Update for Critical Limb Ischemia Interventions

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Critical Limb Ischemia

Table 1 Classification schemes for peripheral arterial disease

Fontaine		Rutherford			
Stage	Clinical	Grade	Category	Clinical	Objective criteria
I	Asymptomatic	0	0	Asymptomatic	Normal treadmill or reactive hyperemia test
IIa	Mild claudication	I	1	Mild claudication	
IIb	Moderate–severe claudication	I	2	Moderate claudication	AP after exercise > 50 mmHg but ≥ 20 mmHg lower than resting value
		I	3	Severe claudication	
III	Ischemic rest pain	II	4	Ischemic rest pain	Resting AP < 60 mmHg, ankle or metatarsal PVR flat or barely pulsatile; TP < 40 mmHg
IV	Ulceration or gangrene	III	5	Minor tissue loss	Resting AP < 60 mmHg, ankle or metatarsal PVR flat or barely pulsatile; TP < 40 mmHg
		IV	6	Ulceration or gangrene	

AP, ankle pressure; PVR, pulse volume recording; TP, toe pressure.
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Critical Limb Ischemia

- Prognosis of CLI is poor
  - Diffuse nature of the arterial obstructions
  - Concurrent cardiac, cerebrovascular, renal & pulmonary co-morbidities
  - 25% mortality rate in first year
    - (less than the survival rate of breast & colon cancers)[4,5,6]
  - 25% amputation rate in first year
  - 50% of all below the knee amputation patients do not survive beyond 5 years

Weitz JI, Byrne J, Clagett P, et al. Diagnosis and treatment of chronic arterial insufficiency of the lower extremities: a critical review. *Circulation.* 1996;94:3026-3049.

TransAtlantic Inter-Society Consensus (TASC) on Management of Peripheral Arterial Disease (PAD). *JVS.* 2000;31:1-296.

Pentacost MJ, Criqui MH, Dorros G, et al. Guidelines for peripheral percutaneous transluminal angioplasty of the abdominal aorta and lower extremity vessels. *Circulation.* 1994;89:511-531.

Focus Points

- **Critical limb Ischemia is not only limb threatening but life threatening**
- In experienced hands Endovascular treatment offers a lower risk, highly successful alternative to surgical bypass for improved arterial flow that compliments appropriate wound care
- Balloon angioplasty is the cornerstone of therapy
- **Aggressively treat CLI early on**

Critical Limb Ischemia

- CHOICE VARIABLES
- Number of vasc. levels involved
- Plantar arch patency
- Amount of tissue destruction
- Presence of infection
- Need of debridement or skin grft
- Available conduit for bypass
- Comorbidity
- Nutritional status

Critical Limb Ischemia

- Typically multi-segmental disease:
  - multiple significant stenoses or occlusions that prevent pulsatile flow from reaching the distal extrmemity
- Risk factors for limb loss include:
  - Diabetes
  - Renal failure
  - Heart failure or cardiogenic shock
  - Vasospastic disease
  - Tobacco use
  - Active infection
  - Skin breakdown/ trauma

Management of Limb Ischemia

Goals –

- Restore adequate perfusion
- Reduce or eliminate ischemic pain
- Achieve wound healing salvage limb

Endovascular Therapy

- Can be initial treatment of choice
- Does not preclude subsequent bypass surgery
- Ideal for patients without conduit, severe medical comorbidities

Tibial Intervention for CLI

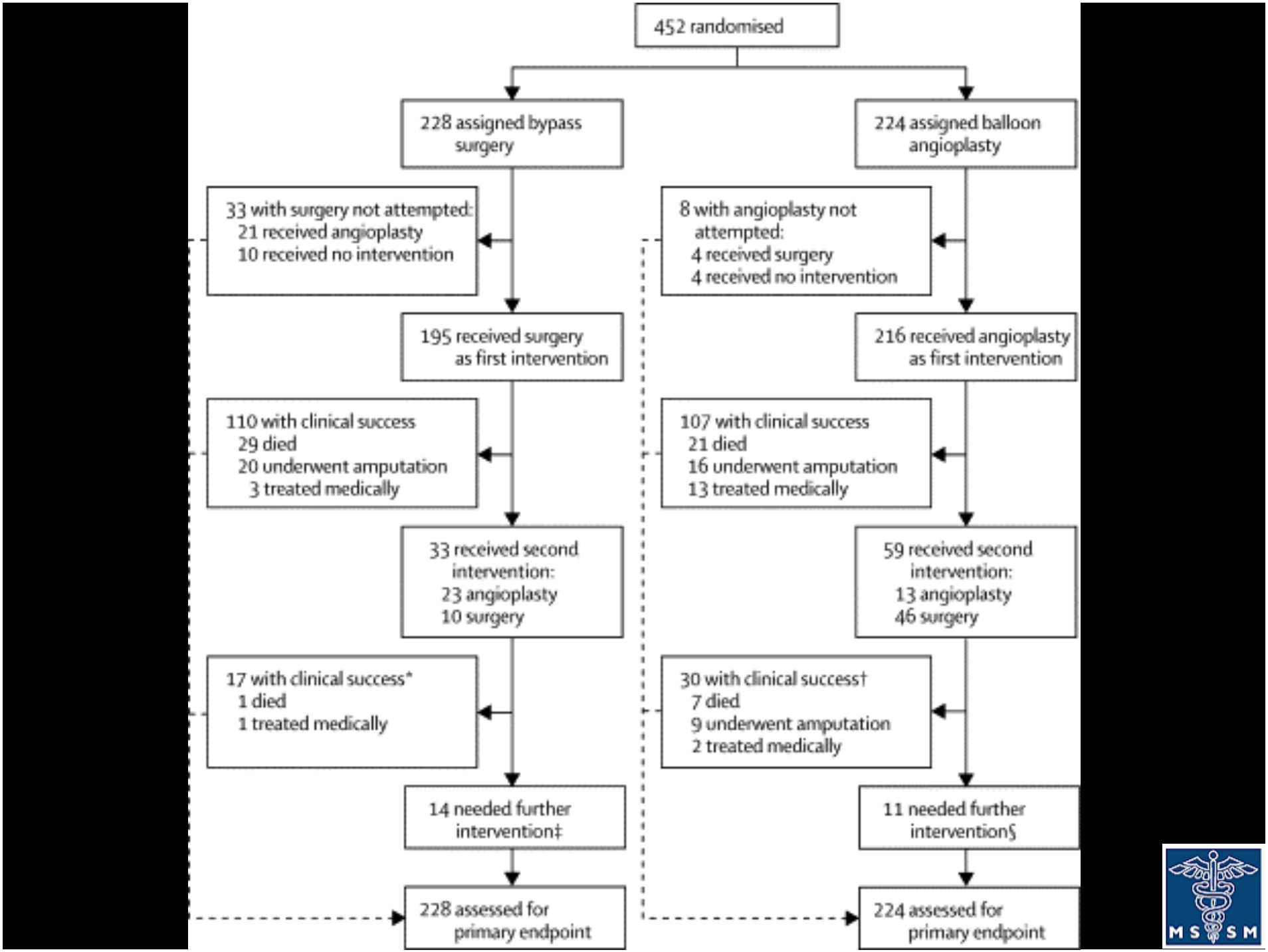
- Most patients are diabetic
- Collateral formation less in diabetics
- Restoration of arterial flow to the foot is more important than in nondiabetics
- Need to restore tibial pressure > 50mmHg
- Straight line flow important
- May need to open plantar arch in pts with renal failure

BASIL

Bypass versus Angioplasty in Severe Ischaemia of the Leg

- Multicenter, randomized controlled trial
- Inclusion: Rest pain, ulceration or gangrene infrainguinal disease
- Study design: Surgery first versus balloon angioplasty first strategy
- Primary endpoint: amputation free survival
- Secondary endpoints:
  - all-cause mortality,
  - 30 day morbidity and mortality,
  - health related quality of life,
  - use of hospital resources,
  - need for re-intervention.

Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial
***Lancet* 2005; 366: 1925–34**


452 randomised
228 assigned bypass surgery
224 assigned balloon angioplasty
33 with surgery not attempted:
21 received angioplasty
10 received no intervention
8 with angioplasty not attempted:
4 received surgery
4 received no intervention
195 received surgery as first intervention
216 received angioplasty as first intervention
110 with clinical success
29 died
20 underwent amputation
3 treated medically
107 with clinical success
21 died
16 underwent amputation
13 treated medically
33 received second intervention:
23 angioplasty
10 surgery
59 received second intervention:
13 angioplasty
46 surgery
17 with clinical success*
1 died
1 treated medically
30 with clinical success†
7 died
9 underwent amputation
2 treated medically
14 needed further intervention‡
11 needed further intervention§
228 assessed for primary endpoint
224 assessed for primary endpoint

Results

- United Kingdom: 27 Centers
- August 1999-June 2004
- 452 patients
  - Angioplasty as first strategy = 224 → 20% immediate failure
  - Surgery as first strategy = 228 → 3% immediate failure
- In patients presenting with severe limb ischemia due to infra-inguinal disease and who are suitable for surgery and angioplasty, a bypass-surgery-first and a balloon -angioplasty-first strategy are associated with broadly similar outcomes in terms of amputation-free survival, and in the short-term, surgery is more expensive than angioplasty.

The BASIL trial clearly indicates that, almost irrespective of what treatment is received, many patients with severe limb ischemia have an extremely poor prognosis.

Amputation free survival

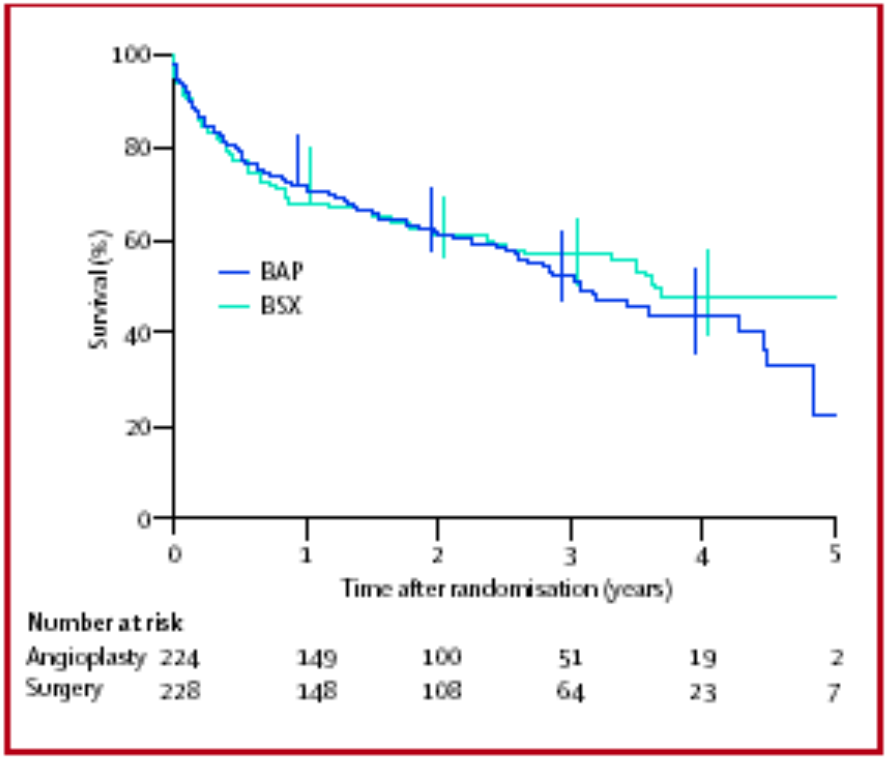


Figure 2: Amputation-free survival after bypass surgery and balloon angioplasty
Bars show 95% CIs for survival up to 1, 2, 3, and 4 years of follow-up, which were calculated from the cumulative hazards.

