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Endovascular Stenting vs Open Endarterectomy to Treat Peripheral Arterial Occlusive Disease in the Common Femoral Artery

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Abstract

Research Question: Do patients with significant lower extremity peripheral arterial occlusive disease (PAD) involving the common femoral artery (CFA) requiring treatment have similar or better patency and safety outcomes with endovascular stent compared to open endarterectomy surgery?

Background, Significance, and Rationale for the Question: For decades, open surgery was the only treatment for PAD. Such treatment included open endarterectomy and bypass, which had excellent outcomes. However, such surgery was traumatic with long recovery times, and many patients had a high body-mass index (BMI) with groins that were difficult to access and maintain cleanliness, leading to high complications rates and infections. In the 1980s-90s, endovascular interventions arose and now have become accepted as standard of care for most vessels in the body. But one area remains controversial and that is the CFA. Initial early attempts with stents at this site were unsuccessful due to bending and misshaping of the stent. Thus endarterectomy remained the standard of care. However, recent reports using new stent materials and techniques have shown that endovascular interventions can be successful. But these reports had small patient numbers and did not have enough data to convincingly show the safety and efficacy of CFA stenting. We report 12 years of data with hundreds of patients from many surgeons to add to the literature to help settle this debate.

Materials and Methods: This is a retrospective chart review study of all consecutive patients with CFA occlusions treated by 15 surgeons in Dallas and Los Angeles from 2012-2021. Patient were evaluated within 30 days, 3, 6, 9, and 12 months and yearly thereafter. We look specifically for Rutherford clinical classification pre- and post-op, postoperative complications, and patency rates. Primary endpoint will be patency. Secondary endpoints will be infection and complication rates, length of hospital stay, and post-operative recovery times. We include comorbidities, such as diabetes mellitus, high blood pressure, and smoking as there may be confounding factors that might explain differences. We analyzed patency using Kaplan-Meier Life tables and ANOVA analysis. The measurements used to compare outcomes include ankle-brachial index (ABI) readings, duplex ultrasound of lower arteries and angiogram outcomes. We also compare our results to those in the literature.

Results: Primary patency was 72.5% and primary assisted patency was 95.7%. 12 limbs (3.9%) thrombosed with 4 failures, achieving a secondary patency of 99.1%. There were 13 (3.7%) 30 day adverse events (see table). Long-term complications include: 2 stent thrombosis, 2 pseudoaneurysms, 1 stent dissection, 1 stent migration, and 1 hematoma >30 days after the procedure. Limb-loss was 4.3% with 8 below knee amputations (BKA) and 7 above knee amputations (AKA) out of the 349 treated limbs. Previous myocardial infarction correlated to loss of primary patency ($p = .002$). Ulcer/gangrene was 1.8x more likely to lose primary patency compared to claudication ($p = .035$). Ulcer/gangrene ($p=.045$) and rest pain ($p=.007$) compared to claudication were 9.5x and 4.9x more likely to have limb loss, respectively. Survival was 70% up to 75 months. Our results show that CFA stenting is safe and effective and provides durable long-term patency, limb salvage, and survival.

Conclusions: Our results show that CFA stenting is safe and effective and provides durable long-term patency, limb salvage, and survival.

Research Question

Do adults who have significant lower extremity peripheral arterial occlusive disease involving the common femoral artery who require treatment have similar or better patency and safety outcomes with endovascular stent compared to open endarterectomy surgery? We hypothesize that femoral stenting will have equal or better outcomes compared to those who receive open endarterectomies.

Goals: One of the major goals of this project is to provide evidence that endovascular stenting of the CFA is a viable alternative treatment for PAD. Additionally, we aim to show that the complications and potential side effects are equal or less than those experienced with open endarterectomy procedures.

Introduction, Significance, and Rationale

Introduction

Peripheral Arterial Disease (PAD) is an occlusive buildup of material (most often atherosclerotic plaque) in the vasculature of the body, including inside the arteries of the lower extremities. This condition leads to a stenosing, or narrowing, of the affected artery and often causes claudication (pain and numbness), delayed wound healing, difficulty walking, ulcers and gangrene and eventual limb loss if left untreated. These symptoms are mostly caused by a decrease in blood flow to the affected area, which in turn causes decreased delivery of oxygen. The most common areas for buildup of plaques are the major arteries, including the coronary arteries, cerebral vasculature, and the lower extremity.[1]

