The CLASE Study: Endovascular Management of the Superficial Femoral Artery

Thesis submitted to the

University of Arizona College of Medicine - Phoenix

in partial fulfillment of the requirements for the degree of

Doctor of Medicine

Hester F. Shieh

Class of 2012

Mentor: Julio A. Rodriguez, MD

Dedication

I dedicate this thesis to my parents for their unconditional love and support.

Acknowledgements

I want to thank Dr. Julio Rodriguez for his invaluable mentorship and guidance, and for inspiring my interest in surgery.

Abstract

Objectives – The purpose of this study was to compare endovascular treatment modalities for peripheral vascular disease in the femoropopliteal arteries with respect to technical success, efficacy, and patency at mid-term follow up.

Methods – A retrospective review of patients that underwent endovascular management of the femoropopliteal segment was conducted to evaluate patency. The CLASE study included five treatment arms: cryoplasty, laser, angioplasty/stent, Silverhawk atherectomy, and Viabahn endoluminal graft.

Results – Between November 2004 and May 2009, 306 patients met inclusion criteria. There was a statistically significant difference in patencies among treatment groups ($p=0.016$), driven by laser having a significantly lower patency than the angioplasty/stent, Silverhawk atherectomy, and Viabahn endoluminal graft groups.

Conclusions – Many of the expensive endovascular devices have poor patencies lasting less than six months. Angioplasty/stent is not inferior to these new devices, and may remain the standard of care.

Table of Contents

1. Title Page……..……1
2. Dedication……2
3. Acknowledgements……3
4. Abstract……4
5. Table of Contents……5
6. List of Figures and Tables.....6
7. Introduction……..7
8. Research Materials and Methods……17
9. Results……..……21
10. Discussion……...…35
11. Future Directions……37
12. Conclusions……38
13. References……...39

List of Figures and Tables

1. Table 1 Comorbidities……23
2. Table 2 Indications……24
3. Table 3 TASC II……25
4. Table 4 Lesions……26
5. Table 5 Distal Runoff Vessels……27
6. Table 6 Concomitant Procedures……28
7. Table 7 Complications……29
8. Table 8 Reinterventions……30
9. Table 9 Mortality……31
10. Table 10 Patencies……33
11. Figure 1 Kaplan-Meier Patency Curve……34

Introduction

Peripheral vascular occlusive disease is a progressive and often debilitating form of atherosclerosis affecting the vessels of the upper and lower extremities. Patients typically present with complaints of pain in the involved extremity and claudication. Others present with numbness, heaviness or fatigue in the affected limb. Up to 10% of patients with intermittent claudication may progress to limb loss over the course of five years.

Most recent studies, however, suggest that the natural history results in more disabling symptoms. McDaniel and Cronenwett reviewed six series involving 2307 patients. Patients were followed for an average of 4.4 years. Although 50% of the patients remained stable, 30% required surgical intervention for rest pain or tissue loss, and 6% underwent amputation. (1)

The superficial femoral artery (SFA) has been the region most difficult to treat and maintain patency. Stenosis and/or occlusion can often occur by six months. Results of balloon angioplasty and stenting in the femoropopliteal segment have been for the most part variable and often without consistent results. The SFA and popliteal arteries are extremely difficult to treat because of the diffuse nature of disease,

high degree of recoil, amplified reactivity, large number of occlusions, calcification, and the impact of inflow and run-off.

Most authors agree that the lesion length and severity of disease in that and more distal regions affect long-term patency. Gray et al treated long femoropopliteal lesions with a mean length of 16.5cm and achieved only 22% primary patency at one year. (2) Henry et al documented 39% patency at four years for femoropopliteal occlusions, however, 80% patency during that same interval for shorter stenoses. (5)

Angioplasty alone is limited by a high frequency of dissection, significant recoil, and unacceptably high restenosis rates. While stenting has made an acute impact on dissection and recoil, restenosis rates have modestly improved with the nitinol stent over time. More aggressive stent utilization, however, has created other problems, namely in-stent restenosis, occlusion, and stent-strut fractures. Percutaneous revascularization has become an option for many patients due to its minimally invasive nature. Newer modalities, such as cryoplasty, laser, Silverhawk atherectomy, and Viabahn endoluminal grafts, have been used in an attempt to obtain better long-lasting results than the standard angioplasty/stent. At present,

few studies have compared the use of these devices to angioplasty/stent based on similar types and characteristics of femoropopliteal lesions. Even less, only one randomized trial in the literature looked at results between angioplasty and open surgery. (3)