All cause mortality

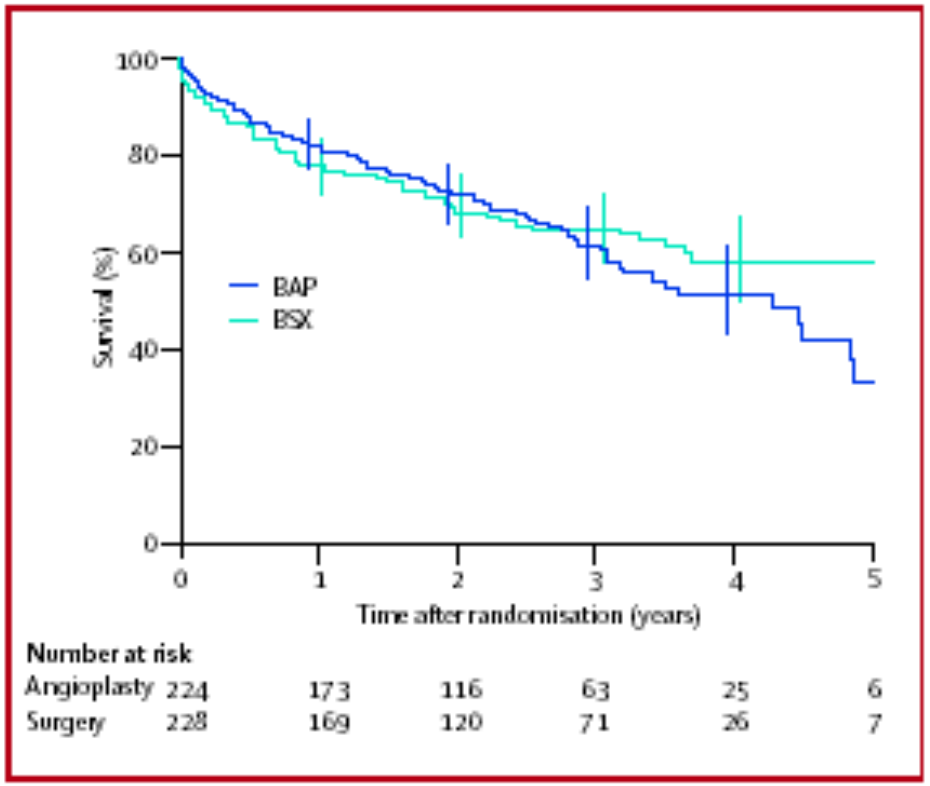


Figure 3: All-cause mortality after bypass surgery and balloon angioplasty
Bars show 95% CIs for survival up to 1, 2, 3, and 4 years of follow-up, which were calculated from the cumulative hazards.

APPROXIMATELY 40% Amputation-free survival

BASIL trial

	Surgery (n=228)		Angioplasty (n=224)		p*
	Mean (SD)	Range	Mean (SD)	Range	
Number of admissions to hospital	2·14 (1·30)	(1–8)	2·06 (1·50)	(0–10)	0·286
Total days spent in hospital	46·14 (53·87)	(0–365)	36·35 (51·39)	(0–334)	<0·0001
Days spent in intensive therapy unit	0·13 (0·94)	(0–12)	0·04 (0·60)	(0–9)	0·012
Days spent in high dependency unit	0·65 (1·60)	(0–11)	0·18 (1·17)	(0–16)	<0·0001
Number of surgical procedures	0·95 (0·50)	(0–4)	0·26 (0·52)	(0–3)	..
Number of angioplasty procedures	0·25 (0·54)	(0–3)	1·05 (0·36)	(0–3)	..

Decreased economic expense due to shorter hospital stay and short or no ICU stay

Limitations

- Endovascular arm was largely limited to plain balloon angioplasty
- 43 out of 224 (19%) endovascular cases were technical failures due to:
  - ✓ inability to cross
  - ✓ inability to re-enter
  - ✓ vessel perforation
  - ✓ vessel thrombosis
  - ✓ distal embolization
- New technology and experience would certainly improve these results

Percutaneous Transluminal Angioplasty (PTA)

Contemporary Efficacy

	Technical Success Rate	Clinical Success Rate	Primary 1- Year Patency	Assisted 5-Year Patency	Limb Salvage Rate	Major Comp. Rate	Patients/ Mean Follow
Faglia, Grazziani, et al (2005)	99%			88%	97%	3%	993/26 months
Kudo, Ahn (2004)	96%	93%		76%	89%	2%	111/15 months
Mousa, Rhee, et al (2005)	98%		89%		97%	9%	66/6 months

Faglia, Paolo, Clerci, Cleressi, Graziani, et al. Peripheral Angioplasty as the First-choice Revascularization Procedure in Diabetic Patients with Critical Limb Ischemia: Prospective Study of 993 Consecutive Patients Hospitalized and Followed Between 1999 and 2003. *Eur J Vasc Endovasc Surg.* 2005;29:620-627.

Kudo, Ahn, Chandra. The effectiveness of percutaneous transluminal angioplasty for the treatment of critical limb ischemia: A 10-year experience. *The Western Vascular Society.* 2005;Sep 11-14, 2004.

Mousa, Rhee, Trocciola, Dayal, et al. Percutaneous Endovascular Treatment for Chronic Limb Ischemia. *Ann Vasc Surg.* 2005;19: 186-191.

Long-term Outcomes after Angioplasty of Isolated, Below-the-knee Arteries in Diabetic Patients with Critical Limb Ischaemia

R. Ferraresi [a], M. Centola [a], M. Ferlini [a], R. Da Ros [b], C. Caravaggi [b], R. Assaloni [b], A. Sganzaroli [b], G. Pomidossi [a], C. Bonanomi [a], G.B. Danzi [a,*]

[a] *Division of Cardiology, IRCCS Fondazione, Ospedale Maggiore Policlinico, Mangiagalli e Regina Elena, Via F. Sforza 35, Milan 20122, Italy*
[b] *Centre for the Study and Treatment of Diabetic Foot Pathology, Ospedale di Abbiategrasso, Milan, Italy*