If medical and lifestyle treatments do not sufficiently lower the level of plaque buildup and stenosis, the next options are either open surgery or endovascular intervention. Open surgery includes open endarterectomy and bypass grafting, whereas endovascular procedures include atherectomy, balloon angioplasty, or stent placement. All of these methods are aimed to increase patency and therefore blood flow in the affected artery. Open endarterectomy involves surgically opening the affected artery and manually removing the plaque buildup.[2] A bypass graft uses a vein from the patient, cadaver, or a prosthetic material to provide an alternative route of blood flow for the affected artery. Endovascular procedures are performed percutaneously (puncture through skin to access artery) using small 5 or 6 French sheaths to open or remove plaque buildups by various methods including atherectomy, balloon angioplasty, or stent placement. Atherectomy is the removal of the plaque either by laser or mechanical means. Balloon angioplasty involves dilating the artery and stretches the walls of the artery, thereby displacing the plaque and opening the space for blood to flow. Stenting is the process of placing a metal mesh that will keep the artery open.[3]

Open endarterectomies and bypasses became the standard of treatment in the 1960s and stayed that way for about 20 years. In the 1980s, balloon angioplasty became more popular, in part due to the greater ease of this procedure. As technology advanced, endovascular stenting began to gain traction in the 1990's. Today, stenting has become the standard of treatment in many places throughout the body for arterial occlusive disease, including the coronary arteries, the iliac arteries, and even in cerebral vasculature. However, one of the last areas of resistance to stenting in the medical community is in the common femoral artery.

The common femoral artery is located at the top of the leg where it meets the hip and passes under the inguinal ligament, and this area of the body has unique properties that increase the difficulty for treatment: the CFA is a short vessel, the hip region has a high degree of motion and trauma, and a bifurcation of the vessel can lead to hemodynamic flow disturbances. Also, there are important branches (including Superficial Femoral Artery (SFA) and Profunda Femoral Artery (PFA)) that come off this vessel, which were thought to be blocked due to stenting.[4] Thus, open surgery has remained the gold standard of treatment for the common femoral artery and made surgeons slow to adopt endovascular techniques.[5]

Open endarterectomy involves surgical incision and visualization of the common femoral artery. That artery is then cut open and the atherosclerotic plaque is manually removed to relieve the occlusion. This can cause significant consequences for the patient, including increased risk of mortality, surgical site infections, and longer recovery times.

Endovascular stent placement starts with a small puncture, usually on the opposite leg. A guide wire directs the stent to the affected site in the artery, reducing the trauma and invasiveness to the patient. Previously, stainless steel stents were used, but they lacked the ability to maintain their original shape once deformed from leg muscles, bending, and other outside forces. In the 1990's, the Nitinol stent was developed, which has properties that give it a "memory", allowing it to return to its original shape after deformation. The Nitinol stent is collapsed inside of a sheath, placed in the CFA, removed from its sheath, and self-expands to open the artery.[6]

Recent data has shown the potential for these newer stents to better handle the stresses associated with this area of the body.[7,8] We aim to show that the use of stents to treat PAD in the common femoral artery is at least equally as effective with fewer complications compared to the open surgery techniques for treatment in the common femoral artery. For this project, we will focus on the outcomes of endovascular stent placement and open endarterectomy surgery for treatment of stenosis of the common femoral artery.

Significance and Rationale

Lower extremity PAD affects roughly 1 in 10 Americans, with almost 40% of affected patients requiring treatment. A major risk factor is increased age, with approximately 30% of people in the United States over the age of 60 with some form of PAD.[9,10] By the year 2050, there will be an estimated 88.5 million Americans over the age of 65, which will only increase the prevalence of PAD in the population.[11] It is clear that safe, effective interventions will be needed.

The standard of care for CFA occlusions has been open endarterectomy for nearly 60 years, and it has been shown to be reasonably safe, effective, and long-lasting. The success of open surgery has given an inertia to the procedure and made it difficult to convince surgeons to adopt a new method, but open femoral endarterectomy is not without its complications.[5] Nugyen et al found that within 30 days of surgery there was: a 3.4% mortality risk, a 10.2% chance of returning to the operating room for follow up procedures, and a 7.9% chance of either superficial or deep wound infections, with an overall rate of 15% combined mortality and major complications.[12]

