Is SFA Nitinol Stenting the New Standard of Care?

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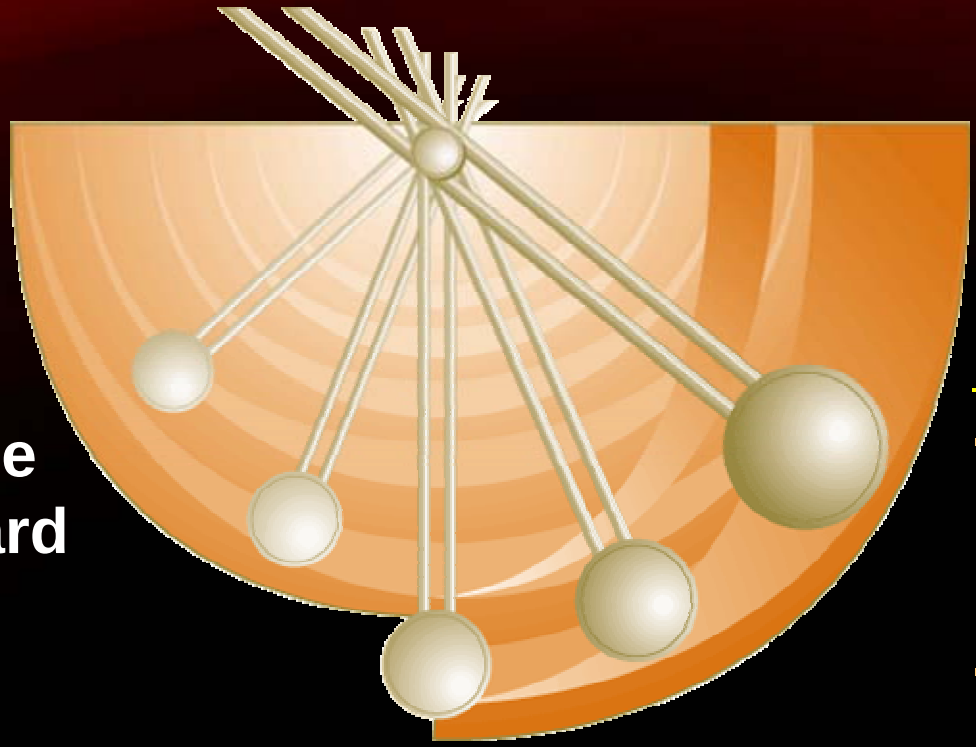
Is SFA Nitinol Stenting the New Standard of Care?

A Provocative Question

- What is the “old” standard of care?
- How should the “new” standard of care be defined and evaluated?
- Review recent interim nitinol stent data

Is SFA Nitinol Stenting the New Standard of Care?