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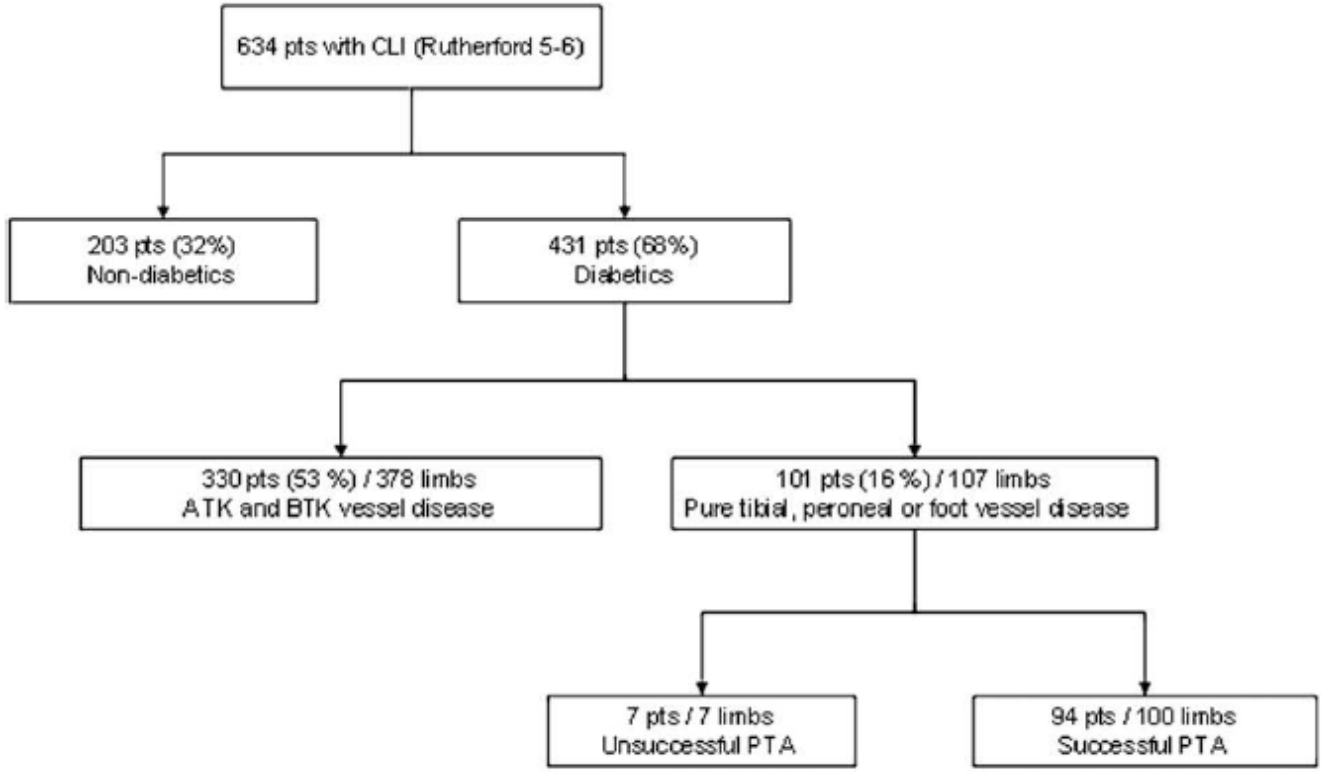
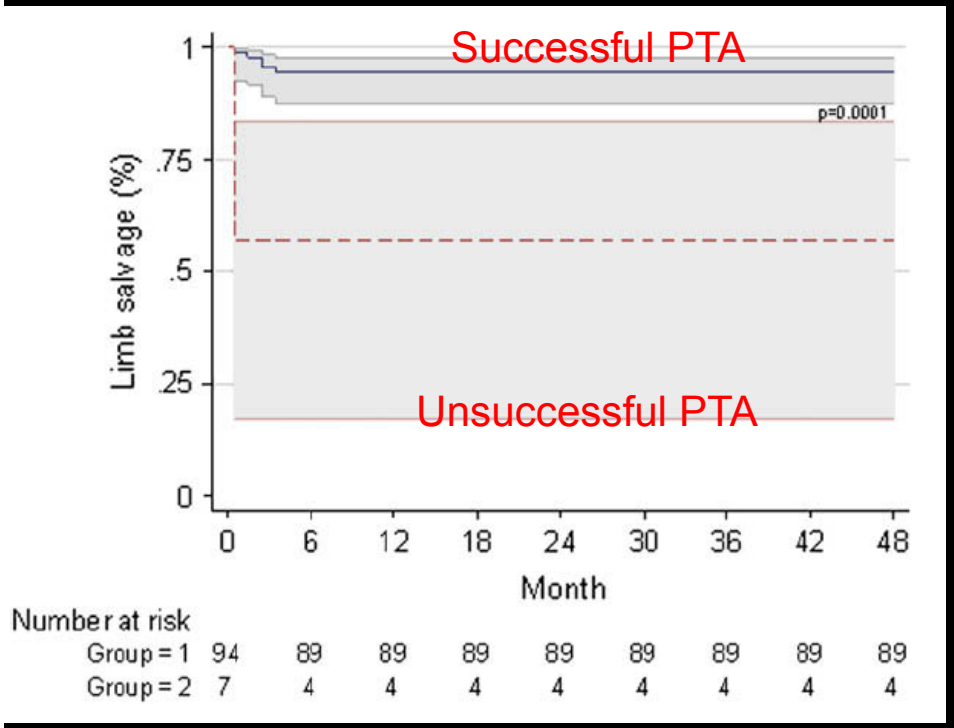
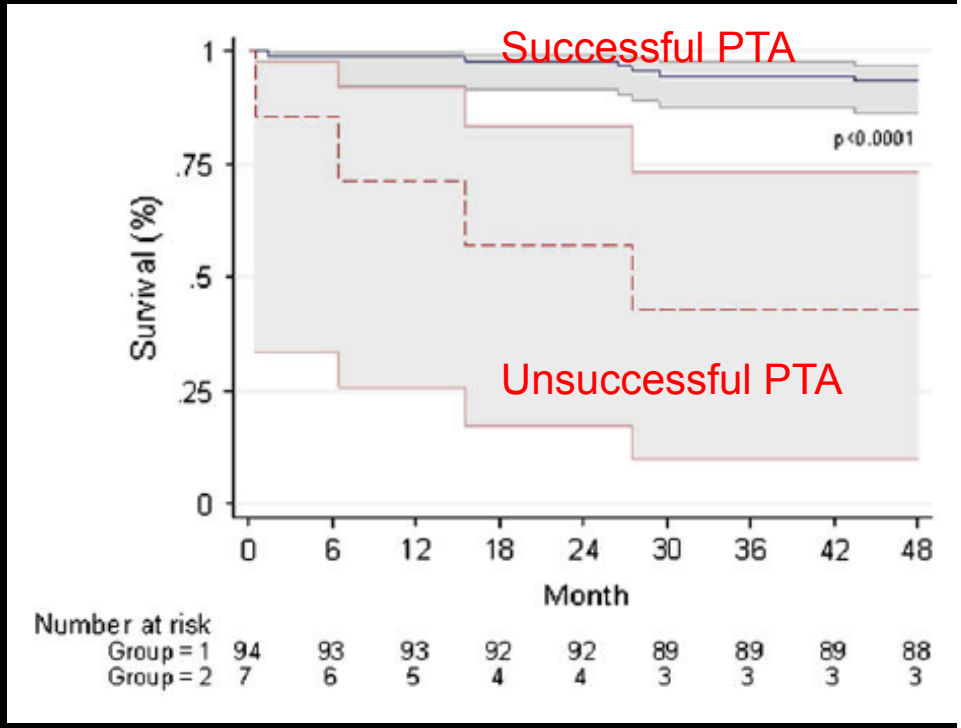


Table 3 Characteristics of successfully treated vessels

Artery	No. (%)	Stenosis (*n*)	Mean length ± SD (mm)	Occlusions (*n*)	Mean length ± SD (mm)
Anterior tibial	57 (36)	30	115 ± 112	27	228 ± 98
Posterior tibial	35 (22)	17	112 ± 105	18	192 ± 101
Peroneal	44 (28)	32	108 ± 81	12	156 ± 92
Pedal artery	15 (9.5)	6	50 ± 23	1	50
Plantar artery	7 (4.4)	15	48 ± 21	0	0
Total	158 (100)	100	98 ± 91	58	199 ± 101





Limb Salvage and Survival Rates for Isolated Infrapopliteal PTA

Conclusion: …for patients with Diabetes and isolated tibial disease, PTA should be ***the*** initial treatment of choice.

Recently Published PTA in CLI Meta-analysis

- 30 articles (1990-2006):
- At least 15 infrapopliteal PTAs reported with 12 mo follow-up; RC 4-6
- Reported 12 mo cumulative patency or limb salvage
- Assessed: Immediate technical success,
- 1º/2º patency, limb salvage, patient survival
- Comparison to distal fem-tibial bypass surgery

Romiti M, Albers M, Brochado-Neto FC, Durazzo AE, et al. Meta-analysis of infrapopliteal angioplasty for chronic critical limb ischemia. J Vasc Surg. 2008;47:975-981

PTA vs Surgery

Table II. Meta-analysis results of crural percutaneous transluminal angioplasty and popliteal-to-distal bypass[a]

Result	*1 month*	*6 months*	*1 year*	*2 years*	*3 years*
Primary patency					
PTA	77.4 ± 4.1	65.0 ± 7.0	58.1 ± 4.6	51.3 ± 6.6	48.6 ± 8.0
Bypass	93.3 ± 1.1	85.8 ± 2.1	81.5 ± 2.0	76.8 ± 2.3	72.3 ± 2.7
P	<.05	<.05	<.05	<.05	<.05
Secondary patency					
PTA	83.3 ± 1.4	73.8 ± 7.1	68.2 ± 5.9	63.5 ± 8.1	62.9 ± 11.0
Bypass	94.9 ± 1.0	89.3 ± 1.6	85.9 ± 1.9	81.6 ± 2.3	76.7 ± 2.9
P	<.05	<.05	<.05		
Limb salvage					
PTA	93.4 ± 2.3	88.2 ± 4.4	86.0 ± 2.7	83.8 ± 3.3	82.4 ± 3.4
Bypass	95.1 ± 1.2	90.9 ± 1.9	88.5 ± 2.2	85.2 ± 2.5	82.3 ± 3.0
Patient survival					
PTA	98.3 ± 0.7	92.3 ± 5.5	87.0 ± 2.1	74.3 ± 3.7	68.4 ± 5.5
Bypass	NA	NA	NA	NA	NA

NA, Estimates not available; *PTA*, percutaneous transluminal angioplasty.
[a]Values are pooled estimate and standard error.

Limited patency, but acceptable clinical benefit

Limb salvage rate equivalent to bypass surgery

MSSM

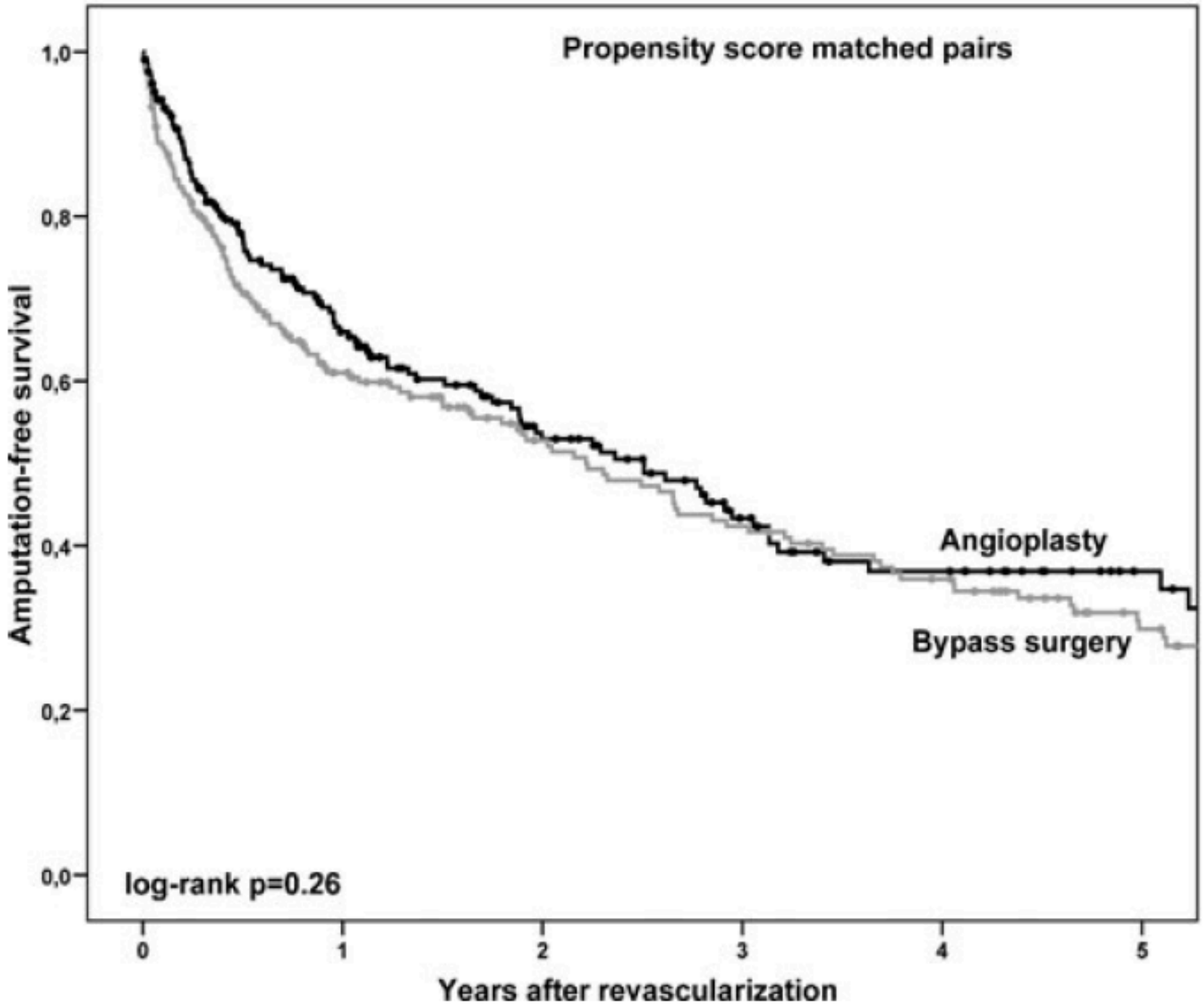
Infrapopliteal Percutaneous Transluminal Angioplasty Versus Bypass Surgery as First-Line Strategies in Critical Leg Ischemia

