Published in final edited form as:

Vascular. 2015 June ; 23(3): 225–233. doi:10.1177/1708538114545109.

Early results with LifeStent implantation in RESILIENT and non-RESILIENT inclusion criteria patients

Patrick A Stone¹, John E Campbell¹, Rashi Fischer², David Phang¹, Stephanie N Thompson², Neil Dippel², and Albeir Mousa¹

¹Department of Surgery, Robert C. Byrd Health Sciences Center, West Virginia University, Charleston, USA

²Charleston Area Medical Center, Charleston, USA

Abstract

The purpose of our study was to determine outcomes of patients receiving the LifeStent (Bard Peripheral Vascular, Tempe, AZ) for femoropopliteal peripheral arterial disease in real-world academic practice outside the limitations of an industry supported trial. All patients from 2009 to 2012 at our institution who received a LifeStent during endovascular interventions and had follow-up were included. Outcomes evaluated included patency and freedom from limb loss. A total of 166 limbs in 151 patients had the LifeStent implanted in de novo vessels (54% male; 68 ± 12 years). Eighty-percent of limbs did not meet RESILIENT criteria due to Rutherford category >3 (51%), TransAtlantic Inter-Society Consensus II classifications C/ D (51%), zero runoff vessels (6%), or stent location (17%). Primary patency rates were 81% at 6 months and 58% at 12 months with predictors for primary patency loss at 1 year including Rutherford category >3 (HR: 1.8 (95% CI: 1.0–3.1), $p = 0.04$), tobacco use (HR: 1.8 (95% CI: 1.0–3.3), $p = 0.04$), and no clopidogrel at discharge (HR: 3.2 (95% CI: 1.6–6.7), $p < 0.01$). A preintervention Rutherford category >3 predicted 24-month limb loss (HR, 16.0 (95% CI: 2.0–122.0), $p < 0.01$). The LifeStent is a viable option regardless of the TransAtlantic Inter-Society Consensus II classification; however, critical limb ischemia, current tobacco use, and absence of clopidogrel on discharge predict decreased patency on follow-up.

Keywords

Peripheral artery disease; angioplasty; stent; superficial femoral artery and popliteal artery

© The Author(s) 2014

Reprints and permissions: sagepub.co.uk/journalsPermissions.nav

Corresponding author: Patrick A Stone, Department of Surgery, Robert C. Byrd Health Sciences Center, West Virginia University, 3110 MacCorkle Avenue SE, Charleston, WV 25304, USA. pstone0627@yahoo.com.

Conflict of interest

None declared.

Introduction

Endovascular treatment in patients with symptomatic femoropopliteal artery occlusive disease provides a minimally invasive approach with excellent immediate technical results. Simple balloon angioplasty results appear inferior to adjunct stent placement up to 2 years.¹ The last TransAtlantic Inter-Society Consensus-II (TASC II) working group supported the use of endovascular interventions for TASC II A, B, and select C lesions. The TASC II criteria increased the lesion length recommended to be treated via endovascular interventions compared to the original TASC consensus.² Some evidence additionally supports endovascular stenting over surgical reconstruction using femoral-above-the-knee prosthetic bypass for TASC II C lesions, with similar results even in TASC II D lesions.³ However, Sacks et al. among others have written reporting standards for evaluating endovascular interventions and have noted varying and inconsistent methods of evaluation, follow-up, and reporting of outcomes among practitioners.⁴

Unfortunately most stent studies that are industry supported for approval treat predominately patients with claudication, shorter lesions, and do not allow adjunct inflow or outflow procedures. Data from the RESILIENT trial appeared promising with the use of the LifeStent (Bard Peripheral Vascular, Tempe, AZ) in the treatment of a select group of patients with femoropopliteal occlusive disease.⁵ Additionally, the 3-year follow-up demonstrated a reduction in target vessel revascularization, clinical success, and a less than 5% stent fracture rate.⁶

Our institution has been using the LifeStent since its approval by the United States Food and Drug Administration (FDA) for use in the superficial femoral and proximal popliteal artery. Although data are available on the outcomes in patients who meet RESILIENT criteria for intervention, this may not represent the patient population treated in many clinical practices. We have reviewed our experience over the study period to determine the outcomes of patients treated for femoropopliteal disease with the LifeStent in an effort to determine predictors of treatment failure and to assess if patients treated outside of the inclusion criteria for the RESILIENT trial have similar results to patients who met inclusion criteria.