Other trials evaluating the efficacy of angioplasty vs. stent demonstrated very poor long-term results, although stents confer excellent early results lasting between 3-9 months before restenosis. (2-5) The mid and long term patencies of these new devices are unknown when compared against the stent. There are, however, several reports on the use of these new devices that indicate that perhaps a better patency and lasting result can be obtained. New technology and devices should optimize acute outcomes, improve long-term vessel patency, allow effective treatment of more difficult lesion subsets, overcome difficult anatomy and access issues, and provide the needed data. We compare the different endovascular treatment modalities for the femoropopliteal arteries through a retrospective review with five treatment arms, and determine the technical success, efficacy, and patency at mid-term follow up.

The following is a description and review of the five treatment arms.

1 - Cryoplasty

The PolarCath peripheral balloon catheter (CryoVascular Systems, Inc., Los Gatos, CA) is a novel angioplasty system that simultaneously dilates and cools the plaque and vessel wall in the area of treatment. Cooling is achieved by inflating the balloon with nitrous oxide rather than the usual saline/contrast mixture.

Cryoplasty involves advancing the balloon catheter to the site of the lesion and delivering liquid nitrous oxide into the balloon, where it expands into gas and inflates. The liquid nitrous oxide cools the vessel while dilating to a predetermined algorithm of temperature (-10°C), pressure (8atm), and dwell time (25sec). This is designed to be gentler on the artery than conventional angioplasty and may offer improved clinical outcomes. By creating apoptosis of smooth muscle cells and other cell lines that lead to restenosis, it can result in limitation of vascular recoil by alteration of elastin fiber morphology, limitation of dissection by minimizing plaque/vessel wall compliance differences, and overall positive remodeling changes.

The FDA sponsored a prospective registry (PVD Chill IDE) of 102 patients with femoropopliteal lesions treated with stand-alone

cryoplasty. The primary clinical patency at nine months was 82.6%. The procedural success rate was 94% and the need for stented lesions was 9% with no device related adverse events. The rate of significant dissection in this series was only 7%, which compares favorably to the expected rate of dissection with conventional angioplasty, reported to be nearly 45%. (6)

2 – Laser

The excimer laser has unique properties that make it ideally suited to debulk atheromatous and thrombotic arterial blockages. LASER is an acronym for Light Amplification by Stimulated Emission of Radiation. However, there are many types of lasers, distinguished by the wavelength of the emitted light, the effective power of the light beam, and whether the light is pulsed (like a flashbulb) or continuous (like a light bulb). The effectiveness of a given laser for intra-arterial applications depends on how the light interacts with tissue inside an artery.

The basic concept of laser atherectomy is to apply light energy directly to the arterial plaque, thereby altering the plaque without damaging the surrounding artery. Lasers suitable for intravascular use produce an intense monochromatic light beam that can be

delivered through fiberoptic catheters to a small area of tissue with great precision.

Spectranetics (Colorado Spring, CO) uses the XeCl (Xenon Chloride) excimer (excited dimmer) laser as a source of energy that is confined to the 308 nanometers in the ultraviolet region of the wavelength spectrum, making this device a "cool" tip laser when compared to other infrared laser devices. Tissue (plaque) ablation can be achieved by forcing the tissue to absorb enough energy in one pulse to vaporize the most volatile liquid in the cells – water. This creates a small crater on one pass and the end result of a new arterial lumen after multiple pulses.

On April 29, 2004, Spectranetics received market clearance from the FDA to treat patients suffering from total refractory occlusions in their leg arteries with their proprietary excimer laser catheters. The market clearance, which was supported by clinical data from a subset of patients enrolled in Spectranetics' LACI (Laser Assisted for Critical-limb Ischemia) trial, applies to most of the company's catheters, ranging in diameter from 0.9mm to 2.5mm.

