



University of Pittsburgh

# Tibial Endovascular repair is not durable / Les résultats de l'endovasculaire ne sont pas durables

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**The University of Pittsburgh**

**CACVS Congress. January 2013**



# Faculty Disclosure

**RABIH CHAER**

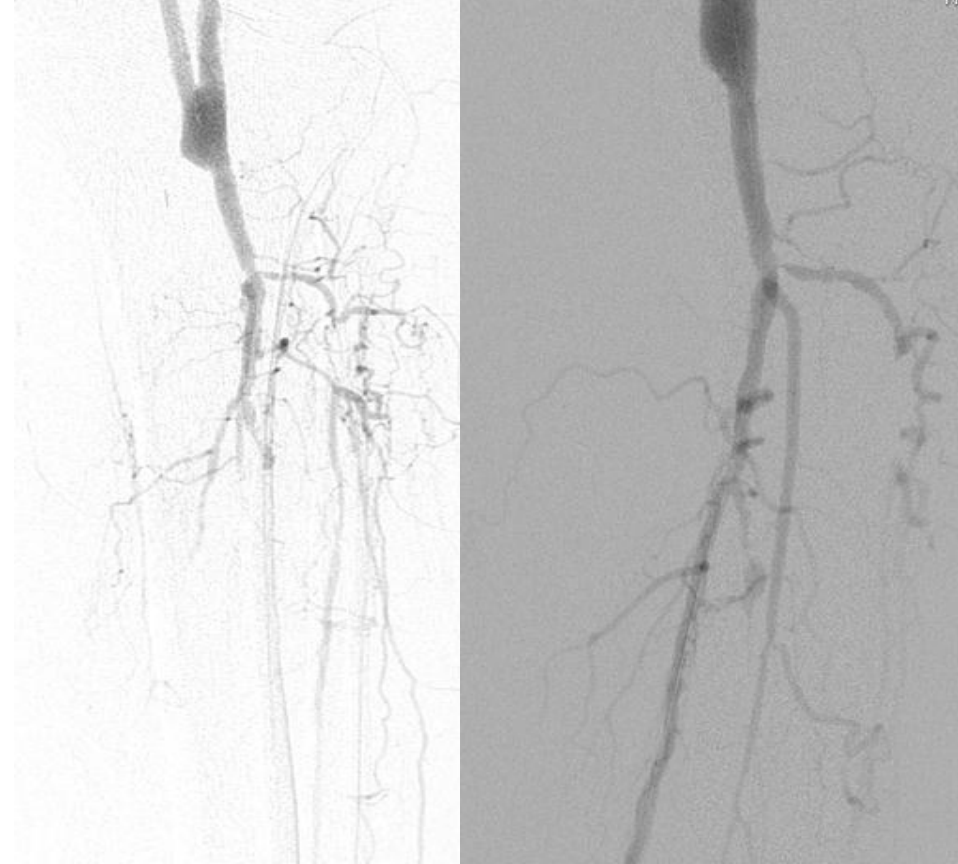
*I disclose the following financial relationships:*

**Receive grant/research support** from **the National Institute of Health, American Venous Forum**

I have **no financial relationships** to disclose.

# DISCLOSURES

- I am an “endo first” enthusiast



# Chaer et al

- Impact of gender and age on outcomes of **tibial** artery endovascular interventions in critical limb ischemia. *Ann Vasc Surg.* 2012 Oct;26(7):937-45.
- Impact of endovascular options on lower extremity revascularization in young patients. *J Vasc Surg.* 2012 Sep;56(3):703-13.
- Multilevel versus isolated endovascular **tibial** interventions for critical limb ischemia. *J Vasc Surg.* 2011 Sep;54(3):722-9.
- Predictors of failure and success of **tibial** interventions for critical limb ischemia. *J Vasc Surg.* 2010 Oct;52(4):834-42.
- Predictors and Outcomes of Restenosis following **Tibial** Artery Endovascular Interventions for Critical Limb Ischemia. *J Vasc Surg.* 2013. In Press.

# Durable: definition

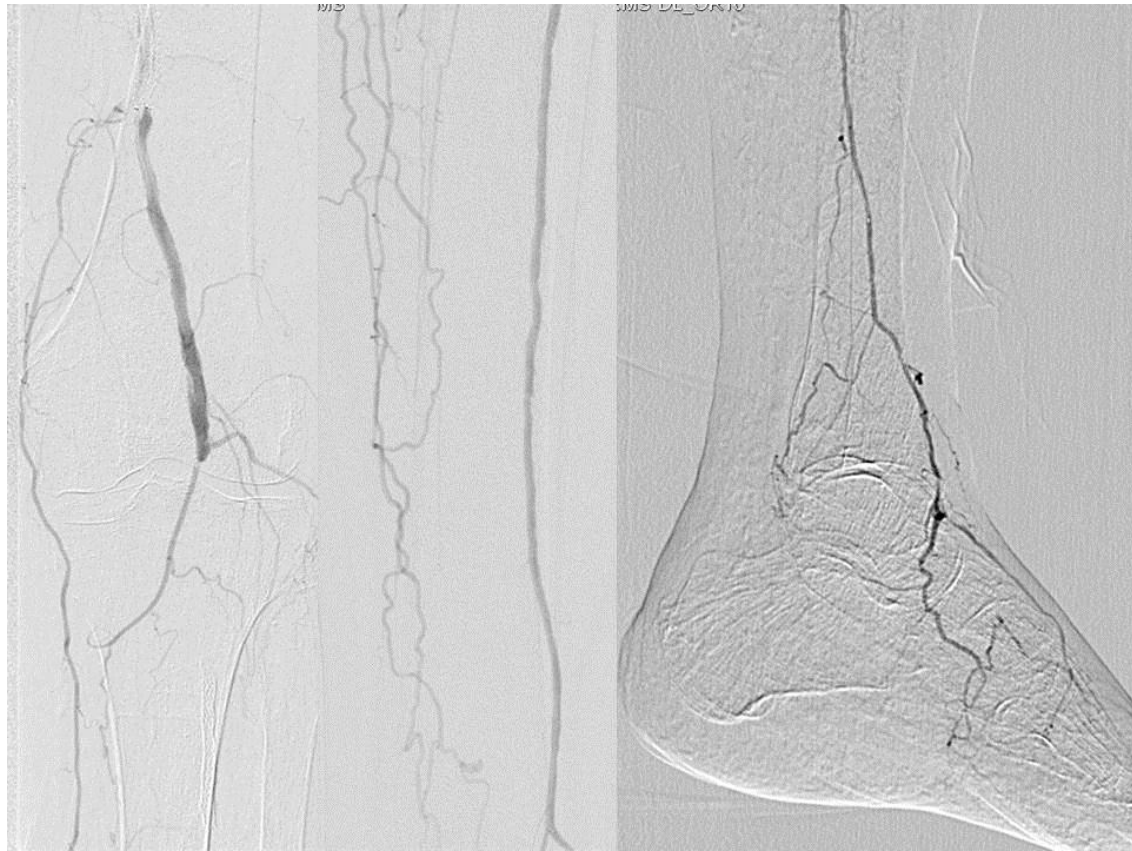
Durabilis. Latin origin

- “Able to exist for a long time without significant deterioration” (Webster)
- “De nature a durer longtemps, qui presente une certaine stabilite, une certaine resistance” (Larousse)