Methods

Our study retrospectively examined all patients who had LifeStents (Bard Peripheral Vascular, Tempe, AZ, USA) implanted in the femoropopliteal arterial segment at Charleston Area Medical Center (CAMC) between June 2009 and May 2012 with objective follow-up. All aspects of the study were reviewed and approved by the CAMC/West Virginia University, Charleston Division Institutional Review Board. A list of patients over the age of 18 who had implantation of the LifeStent during the study period was populated via the stent's billing code. Patients who presented with de novo disease were included while those with acute limb ischemia or prior stent or bypass graft to the ipsilateral limb were excluded from analysis. In addition, patients were excluded if they did not have postprocedure follow-up defined as having one or more of the following: duplex-ultrasound examination, conventional contrast angiography, or ankle-brachial index (ABI) measurements.

Electronic medical records and the patients' angio-grams were evaluated for patient demographics, comorbidities, Rutherford classification of disease, TASC II classification of lesions, presence of occlusion, number of runoff vessels to the foot, number and length of stents, stent location, medications at discharge, follow-up imaging, vessel patency, need for reintervention or amputation, and overall survival. Location of stent placement in the superficial femoral and popliteal arteries meeting RESILIENT criteria is defined as the area extending from 1 cm below the origin of the profunda femoris artery to >3 cm above the intercondylar notch of the femur.⁵ *Primary patency (unassisted)* was defined as uninterrupted patency (i.e. lack of occlusion) of the stent as determined by duplex ultrasound or conventional contrast angiography without the need for revascularization. For those patients not having postprocedure duplex ultrasound or angiography, primary patency was defined as an absence of a >0.15 decrease in ABI during the follow-up period.⁴ *Assisted primary patency* was preserved via secondary endovascular interventions to treat the target vessel for symptomatic severe >70% diameter reducing stenosis. *Secondary patency* was preserved via secondary endovascular interventions to treat target vessel occlusion. All-cause mortality was determined by hospital records and the Social Security Death Index.

The data analysis was performed using IBM SPSS Statistics 19.0. Basic descriptive statistics, such as means and standard deviations for continuous variables and proportions and frequencies for categorical variables were used to report patient, procedure, and outcome characteristics. Demographic and comorbidity information were recorded per patient while patency data were calculated per limb. Patency, limb loss, and all-cause mortality were analyzed using the Kaplan–Meier method with log-rank tests to compare RESILIENT versus non-RESILIENT groups. Cox proportional hazards regression analysis was used to determine predictors of loss of primary patency, limb loss, and mortality. Criterion for inclusion in the multivariate model was a univariate analysis value of $p < 0.20$. Backward stepwise regression was then used for entry in the Cox proportional hazards model. A p level of < 0.05 was used to determine statistical significance.

Results

Between June 2009 and May 2012, a total of 166 limbs in 151 patients were included in analysis and served as the study group. Sixty-nine de novo lesion repairs using LifeStents were additionally performed during this period; however, they did not have imaging performed during follow-up as required for study inclusion.

Eighty-one (54%) patients were male with the mean age of 67.8 ± 11.8 years. Comorbidities were common and are described in Table 1. Eighty-one (49%) procedures were performed for claudication (Rutherford classification: 1–3), 30 (18%) for rest pain (Rutherford classification: 4), and 55 (33%) for ulcers or gangrene (Rutherford classification: 5–6). Thirty-six limbs were classified as TASC II A (21%), 46 TASC II B (28%), 76 TASC II C (46%), and eight TASC II D (5%). A total of 92 of the 166 limbs (55%) treated had an occluded femoropopliteal segment. Only a small number of treated limbs (34, 20%) conformed to RESILIENT inclusion criteria. The remaining 132 limbs possessed one or more characteristics excluding them from meeting RESILIENT inclusion criteria (51% with critical limb ischemia (Rutherford class >3), 51% with a total lesion length >150 mm

(TASC II C/D), 17% with stent placement outside the defined anatomical zone, and 6% with zero runoff vessels, Table 2). The mean length of stents used in interventions was 192 ± 122 mm (range 20–560 mm), with 87 limbs receiving one stent, 54 limbs receiving two stents, 20 limbs receiving three stents, four limbs receiving four stents, and one limb receiving five stents. Medications at discharge are presented in Table 3.