The LACI trial was a multicenter, prospective registry to treat patients that were poor candidates for surgery. The LACI Phase I Trial

enrolled 25 patients and was completed in June 2000. The LACI Phase II Trial enrolled 145 patients with 155 critically ischemic limbs at fourteen sites in the US and Germany. Procedural success with <50% residual stenosis was seen in 86% of limbs. Limb salvage was achieved in 93% of the limbs treated at six month follow up. (10)

3 – Silverhawk Atherectomy

The Silverhawk peripheral catheter system and cutter driver (FoxHollow Technologies, Redwood City, CA) are designed for the treatment of de novo and restenotic atherosclerotic lesions located in native peripheral arteries. The catheter consists of a flexible shaft designed to track over a 0.014" guide wire. At the distal end of the catheter is a small cutting assembly comprised of a rotating inner blade contained within a tubular housing. The proximal end of the catheter contains a connector and positioning lever designed to fit into a small, disposable, battery-driven cutter driver, which powers the device.

Once the catheter is connected to the cutter driver, retracting the positioning lever simultaneously turns on the motor and causes the distal portion of the cutter housing to deflect, forcing the device against the target lesion. At the same time, this motion exposes the inner

rotating blade, preparing the device for lesion treatment. With the blade spinning, the catheter is slowly advanced across the lesion, "shaving" occlusive material from the artery. The excised tissue is captured and stored in the tip of the device. The cutting process is completed by advancing the positioning lever, which brings the inner blade back into the housing, restoring the cutter to its "non-deflected" configuration, and automatically turning off the motor. This cutting sequence can be repeated as many times as necessary to achieve the desired degree of debulking.

Acute procedural results and midterm outcomes from 601 patients and 1258 lesions have been collected in TALON, a national multicenter registry. Procedural success was 97.6% and the six and twelve month rates of survival free of target lesion revascularization were 90% and 80%, respectively. (11) A recent prospective, two center randomized trial of angioplasty vs. atherectomy revealed poor target lesion revascularization rates of 16.7% and 11.1%, respectively, at one year and no statistical difference between the two. (12)

4 – Viabahn Endoluminal Graft

Viabahn Endoprosthesis (W.L. Gore & Associates, Flagstaff, AZ) is a flexible self-expanding endoluminal device consisting of expanded

polytetrafluoroethylene (ePTFE) lining with an external nitinol (NiTi = Nickel:Titanium) support extending along its entire length. The device is compressed and attached to a catheter delivery system. The Gore Viabahn Endoprosthesis is available in a wide range of diameters and lengths.

The Gore Viabahn is positioned across the target lesion using the radiopaque hub and tip markers on the catheter. If balloon dilation of the lesion is performed, the Viabahn should cover the entire luminal segment treated with balloon dilatation. The graft should extend a minimum of 1cm proximal and distal to the margins of the lesion.
The Hemobahn Endoluminal Graft SFA Trial, a prospective randomized study between angioplasty and Hemobahn, enrolled 198 patients. The patencies at one year and two years were 81% vs. 80% and 62% vs. 71%, respectively, for Hemobahn vs. angioplasty. The trial showed equivalent results for both angioplasty and Hemobahn. (9)

5 – Angioplasty / Stent

A stent is a metal scaffold that is also delivered by a catheter and positioned across the narrowing in the artery. The stent is then expanded against the wall of the blood vessel to provide a wider channel for blood flow. The stent remains implanted in the blood

vessel, and after a few weeks, becomes incorporated in the inner lining of the blood vessel.

Research Materials and Methods

A retrospective review of patients that underwent endovascular management of the SFA at Arizona Heart Institute/Hospital between November 2004 and May 2009 was performed. The CLASE study looked at 5 treatment arms: cryoplasty, laser, angioplasty/stent, Silverhawk atherectomy, and Viabahn endoluminal graft.

The pre-operative duplex ultrasound of all adult patients with a femoropopliteal lesion was evaluated by the inclusion and exclusion criteria. Inclusion criteria were: (a) >70% stenosis or total occlusion of the femoropopliteal segment, not including the common femoral artery, (b) SFA and popliteal >4mm in diameter, (c) at least one vessel run-off, and (d) de novo cases with no previous SFA/popliteal intervention or bypass. Exclusion criteria were: (a) total occlusion of the femoral artery with non-visualization of the origin of the SFA and (b) acute ischemia or acute thrombosis of the femoropopliteal segment.

Demographics, including age, gender, and comorbid factors (hypertension, hyperlipidemia, coronary artery disease (CAD), chronic obstructive pulmonary disease (COPD), diabetes mellitus (DM), renal insufficiency, and tobacco use), were recorded. Indication for the procedure, severe claudication or critical limb ischemia (rest pain or

tissue loss), was noted. The number of excluded patients was also noted.