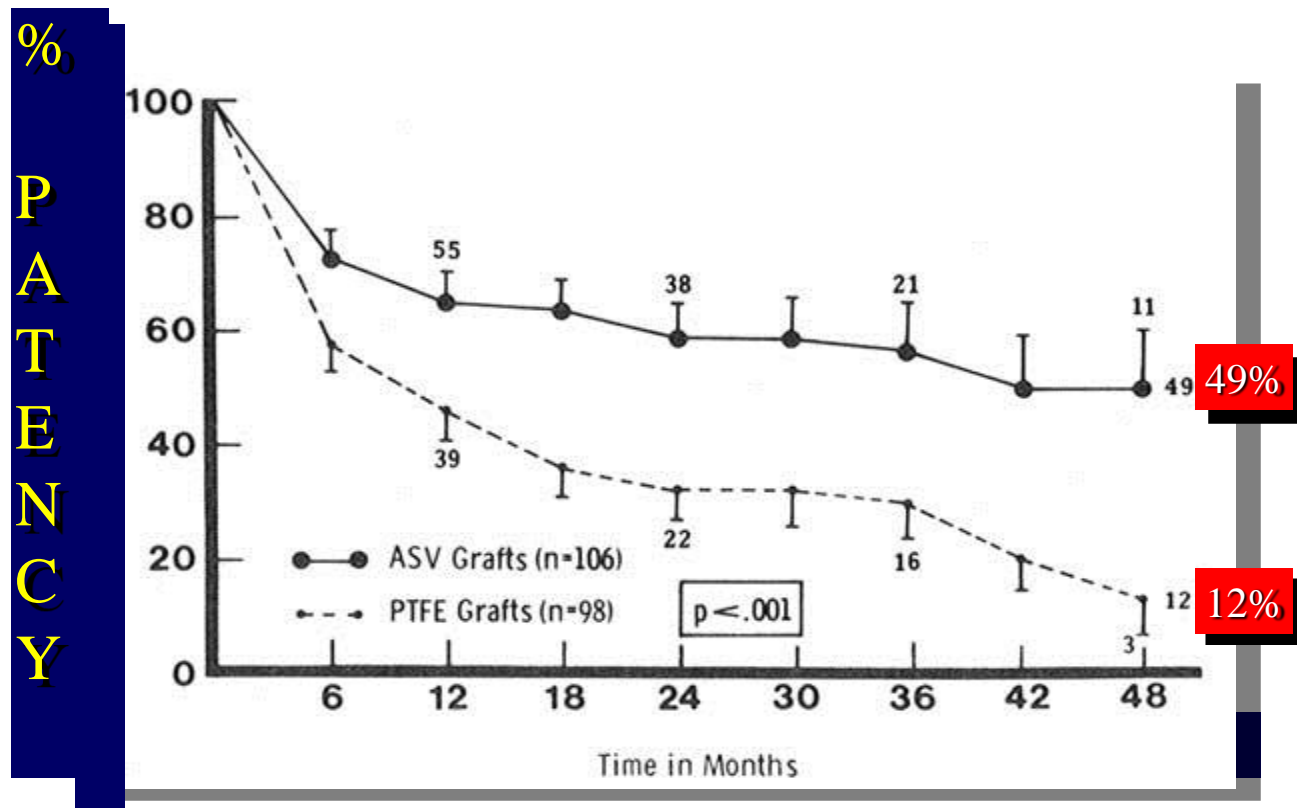
# DURABLE

- High patency rate
- Low rate of reinterventions



# TIBIAL BYPASS. LONG TERM PATENCY

## RCT. Conduit type



%

P  
A  
T  
E  
N  
C  
Y

MONTHS

# Factors Potentially Associated with Poor Results

- Isolated peroneal runoff
- Creatinine > 1.3
- Diabetes
- Female Gender

Davies, JACS 2005  
Chaer et al





## Predictors of failure and success of tibial interventions for critical limb ischemia

Nathan Fernandez, MD, Ryan McEnaney, MD, Luke K. Marone, MD, Robert Y. Rhee, MD, Steven Leers, MD, Michel Makaroun, MD, and Rabih A. Chaer, MD, *Pittsburgh, Pa*

**Objective:** The efficacy of tibial artery endovascular intervention (TAEI) for critical limb ischemia (CLI) and particularly for wound healing is not fully defined. The purpose of this study is to determine predictors of failure and success for TAEI in the setting of CLI.

**Methods:** All TAEI for tissue loss or rest pain (Rutherford classes 4, 5, and 6) from 2004 to 2008 were retrospectively reviewed. Clinical outcomes and patency rates were analyzed by multivariable Cox proportional hazards regression and life table analysis.

**Results:** One hundred twenty-three limbs in 111 patients (62% male, mean age 74) were treated. Sixty-seven percent of patients were diabetics, 55% had renal insufficiency, and 21% required hemodialysis. One hundred two limbs (83%) exhibited tissue loss; all others had ischemic rest pain. All patients underwent tibial angioplasty (PTA). Tibial excimer laser atherectomy was performed in 14% of the patients. Interventions were performed on multiple tibial vessels in 20% of limbs. Isolated tibial procedures were performed on 50 limbs (41%), while 73 patients had concurrent ipsilateral superficial femoral artery or popliteal interventions. The mean distal popliteal and tibial runoff score improved from  $11.8 \pm 3.6$  to  $6.7 \pm 1.6$  ( $P < .001$ ), and the mean ankle-brachial index increased from  $0.61 \pm 0.26$  to  $0.85 \pm 0.22$  ( $P < .001$ ). Surgical bypass was required in seven patients (6%). The mean follow up was  $6.8 \pm 6.6$  months, while the 1-year primary, primary-assisted, and secondary patency rates were 33%, 50%, and 56% respectively. Limb salvage rate at 1 year was 75%. Factors found to be associated with impaired limb salvage included renal insufficiency (hazard ratio [HR] = 5.7;  $P = .03$ ) and the need for pedal intervention (HR = 13.75;  $P = .04$ ). TAEI in an isolated peroneal artery (odds ratio = 7.80;  $P = .01$ ) was associated with impaired wound healing, whereas multilevel intervention (HR = 2.1;  $P = .009$ ) and tibial laser atherectomy (HR = 3.1;  $P = .01$ ) were predictors of wound healing. In patients with tissue loss, 41% achieved complete closure (mean time to healing,  $10.7 \pm 7.4$  months), and 39% exhibited partial wound healing (mean follow up,  $4.4 \pm 4.8$  months) at last follow up. Diabetes, smoking, statin therapy, and revascularization of  $>1$  tibial vessel had no impact on limb salvage or wound healing. Re-intervention rate was 50% at 1 year.

**Conclusions:** TAEI is an effective treatment for CLI with acceptable limb salvage and wound healing rates, but requires a high rate of reintervention. Patients with renal failure, pedal disease, or isolated peroneal runoff have poor outcomes with TAEI and should be considered for surgical bypass. (*J Vasc Surg* 2010;52:834-42.)

Although patients with peripheral artery disease presenting with critical limb ischemia (CLI; rest pain and tissue loss, Rutherford classes 4, 5, 6) have been traditionally treated with surgical bypass, advances in endovascular techniques, including subintimal angioplasty, as well as ad-

The recently published Trans Atlantic Inter-Societal Consensus document (TASC II) promotes endovascular techniques including angioplasty and stenting as first-line therapy for symptomatic femoropopliteal stenotic or occlusive lesions up to 10 cm in length.<sup>4</sup> However, the recom-



# Retrospective Analysis

- All patients treated for CLI between 2004-2008
- 123 limbs treated with a tibial with or without multilevel endovascular intervention (83% tissue loss)
- 62% males, mean age 74 years



# Tibial Interventions. UPMC

- One-year primary, primary-assisted and secondary patency rates were 33%, 50% and 56% respectively
- Reintervention rate was 50% at 1 year



# Tibial Interventions and Wound Healing

- 41% had complete healing (mean time to healing of  $10.7 \pm 7.4$  months).
- 39% of patients treated for tissue loss had improvement in their wounds (mean FU  $4.4 \pm 4.8$  months)
- Impaired wound healing:
  - TAEI in an isolated peroneal artery ([OR]=7.80; P =.01)
  - need for hemodialysis ([HR]=5.63; P=.04)



# IMPACT OF DIABETES

From the New England Society for Vascular Surgery

## Reduced primary patency rate in diabetic patients after percutaneous intervention results from more frequent presentation with limb-threatening ischemia

