

## **Outcomes of direct puncture of a common femoral artery stent**

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### **Abstract**

*Research question:* In patients who have undergone common femoral artery stenting, can the stent be safely and effectively punctured in future vascular procedures without short- or long-term implications?

*Background, significance, and rationale:* Concerns with a common femoral artery (CFA) stent include limited access to the CFA for future procedures, increased risk of complications by puncturing a stented vessel, and decreased stent patency. There are no studies published that focus on outcomes of direct puncture of a CFA stent.

*Materials and methods:* We retrospectively reviewed the charts from two centers of 295 unique patients with 349 CFA lesions treated with stents from 2012-2021. Among the 349 stented CFAs, we identified 91 unique patients with 108 CFA stents that were punctured at least once. These 108 stents had a total of 223 punctures (multiple stents were punctured more than once), constituting the punctured cohort (PC). There were a remaining 241 CFA stents in the non-punctured cohort (NPC). Indications for the 223 punctures are as follows: rest pain (34%), claudication (32%), gangrene (11%), ulceration (11%), intestinal disorder (2%), carotid disorder (2%), and other (8%). Our primary outcome was patency for the NPC versus the PC. Kaplan-Meier curves were used to evaluate patency. Chi squared tests, analyses of variance, and student's t tests were used to evaluate differences in risk factors, demographics, and complications between the PC and NPC. Secondary outcomes were total number of punctures per CFA stent and 30-day complications.

*Results:* There was no statistically significant difference in risk factors, age, or sex between the PC and NPC. The total number of punctures in the PC ranged from 1 to 13 (mean 2.03, SD 2.04). There was no statistically significant difference in closure device failure between the PC and NPC ( $p = .16$ ). Complications occurred in 0.9% of cases following CFA puncture (respiratory arrest (1) and left calf swelling and pain (1)), and both were unrelated to the puncture site. There were no acute thrombotic complications or infections within 30 days. Kaplan Meier curves showed no difference in primary patency or primary assisted patency for the PC vs NPC.

*Conclusion:* Direct puncture of CFA stents is safe and effective and does not adversely affect short- or long-term results.

### **Research Question**

Our study seeks to determine if direct puncture of a common femoral artery stent is safe and effective in future vascular procedures without short- or long-term implications. The study population includes patients who have undergone common femoral artery stenting. We predict that common femoral artery stents can be safely and effectively punctured multiple times without short- or long-term implications.

### **Introduction/Significance/Rationale**

Peripheral arterial disease (PAD) is extremely common in the United States. PAD is an atherosclerotic disease leading to arterial stenosis or occlusion. The clinical features of PAD are a result of the lack of blood flow to musculature, resulting in ischemia.<sup>1</sup> PAD can present with a range of signs and symptoms that are classified on the Rutherford scale, as seen below.<sup>2</sup>

- Stage 0 – Asymptomatic
- Stage 1 – Mild claudication
- Stage 2 – Moderate claudication
- Stage 3 – Severe claudication
- Stage 4 – Rest pain
- Stage 5 – Minor tissue loss with ischemic nonhealing ulcer or focal gangrene with diffuse pedal ischemia
- Stage 6 – Major tissue loss – Extending above transmetatarsal level, functional foot no longer salvageable

In lower extremity PAD, the site of the stenotic lesion and the anatomic location of pain typically follows a predictable pattern. Symptoms located in the buttock and hip indicate aorto-iliac disease, thigh pain indicates aorto-iliac or common femoral artery (CFA) disease, pain in the upper two-thirds of the calf indicates superficial femoral artery (SFA) disease, and pain in the lower one-third of the calf indicates popliteal artery disease.<sup>3</sup> On physical exam, signs of PAD include skin and nail changes, cold extremities, diminished pulses, ulceration, or gangrene.<sup>1</sup>

In patients with signs or symptoms of PAD or in a select group of asymptomatic patients (abnormal or absent pedal pulses; age greater than 70; age 50 to 69 with history of smoking or diabetes), testing for PAD is performed.<sup>4</sup> Bedside ankle brachial index (ABI) can be performed by calculating the ratio of the ankle systolic blood pressure divided by the brachial systolic blood pressure. An ABI less than or equal to 0.9 is suggestive of PAD.<sup>5</sup> Other noninvasive vascular studies include segmental pressures, pulse volume recordings, and exercise testing.