During the entire follow-up period (median: 8.5 months (range: 1 month–44 months)), 76 limbs lost primary patency with 55 limbs losing primary patency by 1 year. At 12 months, the primary patency rate was 58%, primary-assisted rate was 73%, and secondary patency rate was 86% (Figure 1). Patients meeting RESILIENT inclusion criteria had a primary patency rate of 75% at 6 months and 66% at 12 months versus 83% at 6 months and 55% at 12 months in limbs not meeting RESILIENT inclusion criteria, with failure to meet inclusion criteria not affecting primary patency rate (Figure 2, $p = 0.70$). Classification of TASC II C/D, stent placement outside the defined zone for the RESILIENT trial (not between 1 cm below the origin of the profunda femoris artery to >3 cm above the intercondylar notch of the femur), or having zero runoff vessels were not associated with decreased primary patency at 12 months (Table 4). On multivariate analysis, Rutherford classification >3 (Hazard Ratio (HR): 1.8 (95% Confidence Interval (CI): 1.0–3.1), $p = 0.04$), current tobacco use (HR, 1.8 (95% CI: 1.0–3.3), $p = 0.04$), and no clopidogrel at discharge (HR, 3.2 (95% CI: 1.6–6.7), $p < 0.01$) were found to be statistically significant predictors of primary patency loss at 12 months (Table 5).

Sixty limbs received revascularization with 14 limbs of those ultimately requiring bypass surgeries. Two limbs within 3 months of index procedure and three limbs at 1 year (12–15 months) received surgical bypasses in the absence of additional endovascular revascularization to restore blood flow. A total of 41 limbs received secondary endovascular interventions within 12 months, with six limbs ultimately requiring bypass grafts. Another 14 limbs received endovascular revascularization during follow-up after 1 year, with three limbs eventually undergoing open/surgical repair.

Fifteen limbs were amputated during the follow-up period ((median: 15 months (range: 1 month–44 months)). Four limbs were amputated perioperatively (i.e. within 30 days of the procedure). Two limbs with nonhealing wounds, gangrene, and chronic osteomyelitis of the foot and ankle were endovascularly treated using LifeStents within 1 week prior to a below-the-knee amputation as a preplanned measure to assist in wound healing. Two additional limbs had extensive tissue loss (Rutherford classification of 6) at time of femoropopliteal stenting with concomitant infrapopliteal transcatheter therapy, but due to worsened tissue loss after the procedure both patients required a below-the-knee amputation within 1 month of the procedure. From 1 to 12 months postprocedure, four limbs were amputated after target vessel reintervention and two with endovascular intervention and two received surgical bypass. Four other limbs received amputation without reintervention during the same time period. Three additional limbs received amputation after 1 year (range 17–24 months) with all receiving target vessel reintervention (two limbs receiving endovascular reintervention and one limb receiving a surgical bypass) prior to amputation. Rates of limb salvage were 92% at 12 months and 87% at 24 months (Figure 3). Failure to meet RESILIENT inclusion criteria was not associated with limb loss ($p = 0.15$, Figure 3). The

only multivariate predictor of limb loss at 24 months was a Rutherford classification >3 (HR, 16.0 (95% CI: 2.0–122.0), $p = 0.007$).

