Primary stenting of the superficial femoral and popliteal artery

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Objectives: **Over the last decade, the number of endovascular procedures performed on the superficial femoral (SFA) and popliteal arteries (PA) has significantly increased. There is no consensus on the optimal form of intervention used in this arterial segment. While some have advocated balloon angioplasty alone, others have championed either selective or primary stenting of these lesions. It is the purpose of this study to determine the efficacy and durability of primary stenting of the superficial femoral and popliteal artery.**

Methods: **All patients undergoing peripheral angioplasty by a single vascular surgeon were prospectively enrolled in an Institutional Review Board-approved, primary-stenting protocol. During a 44-month period, all patients undergoing percutaneous transluminal angioplasty of the SFA or PA also received primary arterial stenting with bare, self-expanding nitinol stents. Patient demographics and risk factors were identified. TransAtlantic InterSociety Consensus (TASC) classifications were determined for all lesions. Loss of primary patency was said to have occurred when an occlusion or a 50% or greater stenosis in any treated arterial segment was diagnosed by arterial duplex or angiography. Only time to loss of primary patency was recorded. Kaplan-Meier survival curves were plotted and differences between groups tested by log rank method.**

Results: **Between January 16, 2004 and August 13, 2007, 201 angioplasties with primary stenting were performed on 161 patients. One hundred twenty-three stents were placed for claudication, and 78 for critical limb ischemia. Forty-six segments treated were TASC A, 82 were TASC B, 38 were TASC C, and 35 were TASC D. Patient follow-up ranged from three to 1329 days (mean: 426 days). Primary patency rates for TASC A and B lesions were 79%, 67%, and 57% at 12, 24, and 36 months. For TASC C and D lesions, primary patency rates were 52.7%, 36%, and 19% at the same time intervals. Primary patency rates for TASC A and B lesions were significantly higher than for C and D lesions ($P < .001$). The limb salvage rate was 88.5% in patients with critical limb ischemia. Distal runoff did not influence patency ($P = .827$).**

Conclusions: **Primary stenting of the SFA and PA provides durable results in patients with TASC A and B lesions and may be an effective treatment strategy. This approach is significantly less effective when used in treating those with TASC C and D disease. Based on the results in this series, the use of primary stenting does not extend the anatomic limits of the current treatment recommendations for catheter-based intervention in patients with infrainguinal occlusive disease. (J Vasc Surg 2009;50:542-8.)**

It has been over 30 years since Gruntzig introduced the modern balloon angioplasty catheter and ushered in the contemporary era of the percutaneous treatment of peripheral arterial disease.[1] The aging of our population and the resultant increase in the prevalence of peripheral vascular disease has led to an explosive rise in the number of catheter-based procedures being performed in patients with lower limb ischemia.[2] Since endovascular procedures are often used as a first line treatment for lower extremity ischemia, it is becoming increasingly important to determine which modes of therapy are the most durable and cost effective.

While the results of percutaneous treatment of iliac lesions have approached that of open procedures,[3] the same cannot be said for angioplasty (PTA) of the infrainguinal vessels. Routine treatment of the superficial femoral artery (SFA) with balloon expandable stainless-steel stents has been shown to be no more durable than angioplasty alone.[4-8] In hopes of improving on the patency of PTA, some have suggested the use of alternative therapies such as atherectomy, cryoplasty, or the deployment of polytetraflourethylene covered stent grafts in the SFA with varying success.[9-15]

In 1963, while working for U.S. Naval Ordinance, W.J. Buehler discovered the shape memory properties of the binary nickel-titanium alloy later called nitinol.[16] With its enhanced flexibility, it has been used extensively as an adjunct to angioplasty in hopes of improving the durability of endovascular procedures performed on the superficial femoral and popliteal arteries. While some have reserved the use of these stents for salvage following unsuccessful PTA,[17-22] others have promoted primary nitinol stenting as the preferred endovascular method of treating infrainguinal occlusive disease.[23-27] Few prospective studies have evaluated the efficacy of this treatment strategy. It is the purpose of this study to prospectively determine the durability of angioplasty combined with primary nitinol stenting when it is used to treat occlusive disease of the superficial femoral and popliteal arteries.

