Bilateral Lower Arterial Stenting Employing Reopro (BLASTER TRIAL)

12 - Month Results

TCT / Asia Pacific - 2005

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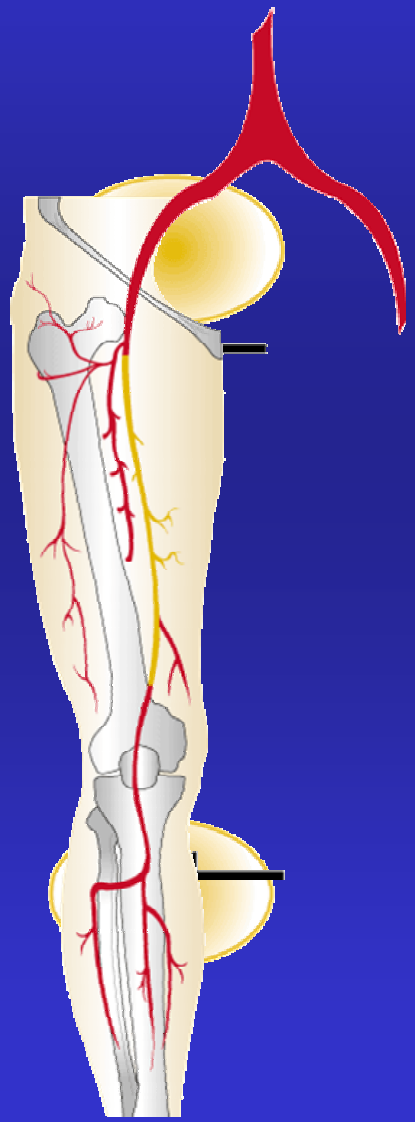
For the BLASTER Trial Investigators

Challenges Of F-P Revascularization
Factors Influencing Success



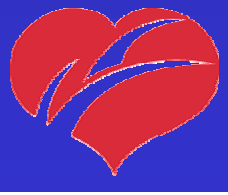
- **Unfavorable Anatomy**
  - **In-Flow and Run-Off**
  - **Two Bifurcations/Articulations**
  - **Unique Vessel Forces: Flexion, Compression, Torsion, Pistoning**
- **Diffuse Disease**
  - **High Incidence of Occlusive Disease**
  - **Complex Lesion Morphologies (ostial lesions/Ca++)**
  - **Competitive Flow via PFA**

SFA Angioplasty: Acute and Late Clinical Results

	Acute	*Late (1-3 yr)*
Aorto-iliac	95-97%	85-93%
SFA/popliteal	72-95%	47-60%
Infrapopliteal	65-87%	35-60%

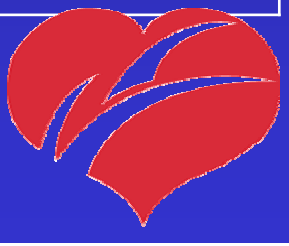
Poor results have sparked pursuit of new technologies

JVS 2000



SFA Stenting

Stent	No. of Limbs	Occl %	Length (cm)	% Restenosis	Primary Patency	Secondary Patency
Wallstent	199	67	8	30	53	67
Palmaz	171	45	5.7	16	81	92
Strecker	141	60	5.8	29	80	82
Wall/Palmaz	57	89	16.5	39	22	46
Wall/Strecker	32	47	3.7	28	75	93
W/VascuCoil	27	39	9.0	33	66	N/A
Total	**627**	**58**	**8.1**	**30**	**63**	**76%**



Stenting for F-P Disease:

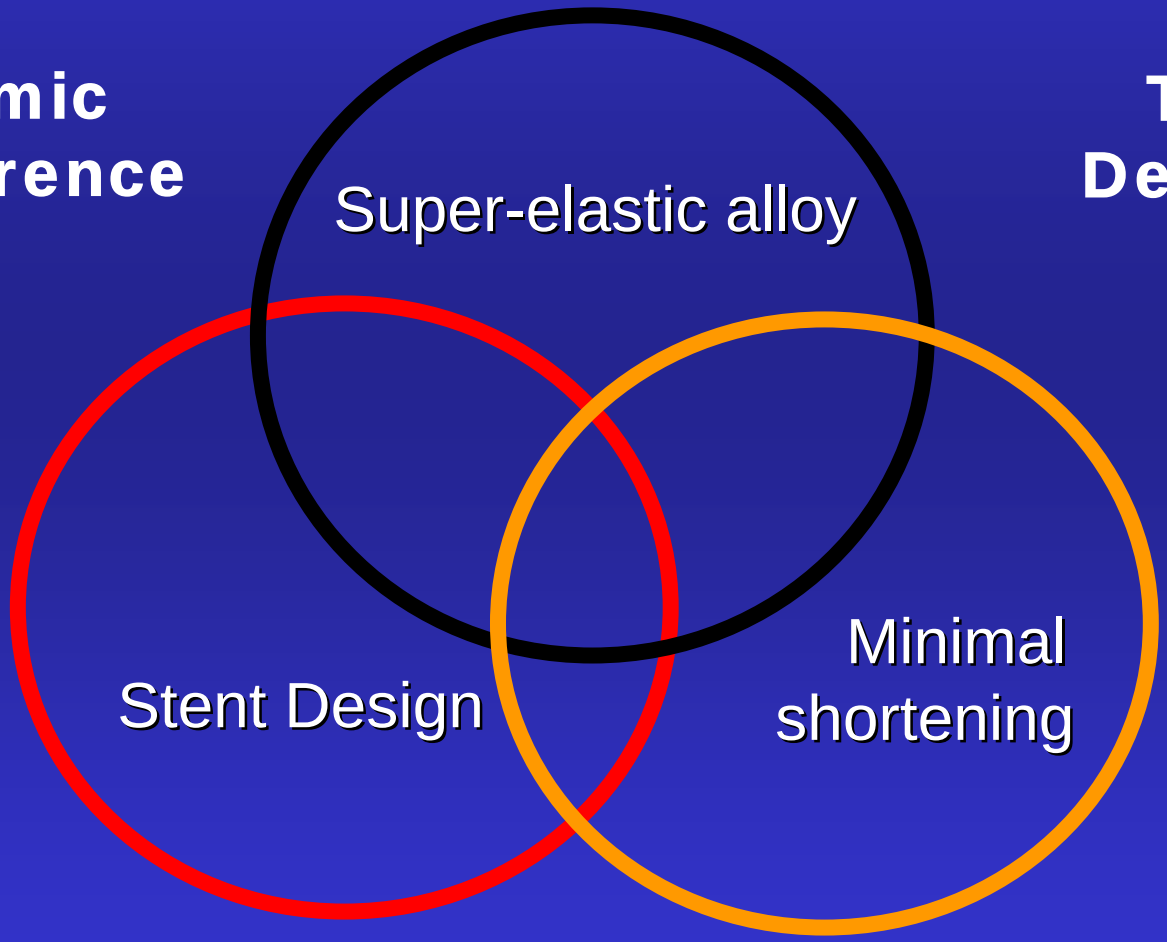
HOWEVER

- Used balloon expandable/self-expanding stents
- Many used Coumadin anticoagulation
- Various clinical/non-invasive endpoints
- No systematic evaluation of “assisted patency” or “2° patency”

Nitinol:
The Right Combination?