A Propensity Score Analysis

Maria I. Söderström, MD, Eva M. Arvela, MD*, Maria Korhonen, MD†, Karoliina H. Halmesmäki, MD, PhD*, Anders N. Albäck, MD, PhD*, Fausto Biancari, MD, PhD‡, Mauri J. Lepäntalo, MD, PhD*, and Maarit A. Venermo, MD, PhD**

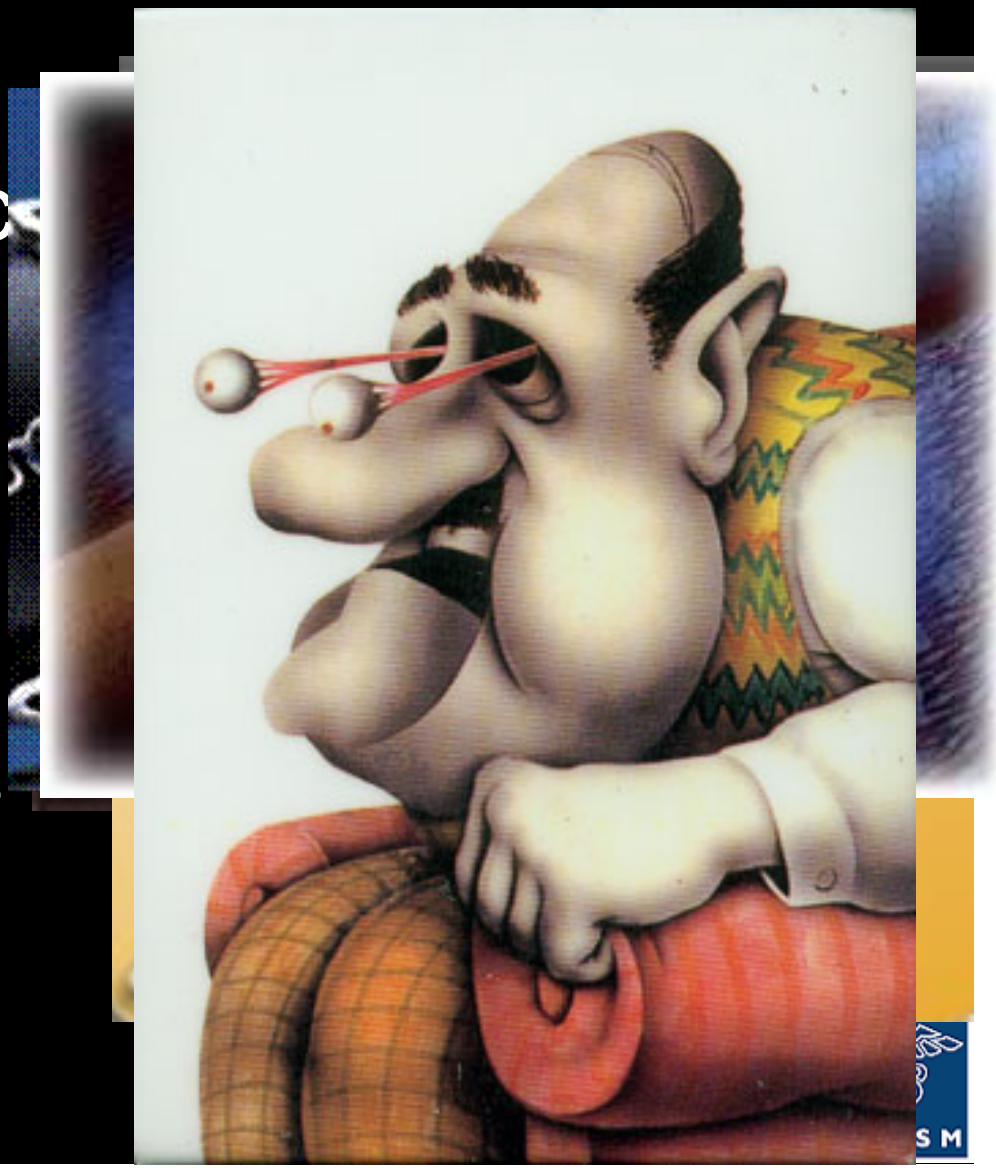
TABLE 3. Kaplan-Meier's Estimates of Early and Late Outcome in the Overall Series*

	30 Days	1 Year	2 Years	3 Years	4 Years	5 Years	*P*
Survival							0.53
Angioplasty	96.5%	73.3%	64.2%	55.4%	49.7%	47.5%	
	(245)	(155)	(107)	(73)	(54)	(34)	
Bypass surgery	94.2%	75.8%	65.8%	56.6%	49.2%	43.3%	
	(712)	(481)	(342)	(283)	(204)	(129)	
Leg salvage							0.78
Angioplasty	96.4%	85.5%	78.2%	77.0%	75.3%	75.3%	
	(237)	(135)	(87)	(56)	(41)	(25)	
Bypass surgery	93.7%	82.2%	80.5%	79.3%	78.2%	76.0%	
	(673)	(422)	(300)	(246)	(181)	(111)	
Amputation-free survival							0.81
Angioplasty	93.4%	64.4%	52.6%	43.6%	37.7%	37.7%	
	(237)	(135)	(87)	(57)	(41)	(25)	
Bypass surgery	88.9%	65.9%	57.9%	49.1%	42.9%	37.3%	
	(673)	(422)	(300)	(246)	(181)	(111)	
Freedom from any revascularization							0.47
Angioplasty	95.3%	78.7%	77.3%	77.3%	77.3%	77.3%	
	(234)	(124)	(85)	(55)	(41)	(27)	
Bypass surgery	92.3%	79.4%	75.2%	74.8%	74.4%	74.4%	
	(657)	(378)	(241)	(195)	(141)	(89)	
Freedom from bypass surgery							<0.001
Angioplasty	96.0%	86.9%	86.2%	86.2%	86.2%	86.2%	
	(236)	(135)	(92)	(60)	(46)	(31)	
Bypass surgery	99.3%	95.5%	95.0%	94.3%	94.3%	94.3%	
	(707)	(458)	(321)	(261)	(191)	(122)	


Propensity score matched pairs
Amputation-free survival
1,0
0,8
0,6
0,4
0,2
0,0
Angioplasty
Bypass surgery
log-rank p=0.26
0
1
2
3
4
5
Years after revascularization

New Technologies

- Excimer Laser
- Directional Atherec
- Cutting balloons
- Bare SE Stents
- Cryoplasty
- Bare BE Stents
- Drug eluting stents



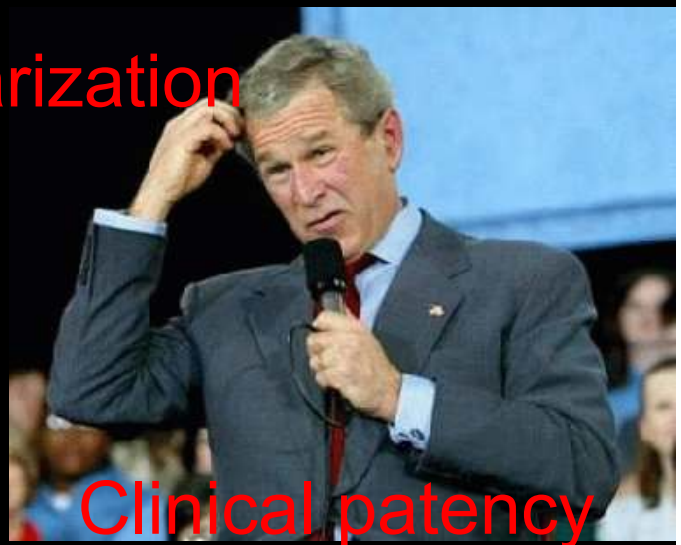
Primary patency by angiography

Primary Assisted patency

Target lesion revascularization

Target Vessel Revascularization

Survival



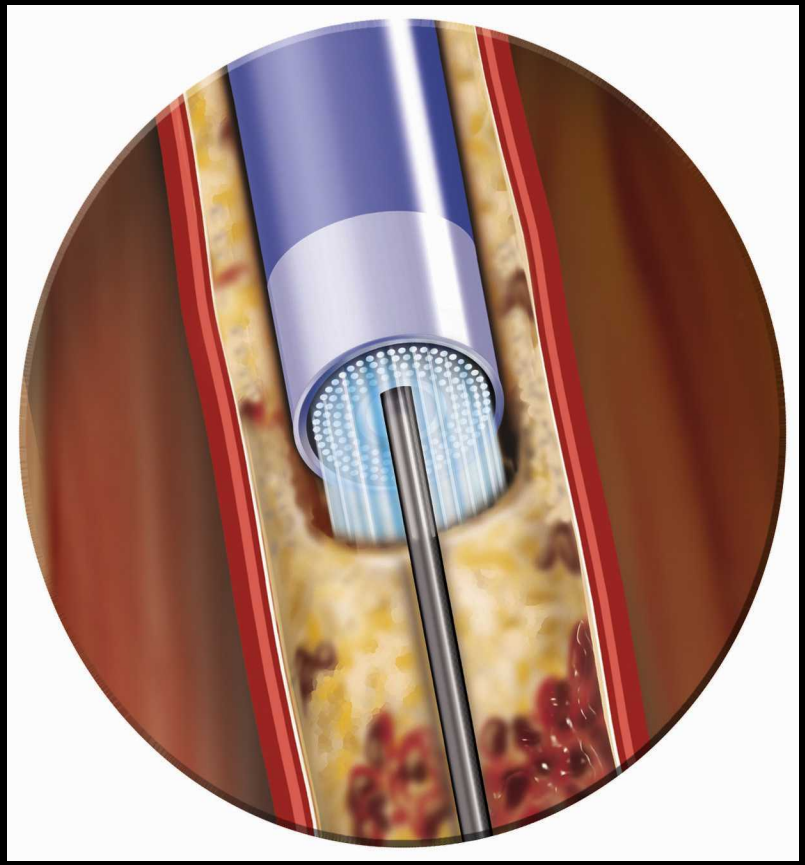
Amputation free survival

Clinical patency

Secondary patency

Excimer Laser

- The CVX-300 Excimer Laser is a pulsed system that vaporizes plaque and thrombus by delivering very high energy in extremely short pulses.
- Debulking prior to balloon angioplasty transforms diffuse, multi-level arterial disease into more easily ballooned stenoses.