METHODS

During a 44-month period, all patients consenting to an Institutional Review Board-approved primary stenting protocol for percutaneous treatment of the SFA and pop-

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liteal artery were eligible for inclusion in the study. Patients having orificial occlusion of the SFA and patients with total occlusion of the SFA, PA, and proximal tibial vessels had no attempts at percutaneous interventions and were preferentially treated surgically. The remaining patients were included in the primary stenting study protocol. Interventions were performed by or under the supervision of one vascular surgeon (SGK) Data were collected according to the guidelines set forth by the Society for Vascular Surgery[28] and stratified by the second TransAtlantic InterSocietal Consensus (TASC II) classification.[29] Patient gender, demographics, presence of co-morbidities, history of smoking, and the use of anticoagulation therapy were recorded. Indication for intervention, location and length of the arterial lesion, diameter of angioplasty balloon, size and type of stent deployed, and quality of distal runoff were noted. Poor distal runoff was defined as the visualization on angiography of one or no tibial runoff distal to the site of intervention. Type and number of secondary interventions were noted. Complications including significant hematomas (those requiring transfusion, operative intervention, or prolonged hospitalization), myocardial infarction, distal embolization, or death were recorded.

Interventions were performed in an angiography suite with fixed imaging. Procedures were most frequently performed from the contra-lateral groin using six or seven French sheaths. Lesions were preferentially crossed using .035-inch hydrophilic guide wires supported by 4F angled glide catheters. Stenotic lesions were crossed in an intraluminal fashion, while most occlusions greater than 5 cm were traversed in a subintimal plane. In the latter part of the series, re-entry devices were occasionally used to enter the artery distal to an occlusive lesion. After angiographic confirmation of position in the true lumen, stenoses and occlusions were dilated with five or six-millimeter non-compliant balloons inflated to six to twelve atmospheres of pressure for a duration of 30 to 45 seconds. Self-expanding nitinol stents were deployed across all segments undergoing PTA. One centimeter of overlap was used when multiple stents were required to cover a treated arterial segment as per manufacturers' recommendations. Stents were chosen on the basis of supply and surgeon preference. All patients received 300 mg of clopridigrel and 325 mg of aspirin prior to the procedure. Seventy-five mg of clopridogrel and 81 mg of aspirin were maintained for at least 30 days post intervention. Low dose aspirin was continued indefinitely. All patients received 5000 units of heparin prior to PTA. Anticoagulation was not reversed at the conclusion of the procedure. Initial procedural success was considered to have occurred when less than 30% stenosis remained in the treated vessel.

All patients received duplex scans within 30 days of intervention and at six-month intervals thereafter. Loss of primary patency was considered to have occurred with vessel occlusion, or when a 50% or greater restenosis at the previous site of angioplasty and stenting was noted whether or not intervention was undertaken. A 50% stenosis was said to be present when a peak systolic velocity of at least 200 cm per second and a 3:1 velocity ratio was seen across the lesion. Time to loss of primary patency was recorded and used as our primary and only outcome measure when plotting survival curves.

Demographic and comorbidity data was recorded per patient and patency data was calculated on a per limb basis. Kaplan-Meier survival curves were calculated on intent to treat basis and differences tested by log rank method. Univariate analysis was performed on factors thought to affect the primary patency of the percutaneous intervention. Comparisons were made between those patients who lost primary patency and those who did not using Cox proportional hazards model. Factors found to be significant in the univariate analysis were then included in a step-wise multivariate Cox proportional hazards regression model to determine individual significance in the presence of other factors. Statistical significance was assumed at a P value of less than .05.