While there has been some hesitancy in the vascular surgeon community to switch from the proven method of open surgery, there are reasons to consider incorporating endovascular stenting when applicable. Recent studies show increasing evidence for shorter average duration of hospital stay, lower perioperative complication rates, and faster recovery times while maintaining equal or better outcomes. Goueffic et al showed that on average, a patient undergoing a CFA stent placement had a length of stay of 3.2 ± 2.9 days, whereas open surgery patients stayed for 6.3 ± 3 days.[12] However, barring any complications, many patients are often able to be discharged home the same day for many endovascular procedures.[13] Additionally, a shorter length of stay is often associated with a decrease in financial cost.[13] With the small puncture outside of the groin, the infection rates decreased compared to open endarterectomy. One study showed up to a 14% surgical site infection with open surgery. This is compared to an infection rate of about 2.5% (range from 0-5%) from a study on infection rates with femoral access for other endovascular procedures.[14,15]

With the advent of new stent materials, there has arisen a debate amongst vascular surgeons on the topic of open endarterectomy and endovascular stent placement and which approach is the best treatment option for patients. To date, there have been very few papers published on the results of CFA

stenting compared to open endarterectomy. Of those few studies, they have had low patient numbers to confidently show. These studies also lacked significant long-term outcomes. Even with those shortcomings, the studies show the potential benefits previously mentioned for CFA stenting. We plan to report data on hundreds of patients over the course of 2009-2019. This follow up information will provide a clearer picture on the benefits to safety and lower complication rates for endovascular CFA interventions.

Materials and Methods

General Study Details and Resources

The data for this project comes from patients who have undergone placement of a stent in either the left or right common femoral artery (may also include stents in other arteries) from 2012-2021 with follow up at the 1, 3, 6, 9, 12 month, and yearly marks in either the Dallas or Los Angeles clinics.

My mentor has set up a remote access server in order to protect patient information and data and all progress was stored on that secure server. In addition, we used the EMR systems of ClinicalKey and GECentricity in order to access the patient data. Vascunote is a program designed by my SPT mentor, Dr. Sam Ahn, and is used to record the procedure and materials used in each stent placement.

Subject Identification

We used CPT codes 37226 and 37227 to identify which patients had a stent placement in the common femoral arteries, and we then used Vascunote to further refine the patient list because those CPT codes also include the popliteal arteries and the focus of this project is on the CFA.

The target population is of any age that required a stent, though most of these patients will be 55 or older, had a stent placed in either the right or left common femoral artery, and had that stent placed endovascularly.

Additional Subject Stratification

Patients in the study were further analyzed based on age, sex, and comorbidities, including diabetes mellitus, hyperlipidemia, hypertension, and coronary artery disease amongst others. We used this data to further identify benefits and risks associated with CFA endovascular stent placement.

Retrospective Data Collection

The patients that meet the above requirements for the project were further analyzed based on the following metrics:

1. Procedure indications (based on the Rutherford Scale)
    a. Rutherford scale is used, amongst other clinical manifestations of disease, to determine eligibility of patients for endovascular stent placement. Generally, anyone at a III or higher on the scale will likely benefit from stent placement.
2. Initial patency pre-procedure
    a. An initial measure of patency will be established to determine the effectiveness of the procedure performed. This was done using Duplex ultrasound
3. Initial patency post-procedure
    a. Immediately following stent placement, a second measurement will be recorded to determine initial patency after stent placement. This will be used to measure long term outcomes.
4. Follow up at 1,3,6,9,12 months and yearly after (patency, ABI, symptoms)
    a. Follow up at these intervals (when data exists) will help show the short, middle, and long term outcomes of the procedures, including patency, clinical improvement, and need for additional procedures.

5. Necessity of a follow-up/secondary procedure on same artery
    a. If additional interventions need to be done, that will be noted and included into the final assessment of the endovascular procedures.
6. Procedure failures (stent migrations, stenosis, infection)
    a. Any failures of the procedure will be recorded and included in the final assessment of the procedure outcomes.
7. Procedure complications
    a. Any instances of surgical site infection, hematoma, critical limb ischemia (CLI) as defined in the Vascular Society Reporting Standards
8. Patient medications
    a. Certain pharmaceuticals can cause complications pre-, peri-, and pos-operatively. Using this data can help us further refine indications for stent placement. We will record any use of anticoagulants, antiplatelets, steroids, antihypertensives, and anti-glycemics.