Laser Angioplasty for Critical Limb Ischemia
Results of the LACI Phase 2 Clinical Trial

Prospective, multi-center study

Patients with CLI

- Rutherford Category 4-6
- Poor surgical candidates
- 60% TASC D

Primary Endpoint:

limb salvage at 6 months

Patient Descriptors

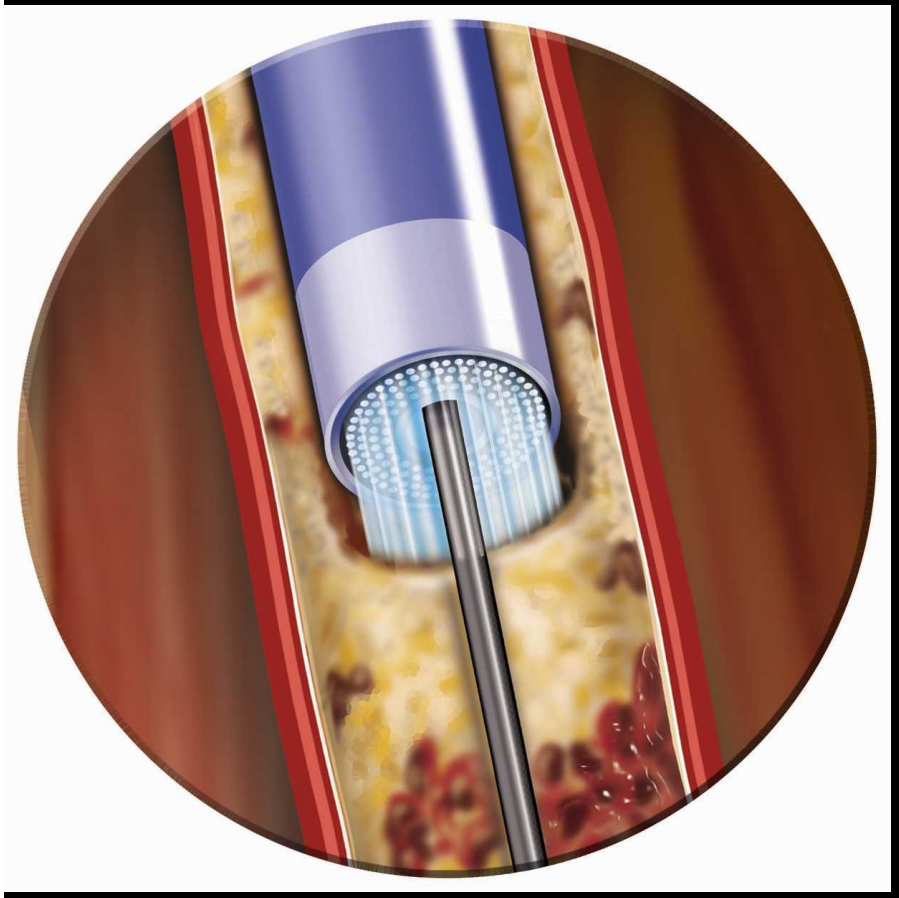
145 patients

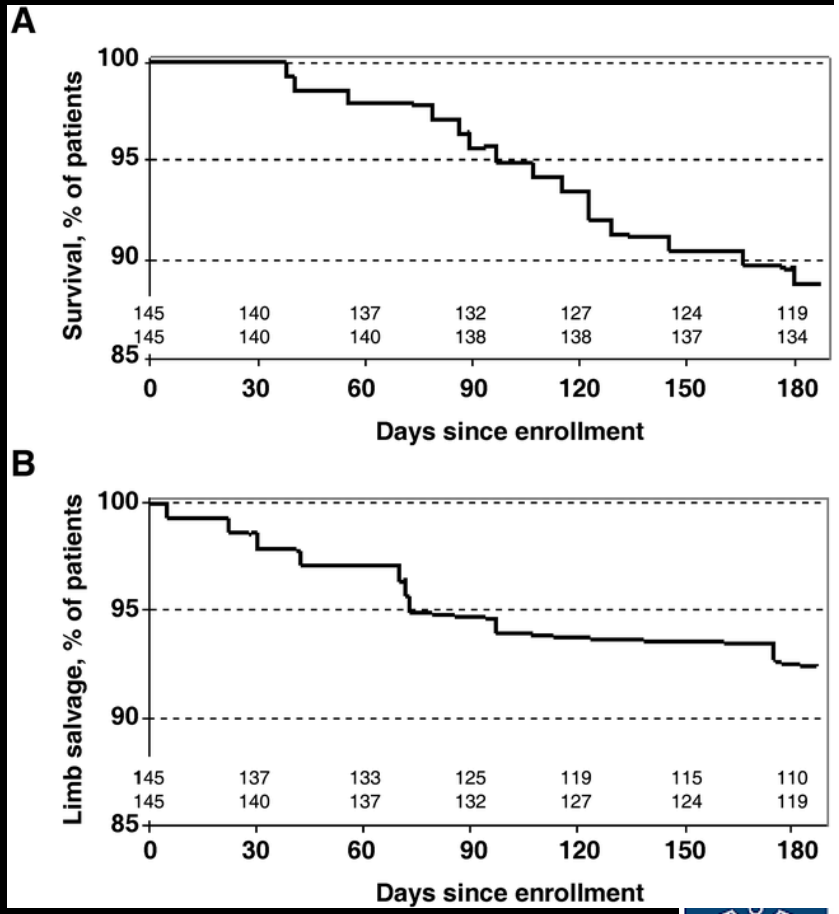
Mean age, years	**72 ± 10 (45 - 91)**	
Men	**53%**	
Duration of CLI, weeks	**25 ± 37 (1 - 261)**	
Risk factors		
Smoking	**53%**	
Coronary artery disease		**50%**
Prior stroke		**21%**
Diabetes mellitus	**66%**	
Hypertension	**83%**	
Dyslipidemia	**56%**	
Obesity	**35%**	

6-Month Results

Total enrollment	**155 limbs**
death	**17**
lost to follow-up	**11**
Reached 6-month follow-up	**127**
Major amputation among survivors	**9**
Survival with limb salvage	**91%**

Excimer Laser



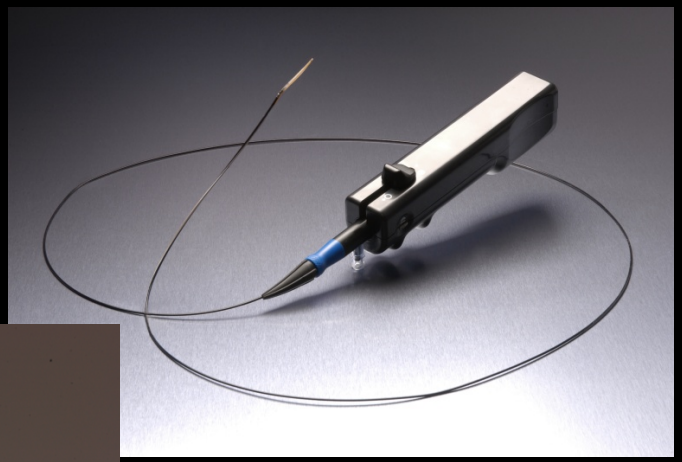


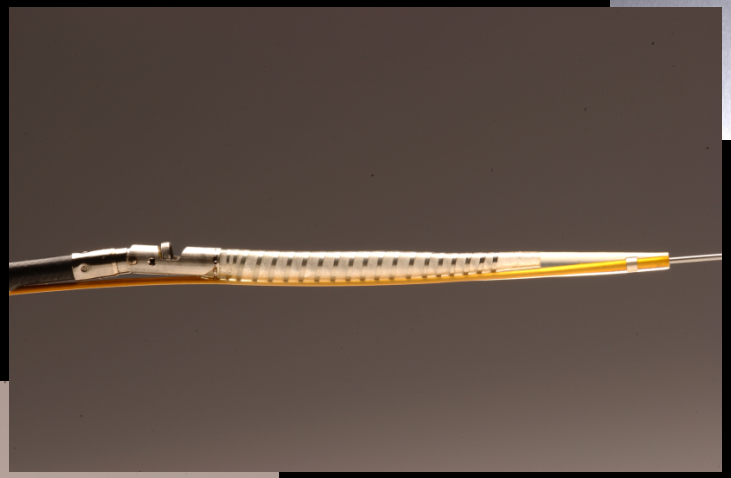
LACI Phase 2 Summary

- Treatment of complex disease
- High risk patient population
- High procedural success
- Excellent limb salvage
- Incidence of surgical intervention is very low

Plaque Excision

- FDA-cleared in June, 2003 for use in femoral-popliteal and tibial-peroneal vessels