All procedures were done under systemic heparinization using 3 to 5K IU of IV heparin. All cases were approached percutaneously from the contralateral common femoral artery to prevent the access site from interfering with outcome. Intraoperative angiogram was used to classify each lesion by the TASC II consensus (A, B, C or D), type of lesion (stenosis, occlusion or tandem lesions), and distal run-off (one, two or three vessels). TASC A is a single stenosis ≤10cm in length or a single occlusion ≤5cm in length. TASC B is multiple lesions (stenoses or occlusions), each ≤5cm, a single stenosis or occlusion ≤15cm not involving the infrageniculate popliteal artery, a heavily calcified occlusion ≤5cm in length or a single popliteal stenosis. TASC C is multiple stenoses or occlusions totaling >15cm with or without heavy calcification. TASC D is chronic total occlusions of the common femoral artery or SFA (>20cm, involving the popliteal artery) or chronic total occlusion of the popliteal artery and proximal trifurcation vessels. The use of stents as adjunctive treatment to enhance the primary treatment and any concomitant procedures to improve inflow or outflow were noted. Primary procedure dissection and perforation rates

were recorded. Technical success was defined as the ability to deliver the device and deploy the stent if applicable.

Complications, including hematoma, thrombosis, bleeding, pseudoaneurysm, and groin infection, or any adverse event within 30 days of the intervention were recorded. 30 day mortality was also recorded. Procedural success was defined as technical success with no acute procedure related serious adverse events or major complications prior to discharge.

Follow up evaluation occurred at time points of two weeks, three months, six months, twelve months, eighteen months, and 24 months. It included clinical symptoms, physical exam, and duplex ultrasound. If duplex ultrasound was inconclusive, CT angiogram or angiogram may have been done. Failure of patency was defined as >70% stenosis or total occlusion of the femoropopliteal segment by duplex ultrasound, or worsening of the clinical symptoms. Follow up ended if any of the following occurred: (a) failure of patency, (b) death, or (c) completion of 24 months of follow up. Reintervention and >30 day mortality rates were also recorded. Treatment success was defined as technical success with no major complications and no failure of patency at 24 months. Standard statistical methods and Kaplan-Meier analysis were used.

Results

During the study period of November 2004 to May 2009, 828 patients with femoropopliteal lesions were treated with endovascular technique. 522 of these were excluded because they did not meet inclusion criteria. 306 patients were included in the study: cryoplasty (61 patients, 20%), laser (55, 18%), angioplasty/stent (63, 21%), Silverhawk atherectomy (65, 21%), and Viabahn endoluminal graft (62, 20%).

The average age of the patients was 72 years (35-90 years). There were 187 (61%) male patients and 119 (39%) female patients. Comorbidities were hypertension (HTN) (278 patients, 91%), coronary artery disease (CAD) (196, 64%), coronary obstructive pulmonary disease (COPD) (60, 20%), renal insufficiency (101, 33%), hyperlipidemia (227, 74%), diabetes mellitus (DM) (155, 51%), and tobacco use (227, 74%), with no statistically significant differences among groups. (Table 1) Indications were severe claudication (225 patients, 74%), rest pain (28, 9%), and tissue loss (53, 17%), with no differences among groups. (Table 2) TASC II classifications were A (83 patients, 27%), B (85, 28%), C (71, 23%), and D (67, 22%), with significant differences $p<0.05$ across treatment groups for A and D.

(Table 3) Lesions were stenosis (125 patients, 41%), occlusion (129, 42%), and tandem (52, 17%), with significant differences $p<0.05$ across treatment groups for stenosis and occlusion. (Table 4) Distal runoff vessels were 1 (85 patients, 28%), 2 (119, 39%), and 3 (102, 33%), with no differences among groups. (Table 5) Concomitant procedures were classified as inflow (52 patients, 17%) or outflow (48, 16%), with significant differences $p<0.05$ across treatment groups for outflow. (Table 6) Complications were dissection (64 patients, 21%), perforation (23, 8%), hematoma (17, 6%), thrombosis (1, 0.3%), bleeding (1, 0.3%), pseudoaneurysm (PSA) (3, 0.9%), and groin infection (2, 0.6%). There were significant differences $p<0.05$ across treatment groups for dissection and perforation, with higher rates in laser and Viabahn endoluminal graft groups. (Table 7) Reinterventions occurred in 129 (42%) patients, with no differences among groups. (Table 8) There were no <30 day mortalities and a 7% (21 patients) >30 day mortality rate, with no differences among groups. (Table 9)