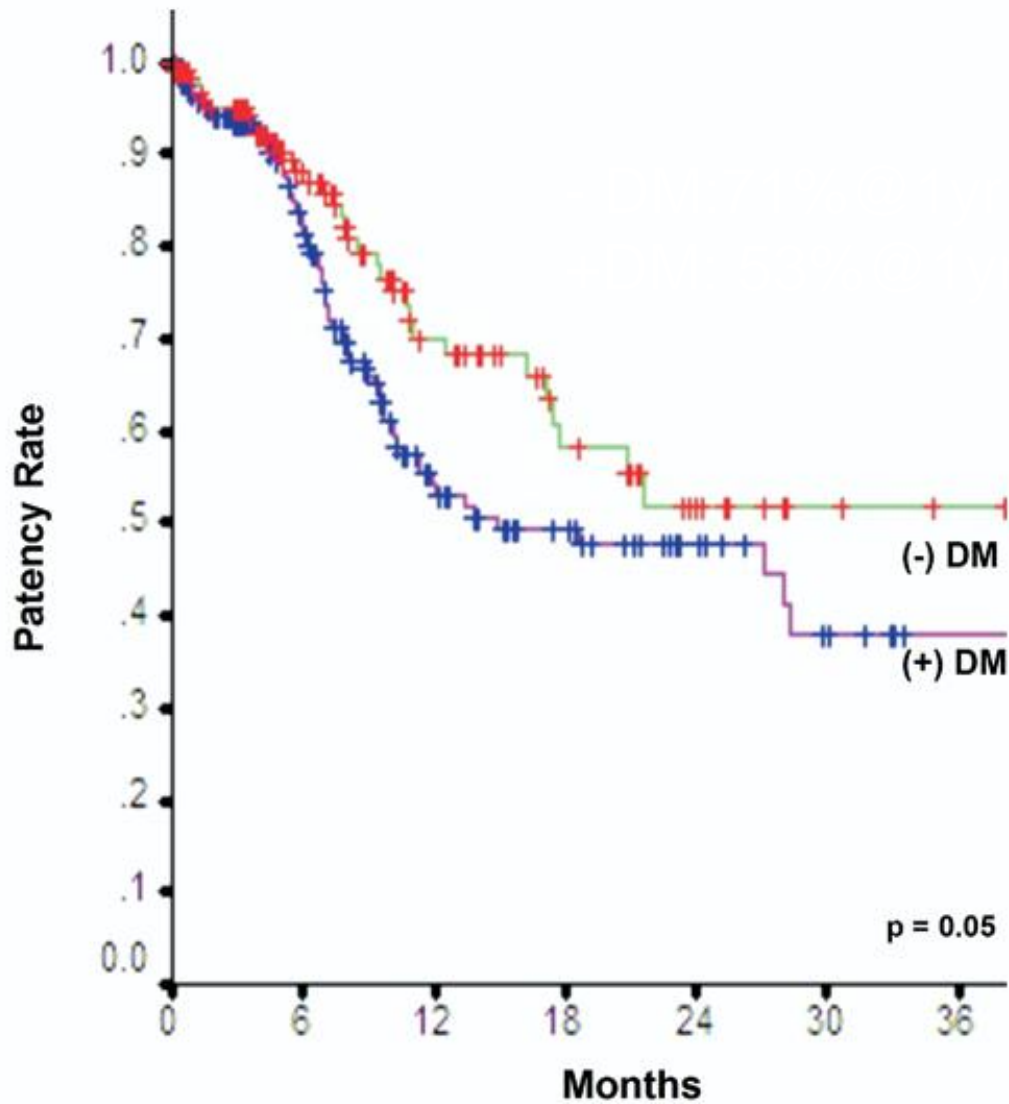
Brian G. DeRubertis, MD, Matthew Pierce, BS, Evan J. Ryer, MD, Susan Trocciola, MD, K. Craig Kent, MD, and Peter L. Faries, MD, *New York, NY*

*Objective:* Although patients with diabetes are at increased risk of amputation from peripheral vascular disease, excellent limb-salvage rates have been achieved with aggressive surgical revascularization. It is less clear whether patients with diabetes will fare as well as nondiabetics after undergoing percutaneous lower extremity revascularization, a modality which is becoming increasingly utilized for this disease process. This study aimed to assess differential outcomes in between diabetics and nondiabetics in lower extremity percutaneous interventions.

*Methods:* We retrospectively studied 291 patients with respect to patient variables, complications, and outcomes for percutaneous interventions performed for peripheral occlusive disease between 2002 and 2005. Tibial vessel run-off was assessed by angiography. Patency (assessed arterial duplex) was expressed by Kaplan-Meier method and log-rank analysis. Mean follow-up was 11.6 months (range 1 to 56 months).

*Results:* A total of 385 interventions for peripheral occlusive disease with claudication (52.2%), rest pain (16.4%), or tissue loss (31.4%) were analyzed, including 336 primary interventions and 49 reinterventions (mean patient age 73.9 years, 50.8% male). Comorbidities included diabetes mellitus (57.2%), chronic renal insufficiency (18.4%), hemodialysis (3.8%), hypertension (81.9%), hypercholesterolemia (57%), coronary artery disease (58%), tobacco use (63.2%). Diabetics were significantly more likely to be female (55.3% vs 40.8%), and suffer from CRI (23.5% vs 12.0%), a history of myocardial infarction (36.5% vs 18.0%), and <three-vessel tibial outflow (83.5% vs 71.8%), compared with nondiabetics, although all other comorbidities and lesion characteristics were equivalent between these groups. Overall primary patency ( $\pm$  SE) at 6, 12, and 18 months was  $85 \pm 2\%$ ,  $63 \pm 3\%$  and  $56 \pm 4\%$ , respectively. Patients with diabetes suffered reduced primary patency at 1 year compared with nondiabetics. For nondiabetics, primary patency was  $88 \pm 2\%$ ,  $71 \pm 4\%$ , and  $58 \pm 4\%$

# Primary Patency Rate of Treated Limbs in Diabetic and Non-diabetic Patients

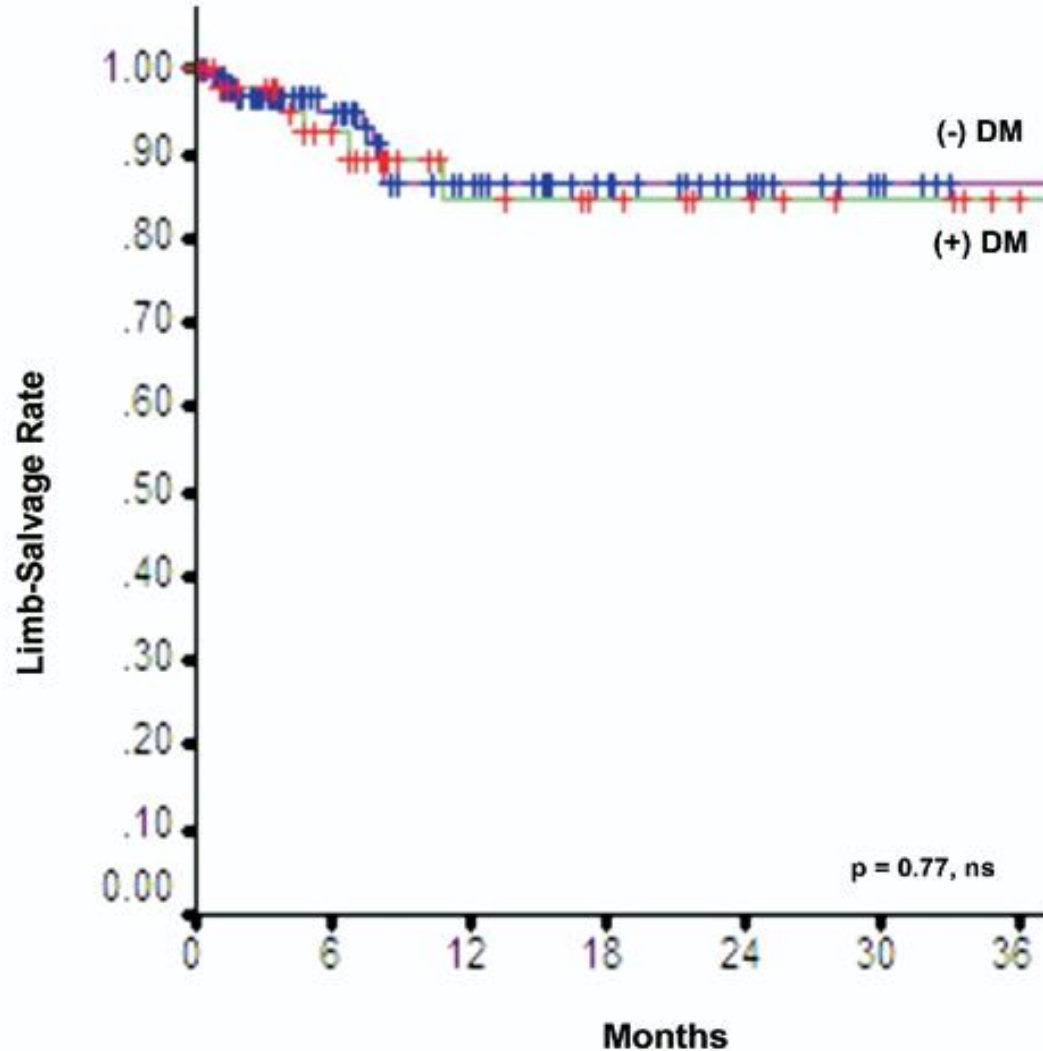


No. at Risk (-DM):	137	80	41	22	15	6	3
No. at Risk (+DM):	199	113	47	38	29	12	6



## Limb-Salvage of Treated Limbs in Diabetic and Non-diabetic Patients with Critical Limb Ischemia

“Despite a higher reintervention rate, diabetics can attain equivalent short-term secondary patency and limb-salvage rates. Therefore, these patient characteristics should not be considered contraindications to endovascular therapy”



No. at Risk (-DM):	49	34	18	14	9	7	3
No. at Risk (+DM):	103	57	39	21	12	5	1



# IMPACT OF GENDER

## Impact of Gender and Age on Outcomes of Tibial Artery Endovascular Interventions in Critical Limb Ischemia

*Natalie Domenick, Naveed U. Saqib, Luke K. Marone, Robert Y. Rhee, Michel S. Makaroun, and Rabih A. Chaer, Pittsburgh, Pennsylvania*

**Background:** Female sex and older age are known risk factors for adverse outcomes in peripheral artery disease. This study reports on the outcomes of tibial artery endovascular intervention (TAEI) by age and gender in patients treated for critical limb ischemia.