Dynamic Interference

Thermal Deployment



BLASTER Trial

Purpose:

To evaluate the feasibility of utilizing SMART™ nitinol stents *with* and *without* intravenous abciximab for the treatment of femoral artery occlusive disease

BLASTER Study Design

Design:

- **Prospective, randomized, placebo controlled, double blinded (abciximab vs placebo [1:1])**
- **Feasibility physician IDE study**
- **Planned 100 patients enrollment across 5 US investigative centers.**

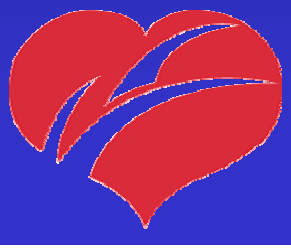
BLASTER Study Design

Primary Endpoint:

- Restenosis rate by Duplex ultrasound ($\geq$2.5 ratio) at 9 months
- Decrease in ABI of $\geq$ .15 at 9 months
- Adverse clinical event, death (30day) or repeat revascularization at 9 months

Secondary Endpoints:

- Acute angiographic success ($\leq$ 20% residual diameter stenosis)
- Acute (30 day) procedural success
  - Acute angiographic success
  - Absence of procedure related complications (I.e., death, stroke, bleeding requiring > 2 units blood transfusion, or any other complication which requires an unanticipated or surgical procedure.
- Change in walking duration/time to claudication to 9 months
- Change in Rutherford category to 9 months



BLASTER Study Criteria

INCLUSION CRITERIA:

- Superficial femoral artery narrowing
  - >60% diameter stenosis (visual)
- Lesion length
  - ≥ 7cm stenosis or an occlusion ≤ 22.0 cm
- Vessel diameter > 4.0 mm
- De novo or restenotic angioplasty lesion
- Symptomatic Rutherford Classification
- Patient has read, understood and signed an IRB approved informed consent

BLASTER Evaluations

- Clinical evaluation at 1, 3, 6, 9, 12 mo.
- Ankle brachial index (ABI) at rest and exercise at discharge and 9 months
- Duplex Ultrasound at 9 mos
- Rutherford categorization at 9 months
- Adverse event evaluation at 1,3, 6, 9, 12 mo.

BLASTER Study Medications

Pre-procedure

- ASA (325 mg) at least 24 hours
- Plavix (75 mg) at least 24 hours

Intra-procedure

- IV heparin bolus 3000 – 5000 units
- Abciximab (Reopro®)
  - Bolus followed by 12 hour infusion

Post-procedure

- Plavix (75 mg) for 2 months
- ASA (325 mg) indefinitely
- Additional anticoagulation therapy at investigator's discretion

BLASTER Study Update

- Study originally planned for 100 patients
- Study stopped at 51 patients due to concern of stent fractures seen in SIROCCO
- 51 patients followed to 12 month timepoint

BLASTER Demographics

Parameter	SMART with Abciximab	SMART w/o Abciximab	All Patients
Patients Enrolled	N = 27	N = 24	N = 51
Age	70.1 ± 9.1	68.0 ± 10.3	69.1 ± 9.6
Gender	63.0 % (male)	75.0 % (male)	68.6 % (male)
Family History of CAD	33.3%	54.2%	43.1%
Hypertension	70.4%	62.5%	66.7%
Diabetes	40.7%	54.2%	47.1%
Dyslipidemia	74.1%	79.2%	76.5%
Smoking (current)	22.2 %	29.2%	25.5%

BLASTER
Lesion Characteristics

Parameter	SMART with Abciximab	SMART w/o Abciximab	All Patients
Lesion Location within Vessel	Proximal (38.7%) Mid (51.6%) Distal (58.1%)	Proximal (39.3%) Mid (57.1%) Distal (46.4%)	Proximal (39.0%) Mid (54.2%) Distal (52.5%)
Lesions Treated per Patient	1 (85.2%) 2 (14.8%)	1 (83.3%) 2 (16.7%)	1 (84.3%) 2 (15.7%)
Total Occlusion	45.2%	50.0%	47.5%
Target Lesion Length mm	112.3 ± 78.9 (4.00 – 360.0)	126.1 ± 52.9 (18.0 – 280.0)	119 ± 68 (4– 360)
Stenosis	115.8 ±79.8	114.6 ±29.3	115.3 ±62.1
Occlusion	110.0 ±78.1	135.6 ±66.1	122.8 ±72.1