Table 1 Comorbidities

	Total	C	L	A	S	E	p
HTN	278 (91%)	53	51	58	56	60	0.21
CAD	196 (64%)	37	37	44	44	34	0.39
COPD	60 (20%)	16	13	11	13	7	0.27
Renal insufficiency	101 (33%)	19	19	19	23	21	0.97
Hyperlipidemia	227 (74%)	41	43	48	48	47	0.69
DM	155 (51%)	32	20	36	34	33	0.98
Tobacco use	227 (74%)	47	37	46	51	46	0.68

C=cryoplasty; L=laser; A=angioplasty/stent; S=Silverhawk atherectomy; E=endoluminal graft (Viabahn)

Table 2 Indications

	Total	C	L	A	S	E	p
Severe claudication	225 (74%)	41	41	48	48	37	0.24
Rest pain	28 (9%)	3	9	4	6	6	0.25
Tissue loss	53 (17%)	17	5	11	11	9	0.10

C=cryoplasty; L=laser; A=angioplasty/stent; S=Silverhawk atherectomy; E=endoluminal graft (Viabahn)

Table 3 TASC II

	Total	C	L	A	S	E	p
A	83 (27%)	23	17	16	20	7	**0.02**
B	85 (28%)	17	15	18	17	19	0.99
C	71 (23%)	15	11	18	14	13	0.80
D	67 (22%)	6	12	11	15	23	**0.006**

C=cryoplasty; L=laser; A=angioplasty/stent; S=Silverhawk atherectomy; E=endoluminal graft (Viabahn)

Table 4 Lesions

	Total	C	L	A	S	E	p
Stenosis	125 (41%)	35	20	32	26	13	**0.0005**
Occlusion	129 (42%)	15	24	19	32	39	**0.00009**
Tandem	52 (17%)	11	11	13	7	10	0.59

C=cryoplasty; L=laser; A=angioplasty/stent; S=Silverhawk atherectomy; E=endoluminal graft (Viabahn)

Table 5 Distal Runoff Vessels

# of Runoff Vessels	Total	C	L	A	S	E	p
1	85 (28%)	21	14	14	17	19	0.59
2	119 (39%)	21	27	26	25	20	0.38
3	102 (33%)	19	14	23	23	23	0.65

C=cryoplasty; L=laser; A=angioplasty/stent; S=Silverhawk atherectomy; E=endoluminal graft (Viabahn)

Table 6 Concomitant Procedures

	Total	C	L	A	S	E	p
Inflow	52 (17%)	10	8	9	10	15	0.56
Outflow	48 (16%)	8	12	11	3	14	**0.04**

C=cryoplasty; L=laser; A=angioplasty/stent; S=Silverhawk atherectomy; E=endoluminal graft (Viabahn)

Table 7 Complications

	Total	C	L	A	S	E	p
Dissection	64 (21%)	6	17	8	14	19	**0.007**
Perforation	23 (8%)	1	6	1	4	11	**0.002**
Hematoma	17 (6%)	3	4	1	5	4	0.57
Thrombosis	1 (0.3%)	1	0	0	0	0	0.40
Bleeding	1 (0.3%)	0	1	0	0	0	0.33
PSA	3 (0.9%)	0	0	1	1	1	0.76
Groin infection	2 (0.6%)	1	0	1	0	0	0.57

C=cryoplasty; L=laser; A=angioplasty/stent; S=Silverhawk atherectomy; E=endoluminal graft (Viabahn)

Table 8 Reinterventions

	Total	C	L	A	S	E	p
Reinterventions	129 (42%)	22	27	27	28	25	0.71

C=cryoplasty; L=laser; A=angioplasty/stent; S=Silverhawk atherectomy; E=endoluminal graft (Viabahn)

Table 9 Mortality

	Total	C	L	A	S	E	p
<30d	0	0	0	0	0	0	
>30d	21 (7%)	5	5	4	4	3	0.90

C=cryoplasty; L=laser; A=angioplasty/stent; S=Silverhawk atherectomy; E=endoluminal graft (Viabahn)

The average length of follow up was 9.14 months with a range of 0 to 60 months. 180 patients were followed until the intervention failed. The other 126 were either lost to follow up or died from other causes.