**Methods:** All TAEIs for tissue loss or rest pain (Rutherford classes 4, 5, and 6) from 2004 to 2010 were retrospectively reviewed. Patient demographics, comorbidities, intervention sites, complications, and outcome measurements, including limb salvage, wound healing, and patency, were recorded for each patient. Data were analyzed by gender and age using Fisher exact test, multivariate logistic regression, and Cox proportional hazards regression.

**Results:** Two hundred twenty-one limbs (201 patients, 40% female) were treated for critical limb ischemia (74% with tissue loss, 26% with rest pain). Mean age of the patients was 73.3 years (39% were aged  $\geq 80$  years). Comorbidities and indications for intervention were comparable. Isolated TAEI was performed in 46% of the limbs, whereas multilevel interventions were performed in 54%. Mean follow-up period was  $8.7 \pm 7.3$  months. Complications were comparable between



# Impact of Gender and Age on tibial artery endovascular interventions for CLI

- 221 limbs (201 patients, 40% female)
- 74% tissue loss, 26% with rest pain
- Mean age 73.3 yrs (39%  $\geq$  80).



# Life Table Analysis

- Overall primary patency: 62% at 1 year, similar in women and octogenarians (p=NS).
- Overall reintervention rate was 53% at 1 year: **higher in females** (65% v. 46%, p=0.03).



# TIBIAL RESTENOSIS IS NOT BENIGN

## Predictors and outcomes of restenosis following tibial artery endovascular interventions for critical limb ischemia

07 **Naveed U. Saqib, MD, Natalie Domenick, MD, Jae S. Cho, MD, Luke Marone, MD, Steven Leers, MD,**  
08 **Michel S. Makaroun, MD, and Rabih A. Chaer, MD, Pittsburgh, Pa**

11 *Objective:* Restenosis following tibial artery endovascular interventions is thought to be benign but is not well  
12 characterized. This study examines the consequences and predictors of recurrent stenosis of tibial artery endovascular  
13 interventions for critical limb ischemia.

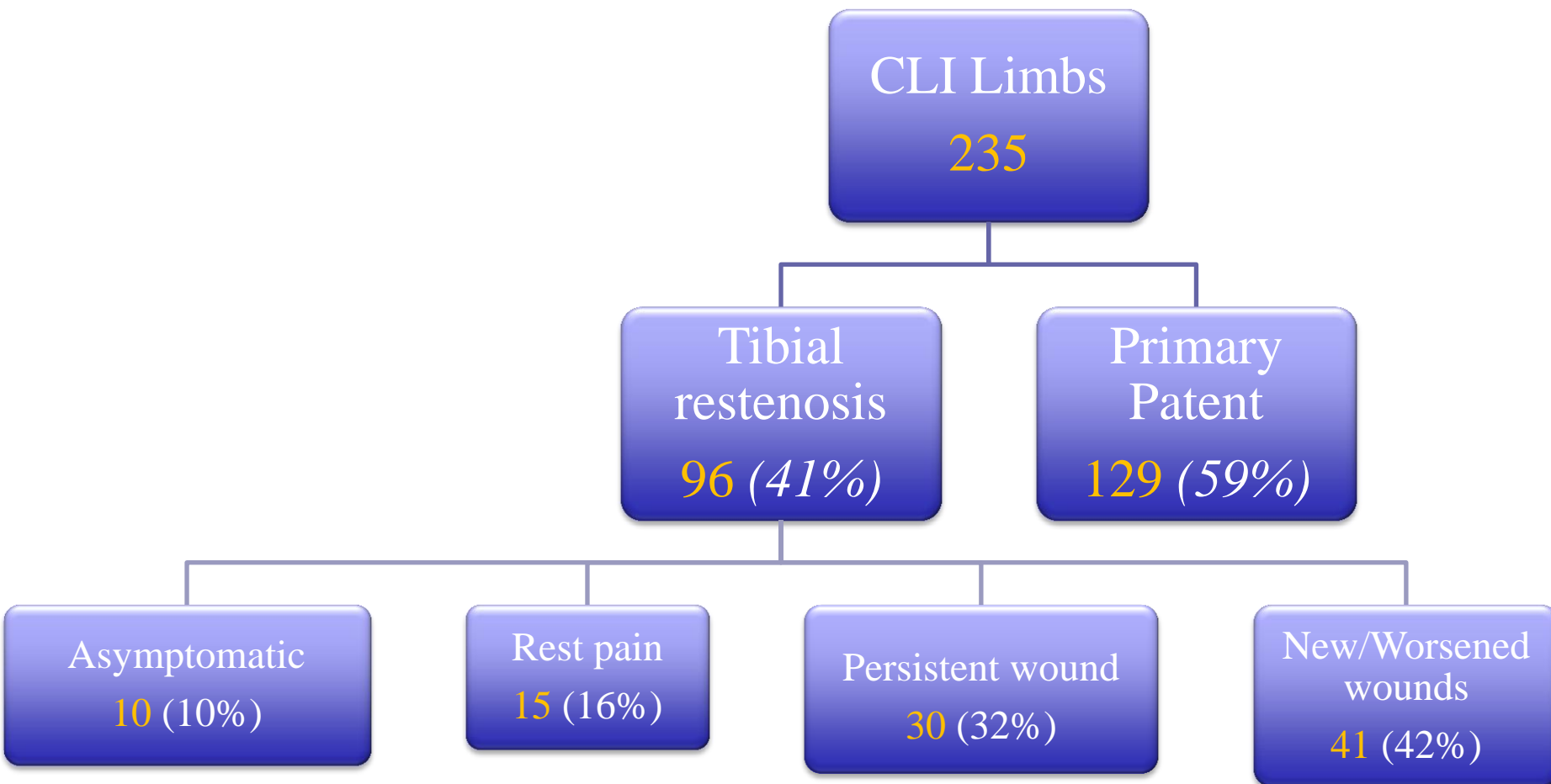
14 *Methods:* All tibial artery endovascular interventions for critical limb ischemia performed between 2004 and 2010 were  
15 retrospectively reviewed. Restenosis was detected by noninvasive imaging and angiography when indicated. Restenoses  
16 were identified and the limb outcomes recorded. Tibial reinterventions were performed only for persistent, worsening, or  
17 recurrent tissue loss or rest pain with evidence of recurrence on duplex ultrasound or hemodynamic imaging. The  $\chi^2$  test  
18 and logistic regression were applied as indicated. One-year patency rates were calculated using the Kaplan-Meier method.

19 *Results:* A total of 235 limbs in 210 patients were treated for critical limb ischemia (70% tissue loss, 30% rest pain). Tissue loss  
20 included gangrene (49%) and ulcers (51%), and involved the forefoot (80%), the heel (14%), or both (6%). Seventy-eight  
21 percent of limbs had Trans-Atlantic InterSociety Consensus C/D lesions, with mean preoperative runoff score of 12.  
22 Interventions were isolated tibial (45%) or multilevel (55%) (including tibial). Mean postoperative runoff score improved to  
23 6.6, but restenosis occurred in 96 limbs (41%) at a mean of 4 months. The 1-year primary patency was 59% at mean follow-up  
24 of 9 months. Restenosis presented with a persistent wound (32%), worsened wound (42%), rest pain (16%), or no symptoms  
25 (10%). A repeat tibial artery endovascular intervention was performed in 42 (44%), major amputation in 26 (27%), open  
26 bypass in 20 (21%), and observation in eight (8%). The overall amputation rate was 13%, but limb loss was significantly higher  
27 in patients with restenosis ( $n = 26$  [27%]) than in patients with no restenosis ( $n = 5$  [4%];  $P < .001$ ). Patients with restenosis  
28 and tissue loss were more likely to have presented with gangrene (63% vs 38%;  $P = .0003$ ) but had comparable wound  
29 distribution ( $P = \text{NS}$ ). There was a trend toward a higher restenosis rate in patients with renal insufficiency (odds ratio, 5.57;  
30  $P = .08$ ), but this was unaffected by diabetes, statin therapy, or smoking ( $P = \text{NS}$ ). The rate of repeat intervention after the  
first reintervention was 36%, with an 87% overall limb salvage rate.