RESULTS

Between January 2004 and August 2007, 219 diagnostic lower extremity angiograms were performed. Twenty-three patients had orificial occlusion of the SFA, 29 patients had occlusion of the SFA, PA, and proximal tibial vessels, and six patients declined endovascular intervention. These patients were excluded from the study. Two hundred and one procedures were performed on 161 patients. Seventy-one patients were male, and 90 were female. Their ages ranged from 42 to 91 years (mean: 76.2 ± 11 years). One hundred seventeen patients had hypertension (72.6%), 84 (55.3%) had significant coronary artery disease, 80 (52.6%) had a history of hypercholesterolemia, 66 (43.4%) had clinically evident diabetes, 43 (28.3%) were active smokers, 29 (18%) patients had a creatinine > 2.0 of which 11 (7.2%) were dialysis dependent, and six (3.9%) were on chronic warfarin anticoagulation.

One hundred twenty-three (61.2%) procedures were performed for claudication, 34 for rest pain (16.9%), and 44 (21.9%) for open ulceration or gangrene. Forty-four percent of the treated lesions were in the SFA, 17% were in the popliteal artery, and 39% spanned both arterial segments. The above-knee popliteal segment was treated in 85 limbs and the below-knee segment in 19 limbs. Forty-six limbs were classified as TASC A (22.9%), 82 TASC B (40.8%), 38 TASC C (18.9%), and 35 TASC D (17.4%). The mean length of arterial segment treated was 12.9 ± 9.4 centimeters (range: 1-45 cm). Forty-three percent of limbs treated had areas of occlusion and 57% had only stenotic lesions. The average number of stents placed in TASC A and B lesions was 1.2 (range: 1-2) and 2.5 in TASC C and D lesions (range: 1-6). Stent brands and their frequency of use are listed in Table I. Runoff was classified as good in 91 limbs (47.4%) and poor in 110 (52.6%).

Initial success of angioplasty and stenting was 95.6%. Mean duration of follow-up was 426 days (range: 3-1329 days), and the median duration was 348 days. Overall primary patency at three years was 38.7% (Fig 1). Primary patency rates at 12, 24, and 36 months were 79%, 67%, and 57% for TASC A and B lesions and 52.7%, 36%, and 19% for TASC C and D lesions (Fig 2). The standard error for

Table I. Stent brands and frequency of use

Stent type	*Number (%)*
Abbott – Exceed	117 (35%)
Cordis – Smart	87 (26%)
Edwards – Lifestent	67 (20%)
Abbott – Absolute	20 (6%)
Bard – Luminex	21 (6%)
EV3 – Protégé	13 (4%)
Abbott – Expert	10 (3%)

calculated Kaplan-Meier survival curves remained less than 10% at 40 months of follow-up. This difference as tested by log rank method was highly significant ($P < .001$). In univariate analysis, history of hypercholesterolemia, limb threat, and TASC C or D stratification negatively impacted the primary patency of the interventions (Table II). In multivariate analysis, only history of hypercholesterolemia and TASC classification were found to be statistically significant (Table III). Balloon diameter, stent diameter, and brand of stent did not significantly influence primary patency ($P > .25$). Stent fractures were noted in two treated segments, and both were associated with loss of primary patency.

Twenty-five secondary endovascular interventions were performed on 24 extremities. Twenty-two re-interventions were performed for intra-stent stenosis; 19 remain patent after one intervention while one limb required two procedures to maintain primary assisted patency. Three interventions were performed for stent occlusions, of which two remain patent after a single re-intervention. Runoff scores were reduced in only three of the above patients following their initial loss of anatomic patency and only one patient presented with acute ischemia requiring urgent re-intervention. Eight patients ultimately required bypass operations. Limb salvage in patients with critical limb ischemia was 88.5% and included four patients who required bypass operations. Five patients (2.4%) developed significant hematomas following their procedure (none requiring operative intervention), two patients (1%) suffered a clinical myocardial infarction, and one patient (0.5%) had a distal embolus requiring thrombolysis. One patient died within 30 days of the procedure. This patient with multiple medical comorbidities expired at home on the 23rd post-procedure day from a presumed myocardial infarction.

DISCUSSION

In many centers, including our own, catheter-based interventions serve as a first line intervention for many patients with infrainguinal occlusive disease. Angioplasty with or without stenting offers the advantage of low morbidity, decreased convalescence, and high patient acceptance. However, longevity and cost effectiveness remain a concern.

