tailed Fisher exact test was used to evaluate differences in patient demographics. The Fisher exact test (generalized version for tables beyond 2 × 2) was used to evaluate differences in grades of chronic limb ischemia pretreatment and in TransAtlantic InterSociety Consensus (TASC) II classification. A two-tailed *t* test was used when determining statistical significance for improvement of ankle-brachial indices and to evaluate cost comparison data. A P value <.05 was considered statistically signifi-

Table II. Pretreatment distribution of chronic limb ischemia categories (Rutherford[16])

Clinical grade	*Stent-graft limbs N = 50*	*Surgical bypass limbs N = 50*
0	0	0
1	2	1
2	23	20
3	16	10
4	4	10
5	4	7
6	1	2

Generalized Fisher exact test, $P = .3676$.

Table III. Lesion TASC II classification per limb[17]

TASC	*Surgical bypass N = 50*	*Stent-graft N = 50*
A	8	10
B	27	29
C	5	6
D	10	5

TASC, TransAtlantic InterSociety Consensus.
Generalized Fisher exact test, $P = .5829$.

cant. A power analysis was done on the study design. With 50 patients in each arm, significance set at $P < .05$, and the assumption that mean patencies are within 23% gives a study power of 80%. The purpose of the study was explorative to show the similarity of the mean estimates and confidence intervals for the treatments along with the *P* value.

RESULTS

Between March 2004 and May 2005, 50 limbs in 40 patients were treated percutaneously with the stent-graft and 50 limbs in 46 patients were treated surgically with femoral to above-knee popliteal artery bypass. Pretreatment clinical categories of chronic limb ischemia using Rutherford's classification[16] of pretreatment limb ischemia are shown in Table II. No significant difference in pretreatment clinical grades between the two treatment groups was noted. By following the TASC II grading system[17] for femoral-popliteal lesions, each limb in both treatment groups was assigned a TASC II classification as shown in Table III. There was not a significant difference in TASC II classification between the two treatment groups.

Stent-graft placement was technically successful in 100% of limbs in the stent-graft group. A total of 114 devices were implanted in 50 limbs with a mean of 2.3 stent-grafts placed per limb. Mean diameter of the stent-grafts was 5.7 mm (range; 5-7 mm). Mean total length of artery covered with the stent-graft was 25.6 cm (SD ±15 cm). Posttreatment, 37 (93%) of 40 patients in the stent-graft group took clopidogrel and aspirin for a minimum of 3 months. One patient claimed an allergy to clopidogrel while two other patients refused to take clopidogrel. These three patients did take aspirin.

Femoral to above knee popliteal artery bypass was successfully performed in 100% of limbs in the surgical group. Dacron grafts were used in 32 limbs (64%) and ePTFE was used in 18 limbs (36%). Mean diameter of the synthetic bypass grafts was 7.4 mm (range; 7-8 mm). Twenty-four of 46 patients (52%) were on clopidogrel and aspirin posttreatment for a minimum of 3 months. Seventeen patients were on aspirin only based on the recommendation of the treating surgeon. The remaining five patients were on warfarin preoperatively and were continued on this regimen postoperatively.

Immediate procedure related and early postoperative, nonthrombotic complications are outlined in our previous series.[14] Complications were noted in four of 40 patients (50 limbs; 8%) treated with the stent-graft. These included an SFA dissection (n = 1), transient mild leg edema (n = 1), transient thigh pain in the treated limb (n = 1), and one patient with a small groin hematoma. In the surgical bypass group, early postoperative complications were observed in three of 46 patients (50 limbs; 6%). These three patients developed a groin lymphocele (n = 2; one requiring exploration and drainage) and a small superficial groin wound dehiscence (n = 1).

Length of hospital stay was analyzed for both groups. The mean hospital stay for the stent-graft group was found to be 0.9 days (SD ± 0.8 days) and the mean stay for the surgical group was found to be 3.1 days (SD ± 1.8 days). This difference proved to be significant ($P < .001$; *t* test).

Complete 24-month follow-up for all patients was available for 39 (78%) of 50 limbs in the stent-graft group. Six patients expired during the study period from conditions unrelated to infrainguinal disease (one with bilateral limbs enrolled), and all but one of these patients had tissue loss preoperatively. Four patients were lost to follow-up. During follow-up, a total of 17 of the stent-grafts failed secondary to thrombosis. Early graft thrombosis occurred in the recovery room the same day of the procedure in one patient. One stent-graft thrombosis occurred within the first month after stent-graft implantation. The other 15 stent-graft thromboses were detected after a mean period of 8.2 months (SD ± 6 months) after placement. None of the three patients in the stent-graft group that were not on clopidogrel posttreatment developed a thrombosed stent-graft. Among the 17 thrombosed stent-grafts, 11 were TASC II B lesions. Of the remaining six thrombosed grafts, there were two each of TASC II A, C, and D lesions.

Of the 17 grafts that thrombosed, five (29%) underwent successful open mechanical balloon thrombectomy. One of the 17 was successfully recanalized with intra-arterial mediated lysis. In 10 of the 17 cases (59%), attempts at thrombectomy or lysis were unsuccessful, and these patients eventually underwent open surgical bypass (six to the above knee popliteal artery; four to tibial vessels). Finally, one of the patients with a thrombosed stent-graft was found to have heparin induced thrombocytopenia and amputation eventually was performed due to progressive tissue loss. This patient had tissue loss preoperatively. Over-

all, 18 interventions had to be performed in the stent-graft treatment group during 24 months.

Complete 24-month follow-up was available for 40 of 50 limbs (80%) in the surgical bypass group. Five patients expired due to conditions unrelated to their infrainguinal disease. Five patients were lost to follow-up. There were 14 incidences of synthetic graft thrombosis and one anastomotic stenosis greater than 50% accounting for a total of 15 graft failures. Of the 14 thrombosed grafts, 10 were TASC II B lesions and four were TASC II D lesions. None were TASC II A or C lesions. One graft thrombosis occurred within the first month after implantation. The other 13 were detected after a mean of 10.8 months (SD ± 7.2 months). Five of the 14 thrombosed synthetic grafts were successfully de-clotted with mechanical balloon thrombectomy. Three patients underwent below knee popliteal artery bypass with great saphenous vein after thrombectomy failed. Two patients underwent a redo femoral above knee popliteal bypass with venous conduit. One patient with a proximal anastomotic stenosis greater than 50% was observed without intervention, and one patient with a graft thrombosis remained with a viable limb without further intervention being required. In three instances, ischemia from clotted grafts eventually led to below-knee amputation. In two cases, progressive tissue loss despite patent grafts led to two additional amputations. All instances of limb amputation occurred in patients that had tissue loss preoperatively. Overall, 17 interventions had to be performed in the surgical bypass group during 24 months.

Cumulative primary and secondary patency rates were calculated with use of the Kaplan-Meier method. The primary patency rate for the stent-graft group at 6, 12, and 24 months was 81%, 72%, and 63%, respectively, while the primary patency for the surgical bypass group was 84%, 77%, and 64%, respectively (Table IV, online only). Secondary patency at 6, 12, and 24 months was 86%, 83%, and 74% for the stent-graft group and 89%, 86%, and 76% for the surgical arm, respectively (Table V, online only). There was no significant difference in primary patency ($P = .716$) or secondary patency ($P = .695$) between the two treatment groups. All limbs in the stent-graft treatment group (100%) and 46 limbs in the surgical bypass group (92%) experienced an initial improvement in the Rutherford classification grade.[16] The overall initial immediate postintervention mean improvement was 2.4 clinical grades in both treatment arms ($P = .109$; Fisher exact test). This was maintained at 24 months (for all primarily patent limbs) with a mean improvement of 2.4 clinical grades for the stent-graft group and 2.5 clinical grades for the surgical group ($P = .095$; Fisher exact test).