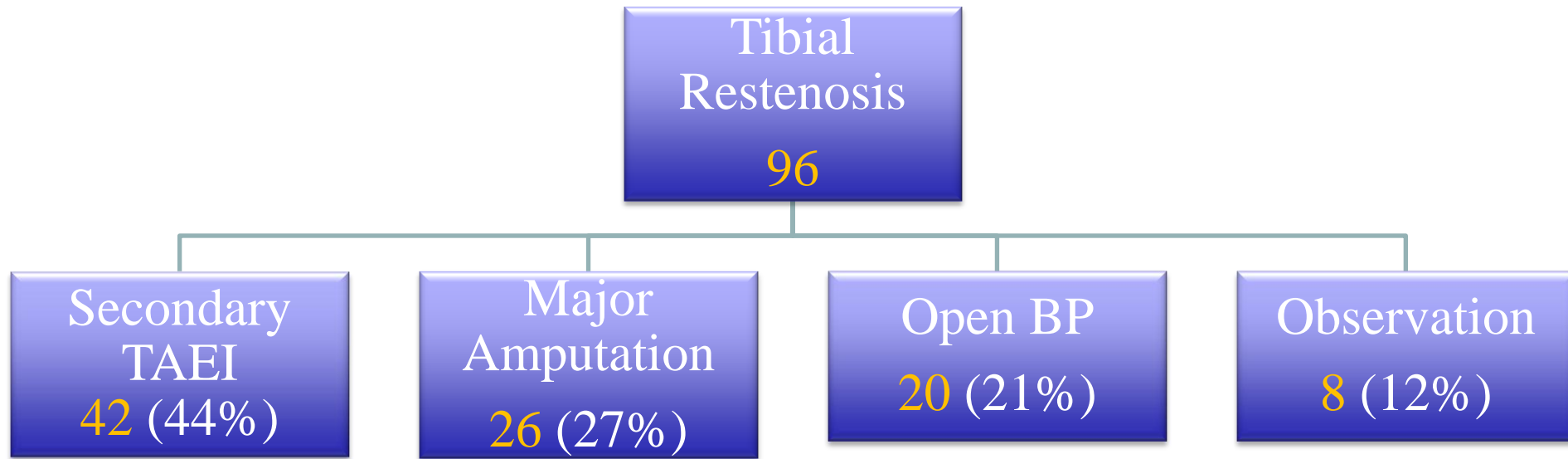
*Conclusions:* Tibial artery endovascular interventions can be used successfully to treat patients with critical limb ischemia

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# Results:

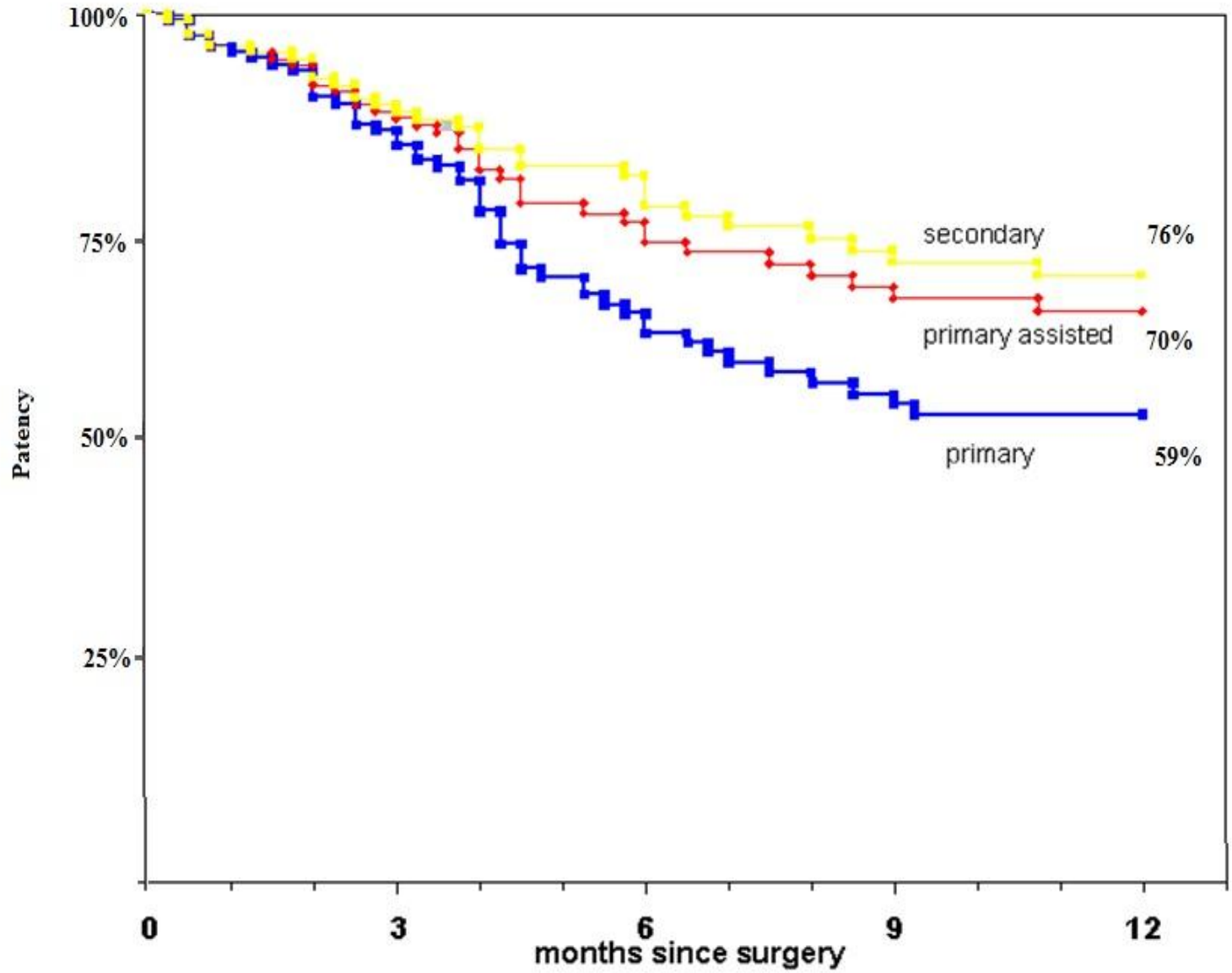


# Results:



# PATENCY

- Primary  
59%
- Primary assisted  
70%
- Secondary  
76%



# Angiographic Patency and Clinical Outcome After Balloon-Angioplasty for Extensive Infrapopliteal Arterial Disease

Andrej Schmidt,<sup>1,2\*</sup> MD, Matthias Ulrich,<sup>1</sup> MD, Bert Winkler,<sup>1</sup> Christina Kläeffling,<sup>3</sup> MD, Yvonne Bausback,<sup>1</sup> MD, Sven Bräunlich,<sup>1</sup> MD, Spiridon Botsios,<sup>4</sup> MD, Hans-Joachim Kruse,<sup>5</sup> MD, Ramon L. Varcoe,<sup>6</sup> FRACS (Vasc), MD, Steven Kum,<sup>1</sup> MD, and Dierk Scheinert,<sup>1,2</sup> MD