In 2007, TASC II made the following recommendations for treatment of femoropopliteal disease.[29] TASC A lesions are best treated by endovascular therapy and TASC D by surgery. It was also their recommendation that endovascular therapy is the preferred treatment for TASC B lesions while surgery is preferable for TASC C lesions. In addition, when treating B and C lesions, patient comorbidities, patient preference, and operator experience play an increasingly important role in the decision-making process.

Technological advances continue to occur at an ever-increasing pace with the intent of increasing the durability of infrainguinal endovascular procedures. Some have suggested that primary nitinol stenting of the superficial and popliteal arteries can provide results that are superior to angioplasty and selective stenting alone and extend the anatomic indications for endovascular intervention. However, these devices add considerable cost to any percutaneous intervention and should demonstrate clear benefit before their routine use can be advocated or current treatment recommendations changed.

This study was undertaken to determine whether the addition of primary stenting to angioplasty of the SFA and popliteal artery would improve the durability of these interventions. Although the design of the current prospective but non-randomized study precluded the formation of a concurrent control group, comparisons of our data to reports in the literature can be made. Primary patency, as defined by Ahn et al,[28] was chosen as our primary outcome measure as it is the variable least likely to be operator-dependent. While primary assisted and secondary patency can be influenced by indications for re-intervention and the willingness of the interventionalist to repetitively intervene before resorting to alternative treatment modalities, primary patency is an objective, direct indicator of the durability of the primary procedure. While some have been less stringent in defining primary patency, we believe that adhering to our strict definition allows for more consistent and unbiased data analysis.

Unlike the present study, very few previous studies on infrainguinal endovascular therapy have been prospective. In addition most patients are not stratified according to TASC classifications, and the results are rarely reported on intent to treat basis. This lack of consistent reporting standards for procedural success or failure contributes significantly to the difficulty in the interpretation of the available information. Our study was performed in an attempt to address some of the gaps in the literature concerning the value of primary stenting.

Consequently, it is not surprising that the literature presents conflicting data. Previous studies have shown that angioplasty alone or with selective stenting have yielded acceptable rates of primary patency in the treatment of short segment TASC A and B lesions, but have proven to be far less effective when used to treat TASC C and D lesions.[17,20,22,30-32] Our study using primary stenting mirrors these results. Recent prospective and randomized studies involving the treatment of short segment disease of the SFA have been performed. Two of the three showed benefit from primary stenting,[23,24,33] and the third used a type of stent that is now rarely used to treat infrainguinal disease.[34] The 79% one-year primary patency achieved in the TASC A