Advanced vascular imaging should only be used after a decision has been made to proceed with revascularization in order to aid with selection and planning of intervention. The decision to revascularize is made on a case-by-case basis with the main goal of functional improvement. It is not dependent solely on the presence of a stenotic lesion on imaging or the extent of anatomic involvement.<sup>6</sup> In patients with suspected inflow disease, that being buttock or thigh claudication, the preferred advanced vascular imaging method is computed tomographic (CT) angiography. In contrast, in patients with suspected outflow disease, that being calf or foot claudication, duplex ultrasound or CT angiography can be used to characterize the lesion.<sup>6</sup> Following vascular imaging studies, the atherosclerotic pattern of disease is classified by the Inter-Society Consensus for the Management of Peripheral Artery Diseases (TASC II) criteria depending on their anatomic distribution, multiplicity of lesions, and degree of stenosis or occlusion.<sup>7</sup>

In a review of 13,827 patients admitted at a single institution over a 40-year period, symptomatic atherosclerotic disease was most prevalent in the aorta and lower extremities with 42 percent of lesions located in the abdominal aorta and lower extremity arteries.<sup>8,9</sup> Amongst symptomatic lower extremity lesions, femoropopliteal disease is the most common location with a prevalence around 50 percent.<sup>10-12</sup> In a study examining prevalence of subclinical atherosclerosis, plaques were detected in 60 percent of participants, with 44 percent of the lesions located in the iliofemoral arteries.<sup>13</sup>

When the decision is made to proceed with revascularization, endovascular versus an open surgical approach is considered. Endovascular options include balloon dilation (angioplasty), atherectomy, and stenting. Endovascular approaches have demonstrated similar cumulative patency rates in the midterm with fewer periprocedural complications and therefore is the preferred initial approach in the majority of cases. Open surgery is favored when anatomic complexity of the lesion is not favorable for an endovascular approach. Complexity is determined by the culmination of location, length of stenoses or occlusions, calcium content, and quality of the runoff vessels. Importantly, Nguyen et al. demonstrated that there is significant morbidity and mortality associated with endarterectomy with combined rates around 15 percent.<sup>14</sup>

To restore inflow circulation, an endovascular approach is preferred for most cases, even when there is complex anatomy.<sup>15-19</sup> Similarly, for femoro-popliteal disease, an endovascular approach is preferred.<sup>20</sup> Conversely, the traditional gold standard of care for common femoral artery lesions is open endarterectomy.<sup>21</sup> CFA endarterectomy has high success rates, with 1- and 5-year primary patencies of 93% and 91%, respectively.<sup>22</sup> Although endovascular therapies are preferred at all other anatomic locations in the lower extremity, including for infrainguinal disease, there is concern that endovascular treatment of the CFA, particularly the use of a stent, would lead to compromise for future femoral surgical approaches, have greater incidence of stent fracture due to flexion of the hip, and lead to increased risk for future CFA intervention. However, the evidence supporting surgery is weak and considered a Level 4, Grade C.<sup>23</sup>

Initial endovascular treatment for CFA lesions involved conventional balloon angioplasty and balloon expandable stainless-steel stents. These studies did not show promising results in favor of endovascular treatments over surgery.<sup>24-26</sup> However, the development of a self-expanding nitinol stent showed that the durability of stenting CFA lesions is comparable to endarterectomy, while the morbidity and mortality is significantly lower.<sup>24,25,27-30</sup>