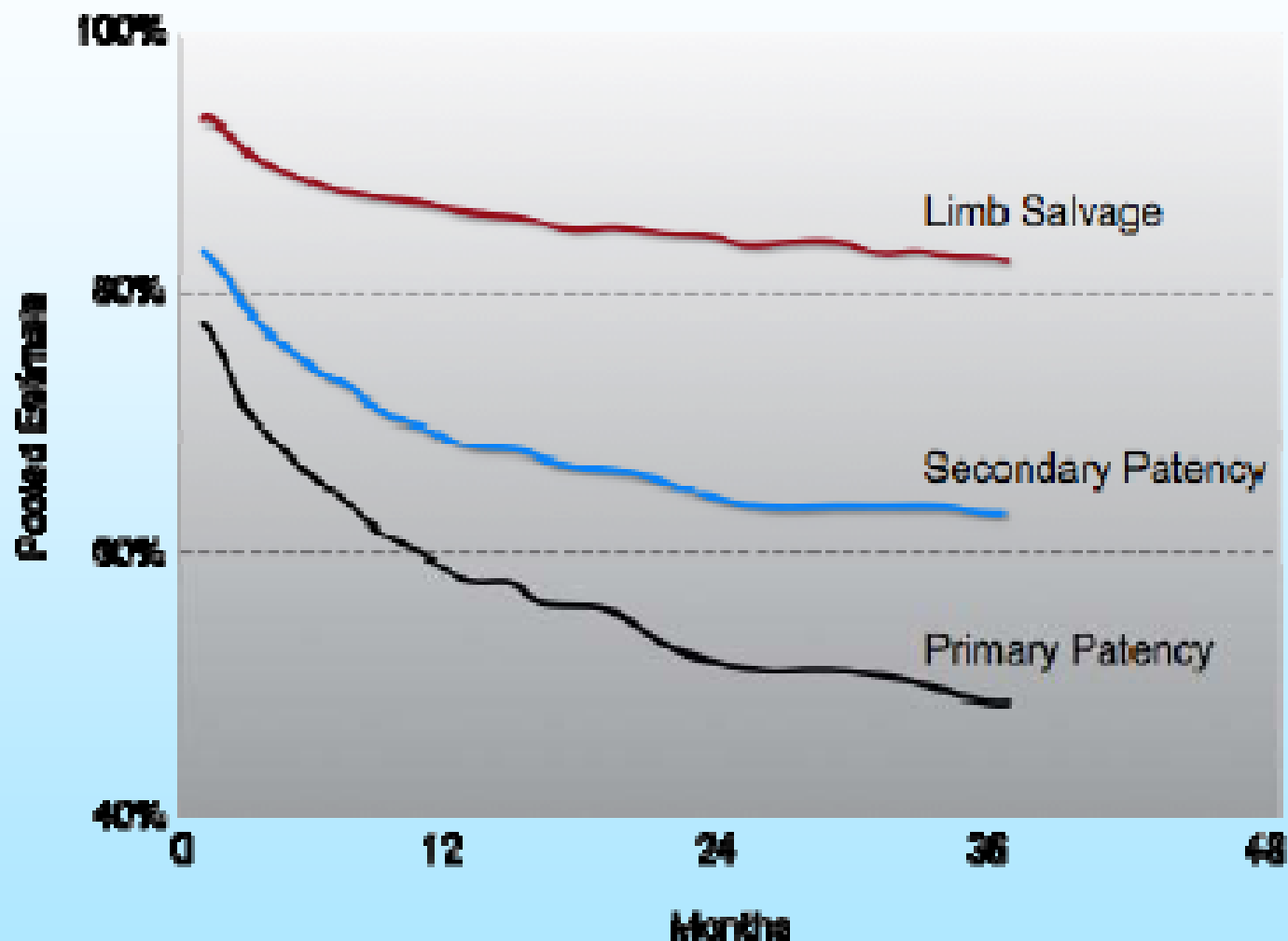
**Background and objective:** Restenosis-rate after balloon-angioplasty of long segment tibial arterial disease is largely unknown. We investigated the restenosis-rates angiographically in patients with critical limb ischemia (CLI) due to extensive infrapopliteal lesions. **Methods:** Angioplasty for infrapopliteal lesions exclusively  $\geq 80$  mm in length was performed using dedicated 80–120 mm long low-profile balloons. Follow-up included angio-

**Restenosis-rate after angioplasty of extensive infrapopliteal arterial disease is high and occurs early after treatment**

graphy. Angiography at 3 months showed no significant restenosis in 24 of 77 (31.2%) treated arteries, a restenosis  $\geq 50\%$  in 24 (31.2%) arteries and a reocclusion in 29 of 77 (37.6%). At 15 months death rate was 10.5%. After repeat angioplasty in case of restenosis cumulative clinical results at 15 months were minor amputations in 8.1%, no major amputations resulting in a limb-salvage rate of 100% with no patient requiring bypass surgery. **Conclusions:** Restenosis-rate after angioplasty of extensive infrapopliteal arterial disease is high and occurs early after treatment. Despite this the clinical results are excellent, especially given the length of the arterial segments diseased. © 2010 Wiley-Liss, Inc.

# Tibial Disease

## Outcomes of Endovascular Treatment



Romiti et al, J Vasc Surg 2008;47:975-81



# Dr Schneider's results. Tibial stenting

- 120 patients, 6-month binary stent restenosis 68.5%
- 12-month AFS rate 78.3%, freedom from major amputation rate 89.6%
- 6, 12-month complete wound-healing rates: 49.0% and 54.4%, respectively.
- Conclusion: primary infrapopliteal nitinol stenting to treat CLI is safe and effective in improving 6-and 12-month clinical outcomes?????

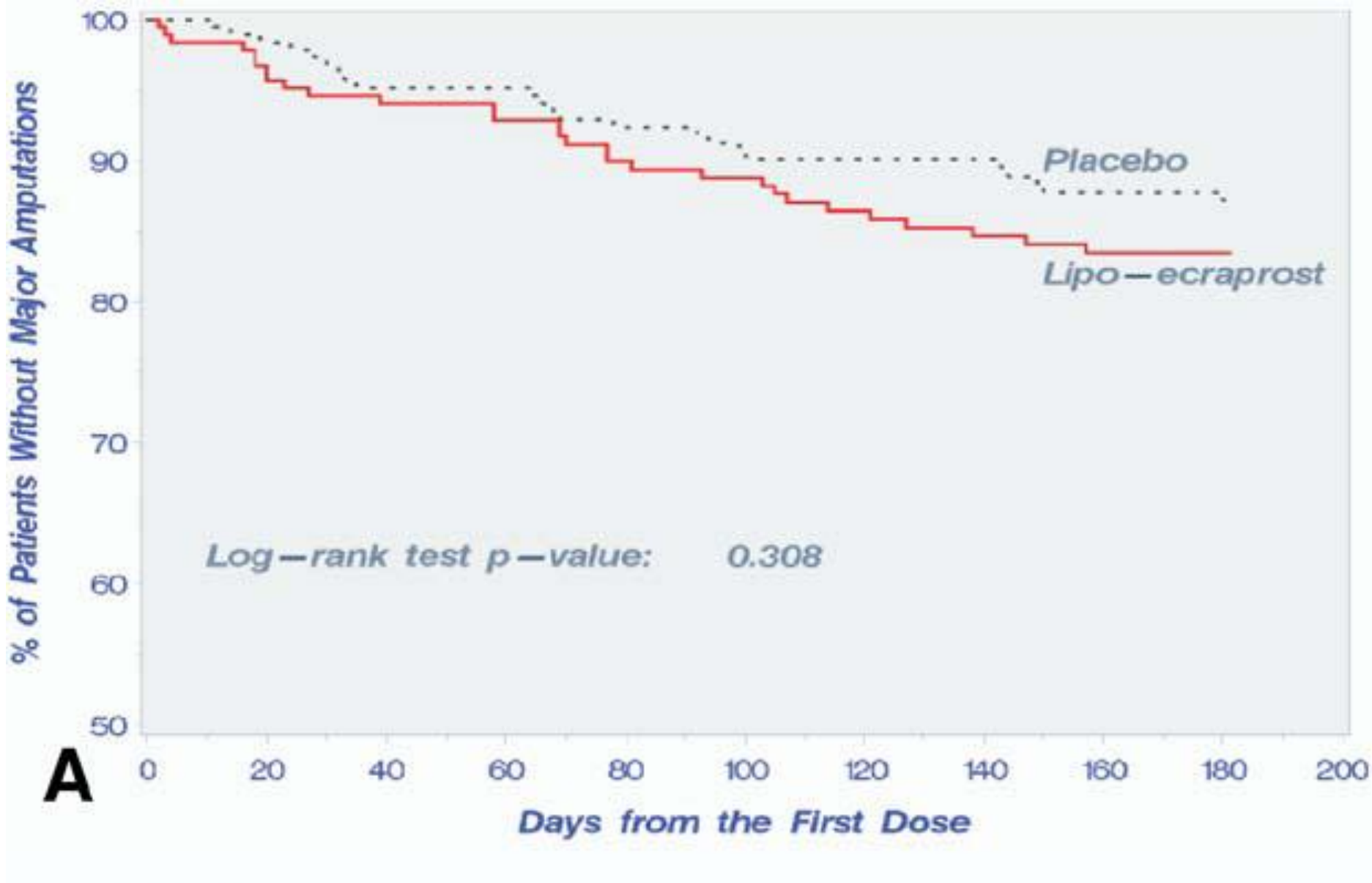
**Beauty is in the eye of the beholder**