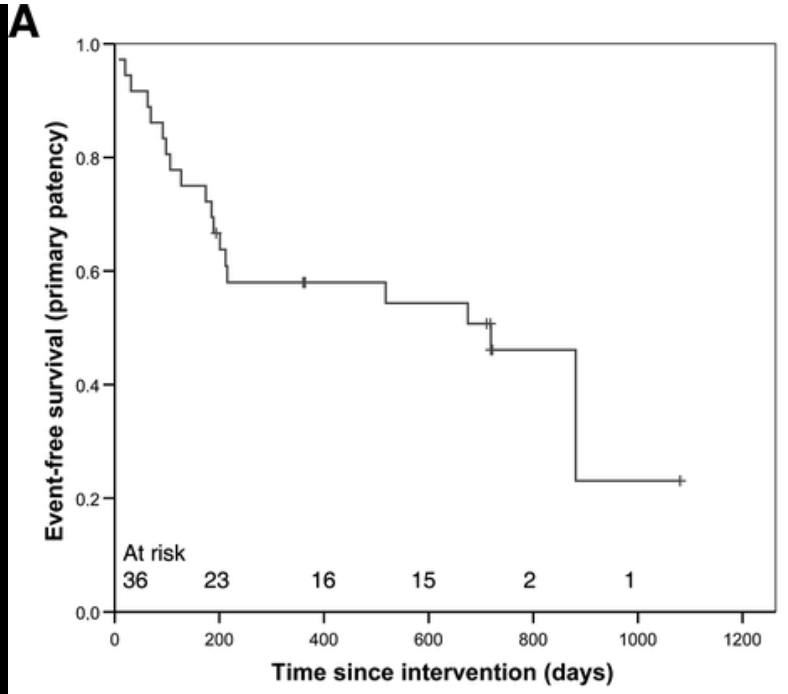


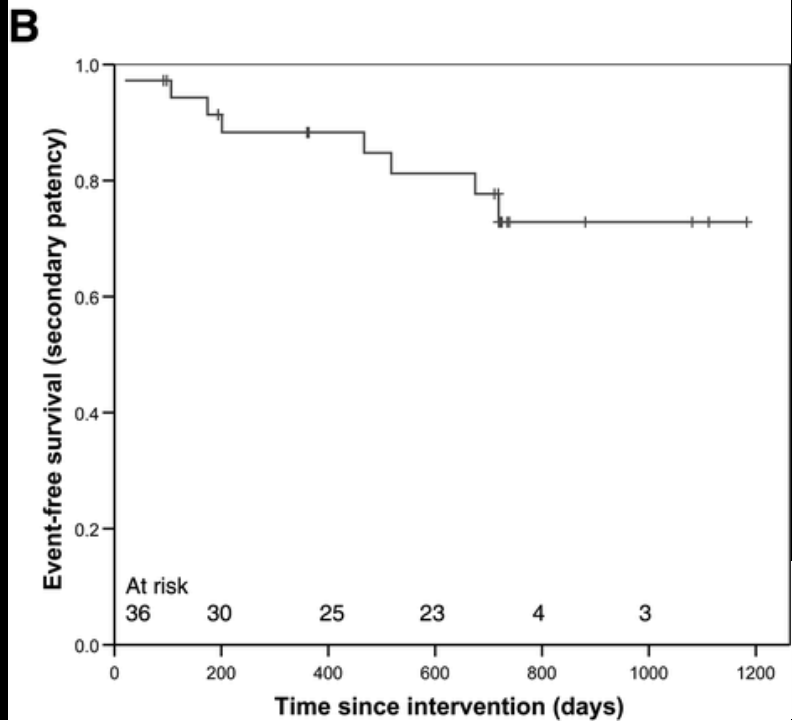


The SilverHawk™ System

Atherectomy

- Zeller et al. JEVT 2006
- 49 tibial lesions in 36 patients
- Follow up with duplex
- All patients had CLI

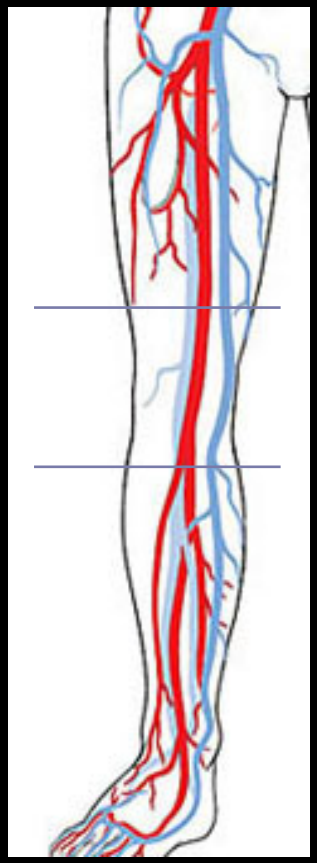




Results

Courtesy of James McKinsey MD, NYP

Lesion Distribution



		SFA	Popliteal	Tibial
N		199	110	218
Length (mm) ± SD		91.6 ± 90.8	37.7 ± 33.5	46.4 ± 51.1
% Stenosis ± SD		88.7 ± 14.1	85.6 ± 13.2	92.0 ± 11.4
# CTO (%)		73 (36.7)	33 (30)	118 (54.6)
TASC	*A*	81	29	15
	B	57	69	24
	C	52	8	55
	D	9	4	124

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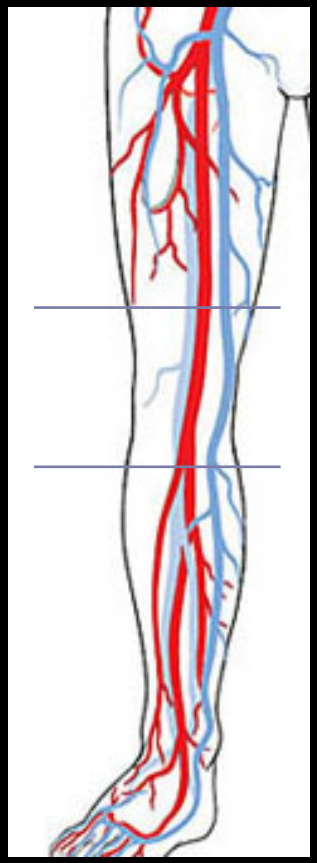

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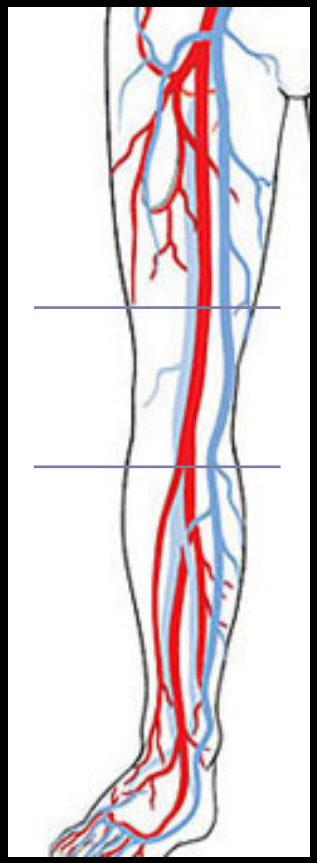

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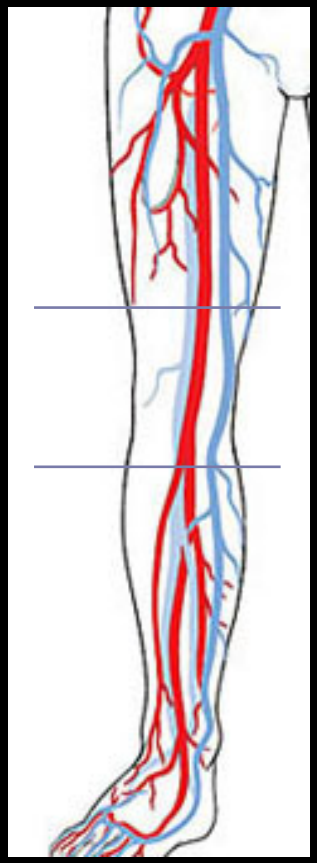
Courtesy of James McKinsey MD, NYP

Lesion Distribution



		SFA	Popliteal	Tibial
N		199	110	218
Length (mm) ± SD		91.6 ± 90.8	37.7 ± 33.5	46.4 ± 51.1
% Stenosis ± SD		88.7 ± 14.1	85.6 ± 13.2	92.0 ± 11.4
# CTO (%)		73 (36.7)	33 (30)	118 (54.6)
TASC	*A*	81	29	15
	B	57	69	24
	C	52	8	55
	D	9	4	124

Results

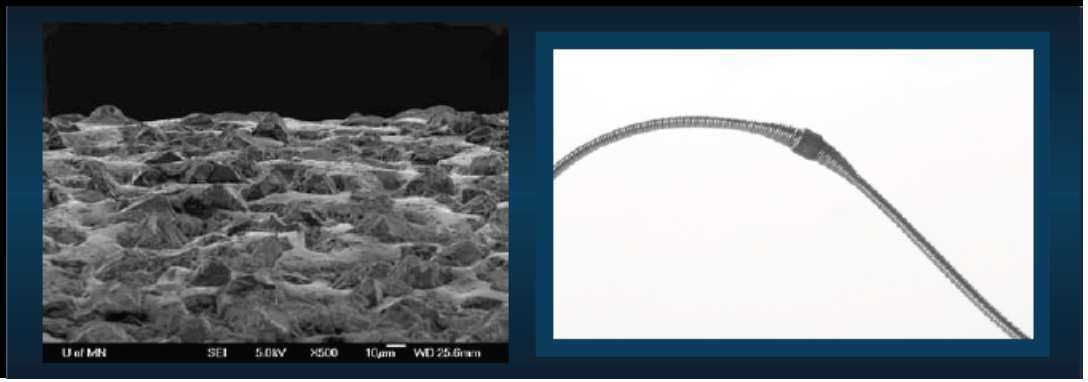
Courtesy of James McKinsey MD, NYP

Patency

	Primary Patency		Secondary Patency		Limb Salvage	
	12 mos	18 mos	12 mos	18 mos	12 mos	18 mos
ALL Lesions	62.2 ± 2.5	52.7 ± 2.8	80.3 ± 2.0	75.0 ± 2.4	89.7 ± 1.6	88.3 ± 1.8
Femoral	61.4 ± 4.3	52.0 ± 4.8	85.4 ± 3.1	80.3 ± 3.9	95.4 ± 1.9	9543 ± 1.9
Popliteal	68.9 ± 5.4	59.2 ± 6.2	84.9 ± 4.1	76.7 ± 5.4	90.9 ± 3.4	88.4 ± 4.1
Tibial	62.7 ± 4.1	53.6 ± 4.8	74.2 ± 3.7	70.0 ± 4.2	83.6 ± 3.2	80.6 ± 3.7
Multilevel	50.5 ± 8.1	40.3 ± 8.3	75.7 ± 6.7	71.7 ± 7.5	89.7 ± 4.9	89.7 ± 4.9

Currently available Atherectomy Devices/ Designs

- Directional atherectomy (Silverhawk)
- Orbital Atherectomy
- Pathway
- Spectranetics



Orbital Atherectomy for Infrapopliteal Disease:
Device Concept and Outcome Data for the Oasis Trial

Robert D. Safian,[1*] MD, FSCAI, Khusrow Niazi,[2] MD, FSCAI, John P. Runyon,[3] MD, FSCAI, Dan Dulas,[4] MD, FACC, Barry Weinstock,[5] MD, FACC, Venkatesh Ramaiah,[6] MD, FACS, and Richard Heuser,[7] MD, FSCAI; For the OASIS Investigators

TABLE II. Vascular Approach and Target Vessels (124 patients, 201 lesions)