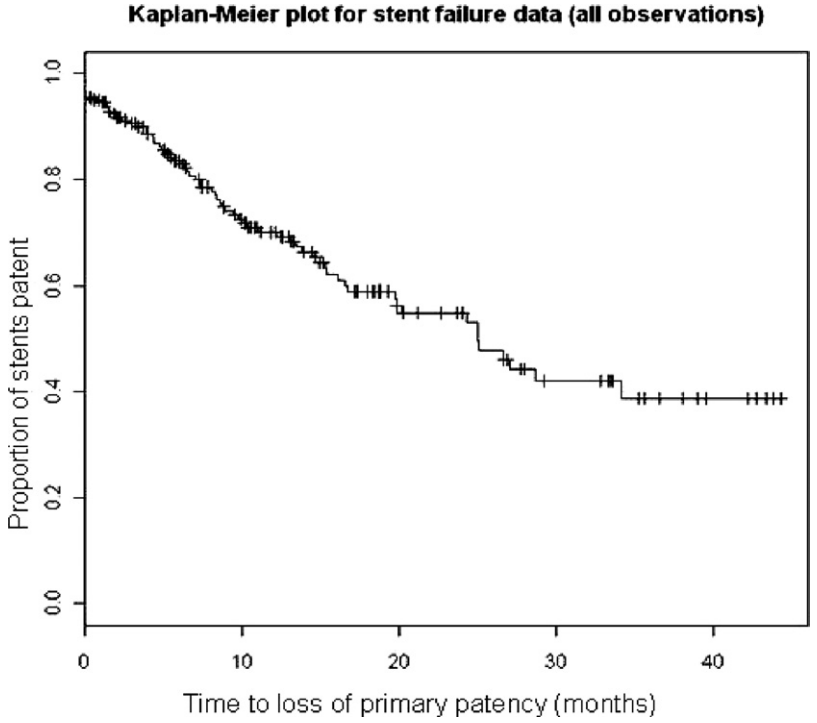

Fig 1. Survival curve showing primary patency for all stented arterial segments. Standard error did not exceed 10% until 40 months of follow-up. Hatch marks represent events in which a stented segment lost primary patency.

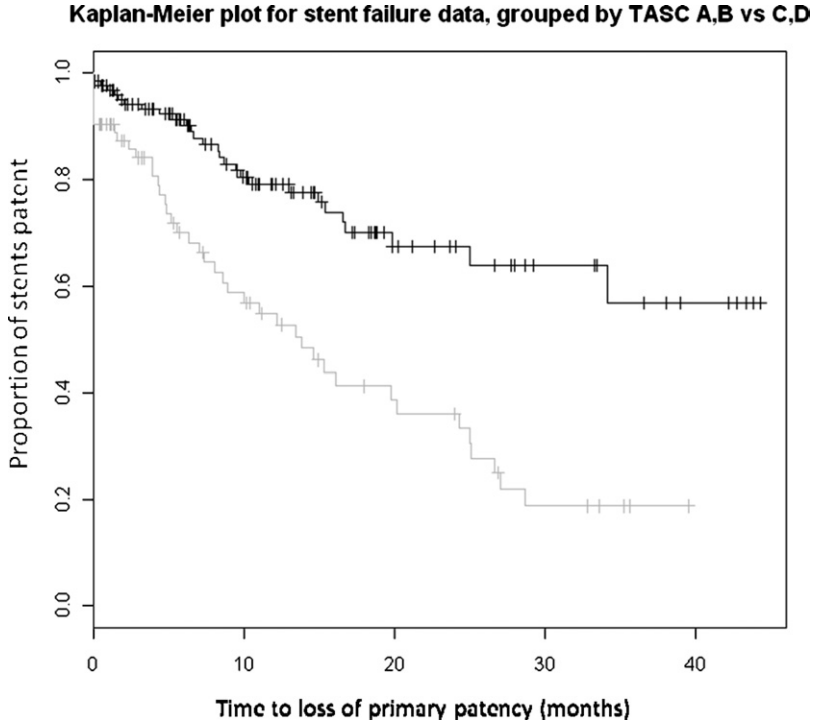

Fig 2. Survival curve showing primary patency for TASC A and B versus TASC C and D treated arterial segments. Standard error did not exceed 10% until 40 months of follow-up. Hatch marks represent events in which a stented segment lost primary patency. Log rank test: $P < .001$. *TASC A/B,* top line. *TASC C/D,* bottom line.

Table II. Univariate analysis

Univariate Cox proportional hazards model		
Variable	*Hazards ratio (95% CI)*	P *value*
Age	1.01 (0.99-1.04)	.365
Gender	1.34 (0.82-2.19)	.243
Coronary artery disease	0.93 (0.56-1.54)	.778
Diabetes mellitus	1.01 (0.60-1.69)	.978
Hypertension	0.83 (0.33-2.08)	.695
Hypercholesterolemia	1.73 (1.03-2.90)	.039
Chronic obstructive pulmonary disease	0.823 (0.44-1.55)	.546
Chronic renal insufficiency	0.614 (0.18-1.74)	.275
Active tobacco smoker	0.873 (0.50-1.53)	.636
Coumadin	0.814 (0.11-5.90)	.839
Indication		
Claudication	ref	
Rest pain	2.70 (1.44-5.05)	.002
Ulcer	1.96 (0.95-3.27)	.071
Runoff score	1.03 (0.77-1.39)	.827
TASC		
A	ref	
B	2.42 (0.98-5.98)	.055
C	3.89 (1.54-9.82)	.004
D	7.68 (3.11-18.94)	<.001

CI, Confidence interval; *TASC,* TransAtlantic InterSociety Consensus.