Thirty-one patients died during follow-up with 28 of those deaths occurring by 12 months. Cumulative rates of survival at 12 and 24 months were 87 and 80%, respectively (Figure 4). Patients with limbs failing to meet RESILIENT inclusion criteria had lower survival with rates of 84% at 12 months and 77% at 24 months compared to 100 and 96% at 12 and 24 months in patients who met inclusion criteria (Figure 4, $p = 0.01$). In multivariate analysis controlling for variables found to be significant in univariate analysis, only age (HR, 1.05 (95% CI: 1.0–1.1), $p = 0.003$), stent placement outside the RESILIENT defined zone (HR, 2.4 (95% CI: 1.1–5.1), $p = 0.03$), and Rutherford classification >3 (HR, 2.9 (95% CI: 1.2–7.3), $p = 0.02$) predicted mortality at 24 months. Figure 5 summarizes the outcomes including stent failure, need for reintervention, and limb amputation during the follow-up period of 166 limbs having a LifeStent implanted.

Discussion

There have been recent clinical trials completed that randomized patients to receive balloon angioplasty or nitinol stent implantation for the treatment of occlusive disease involving the superficial femoral artery and proximal popliteal artery.^{5,7,8} The RESILIENT Trial is one such recently completed trial and it evaluated the LifeStent (Bard Peripheral Vascular, Tempe, AZ). Two other trials that have been completed are the Stroll Trial which assessed the S.M.A.R.T. Vascular Stent System (Cordis Corporation, Bridgewater, NJ) and the Zilver PTX Randomized Clinical Study which evaluated the Zilver PTX Drug-Eluting Stent (Cook Medical, Bloomington, IN). All three trials had similar anatomic inclusion criteria with the maximum lesion length being 15 cm in the Stroll and RESILIENT Trials and 14 cm in the Zilver PTX Randomized Clinical Study. All three trials demonstrated excellent 1 year primary patency rates for the patients that had stents implanted that ranged from 81.1 to 83.1%. However, in our single-center retrospective cohort study we found that the majority of patients (80%) treated for femoropopliteal disease at our institution did not meet the inclusion criteria that were applied for the RESILIENT Trial. Fifty-one percent of patients in our study cohort did not meet the inclusion criteria for the RESILIENT Trial secondary to having TASC II C or D lesions and these patients would also not meet the anatomic criteria for the Stroll Trial or Zilver PTX Randomized Clinical Study. Previously reported trials have demonstrated that increased severity of disease based on TASC II classification predicts decreased primary patency^{9–12} and we felt this would most likely be the case with implantation of the LifeStent at our institution. However, our study demonstrated no significant difference in primary patency rates at 1 year in patients with TASC II A/B lesions compared to TASC II C/D. Other trials have had similar results as our study and have not shown TASC II classification to predict patency.^{13–15}

Our study demonstrated that clinical presentation affects outcome, and patients who presented with critical limb ischemia (Rutherford Stage 4–6) have lower primary patency when compared to patients who present with intermittent claudication (Rutherford Stage 1–3). When examining the three previously mentioned randomized trials that compared balloon angioplasty to nitinol stent implantation for the treatment of femoropopliteal

occlusive disease, there was also a difference in the inclusion criteria for the trials based on Rutherford Classification. The RESILIENT Trial enrolled patients only with claudication (Rutherford 1–3), while both the Stroll Trial (Rutherford 2–4) and the Zilver PTX Randomized Clinical Study (Rutherford 2–6) enrolled patients with critical limb ischemia. However, critical limb ischemia encompassed only a minority of patients in the Stroll Trial (2.8%) and Zilver PTX Randomized Clinical Study (8.9%). Unfortunately these trials provide little information to determine if patients with critical limb ischemia have decreased patency when compared to patients who present with intermittent claudication. Other trials have included a more substantial number of patients with critical limb ischemia in their study cohort and clinical presentation has been shown not to impact patency in multiple trials.^{10,12,14} However, Soga et al. demonstrated a significant difference in the primary patency in patients with intermittent claudication versus critical limb ischemia, however this was not confirmed in multivariate analysis.⁹ Also, Dearing et al. demonstrated in limbs receiving endovascular procedures to the superficial femoral and popliteal arteries that rest pain significantly associated with primary patency loss, and ulceration, though not significant, trended towards to impacting patency.¹¹ However, on multivariate analysis neither predicted primary patency loss. Scali et al. performed a retrospective review of all patients who received either a femoral–popliteal bypass or primary stent placement in the superficial femoral artery at their institution.¹⁵ Interestingly, in the overall cohort critical limb ischemia was predictive of a decreased primary patency; however, when analysis for the bypass and stent groups was performed independently, critical limb ischemia was not a predictor of failure in patients who had a bypass graft but was a predictor of failure in patients who had placement of a stent.¹⁵