If grouped and evaluated independently by less severe (TASC II A/B) vs more severe (TASC II C/D) lesions, primary patency at 24 months for the femoral-popliteal arm was 63% and 67%, respectively, while that of the stent-graft arm was 64% and 47%, respectively (Table VI, online only). Secondary patency was 76% in both TASC II classification groups for the femoral-popliteal arm with 78% and 47% patency found respectively in the stent-graft arm (Table VII, online only). Although this resulted in no significant difference for primary ($P = .978$) or secondary ($P = .653$) patency overall when calculated, the patient numbers separated in this manner are far too small to perform any type of meaningful statistical analysis. The lower patency in the TASC II C/D lesions in the stent-graft arm are attributed to starting with 11 patients in this cohort at the outset, five patients that were censored during the treatment interval and only four stent-graft thrombosis. This is borne out in the wide confidence interval noted for the last 6 months of follow-up in this subset. Nonetheless, the apparent trend certainly cannot be overlooked for a lower patency with treatment of higher TASC II lesions.

Limb salvage at 24-month follow-up was not significantly different at 98% for the stent-graft patients and 89% for surgical bypass patients ($P = .081$; Table VIII, online only). Baseline ABIs for the stent-graft group and the surgical bypass group were 0.57 (SD ± 0.19) and 0.46 (SD ± 0.22), respectively. At 12 months (for patients with primarily patent limbs), the mean improvement in ABI for the stent-graft group was 0.28 and for the surgical group 0.48 ($P = .042$; two tailed t test). At 24 months, these were measured at 0.23 in the stent-graft arm and 0.38 in the surgical arm ($P = .143$; two tailed t test).

Although this study was not originally designed or statistically powered to evaluate cost comparison or patency differences between different sized stent grafts and between surgical grafts, several trends are noted. Retrospective cost analysis was performed for both treatment groups. Costs billed and collected by the hospital facility were obtained retrospectively and mean values were calculated. Some data was unavailable as the collection of this specific data was not originally included in the study design. There is a significant difference between the stent-graft group and surgical treatment group in regards to facility costs as seen in Table IX with the stent-graft cohort being a more costly treatment method. The difference for facility reimbursement was felt to be somewhat tempered by a higher reimbursement for the stent-graft group in comparison with the surgical group. If the stent-graft cohort is further broken down, there was a trend towards higher reimbursement for inpatient services as opposed to outpatient procedures for the stent-graft cohort (Table X).

Evaluating the stent-graft group (Figs 1 and 2; Tables XI and XII, online only), there is a trend towards improved primary and secondary patency for device sizes of 6-7 mm as compared with 5 mm although this trend is not statistically significant for primary ($P = .356$) or secondary patency rates ($P = .670$). The primary patency of the larger stent graft sizes (6-7 mm) is better compared with surgical bypass (69% vs 64%, respectively) and the secondary patency is similar also at 77% vs 76%, respectively. Again, this difference is not significant ($P = .727$; log-rank). Analyzing the stent-graft cohort separately, the 5 mm devices have a lower primary patency rate (54%), but they do approach a

Table IX. Cost analysis by treatment group

	Stent-graft	*Femoral-popliteal bypass*	P *value*[a]
Facility cost (US dollars)			.037
n (data available)	39	29	
Mean (std dev)	$10,798.76 ($4725.52)	$8501.18 ($3930.50)	
Median	$9626.93	$7277.68	
Facility reimbursement (US dollars)			.237
n (data available)	36	28	
Mean (std dev)	$ 9178.00 ($3842.92)	$8023.00 ($3846.93)	
Median	$8609.50	$7023.50	

[a]Two-tailed *t* test.

Table X. Cost analysis of stent-graft patients by type of admission

	In-patient	*Out-patient*	P *value*[a]
Facility cost (US dollars)			.359
n (data available)	12	27	
Mean (std dev)	$11,854.43 ($5458.98)	$10,329.57 ($4391.60)	
Median	$10,502.60	$8996.62	
Facility reimbursement (US dollars)			.252
n (data available)	12	24	
Mean (std dev)	$10,227.33 ($2887.46)	$8653.33 ($4198.08)	
Median	$11,120.50	$7574.00	

[a]Two-tailed *t* test.

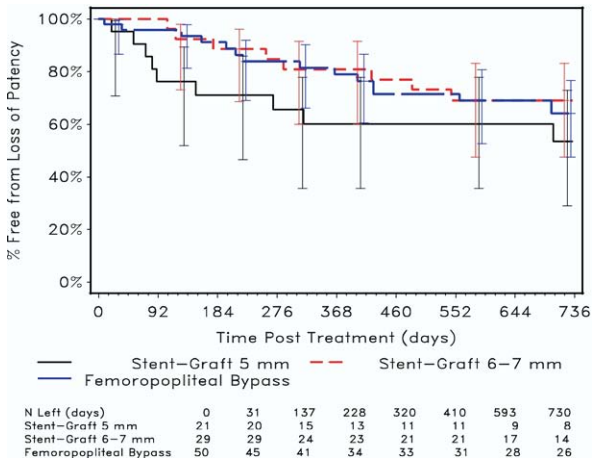

Fig 1. Primary patency by stent-graft size versus surgical group.

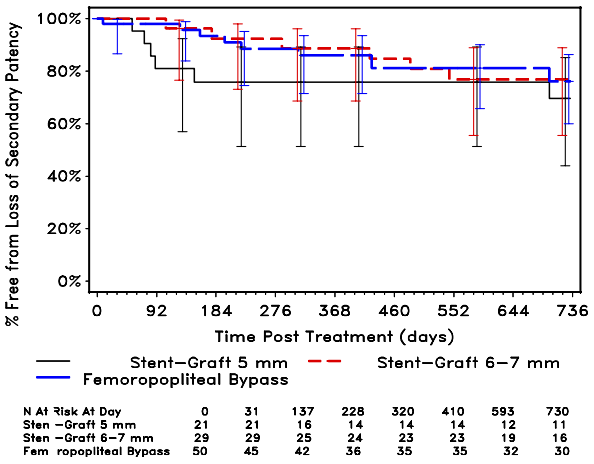

Fig 2. Secondary patency by stent-graft size versus surgical group.

similar secondary patency (70%) to the larger stent graft sizes and to femoral-popliteal bypass. Analysis of stent graft patency by device size and TASC II classification does not demonstrate any observed difference between the TASC II classifications for primary or secondary patency as shown in Tables XIII and XIV, online only, although, as previously noted, there appears to be a possible trend for decreased patency with higher TASC II C/D lesions.

DISCUSSION

The SFA is a common site of atherosclerotic plaque formation in individuals with symptomatic lower extremity arterial occlusive disease. Traditional intervention for this disease required open arterial bypass with debate centered on the choice of bypass conduit; autogenous vein (felt by most to be the "gold standard") vs synthetic graft. Numerous reports have confirmed the long-term superiority in patency of vein over synthetic conduit,[18,19] however, many physicians continue to use synthetic grafts particularly in the above knee position for various reasons such as unavailability of venous conduit or for patients considered to be poor operative risks. Technological advances and maturation of endovascular skills have allowed percutaneous treatment of SFA occlusive disease to flourish, and many lesions previously felt amenable only to open surgical bypass may now be successfully managed percutaneously.