Table III. Multivariate analysis

Multivariate Cox proportional hazards model		
Variable	*Hazards ratio (95% CI)*	P *value*
Age	1.01 (0.98-1.04)	.550
Gender	1.61 (0.92-2.85)	.099
Active tobacco smoker	0.88 (0.48-1.60)	.670
Hypercholesterolemia	2.06 (1.19-3.57)	.010
TASC		
A	ref	
B	2.18 (0.88-5.45)	.094
C	3.77 (1.46-9.76)	.006
D	6.17 (2.39-15.97)	<.001

CI, Confidence interval; *TASC,* TransAtlantic InterSociety Consensus.

and B group in our study is remarkably similar to the preliminary results seen in the recently released prospective and randomized Resilient trial, which was limited to patients with short segment SFA lesions. This study, presented at the Cardiovascular Research Foundation's 19th Annual Transcatheter Cardiovascular Therapeutics scientific symposium in Washington, D.C. on October 23, 2007, has not yet been published.[33]

In our study and others, TASC classification significantly influenced the results of percutaneous intervention on the SFA and popliteal arteries.[17,20,22,31] It is interesting to note that the only other variable negatively impacting patency in this series was a history of hypercholesterolemia. This contrasts with previous studies including our own that have shown that other factors, in particular poor runoff,[20,35-37] significantly decrease the primary patency of infrainguinal vessels treated with the technique of angioplasty and selective stenting. It is unclear why these factors did not influence the results in our current study, but one can speculate that the strategy of primary nitinol stenting in some way alters the risk for anatomic failure in treated segments of the SFA and popliteal arteries. Clearly, more data will need to be obtained before any treatment recommendations based on these observations can be made

Angioplasty in conjunction with the use of nitinol stents can be performed on the majority of patients presenting with infrainguinal occlusive disease. We found it to be quite durable in patients with TASC A and B lesions and less so when more extensive disease is treated. Yet, failure can often be salvaged by repeat percutaneous intervention, infrequently precipitates acute ischemia, and rarely precludes open surgical bypass.

It is of interest that only eight patients in our series required open bypass surgery. The reasons are multifactorial. Many primary treatment failures were salvaged by repetitive endovascular procedures. A number of patients with open ulcerations or limited gangrene were able to heal their lesions before the failure of their percutaneous interventions. Finally, a group of patients who lost primary anatomic patency of their stented arterial segments maintained enough hemodynamic benefit to remain relatively asymptomatic and not require open operation.

In general, given the results of our study, we now adhere to the recommendations for percutaneous intervention set forth in TASC II. We aggressively pursue catheter-based intervention using a policy of selective but liberal stenting in patients with TASC A and B lesions and in many patients with TASC C disease. Percutaneous treatment of TASC D lesions is now reserved for patients with multiple medical comorbidities or those with inadequate conduit for surgical bypass. We would also be more likely to employ angioplasty and selective stenting in patients with TASC D disease whose indication for intervention is healing of an ulcer or digital amputation since they may not require as durable a reconstruction as patients with claudication or ischemic rest pain.

We conclude that primary stenting of the SFA and popliteal arteries provides durable results in patients with TASC A and B lesions and may be an effective treatment strategy. This approach is significantly less effective when used in treating those with TASC C and D disease. Based on the results in this series, the use of primary stenting does not extend the anatomic limits of the current treatment recommendations for catheter-based intervention in patients with infrainguinal occlusive disease.

AUTHOR CONTRIBUTIONS

Conception and design: DD, KP, SK
Analysis and interpretation: DD, KP, JC, MK, FW, SK
Data collection: DD, KP, JC, MK
Writing the article: DD, KP, JC, MK, SK
Critical revision of the article: DD, FW, SK
Final approval of the article: DD, KP, JC, MK, FW, SK

Statistical analysis: DD, KP, SK
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