Our study is unique in that we specifically evaluated the LifeStent and compared outcomes based on meeting the inclusion criteria for the RESILIENT Trial and assessed predictors of loss of patency on follow-up. An extensive literature search found only one study that has been completed that evaluated specifically the LifeStent outside of the RESILIENT Trial. The STenting Long de L' Artère fémorale superficielle (STELLA) cohort evaluated 58 patients who had LifeStents implanted for TASC II C and D lesions.^{16,17} The majority of patients treated had critical limb ischemia (59.7%), and primary patency at 1 year for LifeStents implanted for TASC II C and D lesions was 66%. In the STELLA cohort, 23 patients (37.1%) had TASC II D lesions and there was a significant difference in primary patency rate at 1 year in patients with TASC II C (82%) versus TASC II D (44%) lesions. We did not compare TASC II C to TASC II D lesions in our study given the low number of patients in the TASC II D group (n = 8). In the STELLA trial, primary patency tended to be improved in patients with intermittent claudication (79%) versus critical limb ischemia (61%) but did not reach statistical significance (p = 0.17). There was an increased stent fracture rate at 1-year follow-up in the STELLA Trial (18%) when compared to the RESILIENT Trial (3%); however, in both trials stent fractures did not associate with a loss of patency at 1 year.^{5,17} We did not obtain x-rays routinely in our patients; however, RESILIENT Trial and STELLA Trial results suggest that fracture rates may increase with implantation of LifeStents in TASC II C and D lesions but that fractures appear to have no significant impact on primary patency, though this needs further study.

Limitations

The main limitation of the study was that the median follow-up was only 8.5 months (range: 1 week to 44 months) and that many patients did not have data available for 12-month analysis. The LifeStent was not used in our institution until after it was approved by the FDA for use for atherosclerotic narrowing of the superficial femoral or proximal popliteal artery, which occurred on 13 February 2009. This impacts the reliability of our results and once longer follow-up is available we plan to reanalyze the data.

Another limitation is the small sample size of our cohort that was studied. This could affect the statistical significance of our results. Patients meeting RESILIENT inclusion criteria had a primary patency rate of 66% at 12 months versus 55% at 12 months in limbs not meeting RESILIENT inclusion criteria and that this did not reach statistical significance. If more patients were available to be included in the study, especially in the cohort of patients of meeting RESILIENT inclusion criteria, this may have reached statistical significance.

An additional limitation was that there was variability in the protocol used for follow-up of patients after LifeStent implantation. This was operator dependent with some physicians routinely ordering a duplex examination and other physicians following with ABIs only and potentially only ordering a duplex with the ABIs if they had concerns if the stent was patent. This variability could lead to operator bias and this could affect the results. However, 91% of our patients had duplex imaging of the superficial artery demonstrating patency of the treated segment and 9% had serial ABI only. Additionally, we did not use specific velocity criteria as used in the RESILIENT study, as no consensus has been made on accepted peak systolic velocity or velocity ratio that reliably determines a critical stenosis.

Lastly, this was a retrospective study and patients were only included who had appropriate follow-up. This may cause bias toward a decreased primary patency than what would be determined in a prospective trial. This is secondary to patients potentially being more likely to follow-up if they are experiencing symptoms or “having problems” than patients who are “doing well.” Therefore, the exclusion of the 69 patients who were not reimaged during follow-up might represent patients who are “doing well” and have not returned to our facility.

Conclusions

Our study determined that early results with implantation of the LifeStent are acceptable and that it is a viable treatment option for patients with peripheral arterial disease regardless of the TASC II classification; however, critical limb ischemia, current tobacco use, and absence of use of clopidogrel on discharge predict decreased patency on follow-up.