Treatment of SFA atherosclerotic disease with percutaneous transluminal angioplasty has proven to be effective in short segment stenosis but has proved disappointing as a primary treatment modality for longer segment disease and total occlusions. A 3-year retrospective review of 104 patients (159 lesions) was published by Scott et al in 2007 demonstrating a 12-, 24-, and 36-month primary patency of 55%, 43%, and 35%, respectively.[20] The addition of self-expanding bare metal nitinol stents has improved outcomes slightly for short to moderate length arterial segments (4-12 cm), but also introduced the problems of in-stent stenosis and stent fracture.[21-23] The current study, to our knowledge, is the only randomized prospective trial that directly compares treatment of SFA occlusive disease in both a surgical bypass arm and an endovascular arm. Our initial technical success rate in both arms of 100% and our primary and secondary patency rates in both arms mirrors that of numerous previously published reports.[2-13,18,19]

Our initial report demonstrated a majority of stent-graft patients as TASC C and D lesions, but reclassification into the updated TASC II criteria dropped several of these limbs to TASC II B lesions. Reclassification resulted in approximately 60% of patients in both arms as TASC II B and 25% to 30% as TASC II C or D lesions. Arterial occlusions in the stent-graft cohort were seen within all TASC II classifications. Over two thirds of all occlusions in both groups were in the TASC II B classification corresponding to the group with the highest number of patients overall. Evaluating the treated limbs by TASC II classification results in no observed difference in the TASC II lesion being treated but does suggest a trend for decreased patency in higher TASC II lesions although the number of patients per classification category is too small to draw any significant conclusions in that regard. There remains concern among many that acute failure and/or thrombosis of the stent graft will result in a higher grade of ischemia at presentation necessitating a more complex urgent surgical revascularization and/or eventual higher rate of limb loss.[24] This concern was not validated in our study as we found no statistical difference in limb loss between the two treatment groups with only one amputation in 17 stent graft failures. In addition, of those limbs requiring bypass reconstruction in the stent-graft cohort, 60% were able to be performed above the knee.

There is an observed trend towards decreased patency in patient limbs treated with the 5 mm stent-grafts compared with the 6 and 7 mm devices, although we found no significant difference in patency through 24 months. If we evaluate only the 6 and 7 mm stent-graft patients independently vs the femoral-popliteal bypass patients, the primary and secondary patency of the stent-graft patients is better than those with the femoral-popliteal as previously shown.

A majority of patients treated by endovascular means required only outpatient care and in most instances were discharged on the same day. Although the trend in the cost analysis suggests a higher overall monetary cost per patient of approximately 10%, future calculations must take into account productivity retained by the patient with a shorter length of stay (0.9 days in the current series) resulting in a faster return to work/daily activities with a relative absence of postoperative pain.

CONCLUSION

The choice of percutaneously placed stent-grafts within the SFA vs open surgical bypass for lower extremity revascularization remains a point of discussion and controversy in many areas especially if venous conduit for surgical reconstruction is available. The current study demonstrates through a prospective randomized method, similar primary and secondary patency rates for all TASC II lesions (A-D) in the use of percutaneously placed stent-grafts vs surgically placed synthetic conduit in the SFA at up to 24 months. Commonly held thoughts about a higher rate of limb loss or "loss of options" for above knee reconstruction in the event of stent-graft failure are not demonstrated in the current study.

Percutaneous treatment of TASC II C and D lesions typically have a lower patency than those of TASC II A or B lesions, however, this does not appear to be the case in our current study although there is an apparent trend towards that endpoint. There is not shown to be any significant difference compared with surgical reconstruction for these same lesions although our patient cohort is small for this type of analysis. Additionally, two of four thrombosed stent-grafts in the higher TASC II categories were 5 mm devices. The trends presented regarding stent-graft size suggests that larger diameter devices (>5 mm) may have a better long-term patency with stent-graft reconstruction unless newer modalities with heparin bonded stent-grafts or a more prolonged use of antiplatelet agents can improve the patency of the smaller diameter devices. Again, this data is only presented as a trend as the current study was not designed or powered to demonstrate statistical differences between stent-graft sizes. It is our feeling that for longer SFA lesions/occlusions (over 10 cm), the stent-graft data presented herein and among other authors[2-13] demonstrates superior outcomes compared with other currently available modalities if endovascular treatment is being considered. There are several recognized limitations to the current study including a small total patient cohort and a single center experience, although the data obtained is comparable to previous reports.[2-13] Direct comparison with bare metal nitinol stents in longer lesions and comparison with current atherectomy devices in longer lesions with a prospective randomized study would be enlightening.

AUTHOR CONTRIBUTIONS

Conception and design: DG, BT
Analysis and interpretation: DG, KM, GP, SH
Data collection: DG, KM, SH
Writing the article: DG, BT, GP, SH
Critical revision of the article: DG, KM, GP, SH
Final approval of the article: DG, KM, BT, GP, SH
Statistical analysis: KM, SH
Obtained funding: DG
Overall responsibility: DG

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DISCUSSION

Dr Jon Matsumura (Chicago, Ill). I just wanted to congratulate you for doing such a great randomized trial in just one center randomizing 100 limbs in about 14 months. When Kedora presented the 12-month data a couple years ago, I recall there was an imbalance in the randomization for critical ischemia; there were more in one group or the other. Could you tell me what the patency rates were stratified by Rutherford class 5-6 vs the 4s? Or perhaps you could tell me, of the six amputations, how many of those were initially presenting with claudication vs RC 5 and 6.

Dr Sidawy. (Washington, D.C.). I would like to have the senior author, please.

Dr Gable. You are referring to a slightly higher increase in the number of patients with critical limb ischemia in the femoral-popliteal arm. Of those patients that underwent amputation in the femoral-popliteal arm, only one of those patients was actually included in the critical ischemia subset. The rest of the RC 5 and six patients remained patent and did not come to amputation.

Dr Matsumura. And were your patency rates similar for your claudicants as they were for your critical limb ischemia?

Dr Gable. Patency rates for claudicants vs those with rest pain or tissue loss were essentially equal and there was no difference.

Dr James McKinsey (New York, NY). As a surgeon as well as an endovascular interventionalist, there is a question that arises from all of our interventions; how many of your interventions changed your surgical option if bypass was eventually required? Meaning, if you did a femoral-popliteal stent grafting, did you then negate your ability to perform a fem-pop bypass graft and you would have to go fem-below knee pop using vein. Did you look at what bridges you are burning with your endovascular intervention?

Dr McQuade. Six out of ten of the patients in the stent-graft group that had to go on to subsequent bypass were able to be bypassed to the above-knee segment refuting the belief that people who undergo stent-graft placement in the SFA cannot be later revascularized to the above-knee popliteal segment.

Dr Sidawy. Any addition from the senior author.

Dr Gable. I believe what you are asking is whether or not when you place a stent graft, are you burning your bridges resulting in the inability to do an above-knee fem-pop bypass. That has not been our experience and that is not what we are seeing. We tried to address this issue with the slides demonstrating that of the patients that had thrombosis and had to undergo revascularization with a bypass procedure, 60% of them were able to be done above the knee.

Therefore, I do not believe that thrombosis of a stent graft results in you losing the ability to do a femoral above-knee popliteal bypass. Certainly, some of them did result in either below-knee

or tibial bypass. There were two patients that we had to do a tibial artery bypass, but the majority of them were able to stay above the knee.

Dr Panagiotis Kougias (Houston, Tex). Some people would argue that in the femoral-popliteal segment Dacron grafts have yielded inferior results compared with ePTFE. And I notice that almost two-thirds of your patients had a fem-pop using Dacron graft. If you could comment on this, please.