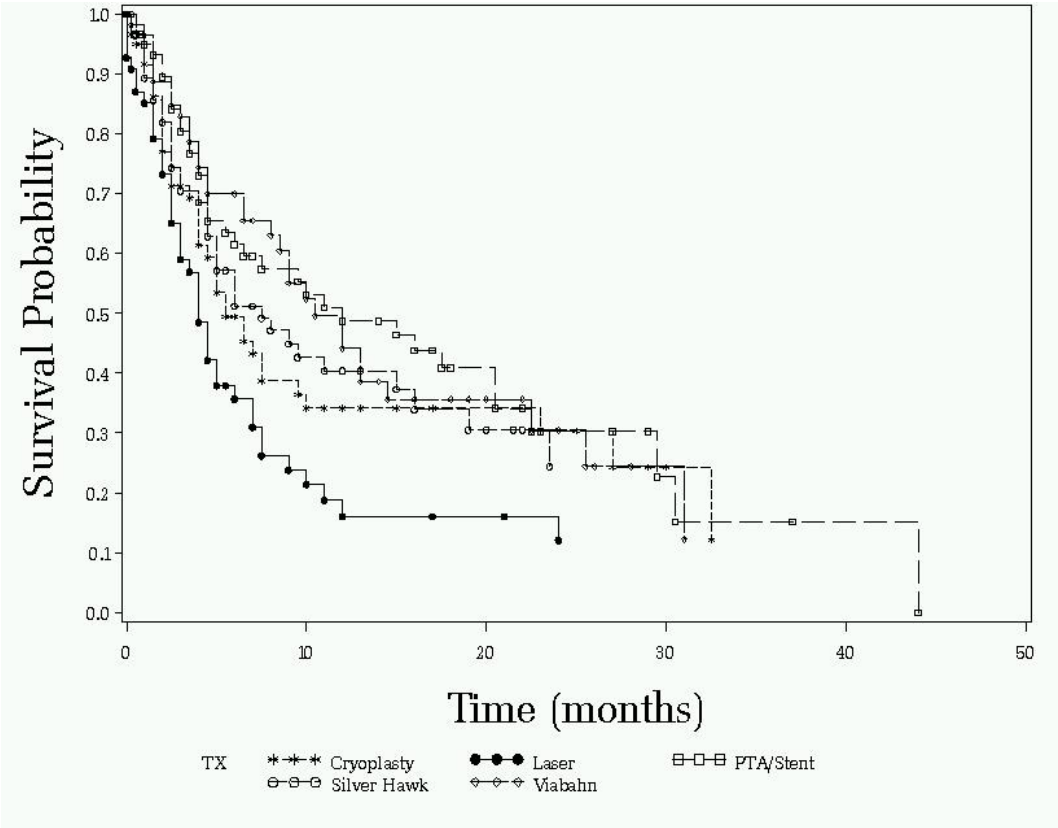
The overall mean patency was 8.35 ± 9.38 months. ANOVA indicated no overall statistical differences (p=0.28) in mean patency across the five groups. On pairwise comparison, laser had a lower mean patency than angioplasty/stent (p=0.029).

Table 10 shows the overall patencies and patencies by treatment at various timepoints. Figure 1 shows the associated Kaplan-Meier patency curve. The log rank test showed a statistically significant difference among treatment groups (p=0.016). Upon pairwise examination, this difference was driven by laser having significantly lower patency than the angioplasty/stent, Silverhawk atherectomy, and Viabahn endoluminal graft groups. Other pairwise comparisons didn't reach statistical significance.

Table 10 Patencies

	Overall	Cryoplasty	Laser	PTA/Stent	Silverhawk	Viabahn
0mos	99%	100%	93%	100%	100%	100%
3mos	76%	71%	59%	80%	71%	83%
6mos	54%	50%	36%	62%	51%	70%
9mos	44%	39%	24%	57%	45%	55%
12mos	37%	34%	16%	49%	40%	44%
18mos	33%	34%	16%	41%	34%	36%
24mos	26%	30%	12%	30%	24%	31%

Figure 1 Kaplan-Meier Patency Curve



Discussion

With the growth of endovascular treatment of peripheral vascular disease, there has been rapid development of new devices that claim to result in improved patencies and patient outcomes. These new technologies have considerably higher costs than the traditional angioplasty/stent technique. Current literature is limited in the evaluation and comparison of these newer techniques against angioplasty/stent. We present a retrospective review of patients with similar femoropopliteal lesions treated with five endovascular modalities, and show that there is a statistically significant difference among treatment groups. The laser group had significantly lower patency than the angioplasty/stent, Silverhawk atherectomy, and Viabahn endoluminal graft groups, but other pairwise comparisons didn't reach statistical significance. It is notable that all of the endovascular treatment modalities had patencies <50% at one year. The laser group had the worst patency, falling to 36% at six months. During the study period, 522 patients (63%) were excluded, mostly cases with prior femoropopliteal intervention or bypass. It is important to note that the results of this study apply to de novo cases. Peripheral vascular interventions have high restenosis rates, accounting for high

reintervention rates, 42% in this study.