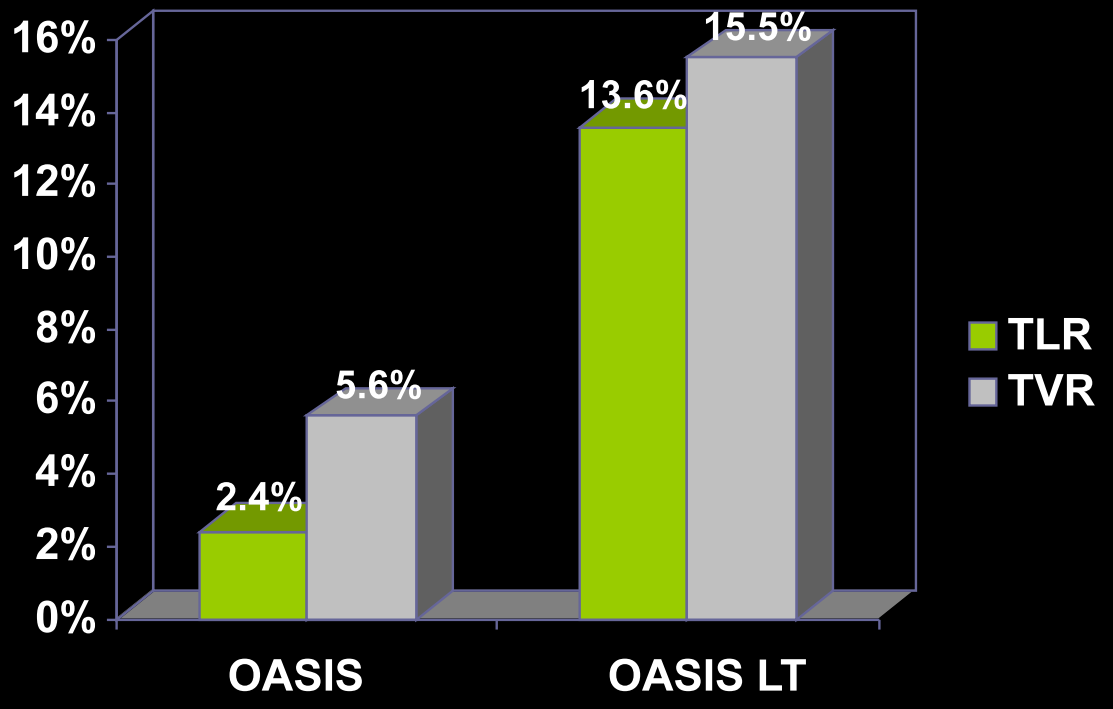
Vascular Access N(%)	
Femoral antegrade	20 (16)
Femoral crossover	104 (84)
Vascular Intervention N(%)	
Non-target vessel	38 (30.4)
Target Vessel OA	201 lesions
Femoropopliteal artery	28 (14)
Runoff circulation	173 (86)
Anterior tibial artery	75 (37.3)
Tibioperoneal trunk	37 (18.4)
Posterior tibial artery	34 (16.9)
Peroneal artery	27 (13.4)
Single lesion OA	68 (55.2)
Multiple lesion OA	56 (44.8)

Large single center registry

- Lesion length/distribution
  - Femoral: 72 mm/59%
  - Popliteal: 54 mm/16%
  - Tibial: 102 mm/26%
- Procedural success (<30% residual):
  - Femoral: 86%
  - Popliteal: 64%
  - Tibial: 93%
- Need for stenting: only in femoral (25%)

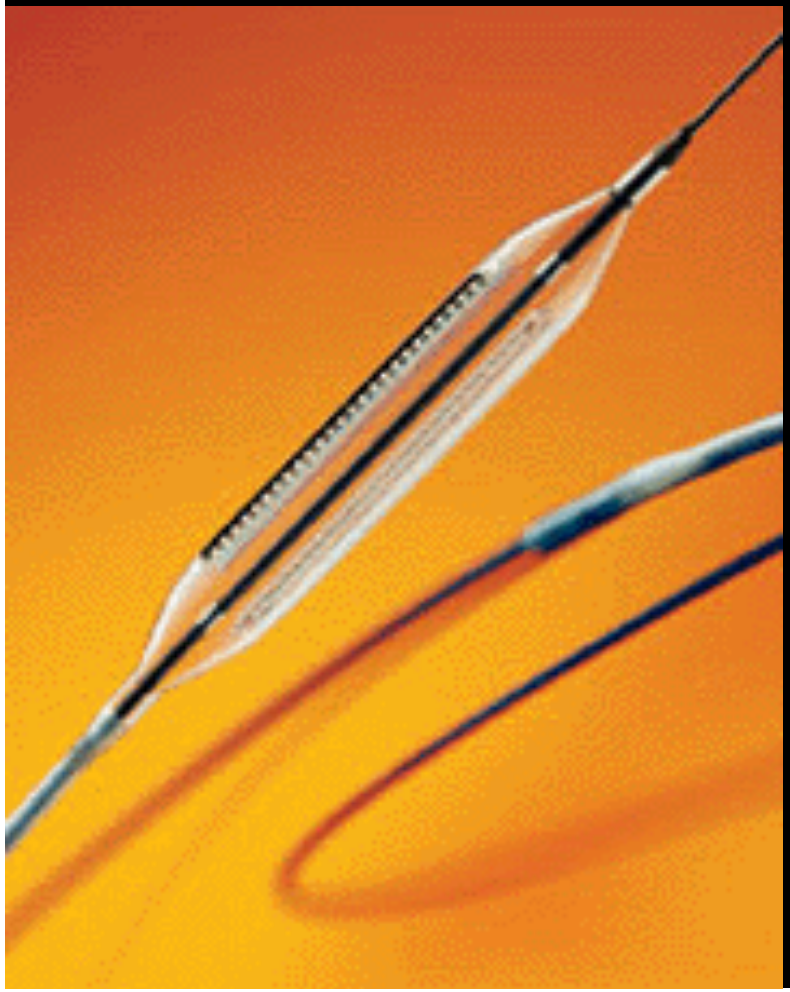
Evidence of Potential DB 360° Durability

Low Incidence of TLR & TVR at 24 Months



- OASIS LT patients followed 24+ months (median 29)

Cutting balloon



- Single clinical series
- 97 lesions in 73 patients
- Most with CLI symptoms
- Lesion length was 27mm
- Limb salvage 89% at 12 months

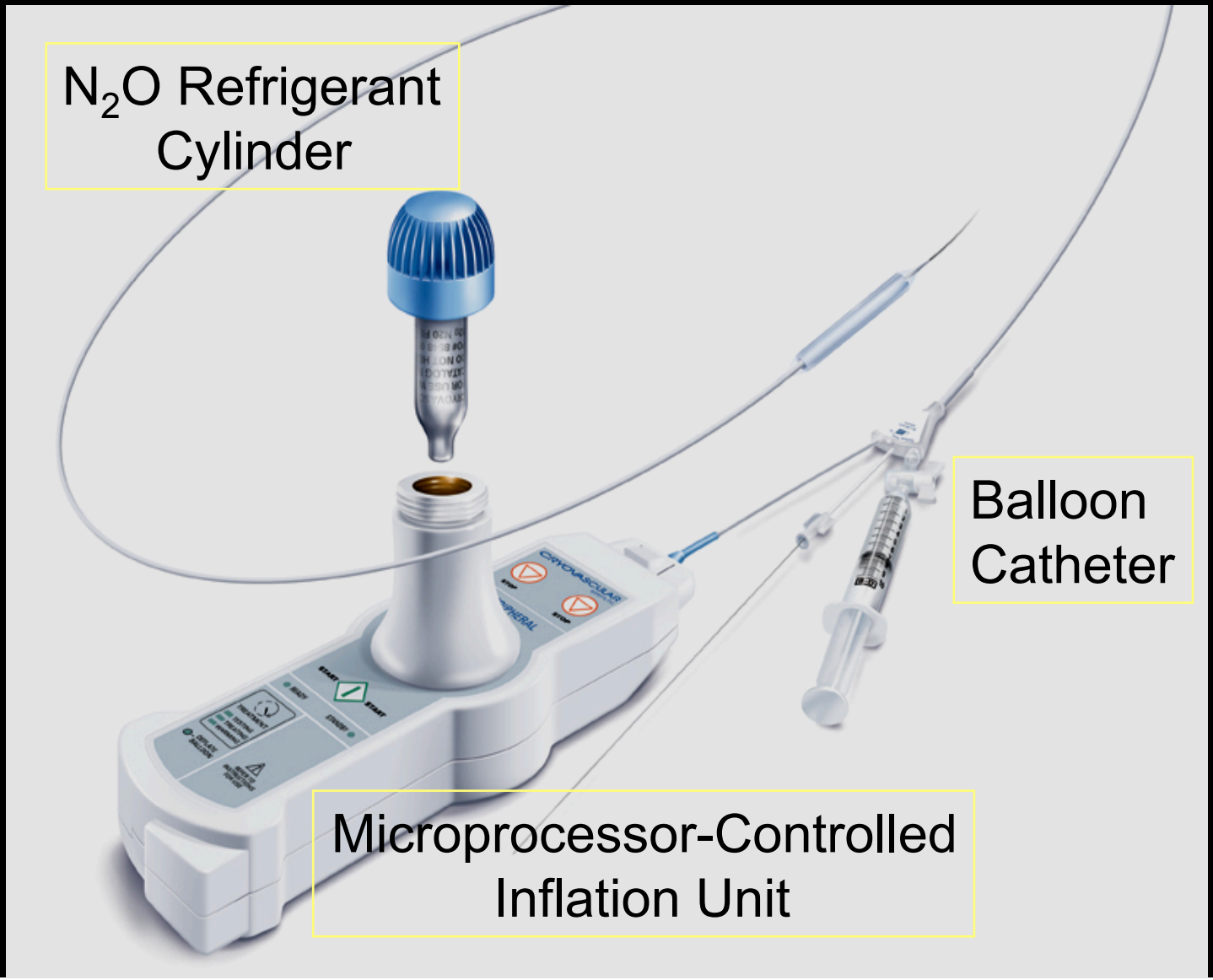
Self Expanding Stents

- Xpert
  self-expanding
  nitinol stent
- 3-8mm diameters
- 4 Fr shaft
  diameter
- Biliary indication

Self Expanding Stents

- Belgian single center series
- 67 stents in 47 patients
- Rutherford category 4 and 5 disease
- 12 month Angiographic follow up
- Primary patency at 12 months 76%
- Limb salvage was 96%
- Proximal calf disease had better prognosis for limb salvage

CRYOPLASTY
The PolarCath™ System



Primary Cryoplasty Therapy Provides Durable Support for Limb Salvage in Critical Limb Ischemia Patients With Infrapopliteal Lesions: 12-month Follow-up Results From the BTK Chill Trial

Tony S. Das, MD[1]; Thomas McNamara, MD[2]; Bruce Gray, DO[3]; Gino J. Sedillo, MD[4]; Brian R. Turley, MD[5]; Kenneth Kollmeyer, MD[6]; Michael Rogoff, MD[7]; and John E. Aruny, MD[8]