Dr Gable. The reason we chose not to mandate either ePTFE or Dacron is that the purpose of the study was to show the patency rates and evaluation of the stent graft vs current or most common prosthetic materials that are available. We are an eight-man group and half of us use ePTFE routinely and half of us use Dacron. There is some data previously published through numerous studies showing that with ePTFE, when it occludes, you may potentially lose the ability to do a shorter segment bypass or may potentially lose some outflow. We have not found those issues to be a big problem and did not feel that we would want to limit the ability to either choose Dacron or ePTFE. In addition, most recent meta-analysis studies of prosthetic fem-pop bypasses do not differentiate the two types of grafts.

Dr Jamal Hoballah (Iowa City, Iowa). In the stent-graft group, did you see any negative effect on the profunda femoris artery, and how would you manage patients who have disease all the way to the level of the femoral bifurcation?

Dr Gable. We did not see any problems or ill effects on the profunda artery or any of the collateralized flow from the profunda artery down the leg. For lesions that came within very close proximity to the SFA origin, we did not, for the purposes of this study, land any lesions closer than 1 cm from the origin of the SFA. Outside of this study, we have come up directly adjacent to the profunda and have not experienced any problems with either embolization or recurrent stenosis in that area. Certainly, that is a concern.

Dr Christopher Kwolek (Boston, Mass). A question about technique. Do you use any type of debulking procedures prior to endovascular stent-graft therapy and are you worried about partial expansion of these endoluminally placed stent grafts? Secondly, was lesion length or perhaps TASC classification a predictor of poorer outcome with the stent grafts? Finally, while your initial results were very good, it seems that your secondary patency rates were on the low side even for the endovascular. Debulking with stenting will often report secondary patency approaching 90%. Do you have any explanation for this?

Dr McQuade. To answer the first question in terms of our technique, we generally use a subintimal dissection technique and we did not use any reentry catheters. No atherectomy catheters or debulking devices were used.

The second question involved TASC criteria and lesion length. Concerning our failures in the stent-graft group, 11 were actually TASC II-B and then there were 2 TASC II-A, 2 TASC II-C, and 2 TASC II-D. For our fem-pop group, 10 of the failures were TASC II-B and 4 of the failures were TASC II-D. We felt that these larger number of TASC II-B failures in both groups were secondary to the fact that the majority of our patients had TASC II-B lesions and that TASC classification had no apparent bearing on patency in our study. In the stent-graft group, 29 of our patients were TASC II-B and in the fem-pop group 27 were TASC II-B.

Dr Gable. As far as the technique for debulking, we did not use any debulking procedures. Everything was done subintimal. We did not have to use any reentry catheters, although we do have that in our armamentarium, but for the purpose of this study and all of these patients, none of them required any type of reentry catheter. We did not use laser or mechanical atherectomy. We did not have any problems obtaining full stent-graft expansion after deployment.

As far as the secondary patency, the data we are presenting here is 24-month follow-up. There are only a handful of randomized prospective studies published with patency data for bare metal stent, atherectomy or angioplasty alone. Out of the studies that I have knowledge of, I do not believe any randomized prospective study demonstrates any patency data that supersedes what we have presented and follow-up in most studies that are available are less than 12 months.

Dr Christos Liapis (Athens, Greece). Regarding the postop medication, you are giving them either clopidogrel plus aspirin or Coumadin plus aspirin. If that's so, for how long and based on which recommendations you're using this kind of treatment?

Dr McQuade. The dual antiplatelet therapy was 325 mg aspirin and 75 mg clopidogrel maintained for 3 months. The patients who were getting Coumadin were only those patients who were receiving Coumadin preoperatively. They were maintained on the pretreatment dose of Coumadin and aspirin 81 mg for 3 months before allowing discontinuation of aspirin. The regimen was outlined in the study protocol but is not specified elsewhere.

Table IV (online only). Primary patency

	N at risk at start of interval	*N events during interval*[a]	*N censored during interval*[a]	*Percent free from loss of patency*	*95% CI*
Group: Femoral-popliteal bypass					
At procedure (day 0)	50	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	50	1 (1)	4 (4)	0.980	(0.866, 0.997)
1-3 mo (31-137 d)	45	2 (3)	2 (6)	0.935	(0.812, 0.979)
3-6 mo (137-228 d)	41	4 (7)	3 (9)	0.839	(0.690, 0.920)
6-9 mo (228-320 d)	34	1 (8)	0 (9)	0.814	(0.661, 0.903)
9-12 mo (320-410 d)	33	2 (10)	0 (9)	0.765	(0.606, 0.866)
12-18 mo (410-593 d)	31	3 (13)	0 (9)	0.691	(0.526, 0.808)
18-24 mo (593-730 d)	28	2 (15)	0 (9)	0.641	(0.476, 0.767)
Group: Stent-graft					
At procedure (day 0)	50	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	50	1 (1)	0 (0)	0.980	(0.866, 0.997)
1-3 mo (31-137 d)	49	6 (7)	4 (4)	0.857	(0.722, 0.929)
3-6 mo (137-228 d)	39	2 (9)	1 (5)	0.813	(0.670, 0.898)
6-9 mo (228-320 d)	36	4 (13)	0 (5)	0.722	(0.569, 0.829)
9-12 mo (320-410 d)	32	0 (13)	0 (5)	0.722	(0.569, 0.829)
12-18 mo (410-593 d)	32	3 (16)	3 (8)	0.654	(0.497, 0.772)
18-24 mo (593-730 d)	26	1 (17)	3 (11)	0.627	(0.468, 0.750)

Log rank *P* value: $P = .716$.
[a]Number in parenthesis represents cumulative events or censored observations through end of interval.

Table V (online only). Secondary patency

	N at risk at start of interval	*N events during interval*[a]	*N censored during interval*[a]	*Percent free from loss of secondary patency*	*95% CI*
Group: Femoral-popliteal bypass					
At procedure (day 0)	50	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	50	1 (1)	4 (4)	0.980	(0.866, 0.997)
1-3 mo (31-137 d)	45	1 (2)	2 (6)	0.957	(0.839, 0.989)
3-6 mo (137-228 d)	42	3 (5)	3 (9)	0.885	(0.745, 0.951)
6-9 mo (228-320 d)	36	1 (6)	0 (9)	0.861	(0.715, 0.935)
9-12 mo (320-410 d)	35	0 (6)	0 (9)	0.861	(0.715, 0.935)
12-18 mo (410-593 d)	35	2 (8)	1 (10)	0.811	(0.657, 0.901)
18-24 mo (593-730 d)	32	2 (10)	0 (10)	0.761	(0.600, 0.864)
Group: Stent-graft					
At procedure (day 0)	50	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	50	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	50	5 (5)	4 (4)	0.899	(0.773, 0.957)
3-6 mo (137-228 d)	41	2 (7)	1 (5)	0.855	(0.719, 0.928)
6-9 mo (228-320 d)	38	1 (8)	0 (5)	0.832	(0.692, 0.913)
9-12 mo (320-410 d)	37	0 (8)	0 (5)	0.832	(0.692, 0.913)
12-18 mo (410-593 d)	37	3 (11)	3 (8)	0.764	(0.614, 0.862)
18-24 mo (593-730 d)	31	1 (12)	3 (11)	0.738	(0.583, 0.843)

Log rank *P* value: $P = .695$.
[a]Number in parenthesis represents cumulative events or censored observations through end of interval.