As mentioned above, a primary concern for the use of stents in the CFA is the potential to limit access for future vascular procedures. As a solution to this potential issue, Strickler et al. proposed that puncture of the stent could be avoided using fluoroscopic control to identify a puncture site just above or just below the stent. They reported 4 punctures of a stented CFA with no complications.<sup>31</sup> However, few studies have evaluated the effect of direct puncture of a CFA stent. Paris et al. reported two patients in their study with puncture to the stented CFA for additional vascular procedures without damage to the stent.<sup>28</sup> Similarly, de Blic et al. reported puncture of 2 stented CFAs with no adverse events.<sup>32</sup> Another case was reported by Biondi-Zoccai et al. with successful access through a stented CFA, however the case was complicated by a significant retroperitoneal bleed.<sup>33</sup>

This study seeks to demonstrate that direct puncture of a CFA stent is safe and effective on a larger scale than has been demonstrated in the studies above. It will also be the first of its kind to demonstrate the effect of direct stent puncture on long-term patency of the CFA stent. If direct stent puncture is found to be safe and effective with no effect on long-term patency, it will demonstrate that CFA stenting does not prevent access for future vascular procedures.

## **Research Materials and Methods**

### *Case Identification and Participant Cohorts*

A retrospective chart review was performed from two centers for patients presenting with peripheral arterial disease. From 2012 to 2021, 295 unique patients were identified that

underwent stenting of the CFA. In total, there were 349 CFA stenoses or occlusions that were treated with stents. Each patient either had unilateral or bilateral CFA stenting performed. Indications for placement of the CFA stent are as follows: claudication (48%), rest pain (48%), and ulcer or gangrene (2%). Data was collected with IRB approval in compliance with Health Insurance Portability and Accountability Act (HIPPA) standards. All patients received oral and written information about the procedure, benefits, and complications. Information regarding the patient's demographics, comorbidities, medication use, non-invasive and invasive imaging, endovascular procedure details, stent puncture status, technical success, complications and death, re-interventions, and patency were collected.

Among the 349 cases, there were 91 unique patients with 108 CFA stents that were subsequently punctured at least once for future vascular procedures. Multiple stents were punctured more than once and in total there was 219 punctures among the 108 CFA stents, constituting the punctured cohort (PC). The remaining 241 CFA stents were never punctured, constituting the non-punctured cohort (NPC). Indications for the vascular procedures leading to the stent puncture are as follows: rest pain (34%), claudication (32%), gangrene (11%), ulceration (11%), intestinal disorder (2%), carotid disorder (2%), and other (8%).

### *Setting and Procedure*

- a. **Initial stent placement:** All procedures were performed in an outpatient angi suite by a board-certified vascular surgeon. Local anesthesia with conscious sedation was used for all cases. Surgical sites were sterilely prepped and draped in the usual fashion. Puncture of the common femoral artery was achieved using 2-D ultrasound guidance and Seldinger's technique to insert a five French or six French introducer sheath. A heparin sodium solution, typically 75-100 IU per kg body weight, was administered systemically. Digital subtraction angiography was performed to assess the extent of the disease. Identified lesions in the CFA were treated first with tissue plasminogen activator (t-PA), nitroglycerin and/or balloon dilation; when post angiographies showed little or inadequate change in the lesion, stenting was performed. The stent dimensions were chosen such that the normal vessel was oversized by 20% in order to cover the lesion with a single stent. Last generation self-expandable stents (Everflex®eV3, E. Luminexx® and LifeStent Flexstar® Bard) were used. After the stent placement, balloon dilation was performed. The balloon dimensions (Evercross® eV3 and Apex® Boston Scientific) were chosen such that the nominal diameter was inferior to the stent diameter by one mm to reduce medial damage. An angiography was performed after these procedures to assess technical results. Closure was achieved via a closure device (Angioseal®, Perclose®, Starclose® or Mynx®).
- b. **Subsequent stent puncture:** Subsequent puncture of the CFA was performed with the same procedure as described above.