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[redacted]

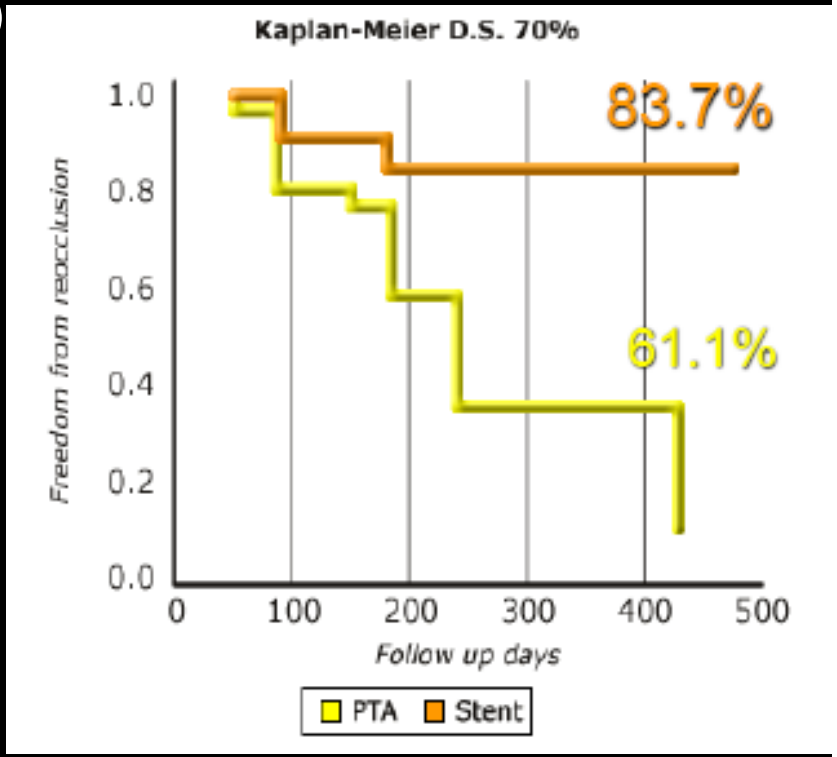
Symptoms	
Rest pain	71/108 (65.7%)
Nonhealing ulcers	73/110 (66.4%)
Gangrene	28/76 (36.8%)
Claudication	76/108 (70.4%)
Anticipated amputation	19/77 (24.7%)
Skin discoloration	84/110 (76.4%)
Sensory deficit	68/108 (63.0%)
Edema	47/110 (42.7%)
Clinical categories (Rutherford)	
Class 4	22/111 (19.8%)
Class 5	49/111 (44.1%)
Class 6	28/111 (25.2%)
Class unknown	12/111 (10.8%)
Lesion characteristics	
Mean vessel diameter, mm	3.2±0.7 (2.0–6.0)
Mean stenosis, %	86.9±13.6 (50–100)
Mean lesion length, mm	41.1±30.4 (2.0–110.0)
Occlusions	39 (33.9%)
Location	
Anterior tibial	35 (28.5%)
Peroneal	33 (26.8%)
Posterior tibial	23 (18.7%)
Popliteal	19 (15.4%)
Tibioperoneal trunk	11 (8.9%)
Dorsalis pedis	1 (0.8%)
Other	1 (0.8%)

TABLE 2
Cumulative Clinical Outcomes for 108 Patients With 111 Treated Limbs

	1 Month	3 Months	6 Months	12 Months
Death	0/104 (0.0%)	2/95 (2.1%)	5/93 (5.4%)	8/87 (9.2%)
Major amputation overall*	3/107 (2.8%)	4/96 (4.2%)	6/91 (6.6%)	12/81 (14.8%)
Minor amputation overall†	1/107 (0.9%)	4/96 (4.2%)	5/91 (5.5%)	7/81 (8.6%)
In 19 limbs with planned amputation at baseline				
Major amputation	0/19 (0.0%)	1/15 (6.7%)	1/13 (7.7%)	2/12 (16.7%)
Minor amputation	1/19 (5.3%)	2/15 (13.3%)	3/13 (23.1%)	4/12 (33.3%)
Target limb revascularization				
Endovascular	1/107 (0.9%)	3/96 (3.1%)	12/91 (13.2%)	13/81 (16.0%)
Surgical bypass	2/107 (1.9%)	2/96 (2.1%)	2/91 (2.2%)	4/81 (4.9%)
Rehospitalization and other‡	6/108 (5.6%)	9/96 (9.4%)	15/91 (16.5%)	23/81 (28.4%)

Balloon Expandable Stent: Carbostent

- **Passive coating: InPeria CarboStent (Sorin)**
- **•Randomized trial PTA vs. Stenting BTK**
- –Enrollment
- •95 cases (53 PTA -42 Stent)
- –Follow-up
- •57 cases (32 PTA -25 Stent)
- •Endpoint
- –6 months **angiographic patency**
- •PTA = **61.1%**
- •Stents = **83.7%**



Rand, Lammer et al. Cardiovasc Intervent Radiol. 2006 Jan-Feb;29(1):29-38.

Percutaneous Transluminal Angioplasty versus Turbostatic Carbon–coated Stents in Infrapopliteal Arteries: InPeria II Trial[1]

Thomas Rand, MD
Johannes Lammer, MD
Claudio Rabbia, MD
Manuel Maynar, MD, PhD
Tobias Zander, MD
Thomas Jahnke, MD
Stefan Müller-Hülsbeck, MD
Dierk Scheinert, MD
Hannu I. Manninen, MD, PhD

Purpose: To determine the clinical outcome and the success of stent application for high-grade lesions of the infrapopliteal arteries compared with treatment with percutaneous transluminal angioplasty (PTA) in critical limb ischemia (CLI).

Materials and Methods: In this ethics board–approved randomized prospective study, PTA or stent application was performed on 131 lesions in 88 patients with CLI. The primary end points were clinical improvement after endovascular treatment and limb salvage rate. Secondary end points were defined by

Baseline Procedural and Angiographic Results

Characteristic	PTA Group ($n = 69$ Lesions)	Stent Group ($n = 62$ Lesions)	*P* Value
Procedural success (%)*	95.7 (66/69)	100 (62/62)	NS
Preprocedure angiographic results			
RVD (mm)	2.66 ± 0.72	2.54 ± 0.66	NS
MLD (mm)	0.65 ± 0.61	0.67 ± 0.66	NS
DS (%)	69.33 ± 19.54	69.69 ± 22.69	NS
Lesions length (mm)	20.68 ± 20.13	21.08 ± 12.18	NS
Postprocedure angiographic results			
RVD (mm)	2.55 ± 0.58	2.70 ± 0.66	NS
MLD (mm)	1.81 ± 0.36	2.23 ± 0.49	.0022
DS (%)	26.56 ± 12.46	15.62 ± 11.02	.0001

Angiographic Results at 9 Months

Characteristic	PTA Group ($n = 26$)*	Stent Group ($n = 21$)*
RVD (mm)	2.83 ± 0.75	2.59 ± 0.61
MLD (mm)	1.02 ± 1.02	1.19 ± 0.92
DS (%)	43.31 ± 28.37	38.68 ± 25.47
Restenosis (%)		
DS ≥50%	34.6 (9/26)	23.8 (5/21)
DS ≥70%	15.4 (4/26)	9.5 (2/21)

Note.—None of the angiographic results were significantly different between the PTA and stent groups. RVD = reference vessel diameter.

* Data are means ± standard deviations. Numbers in parentheses were used to calculate percentages.

Balloon Expandable Stents: Bare Metal and Drug Eluting

- DES has already received CE mark in Europe for below the knee application
- Numerous single center series from Europe
- Large coronary literature showing efficacy compared to bare metal balloon expandable stents

DES vs BMS -BTK

- Numerous single center series showing benefit
- Greek Interventional Radiology Series with Angiographic Follow-up at 6 mos and 12 mos compared with BMS

CLI stage‡	4 (4–5)	5 (4–5)	0.090
Rest pain (Fontaine III/Rutherford 4)	21 (72.4%)	13 (44.8%)	0.020
Minor tissue loss (Fontaine IV/ Rutherford 5)	6 (20.7%)	14 (48.3%)	0.010
Major tissue loss (Fontaine IV/ Rutherford 6)	2 (6.9%)	2 (6.9%)	0.500
Limbs treated	29	29	
Arteries treated	40	41	
Lesions treated	65	66	
Lesion length, cm§	1.3 (1.1–2.0)	1.4 (0.8–1.95)	0.178
Occlusions	27 (41.5%)	20 (30.3%)	0.090
Stenoses	38 (58.5%)	46 (69.7%)	0.090
Stent brands	Evolution (n=10) Spiral Force, (n=24) Tsunami (n=18), Zeus (n=13)	Cypher	
Femoropopliteal treatment	21 (72.4%)	23 (79.3%)	0.290
Runoff score (baseline)¶	0 (0–1)	0 (0–1)	0.990
Runoff score (post procedure)¶	1 (1–2)	1 (1–2)	0.820

One-Year Angiographic Outcome and Endpoints

	Group B	Group S	p
All Patients	29	29	
Technical success	28 (96.6%)	29 (100.0%)	0.170
Angiographic follow-up	20 (68.9%)	18 (62.1%)	0.290
Patients at 1 Year	20	18	
Femoropopliteal restenosis >50%	15 (75.0%)	12 (66.7%)	0.290
Femoropopliteal re-intervention	8 (40.0%)	7 (38.9%)	0.470
Runoff score* at 6 months	1 (1–2)	1 (1–2)	0.810
Runoff score* at 1 year	1 (1–1.5)	1 (0.5–2)	0.467
All Lesions	65	66	
1-year angiographic follow-up	42 (64.6%)	44 (66.7%)	0.400
All Lesions at 1 Year	42	44	
Primary patency	17 (40.5%)	38 (86.4%)	<0.001
In-stent restenosis	33 (78.6%)	16 (36.7%)	<0.001
In-segment restenosis	39 (92.9%)	26 (59.1%)	<0.001
TLR	11 (26.2%)	4 (9.1%)	0.020
Stenoses at 1 Year	25	28	
Primary patency	8 (32.0%)	24 (85.7%)	<0.001
In-stent restenosis	20 (80.0%)	12 (42.9%)	0.003
In-segment restenosis	24 (96.0%)	15 (53.6%)	<0.001
Occlusions at 1 Year	17	16	
Primary patency	9 (52.9%)	14 (87.5%)	0.015
In-stent restenosis	13 (76.5%)	4 (25.0%)	0.002
In-segment restenosis	15 (88.2%)	11 (68.8%)	0.090