Table VI (online only). Primary patency by TASC II lesions A/B and C/D

	N at risk at start of interval	*N events during interval*[a]	*N censored during interval*[a]	*Percent free from loss of patency*	*95% CI*
Group: Femoral-popliteal bypass TASC II A-B					
At procedure (day 0)	35	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	35	1 (1)	3 (3)	0.971	(0.814, 0.996)
1-3 mo (31-137 d)	31	1 (2)	1 (4)	0.940	(0.781, 0.985)
3-6 mo (137-228 d)	29	2 (4)	2 (6)	0.873	(0.694, 0.950)
6-9 mo (228-320 d)	25	1 (5)	0 (6)	0.838	(0.652, 0.929)
9-12 mo (320-410 d)	24	2 (7)	0 (6)	0.768	(0.573, 0.883)
12-18 mo (410-593 d)	22	2 (9)	0 (6)	0.698	(0.499, 0.831)
18-24 mo (593-730 d)	20	2 (11)	0 (6)	0.628	(0.429, 0.775)
Group: Femoral-popliteal bypass TASC II C-D					
At procedure (day 0)	15	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	15	0 (0)	1 (1)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	14	1 (1)	1 (2)	0.923	(0.566, 0.989)
3-6 mo (137-228 d)	12	2 (3)	1 (3)	0.755	(0.416, 0.914)
6-9 mo (228-320 d)	9	0 (3)	0 (3)	0.755	(0.416, 0.914)
9-12 mo (320-410 d)	9	0 (3)	0 (3)	0.755	(0.416, 0.914)
12-18 mo (410-593 d)	9	1 (4)	0 (3)	0.671	(0.342, 0.862)
18-24 mo (593-730 d)	8	0 (4)	0 (3)	0.671	(0.342, 0.862)
Group: Stent-graft TASC II A-B					
At procedure (day 0)	39	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	39	1 (1)	0 (0)	0.974	(0.832, 0.996)
1-3 mo (31-137 d)	38	4 (5)	3 (3)	0.869	(0.714, 0.944)
3-6 mo (137-228 d)	31	2 (7)	1 (4)	0.813	(0.647, 0.907)
6-9 mo (228-320 d)	28	4 (11)	0 (4)	0.697	(0.519, 0.820)
9-12 mo (320-410 d)	24	0 (11)	0 (4)	0.697	(0.519, 0.820)
12-18 mo (410-593 d)	24	2 (13)	1 (5)	0.639	(0.459, 0.773)
18-24 mo (593-730 d)	21	0 (13)	1 (6)	0.639	(0.459, 0.773)
Group: Stent-graft TASC II C-D					
At procedure (day 0)	11	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	11	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	11	2 (2)	1 (1)	0.818	(0.447, 0.951)
3-6 mo (137-228 d)	8	0 (2)	0 (1)	0.818	(0.447, 0.951)
6-9 mo (228-320 d)	8	0 (2)	0 (1)	0.818	(0.447, 0.951)
9-12 mo (320-410 d)	8	0 (2)	0 (1)	0.818	(0.447, 0.951)
12-18 mo (410-593 d)	8	1 (3)	2 (3)	0.716	(0.350, 0.899)
18-24 mo (593-730 d)	5	1 (4)	2 (5)	0.477	(0.086, 0.800)

TASC, TransAtlantic InterSociety Consensus.

Log rank *P* value: $P = .978$.

[a]Number in parenthesis represents cumulative events or censored observations through end of interval.

Table VII (online only). Secondary patency by TASC II lesions A/B and C/D

	N at risk at start of interval	*N events during interval*[a]	*N censored during interval*[a]	*Percent free from loss of patency*	*95% CI*
Group: Femoral-popliteal bypass TASC II A-B					
At procedure (day 0)	35	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	35	1 (1)	3 (3)	0.971	(0.814, 0.996)
1-3 mo (31-137 d)	31	0 (1)	1 (4)	0.971	(0.814, 0.996)
3-6 mo (137-228 d)	30	2 (3)	2 (6)	0.904	(0.730, 0.968)
6-9 mo (228-320 d)	26	1 (4)	0 (6)	0.869	(0.687, 0.949)
9-12 mo (320-410 d)	25	0 (4)	0 (6)	0.869	(0.687, 0.949)
12-18 mo (410-593 d)	25	1 (5)	1 (7)	0.835	(0.646, 0.928)
18-24 mo (593-730 d)	23	2 (7)	0 (7)	0.762	(0.563, 0.879)
Group: Femoral-popliteal bypass TASC II C-D					
At procedure (day 0)	15	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	15	0 (0)	1 (1)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	14	1 (1)	1 (2)	0.923	(0.566, 0.989)
3-6 mo (137-228 d)	12	1 (2)	1 (3)	0.839	(0.494, 0.957)
6-9 mo (228-320 d)	10	0 (2)	0 (3)	0.839	(0.494, 0.957)
9-12 mo (320-410 d)	10	0 (2)	0 (3)	0.839	(0.494, 0.957)
12-18 mo (410-593 d)	10	1 (3)	0 (3)	0.755	(0.416, 0.914)
18-24 mo (593-730 d)	9	0 (3)	0 (3)	0.755	(0.416, 0.914)
Group: Stent-graft TASC II A-B					
At procedure (day 0)	39	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	39	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	39	3 (3)	3 (3)	0.923	(0.780, 0.975)
3-6 mo (137-228 d)	33	2 (5)	1 (4)	0.867	(0.709, 0.943)
6-9 mo (228-320 d)	30	1 (6)	0 (4)	0.838	(0.674, 0.924)
9-12 mo (320-410 d)	29	0 (6)	0 (4)	0.838	(0.674, 0.924)
12-18 mo (410-593 d)	29	2 (8)	1 (5)	0.780	(0.608, 0.884)
18-24 mo (593-730 d)	26	0 (8)	1 (6)	0.780	(0.608, 0.884)
Group: Stent-graft TASC II C-D					
At procedure (day 0)	11	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	11	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	11	2 (2)	1 (1)	0.818	(0.447, 0.951)
3-6 mo (137-228 d)	8	0 (2)	0 (1)	0.818	(0.447, 0.951)
6-9 mo (228-320 d)	8	0 (2)	0 (1)	0.818	(0.447, 0.951)
9-12 mo (320-410 d)	8	0 (2)	0 (1)	0.818	(0.447, 0.951)
12-18 mo (410-593 d)	8	1 (3)	2 (3)	0.716	(0.350, 0.899)
18-24 mo (593-730 d)	5	1 (4)	2 (5)	0.477	(0.086, 0.800)

TASC, TransAtlantic InterSociety Consensus.
Log rank *P* value: $P = .653$.
[a]Number in parenthesis represents cumulative events or censored observations through end of interval.

Table VIII (online only). Limb salvage

	N at risk at start of interval	*N events during interval*[a]	*N censored during interval*[a]	*Percent free from amputation*	*95% CI*
Group: Femoral-popliteal bypass					
At procedure (day 0)	50	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	50	2 (2)	3 (3)	0.960	(0.849, 0.990)
1-3 mo (31-137 d)	45	1 (3)	1 (4)	0.938	(0.820, 0.980)
3-6 mo (137-228 d)	43	1 (4)	5 (9)	0.914	(0.786, 0.967)
6-9 mo (228-320 d)	37	1 (5)	0 (9)	0.889	(0.753, 0.953)
9-12 mo (320-410 d)	36	0 (5)	0 (9)	0.889	(0.753, 0.953)
12-18 mo (410-593 d)	36	0 (5)	1 (10)	0.889	(0.753, 0.953)
18-24 mo (593-730 d)	35	0 (5)	0 (10)	0.889	(0.753, 0.953)
Group: Stent-graft					
At procedure (day 0)	50	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	50	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	50	1 (1)	5 (5)	0.980	(0.866, 0.997)
3-6 mo (137-228 d)	44	0 (1)	1 (6)	0.980	(0.866, 0.997)
6-9 mo (228-320 d)	43	0 (1)	0 (6)	0.980	(0.866, 0.997)
9-12 mo (320-410 d)	43	0 (1)	0 (6)	0.980	(0.866, 0.997)
12-18 mo (410-593 d)	43	0 (1)	3 (9)	0.980	(0.866, 0.997)
18-24 mo (593-730 d)	40	0 (1)	4 (13)	0.980	(0.866, 0.997)

Log rank *P* value: $P = .081$.
[a]Number in parenthesis represents cumulative events or censored observations through end of interval.