### *Outcomes*

The primary outcome was primary and primary-assisted patency for the NPC versus the PC. Primary patency is described as uninterrupted patency with either no procedure performed on the area of revascularization or a procedure (e.g., transluminal dilation or a proximal or distal extension to the graft) to deal with disease progression in the adjacent native vessel. Primary assisted patency is described as interventions that never occluded but underwent minor

procedures to protect patency.<sup>2</sup> Secondary outcomes included the total number of punctures per CFA stent, closure device failure rate, and immediate and 30-day complications.

### *Statistical Methods*

Kaplan-Meier curves were used to evaluate patency. Chi squared tests, analyses of variance, and student's t tests were used to evaluate differences in risk factors, demographics, and complications between the PC and NPC. For the purpose of this study, reported outcomes were considered statistically significant if  $p < .05$ .

## **Results**

### *Demographics*

The mean age of the NPC was 71.3 years, and the mean age of the PC was 71.5 years. There was no significant difference between the two cohorts,  $p = .823$ . ANOVA test was used to determine significance.

The NPC was comprised of 51.3% male and 48.7% female, while the PC was comprised of 56.1% male and 43.9% female. There was no significant difference in sex between the PC and the NPC,  $p = .407$ . Chi-square test was used to determine significance.

<b>Sex</b>	<b>NPC Count</b>	<b>PC Count</b>
Female	116 (48.7%)	47 (43.9%)
Male	122 (51.3%)	60 (56.1%)

\* There was no significant difference between sex between the PC and the NPC;  $p = .407$ . Chi-square test used to determine significance.

### *Risk factors and comorbidities*

There was no statistically significant difference in pre-existing conditions or comorbidities between the PC and NPC. Please see the figure below for a full list of conditions evaluated.

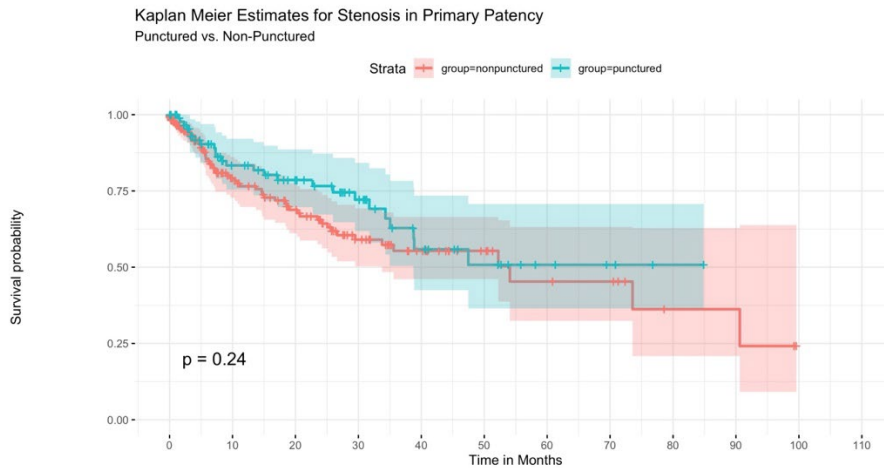
<b>Pre-existing Condition/ Comorbidity</b>	<b>NPC Count</b>	<b>PC Count</b>	<b>Percent difference between NPC &amp; PC</b>
Diabetes mellitus	105 (43.6%)	55 (50.9%)	7.3%, $p = .202$
Hypertension	211 (87.6%)	100 (92.6%)	5.0%, $p = .162$
Chronic renal insufficiency/chronic kidney disease	42 (17.4%)	14 (13.0%)	4.4%, $p = .294$
Coronary artery disease	72 (29.9%)	29 (26.9%)	3.0%, $p = .565$
Transient ischemic attack	44 (18.3%)	22 (20.4%)	2.1%, $p = .641$
Hyperlipidemia	166 (68.9%)	76 (70.4%)	1.5%, $p = .780$
Coronary artery bypass graft	38 (15.8%)	16 (14.8%)	1.0%, $p = .820$
Pacer	12 (5.0%)	2 (1.9%)	3.1%, $p = .169$