BLASTER
Stent Characteristics

Parameter	SMART with Abciximab	SMART without Abciximab	All Patients
Total # Stents	49	47	96
Number 1 stents	48.1%	33.3%	41.2%
2	29.6%	37.5%	33.3%
3	18.5%	29.2%	23.5%
4	3.7%	0.0%	2.0%
Stent diameters	6.67 ± 1.07	6.85 ± 0.78	6.76 ± 0.94
Length of Stented Segment	172 ± 93	182 ± 72	178 ± 83

BLASTER Efficacy Results

Parameter	SMART w/ Abciximab	SMART w/o Abciximab	All Patients
Technical Success	**100%**	**100%**	**100%**
Acute Angiographic Success	**100%**	**100%**	**100%**

BLASTER Efficacy Results

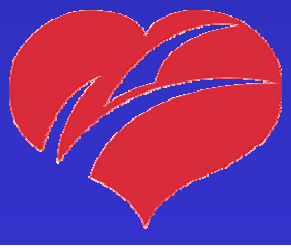
Parameter	SMART w/ Abciximab	SMART w/o Abciximab	All Patients
Duplex Primary Restenosis	22%	13%	17%
9 Month Assisted Primary Patency	96%	100%	97.6%

BLASTER ABI Results (Through 9 Months)

Parameter	Baseline	Discharge	9 Month	Change
SMART w/ Abciximab	0.66 ± 0.14 (0.45 – 0.96)	0.86 ±0.15 (0.57 - 1.08)	0.84 ± 0.17 (0.44 – 1.25)	-0.19 ± 0.21 (-0.55 – 0.18)
SMART w/o Abciximab	0.66 ± 0.14 (0.39 – 0.87)	0.90 ±0.16 (0.56 - 1.16)	0.84 ± 0.20 (0.51 – 1.29)	-0.19 ± 0.21 (-0.54 – 0.18)
All Patients	**0.6 ± 0.14 (0.4 – 0.9)**	**0.8 ±0.15 (0.5 - 1.2)**	**0.8 ± 0.18 (0.4 – 1.3)**	**-0.18 ± 0.2 (-0.6 – 0.2)**

BLASTER Treadmill Results (Baseline through 9 Mos.)

Measured in Time / minutes			
Parameter	**Baseline**	**9 Month**	**Change**
SMART w/ Abciximab	2.65 ± 1.91 (0.5 – 7.5)	3.95 ± 2.84 (1– 10)	0.96 ± 2.05 (-3 – 3.7)
SMART w/o Abciximab	2.65 ± 2.07 (0.5– 7.0)	4.43 ± 2.49 (0.5 – 1)	1.78 ± 2.85 (-4.6 – 8.6)
All Patients	2.65 ± 1.97 (0.5– 7.5)	4.17 ± 2.67 (0.5 – 1)	1.35 ± 2.47 (-4.6 – 8.6)



BLASTER 1 Year Clinical Results

Parameter	SMART with Abciximab	SMART without Abciximab	All Patients
Target Lesion Revascularization	18.5	8.3%	13.7%

Recent Results w/ SFA Stenting

Study	Mean Lesion Length	Stent	Primary Patency (1 Year)	Secondary Patency (1 Year)
Gray et al, 1997	16.5 cm	Wallstent and Palmaz	22%	46%
Gordon et al, 2001	14.4 cm	Wallstent	55%	82%
Bosiers, Euro PCR 2002	4.7 cm	SMART	85%	95%
Ansel, et al, 2004	11.8 cm	SMART	83%	97%
Mewissen, 2003	12.2 cm	SMART	76%	NA