Table XI (online only). Primary patency by stent-graft size

	N at risk at start of interval	*N events during interval*[a]	*N censored during interval*[a]	*Percent free from loss of patency*	*95% CI*
Group: Femoral-popliteal bypass					
At procedure (day 0)	50	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	50	1 (1)	4 (4)	0.980	(0.866, 0.997)
1-3 mo (31-137 d)	45	2 (3)	2 (6)	0.935	(0.812, 0.979)
3-6 mo (137-228 d)	41	4 (7)	3 (9)	0.839	(0.690, 0.920)
6-9 mo (228-320 d)	34	1 (8)	0 (9)	0.814	(0.661, 0.903)
9-12 mo (320-410 d)	33	2 (10)	0 (9)	0.765	(0.606, 0.866)
12-18 mo (410-593 d)	31	3 (13)	0 (9)	0.691	(0.526, 0.808)
18-24 mo (593-730 d)	28	2 (15)	0 (9)	0.641	(0.476, 0.767)
Group: Stent-graft 5 cm					
At procedure (day 0)	21	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	21	1 (1)	0 (0)	0.952	(0.707, 0.993)
1-3 mo (31-137 d)	20	4 (5)	1 (1)	0.762	(0.519, 0.893)
3-6 mo (137-228 d)	15	1 (6)	1 (2)	0.711	(0.466, 0.859)
6-9 mo (228-320 d)	13	2 (8)	0 (2)	0.602	(0.357, 0.779)
9-12 mo (320-410 d)	11	0 (8)	0 (2)	0.602	(0.357, 0.779)
12-18 mo (410-593 d)	11	0 (8)	2 (4)	0.602	(0.357, 0.779)
18-24 mo (593-730 d)	9	1 (9)	0 (4)	0.535	(0.290, 0.729)
Group: Stent-graft 6-7 cm					
At procedure (day 0)	29	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	29	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	29	2 (2)	3 (3)	0.924	(0.730, 0.981)
3-6 mo (137-228 d)	24	1 (3)	0 (3)	0.886	(0.687, 0.962)
6-9 mo (228-320 d)	23	2 (5)	0 (3)	0.809	(0.600, 0.916)
9-12 mo (320-410 d)	21	0 (5)	0 (3)	0.809	(0.600, 0.916)
12-18 mo (410-593 d)	21	3 (8)	1 (4)	0.691	(0.476, 0.832)
18-24 mo (593-730 d)	17	0 (8)	3 (7)	0.691	(0.476, 0.832)

Log rank *P* value: $P = .356$.
[a]Number in parenthesis represents cumulative events or censored observations through end of interval.

Table XII (online only). Secondary patency by stent-graft size vs surgical group

	N at risk at start of interval	*N events during interval*[a]	*N censored during interval*[a]	*Percent free from loss of secondary patency*	*95% CI*
Group: Femoral-popliteal bypass					
At procedure (day 0)	50	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	50	1 (1)	4 (4)	0.980	(0.866, 0.997)
1-3 mo (31-137 d)	45	1 (2)	2 (6)	0.957	(0.839, 0.989)
3-6 mo (137-228 d)	42	3 (5)	3 (9)	0.885	(0.745, 0.951)
6-9 mo (228-320 d)	36	1 (6)	0 (9)	0.861	(0.715, 0.935)
9-12 mo (320-410 d)	35	0 (6)	0 (9)	0.861	(0.715, 0.935)
12-18 mo (410-593 d)	35	2 (8)	1 (10)	0.811	(0.657, 0.901)
18-24 mo (593-730 d)	32	2 (10)	0 (10)	0.761	(0.600, 0.864)
Group: Stent-graft 5 cm					
At procedure (day 0)	21	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	21	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	21	4 (4)	1 (1)	0.810	(0.569, 0.924)
3-6 mo (137-228 d)	16	1 (5)	1 (2)	0.759	(0.514, 0.892)
6-9 mo (228-320 d)	14	0 (5)	0 (2)	0.759	(0.514, 0.892)
9-12 mo (320-410 d)	14	0 (5)	0 (2)	0.759	(0.514, 0.892)
12-18 mo (410-593 d)	14	0 (5)	2 (4)	0.759	(0.514, 0.892)
18-24 mo (593-730 d)	12	1 (6)	0 (4)	0.696	(0.439, 0.852)
Group: Stent-graft 6-7 cm					
At procedure (day 0)	29	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	29	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	29	1 (1)	3 (3)	0.963	(0.765, 0.995)
3-6 mo (137-228 d)	25	1 (2)	0 (3)	0.924	(0.730, 0.981)
6-9 mo (228-320 d)	24	1 (3)	0 (3)	0.886	(0.687, 0.962)
9-12 mo (320-410 d)	23	0 (3)	0 (3)	0.886	(0.687, 0.962)
12-18 mo (410-593 d)	23	3 (6)	1 (4)	0.768	(0.555, 0.889)
18-24 mo (593-730 d)	19	0 (6)	3 (7)	0.768	(0.555, 0.889)

Log rank *P* value: $P = .670$.

[a]Number in parenthesis represents cumulative events or censored observations through end of interval.