Statistical Analysis of Follow Up Data

The standard reporting procedure for follow up on patency data is to use Kaplan-Meier Life Tables. These tables visually represent how long the vessels remain patent and sustained clinical improvement, and can be used to directly compare endovascular outcomes to those from open surgery interventions. When discussing patency, there are several classifications:

- Primary patency – Primary intervention stays open with no further procedures performed
- Primary assisted patency – Initial opening did not close/collapse completely but needs a second intervention to maintain opening
- Secondary Patency – Primary procedure closed completely, but was able to reopen and keep it open with follow up procedure
- Failure – opening collapsed completely and cannot be reopened at all

The patency data will be a major part of this project as this is one of the controversial points about CFA stenting. Additionally, we will need the complication rates and tables to show that CFA stenting is a safe and effective alternative. The complication rates will be broken down into major and minor complications and will be calculated as a simple percentage of complications/cases.

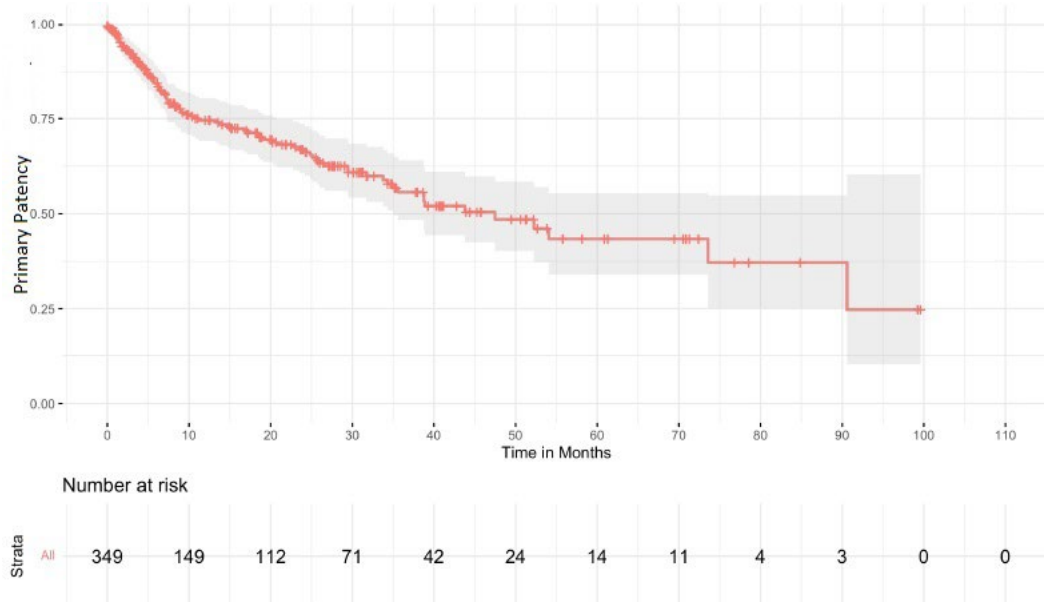
Results

Primary patency was 72.5% (Figure 1) and primary assisted patency (Figure 2) was 95.7%. 12 limbs (3.9%) thrombosed with 4 failures, achieving a secondary patency of 99.1%. There were 13 (3.7%) 30 day adverse events (see Table 1). Long-term complications include: 2 stent thrombosis, 2 pseudoaneurysms, 1 stent dissection, 1 stent migration, and 1 hematoma >30 days after the procedure(See Table 1). Limb-loss was 4.3% with 8 BKA and 7 AKA out of the 349 treated limbs (Figure 3). Previous myocardial infarction correlated to loss of primary patency ($p = .002$). Ulcer/gangrene was 1.8x more likely to lose primary patency compared to claudication ($p = .035$). Ulcer/gangrene ($p=.045$) and rest pain ($p=.007$) compared to claudication were 9.5x and 4.9x more likely to have limb loss, respectively. Survival was 70% up to 75 months (Figure 4).

Table 1. 30 Day Complication rates

30 Day Complication	Number of Incidences
Puncture site infection	2
Hematoma	2
Vasovagal Episode	1
Chest Pain	1
Internal Bleed	1
Cellulitis	1
Balloon Rupture Intraoperatively	1
Hypertensive Episode	1
Stroke	1
Respiratory Arrest	1
Death	1

Figure 1. Primary Patency



Our results showed primary patency of 50% at 48 months.