Chronic obstructive pulmonary disease	54 (22.4%)	26 (24.1%)	1.7%, p = .732
Arrythmia	29 (12.0%)	9 (8.3%)	3.7%, p = .305
Congestive heart failure	27 (11.2%)	12 (11.1%)	0.10%, p = .980
Smoking (current or former)	184 (76.3%)	85 (78.7%)	2.4%, p = .096

\* Chi-square test was used to determine significance

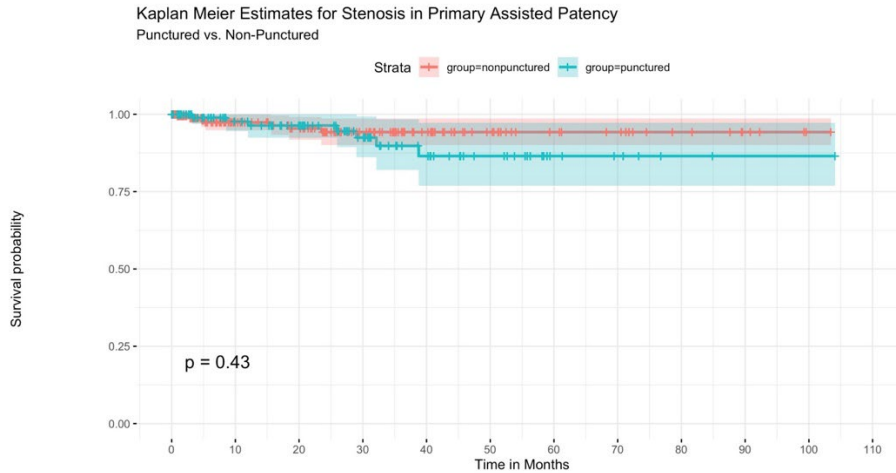
### Primary Patency PC vs NPC

Primary patency is described as uninterrupted patency with either no procedure performed on the site of revascularization or a procedure (e.g., transluminal dilation or a proximal or distal extension to the graft) to deal with disease progression in the adjacent native vessel.<sup>2</sup> Kaplan Meier curves showed no significant difference in primary patency for the PC vs NPC, p = .24.



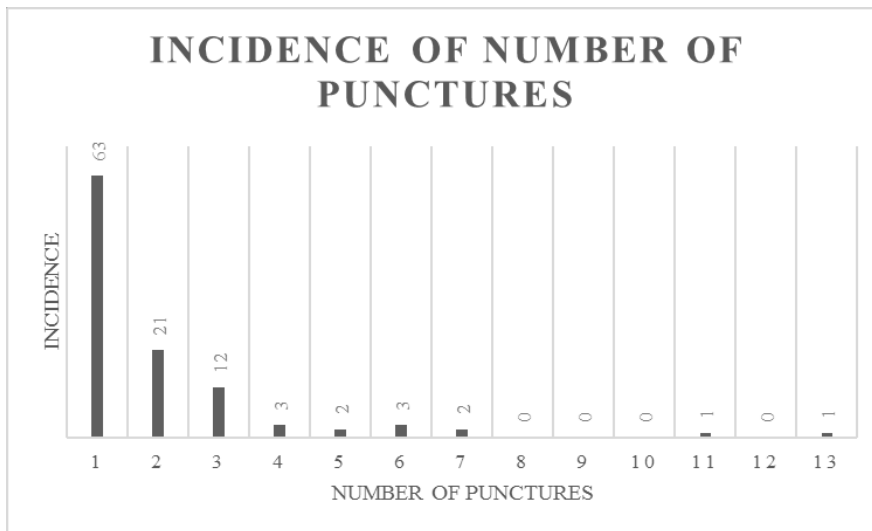
### Primary-Assisted Patency PC vs NPC

Primary assisted patency is described as interventions that never occluded but underwent minor procedures to protect patency. Kaplan Meier curves showed no significant difference in primary-assisted patency for the PC vs NPC, p = .43.