Acknowledgments

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

References

1. Schillinger M, Sabeti S, Dick P, et al. Sustained benefit at 2 years of primary femoropopliteal stenting compared with balloon angioplasty with optional stenting. *Circulation*. 2007; 115:2745–2749. [PubMed: 17502568]
2. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg*. 2007; 45:S5–S67. [PubMed: 17223489]
3. Dosluoglu HH, Cherr GS, Lall P, et al. Stenting vs above knee polytetrafluoroethylene bypass for TransAtlantic Inter-Society Consensus-II C and D superficial femoral artery disease. *J Vasc Surg*. 2008; 48:1166–1174. [PubMed: 18692357]
4. Sacks D, Marinelli DL, Martin LG, et al. Reporting standards for clinical evaluation of new peripheral arterial revascularization devices. *J Vasc Interv Radiol*. 2003; 14:S395–S400. [PubMed: 14514855]
5. Laird JR, Katzen BT, Scheinert D, et al. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: Twelve-month results from the RESILIENT randomized trial. *Circ Cardiovasc Interv*. 2010; 3:267–276. [PubMed: 20484101]
6. Laird JR, Katzen BT, Scheinert D, et al. Nitinol stent implantation vs. balloon angioplasty for lesions in the superficial femoral and proximal popliteal arteries of patients with claudication: Three-year follow-up from the RESILIENT randomized trial. *J Endovasc Ther*. 2012; 19:1–9. [PubMed: 22313193]
7. Jaff MR. SMART nitinol self-expanding stent for the treatment of peripheral artery disease: 1-Year results of the STROLL Trial. Presented at VIVA 2012: Vascular InterVentional Advances meeting; Las Vegas, Nevada. 2012;
8. Dake MD, Ansel GM, Jaff MR, et al. Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: Twelve-month Zilver PTX randomized study results. *Circ Cardiovasc Interv*. 2011; 4:495–504. [PubMed: 21953370]
9. Soga Y, Iida O, Hirano K, et al. Mid-term clinical outcome and predictors of vessel patency after femoropopliteal stenting with self-expandable nitinol stent. *J Vasc Surg*. 2010; 52:608–615. [PubMed: 20573476]
10. Iida O, Soga Y, Hirano K, et al. Long-term outcomes and risk stratification of patency following nitinol stenting in the femoropopliteal segment: Retrospective multicenter analysis. *J Endovasc Surg*. 2011; 18:753–761.
11. Dearing DD, Patel KR, Compoginis JM, et al. Primary stenting of the superficial femoral and popliteal artery. *J Vasc Surg*. 2009; 50:542–548. [PubMed: 19540706]
12. Suzuki K, Iida O, Soga Y, et al. Long-term results of the S.M.A.R.T. Control™ stent for superficial femoral artery lesions, J-Smart Registry. *Circ J*. 2011; 75:939–944. [PubMed: 21325721]
13. Schoenefeld E, Donas KP, Schönefeld T, et al. Mid-term outcome after endovascular therapy in the superficial femoral and popliteal artery using long stents. *Vasa*. 2012; 41:49–56. [PubMed: 22247060]
14. Schonefeld E, Torsello G, Osada N, et al. Long-term outcome of femoropopliteal stenting. Results of a prospective study. *J Cardiovasc Surg*. 2013; 54:617–623. [PubMed: 24002391]
15. Scali ST, Rzuclido EM, Bjerke AA, et al. Long-term results of open and endovascular revascularization of superficial femoral artery occlusive disease. *J Vasc Surg*. 2011; 54:714–721. [PubMed: 21620611]
16. Davaine JM, Azéma L, Guyomarch B, et al. One-year clinical outcome after primary stenting for Trans- Atlantic Inter-Society Consensus (TASC) C and D femoropopliteal lesions (The STELLA “STenting Long de L’Artère fémorale superficielle” Cohort). *Eur J Vasc Endovasc Surg*. 2012; 44:432–441. [PubMed: 22920949]
17. Davaine JM, Quérat J, Guyomarch B, et al. Incidence and the clinical impact of stent fractures after primary stenting for TASC C and D femoropopliteal lesions at 1 year. *Eur J Vasc Endovasc Surg*. 2013; 46:201–212. [PubMed: 23773773]

Figure 1.