Table XIII (online only). Primary patency by TASC II classification

	N at risk at start of interval	*N events during interval*[a]	*N censored during interval*[a]	*Percent free from loss of patency*	*95% CI*
Group: 5 mm stent-graft TASC II A					
At procedure (day 0)	7	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	7	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	7	0 (0)	0 (0)	1.000	(1.000, 1.000)
3-6 mo (137-228 d)	7	0 (0)	0 (0)	1.000	(1.000, 1.000)
6-9 mo (228-320 d)	7	1 (1)	0 (0)	0.857	(0.334, 0.979)
9-12 mo (320-410 d)	6	0 (1)	0 (0)	0.857	(0.334, 0.979)
12-18 mo (410-593 d)	6	0 (1)	0 (0)	0.857	(0.334, 0.979)
18-24 mo (593-730 d)	6	0 (1)	0 (0)	0.857	(0.334, 0.979)
Group: 5 mm stent-graft TASC II B					
At procedure (day 0)	11	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	11	1 (1)	0 (0)	0.909	(0.508, 0.987)
1-3 mo (31-137 d)	10	3 (4)	1 (1)	0.636	(0.297, 0.845)
3-6 mo (137-228 d)	6	1 (5)	1 (2)	0.530	(0.209, 0.773)
6-9 mo (228-320 d)	4	1 (6)	0 (2)	0.398	(0.110, 0.680)
9-12 mo (320-410 d)	3	0 (6)	0 (2)	0.398	(0.110, 0.680)
12-18 mo (410-593 d)	3	0 (6)	1 (3)	0.398	(0.110, 0.680)
18-24 mo (593-730 d)	2	0 (6)	0 (3)	0.398	(0.110, 0.680)
Group: 5 mm stent-graft TASC II C					
At procedure (day 0)	2	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	2	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	2	1 (1)	0 (0)	0.500	(0.006, 0.910)
3-6 mo (137-228 d)	1	0 (1)	0 (0)	0.500	(0.006, 0.910)
6-9 mo (228-320 d)	1	0 (1)	0 (0)	0.500	(0.006, 0.910)
9-12 mo (320-410 d)	1	0 (1)	0 (0)	0.500	(0.006, 0.910)
12-18 mo (410-593 d)	1	0 (1)	0 (0)	0.500	(0.006, 0.910)
18-24 mo (593-730 d)	1	1 (2)	0 (0)	0.000	(0.006, 0.910)
Group: 5 mm stent-graft TASC II D					
At procedure (day 0)	1	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	1	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	1	0 (0)	0 (0)	1.000	(1.000, 1.000)
3-6 mo (137-228 d)	1	0 (0)	0 (0)	1.000	(1.000, 1.000)
6-9 mo (228-320 d)	1	0 (0)	0 (0)	1.000	(1.000, 1.000)
9-12 mo (320-410 d)	1	0 (0)	0 (0)	1.000	(1.000, 1.000)
12-18 mo (410-593 d)	1	0 (0)	1 (1)	.	
18-24 mo (593-730 d)	0	0 (0)	0 (1)	.	
Group: 6-7 mm stent-graft TASC II A					
At procedure (day 0)	3	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	3	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	3	0 (0)	1 (1)	1.000	(1.000, 1.000)
3-6 mo (137-228 d)	2	0 (0)	0 (1)	1.000	(1.000, 1.000)
6-9 mo (228-320 d)	2	0 (0)	0 (1)	1.000	(1.000, 1.000)
9-12 mo (320-410 d)	2	0 (0)	0 (1)	1.000	(1.000, 1.000)
12-18 mo (410-593 d)	2	1 (1)	0 (1)	0.500	(0.006, 0.910)
18-24 mo (593-730 d)	1	0 (1)	0 (1)	0.500	(0.006, 0.910)
Group: 6-7 mm stent-graft TASC II B					
At procedure (day 0)	18	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	18	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	18	1 (1)	1 (1)	0.941	(0.650, 0.991)
3-6 mo (137-228 d)	16	1 (2)	0 (1)	0.882	(0.606, 0.969)
6-9 mo (228-320 d)	15	2 (4)	0 (1)	0.765	(0.488, 0.904)
9-12 mo (320-410 d)	13	0 (4)	0 (1)	0.765	(0.488, 0.904)
12-18 mo (410-593 d)	13	1 (5)	0 (1)	0.706	(0.431, 0.866)
18-24 mo (593-730 d)	12	0 (5)	1 (2)	0.706	(0.431, 0.866)
Group: 6-7 mm stent-graft TASC II C					
At procedure (day 0)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
3-6 mo (137-228 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
6-9 mo (228-320 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
9-12 mo (320-410 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
12-18 mo (410-593 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
18-24 mo (593-730 d)	4	0 (0)	2 (2)	1.000	(1.000, 1.000)

Table XIII. Continued

	N at risk at start of interval	*N events during interval*[a]	*N censored during interval*[a]	*Percent free from loss of patency*	*95% CI*
Group: 6-7 mm stent-graft TASC II D					
At procedure (day 0)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	4	1 (1)	1 (1)	0.750	(0.128, 0.961)
3-6 mo (137-228 d)	2	0 (1)	0 (1)	0.750	(0.128, 0.961)
6-9 mo (228-320 d)	2	0 (1)	0 (1)	0.750	(0.128, 0.961)
9-12 mo (320-410 d)	2	0 (1)	0 (1)	0.750	(0.128, 0.961)
12-18 mo (410-593 d)	2	1 (2)	1 (2)	.	
18-24 mo (593-730 d)	0	0 (2)	0 (2)	.	
Group: Femoral-popliteal bypass TASC II A					
At procedure (day 0)	8	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	8	0 (0)	1 (1)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	7	0 (0)	1 (2)	1.000	(1.000, 1.000)
3-6 mo (137-228 d)	6	0 (0)	1 (3)	1.000	(1.000, 1.000)
6-9 mo (228-320 d)	5	0 (0)	0 (3)	1.000	(1.000, 1.000)
9-12 mo (320-410 d)	5	0 (0)	0 (3)	1.000	(1.000, 1.000)
12-18 mo (410-593 d)	5	0 (0)	0 (3)	1.000	(1.000, 1.000)
18-24 mo (593-730 d)	5	0 (0)	0 (3)	1.000	(1.000, 1.000)
Group: Femoral-popliteal bypass TASC II B					
At procedure (day 0)	27	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	27	1 (1)	2 (2)	0.963	(0.765, 0.995)
1-3 mo (31-137 d)	24	1 (2)	0 (2)	0.923	(0.725, 0.980)
3-6 mo (137-228 d)	23	2 (4)	1 (3)	0.841	(0.629, 0.937)
6-9 mo (228-320 d)	20	1 (5)	0 (3)	0.799	(0.581, 0.911)
9-12 mo (320-410 d)	19	2 (7)	0 (3)	0.715	(0.492, 0.853)
12-18 mo (410-593 d)	17	2 (9)	0 (3)	0.631	(0.409, 0.788)
18-24 mo (593-730 d)	15	2 (11)	0 (3)	0.546	(0.332, 0.718)
Group: Femoral-popliteal bypass TASC II C					
At procedure (day 0)	5	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	5	0 (0)	1 (1)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	4	0 (0)	0 (1)	1.000	(1.000, 1.000)
3-6 mo (137-228 d)	4	0 (0)	0 (1)	1.000	(1.000, 1.000)
6-9 mo (228-320 d)	4	0 (0)	0 (1)	1.000	(1.000, 1.000)
9-12 mo (320-410 d)	4	0 (0)	0 (1)	1.000	(1.000, 1.000)
12-18 mo (410-593 d)	4	0 (0)	0 (1)	1.000	(1.000, 1.000)
18-24 mo (593-730 d)	4	0 (0)	0 (1)	1.000	(1.000, 1.000)
Group: Femoral-popliteal bypass TASC II D					
At procedure (day 0)	10	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	10	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	10	1 (1)	1 (1)	0.889	(0.433, 0.984)
3-6 mo (137-228 d)	8	2 (3)	1 (2)	0.635	(0.238, 0.866)
6-9 mo (228-320 d)	5	0 (3)	0 (2)	0.635	(0.238, 0.866)
9-12 mo (320-410 d)	5	0 (3)	0 (2)	0.635	(0.238, 0.866)
12-18 mo (410-593 d)	5	1 (4)	0 (2)	0.508	(0.157, 0.781)
18-24 mo (593-730 d)	4	0 (4)	0 (2)	0.508	(0.157, 0.781)

TASC, TransAtlantic InterSociety Consensus.

[a]Number in parenthesis represents cumulative events or censored observations through end of interval.