### *Number of punctures per stent*

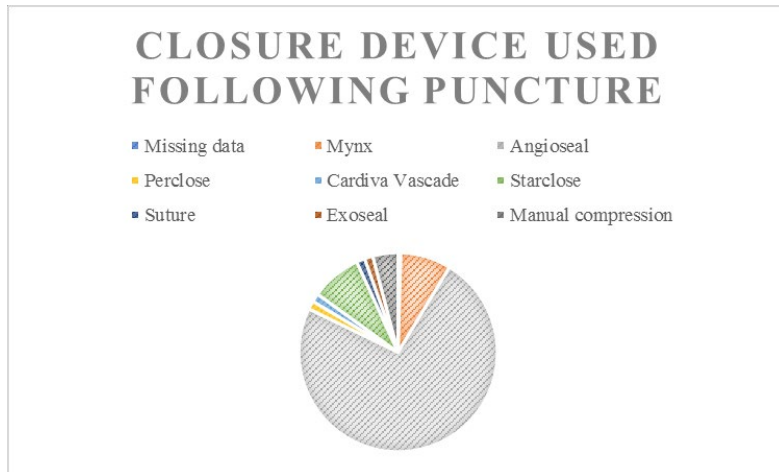
The total number of punctures in the PC ranged from 1 to 13 with a mean of 2.03 and standard deviation of 2.04. Please see the figure below highlighting the number of punctures per stent.



### *Closure device*

Eight devices or techniques were used for closure following puncture of the CFA stent. Percent usage are as follows: Angioseal 73.5%, Mynx 8.2%, Starclose 8.2%, Manual compression 4.1%, Perclose 1.37%, Cardiva Vascade 1.37%, Suture 1.37%, and Exoseal 1.37%. There were 4 total failures of closure device in the PC, occurring in 1.83% (4/219) of cases with CFA stent puncture. Of the closure device failures, 2 occurred with an Angioseal and 2 with a Perclose. In each case, the secondary device used for closure was successful. As a comparison, closure device failure at the time of stent placement was considered. At the time of stent placement, there were 2 total failures of closure device, occurring in 0.57% (2/349) of cases. Of the closure device failures, 1 occurred with Starclose and 1 with Perclose. There was no significant difference between the failure rate between the PC and at the time of stent placement,  $p = .161$ .

Closure Technique	Usage Count	Total Closures	Percent of Total
Angioseal	161	219	73.52%
Mynx	18	219	8.22%
Starclose	18	219	8.22%
Manual compression	9	219	4.11%
Perclose	3	219	1.37%
Cardiva Vascade	3	219	1.37%
Suture	3	219	1.37%
Exoseal	3	219	1.37%
Missing data	1	219	0.45%



### *Complications*

There were 2 reports of complications following CFA stent puncture, occurring in 0.9% of cases. Respiratory arrest occurred in one case and was treated with an oral airway and ambubag without further incidence. In another case, left calf swelling and pain occurred 24 hours post-procedure. Both complications were unrelated to the puncture site. No stent fractures were reported. There were no acute thrombotic complications or infections within 30 days.

### **Discussion and Innovation**

Puncture of a CFA stent has been documented previously on a small scale, with technical success and immediate complications as the only outcomes reported. This study was the first of its kind to demonstrate the long-term durability and safety of direct puncture of a CFA stent in a large patient cohort. In short, this study demonstrates that it is safe and effective to directly puncture a



CFA stent for additional vascular procedures without any short or long-term effect on patency. The concern for maintaining CFA access for future vascular procedures should not be a barrier to stenting the CFA. Interpretation of specific outcomes measures can be found below.