Kaplan–Meier curve showing primary, primary assisted, and secondary patency in limbs receiving a LifeStent for the treatment of femoropopliteal arterial disease.

Figure 2.

Kaplan–Meier curve showing primary patency in limbs meeting RESILIENT criteria versus those not meeting RESILIENT criteria.

Figure 3.

Kaplan–Meier curve showing limb salvage in limbs meeting RESILIENT criteria versus those not meeting RESILIENT criteria.

Figure 4.

Kaplan–Meier curve showing cumulative survival in patients meeting RESILIENT criteria versus those not meeting RESILIENT criteria.

Figure 5.

A flow diagram summarizing outcomes of the 166 limbs treated with a LifeStent for the treatment of femoropopliteal arterial disease.

Table 1

Patient demographics and comorbidities.

	N (%)
Age, years (mean $\pm$ SD)	67.8 $\pm$ 11.8
Gender: Male	81 (54%)
Race: Caucasian	143 (95%)
Current tobacco use	37 (36%)
Comorbidities	
Diabetes mellitus	84 (56%)
Hyperlipidemia	112 (74%)
Coronary artery disease	92 (61%)
Chronic kidney disease	44 (29%)
Hypertension	130 (86%)

Table 2

Limbs meeting and not meeting RESILIENT criteria.

Meeting RESILIENT criteria	34 (20%)
Not meeting RESILIENT criteria	132 (80%)
<i>Reason for limbs not meeting RESILIENT criteria</i>	
Rutherford classification >3	85 (51%)
A total lesion length >150 mm (TASC II classification of C or D)	84 (51%)
Stent placement outside the <i>RESILIENT</i> defined zone (1 cm below the origin of the profunda femoris artery to >3 cm above the intercondylar notch of the femur)	29 (17%)
Zero runoff vessels to the foot	10 (6%)

Table 3

Medications at discharge.

	N (%)
Aspirin	126 (83%)
Clopidogrel	139 (92%)
Dual therapy (aspirin+clopidogrel)	119 (79%)
Statin	97 (64%)
Coumadin	14 (9%)
Pletal	10 (7%)
HTN medication (if indicated)	107 (71%)

Table 4

Univariate analysis of factors associated with the loss of primary patency at 12 months.

Univariate Cox proportional-hazards model		
Variable	Hazards ratio (95% CI)	P value
Age	1.0 (1.0–1.0)	0.54
Gender (male)	1.2 (0.7–2.0)	0.54
Diabetes mellitus	1.4 (0.8–2.4)	0.22
Hyperlipidemia	1.0 (0.5–1.8)	0.99
Coronary artery disease	1.1 (0.6–1.9)	0.71
Chronic kidney disease	1.1 (0.6–2.0)	0.65
Hypertension	0.9 (0.6–1.4)	0.70
Current tobacco use	2.0 (1.1–3.4)	0.02
LifeStent use not meeting RESILIENT criteria	1.1 (0.6–2.3)	0.70
Rutherford classification >3	1.7 (1.0–2.9)	0.049
TASCII classification (C or D)	1.3 (0.7–2.6)	0.40
Zero runoff vessels to foot	1.0 (0.3–3.3)	0.95
Stent placement outside the RESILIENT defined zone	1.3 (0.7–2.6)	0.40
Vessel occlusion	1.3 (0.8–2.3)	0.32
Number of stents (>1)	1.0 (0.8–1.3)	0.86
No aspirin at discharge	1.6 (0.9–2.9)	0.15
No clopidogrel at discharge	3.2 (1.6–6.5)	0.002
No statin at discharge	0.9 (0.5–1.6)	0.76
No hypertension medicine at discharge	1.4 (0.8–2.5)	0.25

Table 5

Multivariate analysis of factors associated with the loss of primary patency at 12 months.

Multivariate Cox proportional-hazards model		
Variable	Hazards ratio (95% CI)	P value
Rutherford classification >3	1.8 (1.0–3.1)	0.04
Current tobacco use	1.8 (1.0–3.3)	0.04
No clopidogrel at discharge	3.2 (1.6–6.7)	0.001