Figure 2. Primary Assisted Patency

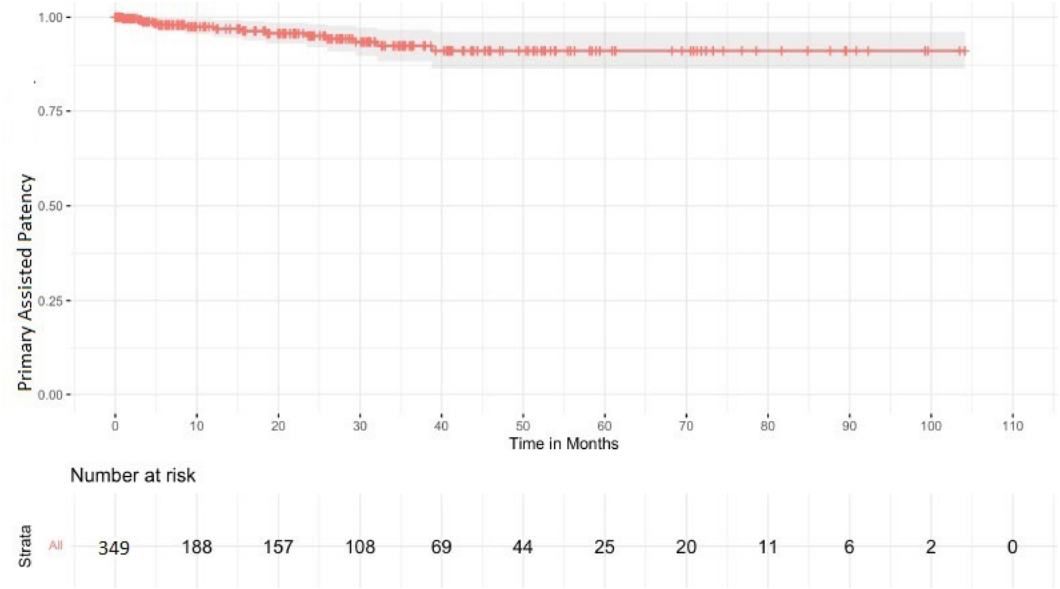


Figure 3. Limb Loss

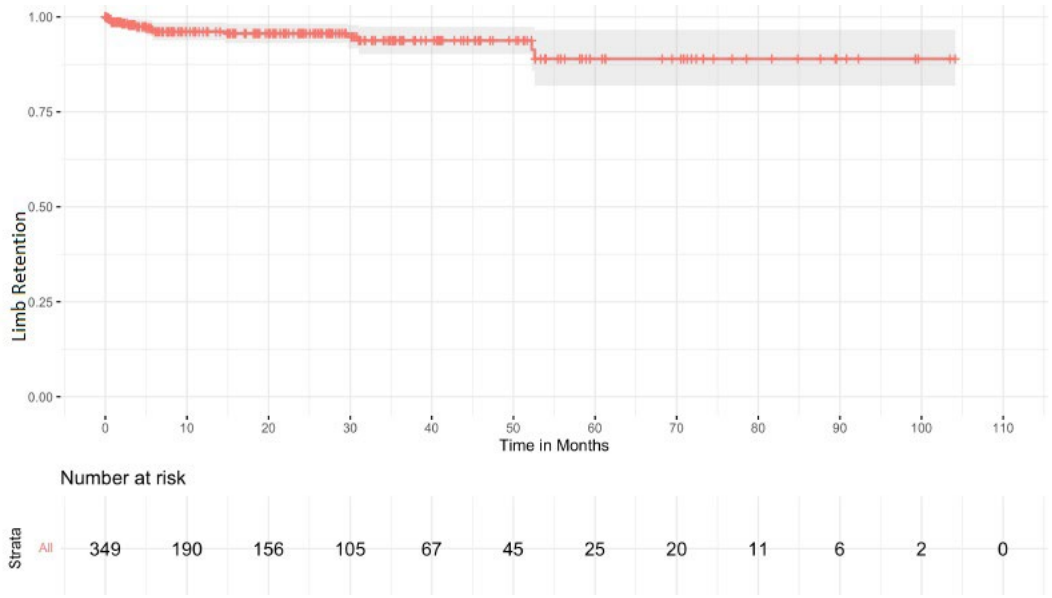
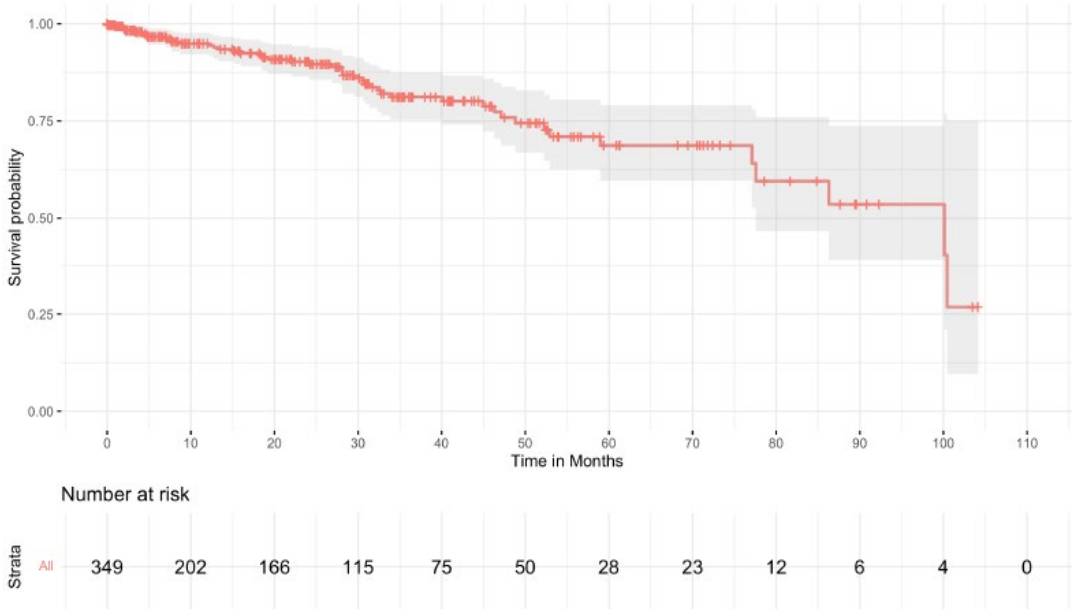