#### *Demographics, Pre-Existing Conditions, and Comorbidities*

No significant difference was demonstrated between the PC and NPC for age, sex, pre-existing conditions, or comorbidities. This is a strength of the study as the two groups were appropriate for comparison, without additional confounders.

#### *Patency*

For the primary outcome measure of patency, no significant difference was found for primary or primary-assisted patency between the PC and the NPC. This demonstrates that direct puncture of a stented CFA does not have any effect on short- or long-term patency. A weakness of the study is the loss to follow up that occurred in both the PC and the NPC. However, the attrition occurred equally in both the PC and the NPC, therefore we do not anticipate that it had any effect on our conclusion. This study was the first of its kind to demonstrate the effect of direct stent puncture on short- and long-term patency.

#### *Number of Punctures Per Stent*

In the PC, 1 to 13 punctures per stent were documented. There was no increase in the incidence of complications for stents with higher puncture counts. This is the first study to document multiple punctures of a single stented CFA on different occasions. These results demonstrate that it is safe and effective to puncture CFA stents multiple times and support the claim that stenting the CFA does not limit the CFA for future vascular access.

#### *Closure Technique*

A wide variety of closure techniques were used following direct puncture of a CFA stent. There was no significant difference in closure device failure between a punctured CFA stent and a non-punctured CFA stent. These results demonstrate that gaining vascular access through a stented CFA does not require a change in surgical technique as compared to a non-stented CFA.

#### *Complications*

In this study, only 2 complications were reported among the PC and neither of which were related to the puncture site. There were no reports of stent fractures, bleeding, thrombosis, or infection. This is in contrast to Biondi-Zoccai et al., that reported upon successful puncture of a CFA stent, they encountered a retroperitoneal bleeding.<sup>33</sup> These results demonstrate that puncture of a CFA stent is safe, with no additional morbidity or mortality as compared to a non-punctured CFA stent.

#### **Future Directions**

The findings from this study suggest that the concern for maintaining CFA access for future vascular procedures should not be a barrier to stenting the CFA as direct stent puncture is safe and does not affect short- or long-term patency. However, limitations exist due to the retrospective nature of this study. There has been 1 randomized controlled trial that evaluated the use of stent versus endarterectomy for CFA lesions, however the longest follow up was 24 months.<sup>27</sup> An area of future interest would be a randomized controlled trial studying the long-

term outcomes of a CFA stent vs endarterectomy. Outcomes of interest include long-term patency, incidence of stent fracture, and the number of re-interventions required in order to address additional concerns for stenting the CFA including potential stent damage and decreased durability of the stent due to flexion of the hip joint.

In the Medicare population alone, peripheral arterial disease cost the United States \$4.37 billion in 2001 with 88% of that cost for inpatient care.<sup>34</sup> Studies have demonstrated that endovascular treatment of CFA lesions significantly decreases morbidity and mortality as compared to endarterectomy.<sup>27</sup> By decreasing morbidity and mortality with endovascular treatment, there are potentially significant savings for patients and the healthcare system as a whole.

### **Conclusions**

Our findings demonstrate that direct puncture of a stented CFA is safe and effective with no effect on short- or long-term patency. This suggests that concern for future CFA access should not prevent the use of a stent for revascularization. Implications of these findings, combined with other studies that indicate lower morbidity and mortality associated with endovascular procedures, support stenting of common femoral artery lesions as the standard of care for revascularization, rather than surgery.<sup>27</sup>

### **Compliance**

IRB approval for our study was granted approval through the Methodist Health System. The IRB tracking number is 520140140. All procedures were thoroughly explained to the patient beforehand including risks, benefits, and alternatives. All data was stored on an encrypted server.

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