Table XIV (online only). Secondary patency by TASC II classification

	N at risk at start of interval	*N events during interval*[a]	*N censored during interval*[a]	*Percent free from loss of patency*	*95% CI*
Group: 5 mm stent-graft TASC II A					
At procedure (day 0)	7	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	7	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	7	0 (0)	0 (0)	1.000	(1.000, 1.000)
3-6 mo (137-228 d)	7	0 (0)	0 (0)	1.000	(1.000, 1.000)
6-9 mo (228-320 d)	7	0 (0)	0 (0)	1.000	(1.000, 1.000)
9-12 mo (320-410 d)	7	0 (0)	0 (0)	1.000	(1.000, 1.000)
12-18 mo (410-593 d)	7	0 (0)	0 (0)	1.000	(1.000, 1.000)
18-24 mo (593-730 d)	7	0 (0)	0 (0)	1.000	(1.000, 1.000)
Group: 5 mm stent-graft TASC II B					
At procedure (day 0)	11	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	11	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	11	3 (3)	1 (1)	0.727	(0.371, 0.903)
3-6 mo (137-228 d)	7	1 (4)	1 (2)	0.623	(0.277, 0.840)
6-9 mo (228-320 d)	5	0 (4)	0 (2)	0.623	(0.277, 0.840)
9-12 mo (320-410 d)	5	0 (4)	0 (2)	0.623	(0.277, 0.840)
12-18 mo (410-593 d)	5	0 (4)	1 (3)	0.623	(0.277, 0.840)
18-24 mo (593-730 d)	4	0 (4)	0 (3)	0.623	(0.277, 0.840)
Group: 5 mm stent-graft TASC II C					
At procedure (day 0)	2	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	2	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	2	1 (1)	0 (0)	0.500	(0.006, 0.910)
3-6 mo (137-228 d)	1	0 (1)	0 (0)	0.500	(0.006, 0.910)
6-9 mo (228-320 d)	1	0 (1)	0 (0)	0.500	(0.006, 0.910)
9-12 mo (320-410 d)	1	0 (1)	0 (0)	0.500	(0.006, 0.910)
12-18 mo (410-593 d)	1	0 (1)	0 (0)	0.500	(0.006, 0.910)
18-24 mo (593-730 d)	1	1 (2)	0 (0)	0.000	(0.006, 0.910)
Group: 5 mm stent-graft TASC II D					
At procedure (day 0)	1	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	1	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	1	0 (0)	0 (0)	1.000	(1.000, 1.000)
3-6 mo (137-228 d)	1	0 (0)	0 (0)	1.000	(1.000, 1.000)
6-9 mo (228-320 d)	1	0 (0)	0 (0)	1.000	(1.000, 1.000)
9-12 mo (320-410 d)	1	0 (0)	0 (0)	1.000	(1.000, 1.000)
12-18 mo (410-593 d)	1	0 (0)	1 (1)	.	
18-24 mo (593-730 d)	0	0 (0)	0 (1)	.	
Group: 6-7 mm stent-graft TASC II A					
At procedure (day 0)	3	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	3	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	3	0 (0)	1 (1)	1.000	(1.000, 1.000)
3-6 mo (137-228 d)	2	0 (0)	0 (1)	1.000	(1.000, 1.000)
6-9 mo (228-320 d)	2	0 (0)	0 (1)	1.000	(1.000, 1.000)
9-12 mo (320-410 d)	2	0 (0)	0 (1)	1.000	(1.000, 1.000)
12-18 mo (410-593 d)	2	1 (1)	0 (1)	0.500	(0.006, 0.910)
18-24 mo (593-730 d)	1	0 (1)	0 (1)	0.500	(0.006, 0.910)
Group: 6-7 mm stent-graft TASC II B					
At procedure (day 0)	18	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	18	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	18	0 (0)	1 (1)	1.000	(1.000, 1.000)
3-6 mo (137-228 d)	17	1 (1)	0 (1)	0.941	(0.650, 0.991)
6-9 mo (228-320 d)	16	1 (2)	0 (1)	0.882	(0.606, 0.969)
9-12 mo (320-410 d)	15	0 (2)	0 (1)	0.882	(0.606, 0.969)
12-18 mo (410-593 d)	15	1 (3)	0 (1)	0.824	(0.547, 0.939)
18-24 mo (593-730 d)	14	0 (3)	1 (2)	0.824	(0.547, 0.939)
Group: 6-7 mm stent-graft TASC II C					
At procedure (day 0)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
3-6 mo (137-228 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
6-9 mo (228-320 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
9-12 mo (320-410 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
12-18 mo (410-593 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
18-24 mo (593-730 d)	4	0 (0)	2 (2)	1.000	(1.000, 1.000)

Table XIV. Continued

	N at risk at start of interval	*N events during interval*[a]	*N censored during interval*[a]	*Percent free from loss of patency*	*95% CI*
Group: 6-7 mm stent-graft TASC II D					
At procedure (day 0)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	4	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	4	1 (1)	1 (1)	0.750	(0.128, 0.961)
3-6 mo (137-228 d)	2	0 (1)	0 (1)	0.750	(0.128, 0.961)
6-9 mo (228-320 d)	2	0 (1)	0 (1)	0.750	(0.128, 0.961)
9-12 mo (320-410 d)	2	0 (1)	0 (1)	0.750	(0.128, 0.961)
12-18 mo (410-593 d)	2	1 (2)	1 (2)	.	
18-24 mo (593-730 d)	0	0 (2)	0 (2)	.	
Group: Femoral-popliteal bypass TASC II A					
At procedure (day 0)	8	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	8	0 (0)	1 (1)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	7	0 (0)	1 (2)	1.000	(1.000, 1.000)
3-6 mo (137-228 d)	6	0 (0)	1 (3)	1.000	(1.000, 1.000)
6-9 mo (228-320 d)	5	0 (0)	0 (3)	1.000	(1.000, 1.000)
9-12 mo (320-410 d)	5	0 (0)	0 (3)	1.000	(1.000, 1.000)
12-18 mo (410-593 d)	5	0 (0)	0 (3)	1.000	(1.000, 1.000)
18-24 mo (593-730 d)	5	0 (0)	0 (3)	1.000	(1.000, 1.000)
Group: Femoral-popliteal bypass TASC II B					
At procedure (day 0)	27	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	27	1 (1)	2 (2)	0.963	(0.765, 0.995)
1-3 mo (31-137 d)	24	0 (1)	0 (2)	0.963	(0.765, 0.995)
3-6 mo (137-228 d)	24	2 (3)	1 (3)	0.881	(0.674, 0.960)
6-9 mo (228-320 d)	21	1 (4)	0 (3)	0.839	(0.625, 0.936)
9-12 mo (320-410 d)	20	0 (4)	0 (3)	0.839	(0.625, 0.936)
12-18 mo (410-593 d)	20	1 (5)	1 (4)	0.797	(0.578, 0.910)
18-24 mo (593-730 d)	18	2 (7)	0 (4)	0.708	(0.482, 0.850)
Group: Femoral-popliteal bypass TASC II C					
At procedure (day 0)	5	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	5	0 (0)	1 (1)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	4	0 (0)	0 (1)	1.000	(1.000, 1.000)
3-6 mo (137-228 d)	4	0 (0)	0 (1)	1.000	(1.000, 1.000)
6-9 mo (228-320 d)	4	0 (0)	0 (1)	1.000	(1.000, 1.000)
9-12 mo (320-410 d)	4	0 (0)	0 (1)	1.000	(1.000, 1.000)
12-18 mo (410-593 d)	4	0 (0)	0 (1)	1.000	(1.000, 1.000)
18-24 mo (593-730 d)	4	0 (0)	0 (1)	1.000	(1.000, 1.000)
Group: Femoral-popliteal bypass TASC II D					
At procedure (day 0)	10	0 (0)	0 (0)	1.000	(1.000, 1.000)
Postoperative (0-31 d)	10	0 (0)	0 (0)	1.000	(1.000, 1.000)
1-3 mo (31-137 d)	10	1 (1)	1 (1)	0.889	(0.433, 0.984)
3-6 mo (137-228 d)	8	1 (2)	1 (2)	0.762	(0.332, 0.935)
6-9 mo (228-320 d)	6	0 (2)	0 (2)	0.762	(0.332, 0.935)
9-12 mo (320-410 d)	6	0 (2)	0 (2)	0.762	(0.332, 0.935)
12-18 mo (410-593 d)	6	1 (3)	0 (2)	0.635	(0.238, 0.866)
18-24 mo (593-730 d)	5	0 (3)	0 (2)	0.635	(0.238, 0.866)

TASC, TransAtlantic InterSociety Consensus.

[a]Number in parenthesis represents cumulative events or censored observations through end of interval.