For many patients with multiple comorbidities and threatened limb salvage, there are advantages to endovascular technique over open surgery. In this study, we treated 53 patients with rest pain or tissue loss. All of the treatments achieved limb salvage, and have a role in treating patients with critical limb ischemia.

Future Directions

Randomized studies and multicenter trials need to be done to better evaluate whether the newer endovascular devices truly result in a better patency than the standard angioplasty/stent.

Conclusions

In patients with femoropopliteal lesions treated with five endovascular modalities, there was a statistically significant difference in patencies, driven by laser having significantly lower patency than the angioplasty/stent, Silverhawk atherectomy, and Viabahn endoluminal graft groups. All therapies are useful in limb salvage for patients with critical limb ischemia. Many of the expensive technologies used in the femoropopliteal arteries have poor patencies lasting less than six months, suggesting that angioplasty/stent is not inferior to these new devices and remains the standard of care.

References

1. McDaniel MD and Cronenwett JL. Basic Data Related to the Natural History of Intermittent Claudication. Ann Vasc Surg 1989 Jul;3(3):273-7.
2. Gray BH and Olin JW. Limitations of percutaneous transluminal angioplasty with stenting for femoropopliteal arterial occlusive disease. Semin Vasc Surg 1997 Mar;10(1):8-16.
3. Wilson SE, Wolf GL, Cross AP. Percutaneous transluminal angioplasty versus operation for peripheral arteriosclerosis. Report of a prospective randomized trial in a selected group of patients. J Vasc Surg 1989 Jan;9(1):1-9.
4. Ansel GM. Endovascular treatment of SFA and popliteal arterial occlusive disease. J Interv Card vol 12, no. 7, July 2000.
5. Henry M, Amor M, Ethevenot G, Henry I, Amicabile C, Beron R, Mentre B, Allaoui M, Touchot N. Palmaz stent placement in iliac and femoropopliteal arteries: primary and secondary patency in 310 patients with 2-4 year follow-up. Radiology 1995 Oct;197(1):167-174.
6. Joye, JD. An Overview of Cryoplasty. Endovasc Today 2004; vol 3, No. 9, 54-56.

7. Ramaiah V, Cardenas J et al. Arizona Heart Hospital SilverHawk Experience. Endovasc Today Supplement Sept 2.004. pp. 11.
8. Rodriguez JA, Soler L et al. Long-term follow-up of endoluminal grafting for aneurismal and occlusive disease in the superficial femoral artery. J Endovasc Surg. 1999 Aug; 6(3):270-7.
9. Rubin BG, Sicard GA et al. The Hemobahn endoprothesis: A self-expanding polytetrafluoroethylene-covered endoprothesis for the treatment of peripheral arterial occlusive disease after balloon angioplasty. J Vasc Surg. 2001;33:S124-8.
10. Laird JR, Zeller T, Gray BH, Scheinert D, Vranic M, Reiser C, Biamino G; LACI Investigators. Limb salvage following laser-assisted angioplasty for critical limb ischemia: results of the LACI multicenter trial. J Endovasc Ther 2006 Feb;13(1):1-11.
11. Ramaiah V, Gammon R, Kiesz S, Cardenas J, Runyon JP, Fail P, Walker C, Allie DE, Chamberlin J, Solis M, Garcia L, Kandzari D; TALON Registry. Midterm outcomes from the TALON Registry: treating peripherals with SilverHawk: outcomes collection. J Endovasc Ther 2006 Oct;13(5):592-602.
12. Shammas NW, Coiner D, Shammas GA, Dippel EJ, Christensen

L, Jerin M. Percutaneous Lower-extremity arterial interventions with primary balloon angioplasty versus silverhawk atherectomy and adjunctive balloon angioplasty: randomized trial. J Vasc Interv Radiol 2011 Sep;22(9):1223-8.