Figure 4. Survival



Discussion/Innovation

When the idea of endovascular stenting across the common femoral artery was previously addressed at conferences and presentations, it was met with much skepticism and doubt. Previous knowledge showed that the stent would not stay open across the artery. If the anticipated results of this project hold true, then we will present a viable, less traumatic option for patients. This shift in approach to treatment of femoral artery occlusion would provide more tools in the box of vascular surgeons to best treat their patients.

The difficulty lies in convincing and changing mindsets. The current trend is that open surgery works well, so there is really no reason or need to improve upon it. The history and outcomes of open surgery prove that it is a viable treatment for those patients that can have it. However, continually expanding the current understanding of PAD and how to treat it allows for more options for the patient to best treat them individually and personally in a way tailored to their needs.

When treating patients, we must look at more than just the physical aspects of any procedure. Of course this is a crucial aspect, but many other factors can affect the treatment plan. The financial aspects of shorter surgery times, fewer complications, and shorter hospital stays would likely ease the monetary burdens faced by PAD patients requiring treatment. Also, the increased efficiency of endovascular procedures in terms of recovery time and complications cannot be overlooked. PAD is a chronic condition that requires extensive follow up and long-term treatments over the lifetime of the patient.

Our results show that the treatment of PAD with endovascular stenting is a safe and efficacious option. We found that endovascular treatment had complications rates lower than that of open treatment, as seen in Table 2 below. We compared our results to historical published data and found that our results were comparable to other endovascular results and better than open.

Table 2. Comparison of Data between open, endovascular, and our results[17]

	Open (%)	Endo (%)	Our Results (%)
Primary Patency (12 months)	84	93	75
Primary Assisted (12 months)	94	97	96
Limb Loss	4.5	3	4.2
30 Day Mortality	0.8	1.3	0.6
Complications (non-infection)	15	5.1	3.2
Surgical Site Infections	7.3	0.3	0.5

Future Directions

With any attempt at changing the common treatment method, we will continue to evaluate the long term outcomes of our stented patients. Additionally, there is some debate as to whether stenting of the CFA causes increased occlusion of further distal vessels. We plan to investigate the outcomes of these vessels and their occlusion rates. We also want to look further into the affects of age, sex, and other comorbidities.

Conclusions

We have found that endovascular treatment of CFA lesions with self-expanding nitinol stents is safe and effective treatments for PAD. Additionally, we report that short, mid, and long term patency results are good and comparable to open modalities. We report lower infection rates and surgical complications compared to historical open procedures.

Compliance Plan

I have completed all necessary HIPAA and CITI trainings for the school and the hospitals that Dr. Ahn, my mentor, is affiliated with and the IRB review process was completed at Dallas Methodist.

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