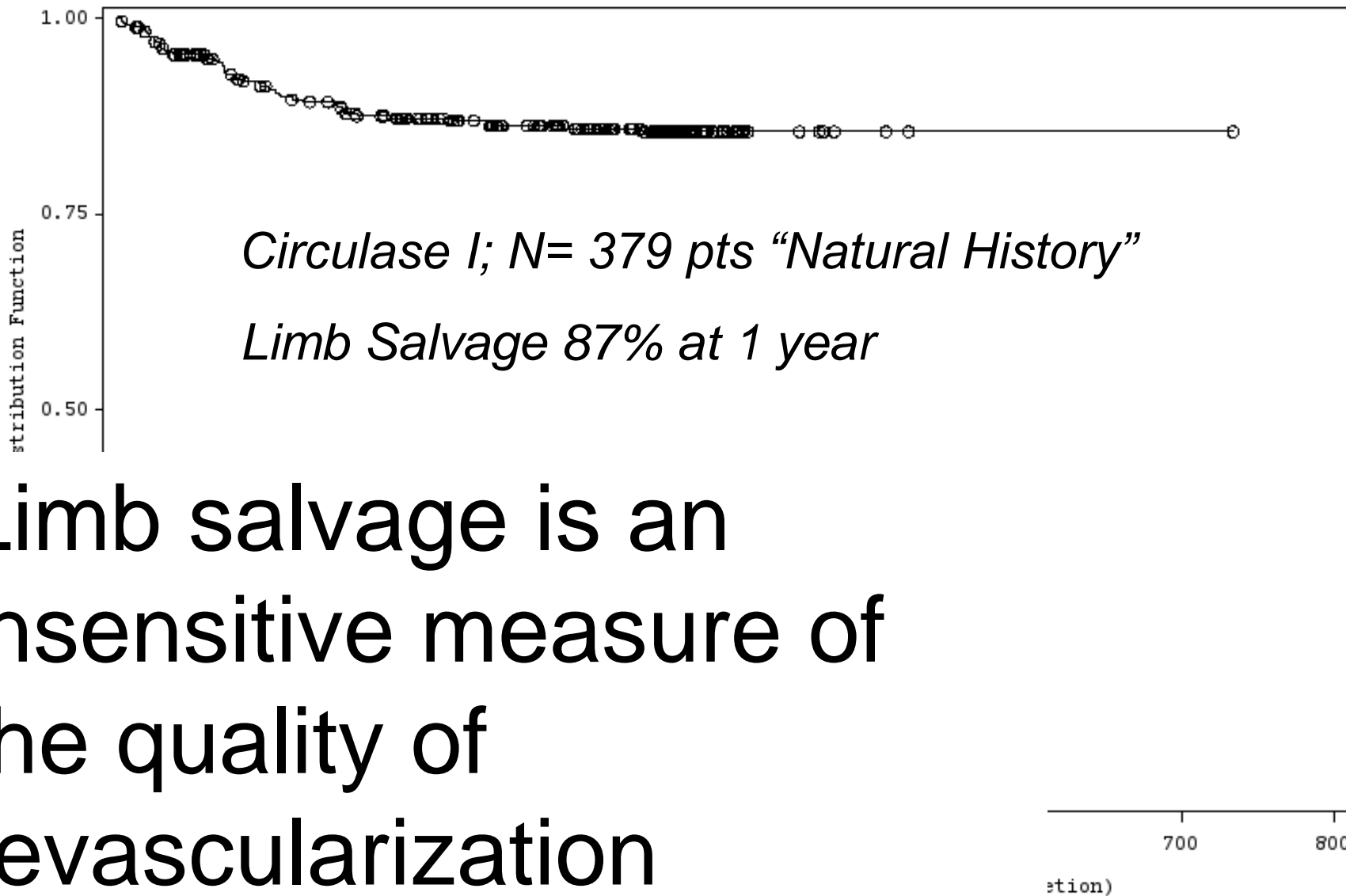
# Tibial Disease

## Outcomes of Endovascular Treatment

Primary Therapy	Author	n	CLI	Procedural Success (%)	Follow-up (mths)	Limb Salvage (%)	Survival (%)
<i>Endovascular</i>							
<i>PTA</i>	Romiti	2557	94.7	89	36	82.4	68.4
<i>Cryoplasty</i>	Das	108	100	97.3	6	93.4	95.4
<i>Cutting balloon</i>	Ansel	73	71	100	12	89.5	84
<i>BMS</i>	Feiring	82	68	94	12	87	100
<i>DES</i>	Commeau	30	87			100	
<i>Self-expanding stent</i>	Kickuth	35	46	100	6	100	89
<i>Rotablator</i>	Jahnke	15	13	94	6	100	100
<i>Orbital atherectomy</i>	Safian	124	32	90.1	6	100	97.6
<i>Silverhawk atherectomy</i>	Zeller	33	51	97	6	100	97
<i>Surgery</i>							
<i>Tibial</i>	Schanzer	719	100	-	12	85.6	83.4
<i>Pedal</i>	Schanzer	160	100	-	12	86.8	84.5

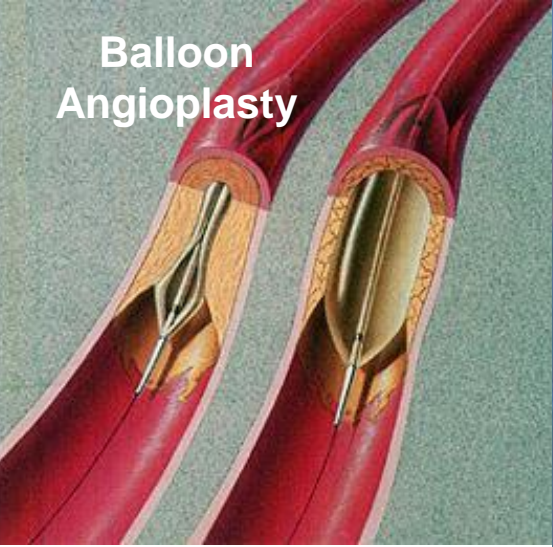


Brass E, et al. Parenteral therapy with lipo-ecraprost, a lipid-based formulation of a PGE1 analog, does not alter six-month outcomes in patients with critical leg ischemia. JVS 2006.

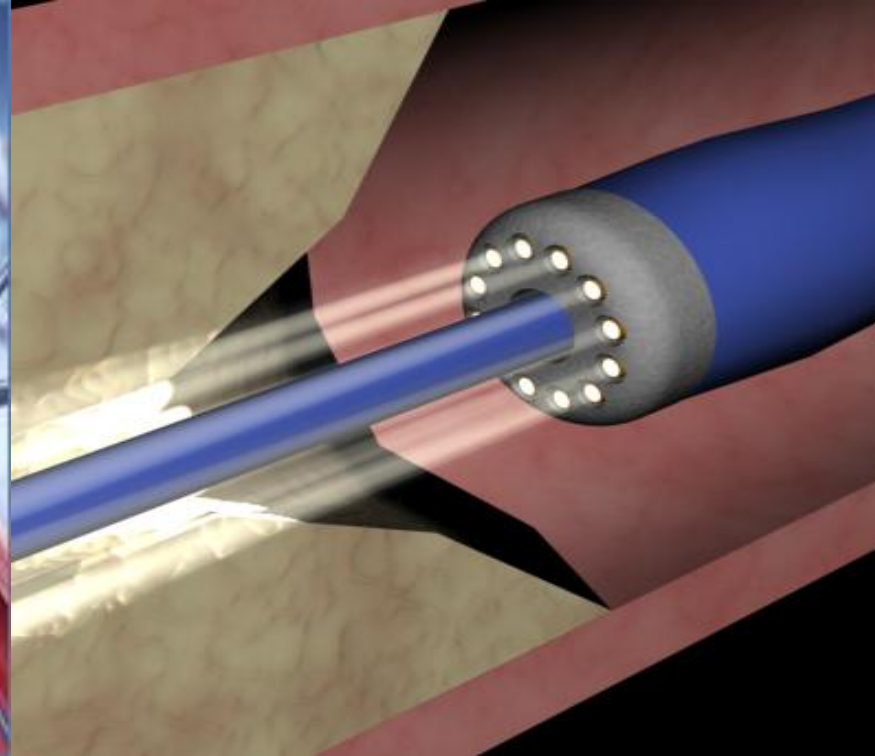
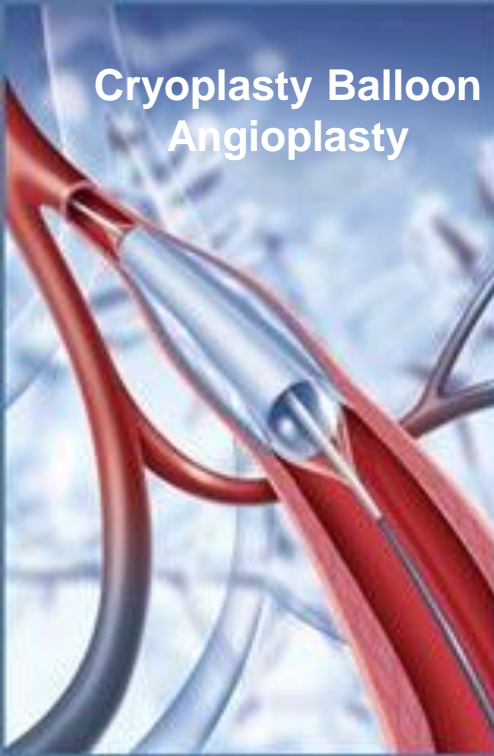