SIROCCO II
Duplex Doppler -18 Month

In-stent	Sirolimus (n=29)	Control (n=28)	P-value
Binary Restenosis	6 (20.7%)	4 (14.3%)	0.73
Occlusion	0	1 (3.6%)	0.49
Total	6 (20.7%)	5 (17.9%)	1.00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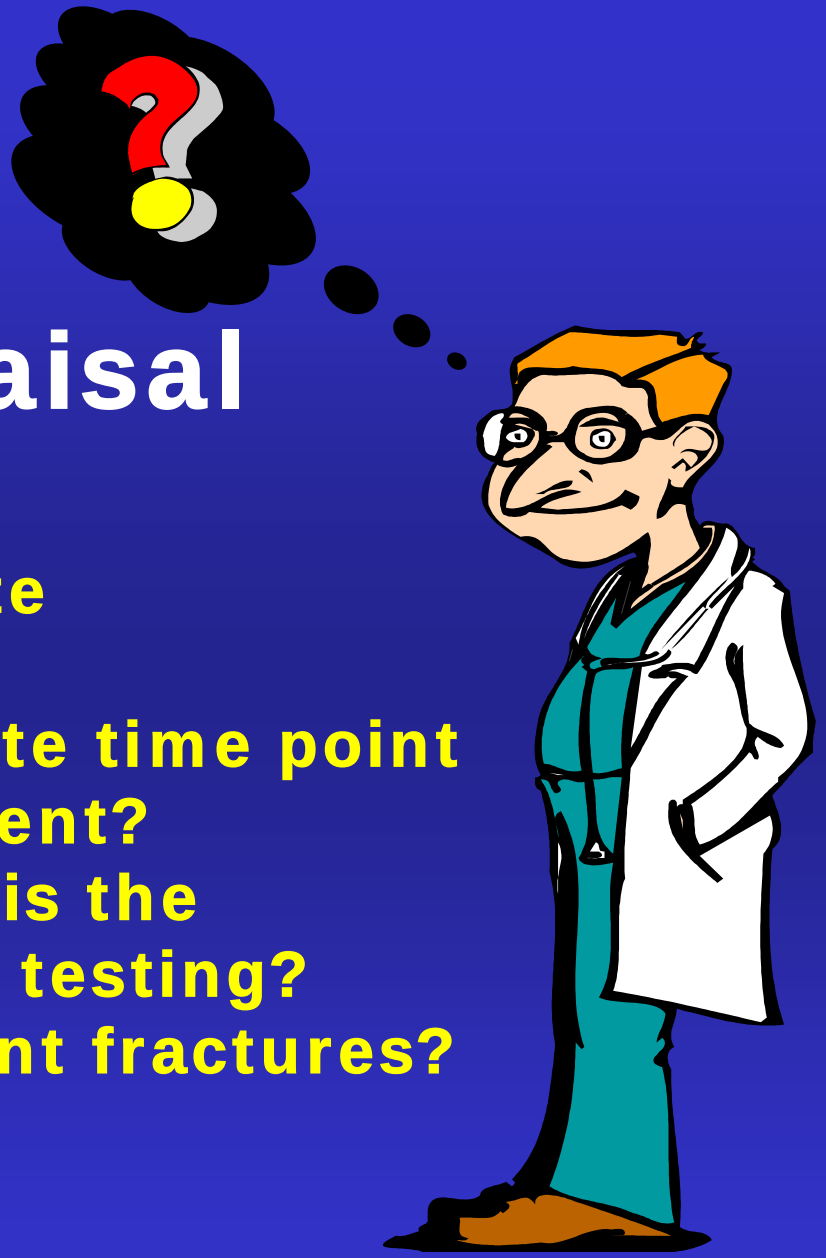
BLASTER:
A Critical Appraisal



1. What is the appropriate surrogate end-point?
2. What is the appropriate time point for end-point assessment?
3. For claudicants: What is the appropriate functional testing?
4. What is the role of stent fractures?

BLASTER Summary

- IIb/IIIa inhibition does not decrease restenosis of nitinol stents in the SFA
- Nitinol stents perform better than historic controls of PTA and Wallstent in similar lesion lengths
- Stent based therapy is efficacious for the treatment of diffuse SFA disease