Limb salvage is an insensitive measure of the quality of revascularization

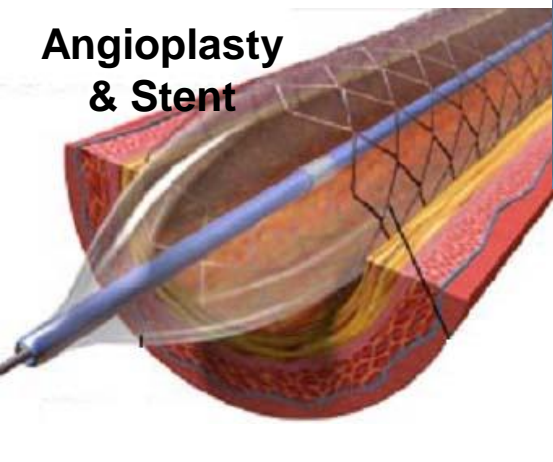
**Balloon  
Angioplasty**



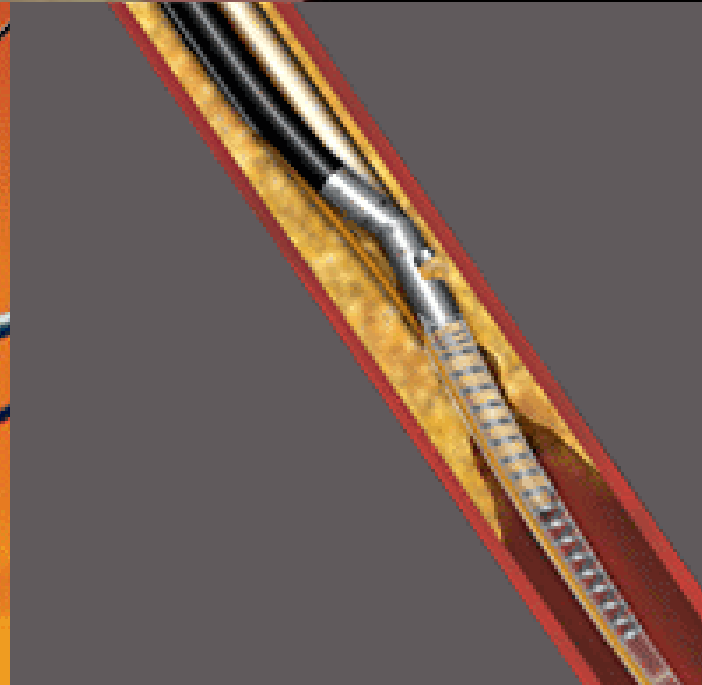
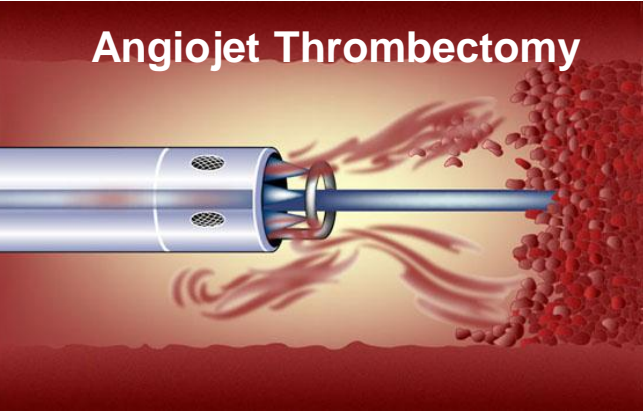
**Cryoplasty Balloon  
Angioplasty**



**Angioplasty  
& Stent**



**Angiojet Thrombectomy**



# 1. Recent Atherectomy Reports

Author	Device	N (patients)	Adjunctive Rx	Primary patency/TLR	Limb Salvage
Zeller 2011	SH	476	NA	87% 6mo	
McKinsey 2008	SH	275		53%@18mo	92%@18mo
Talon 2006	SH	728	21%PTA, 6%stent	80%@12mo TLR freedom	
Safian 2009 OASIS	DB360	124	39%PTA, 2.5%stent	61%@12mo	100%
Zeller 2009	Jetstream	172		TLR 26%@12mo	
Stoner 2007	Laser	40	75%PTA	44%@12mo	55% in CLI
Laird 2006	Laser	145	96%PTA, 45%stent		92%@6mo
Laird 2002 PELA	Laser	251	100%PTA, 42%stent	51%@12mo	

# 2. Drug Eluting Technology

## First Experience With Drug-Eluting Balloons in Infrapopliteal Arteries

### Restenosis Rate and Clinical Outcome

Andrej Schmidt, MD,\* Michael Piorkowski, MD,\* Martin Werner, MD,\* Matthias Ulrich, MD,\*  
Yvonne Bausback, MD,\* Sven Bräunlich, MD,\* Henrik Ick, MD,\* Johannes Schuster, MD,\*  
Spiridon Botsios, MD,\* Hans-Joachim Kruse, MD,† Ramon L. Varcoe, MD,‡ Dierk Scheinert, MD\*  
*Leipzig and Zschopau, Germany; and Sydney, Australia*

#### Objectives

The purpose of this study was to investigate the efficacy of drug-eluting balloons (DEBs) in the treatment of long infrapopliteal lesions with regard to the short-term restenosis rate and midterm clinical result.

**at 3 months: restenosis in 27.4% (19.1% had restenosis of more than 50%, and 8.3% were totally occluded)**

showed a restenosis in 27.4% (19.1% had restenosis of more than 50%, and 8.3% were totally occluded) and usually occurred focally. Only in 9.5% of all angiographically followed up arteries was the entire treated segment restenosed or reoccluded. During a follow-up period of  $378 \pm 65$  days, 1 patient was lost and 17 died. Of the 91 limbs remaining in the analysis, clinical improvement was present in 83 (91.2%). Complete wound healing occurred in 74.2%, whereas major amputation occurred in 4 patients, resulting in limb salvage of 95.6% for patients with critical limb ischemia.

#### Conclusions

The early restenosis rate of long-segment infrapopliteal disease is significantly lower after treatment with DEBs compared with historical data using uncoated balloons. Randomized trials are required to show whether this



# Randomized comparison of everolimus-eluting versus bare-metal stents in patients with critical limb ischemia and infrapopliteal arterial occlusive disease

Marc Bosiers, MD,<sup>a</sup> Dierk Scheinert, MD,<sup>b</sup> Patrick Peeters, MD,<sup>c</sup> Giovanni Torsello, MD,<sup>d</sup> Thomas Zeller, MD,<sup>e</sup> Koen Deloose, MD,<sup>a</sup> Andrej Schmidt, MD,<sup>b</sup> Jörg Tessarek, MD,<sup>d</sup> Erwin Vinck,<sup>a</sup> and Lewis B. Schwartz, MD,<sup>f</sup> *Dendermonde and Bonheiden, Belgium; Leipzig, Münster, and Bad Krozingen, Germany; and Abbott Park, Ill*

*Objective:* Critical limb ischemia, the most severe form of peripheral arterial disease, results in extremity amputation if left untreated. The objective of this study was to determine whether treatment with an everolimus-eluting stent (Xience V) would provide superior patency to treatment with a bare-metal stent (Multi-Link Vision).

**Primary patency of 85% at 12 months**  
**Freedom from TLR 91%**

*Methods:* A sample size of 140 patients was planned to be enrolled at five European investigative sites. The primary end point was arterial patency at 12 months, defined as the absence of  $\geq 50\%$  restenosis based on quantitative analysis of contrast angiography.

*Results:* Between March of 2008 and September of 2009, 74 patients were treated with Xience V and 66 patients were treated with Vision. After 12 months, the primary patency rate after treatment with Xience V was 85% compared with 54% after treatment with Vision ( $P = .0001$ ). Treatment with Xience V significantly reduced mean in-stent diameter stenosis ( $21\% \pm 21\%$  vs  $47\% \pm 27\%$ ;  $P < .0001$ ) and mean in-stent late lumen loss ( $0.78 \pm 0.63$  vs  $1.41 \pm 0.89$  mm;  $P = .001$ ). There were no differences in the percentage of patients receiving a designation of Rutherford class 0 or 1 at the 12-month follow-up visit (56% for Vision vs 60% for Xience V;  $P = .68$ ). Major extremity amputations were rare in both groups.

# DURABILITY

- Tibial interventions are **not** durable
  - Women
  - Diabetic patients
  - Renal failure patients
- Drug eluting technology seems to improve durability but is not perfect
  - Neither I nor Dr Schneider have access to DEB!!



# DURABILITY



- High rate of limb loss with restenosis
- Achilles heel of tibial interventions
  - Need for ongoing device improvements
  - Improved medical therapy



**THANK YOU. chaerra@upmc.edu**



**PITTSBURGH**



# UPMC DIVISION OF VASCULAR SURGERY