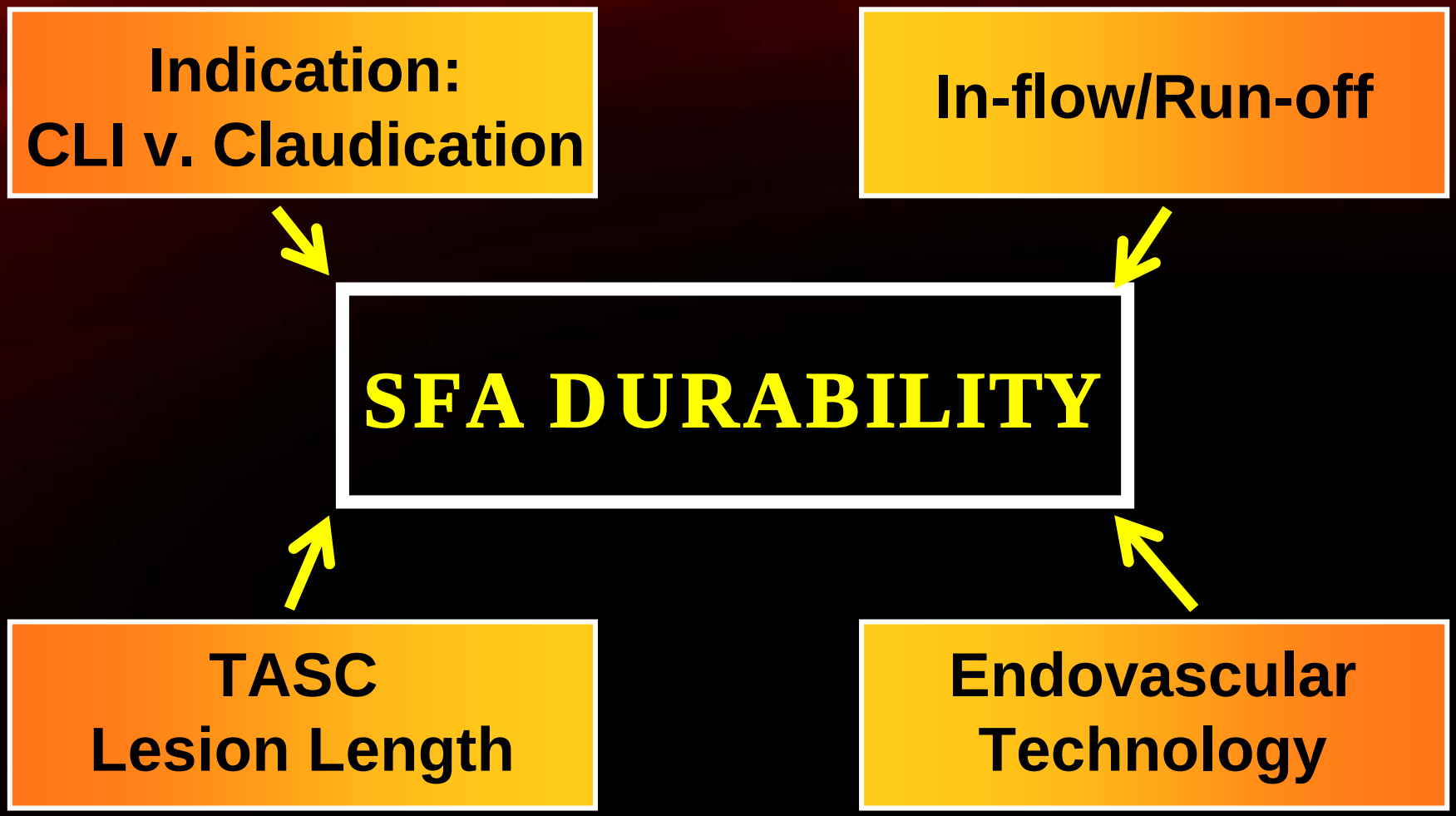


Surgery
- More durable
- Gold standard
- M/M and $

- Less M/M
- Outpatient setting
- Shorter LOS

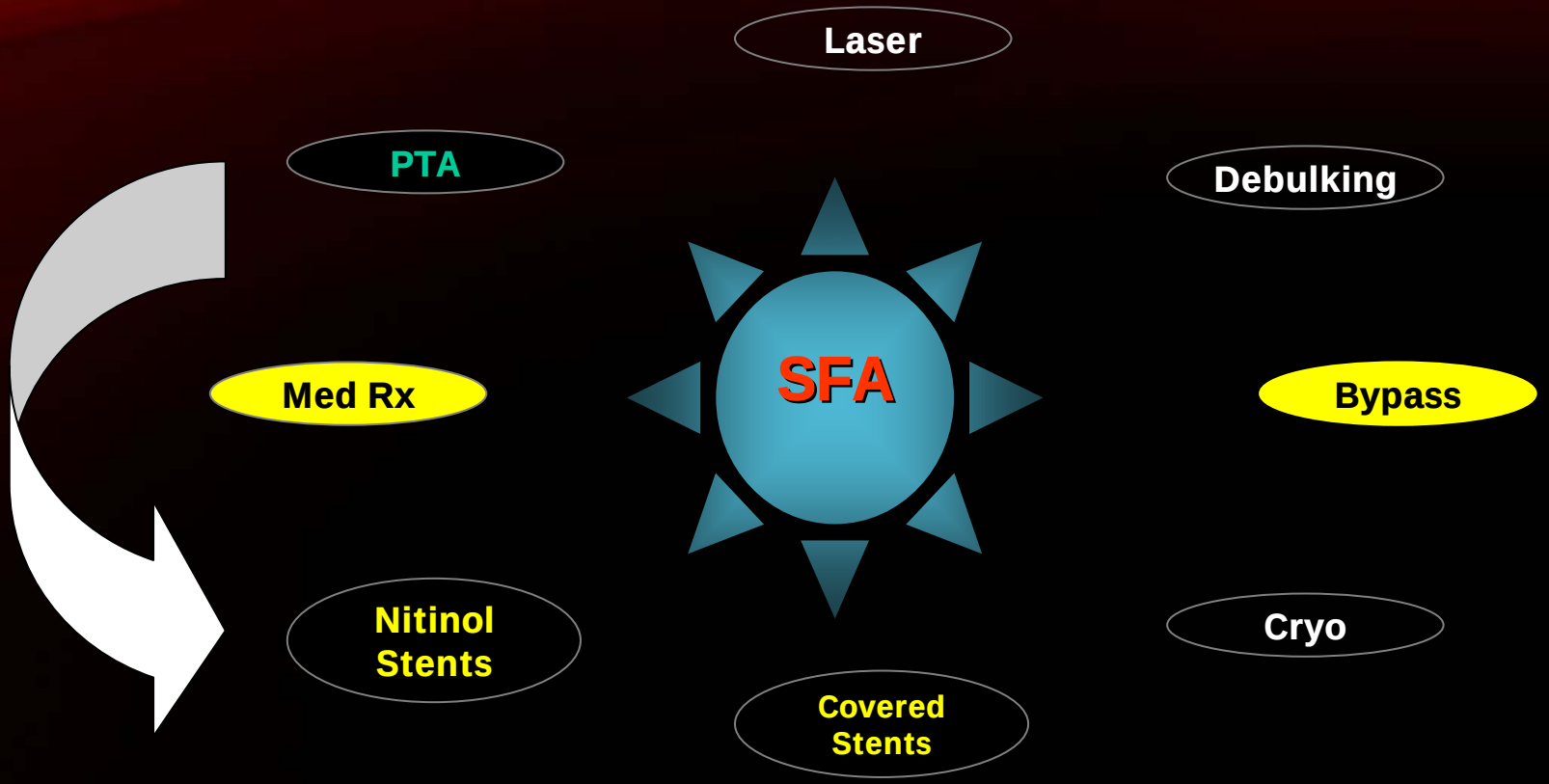
Endovascular
- De facto standard of care (renals)
- Patient preference
- ? Less durable in the SFA

Elements of SFA Durability

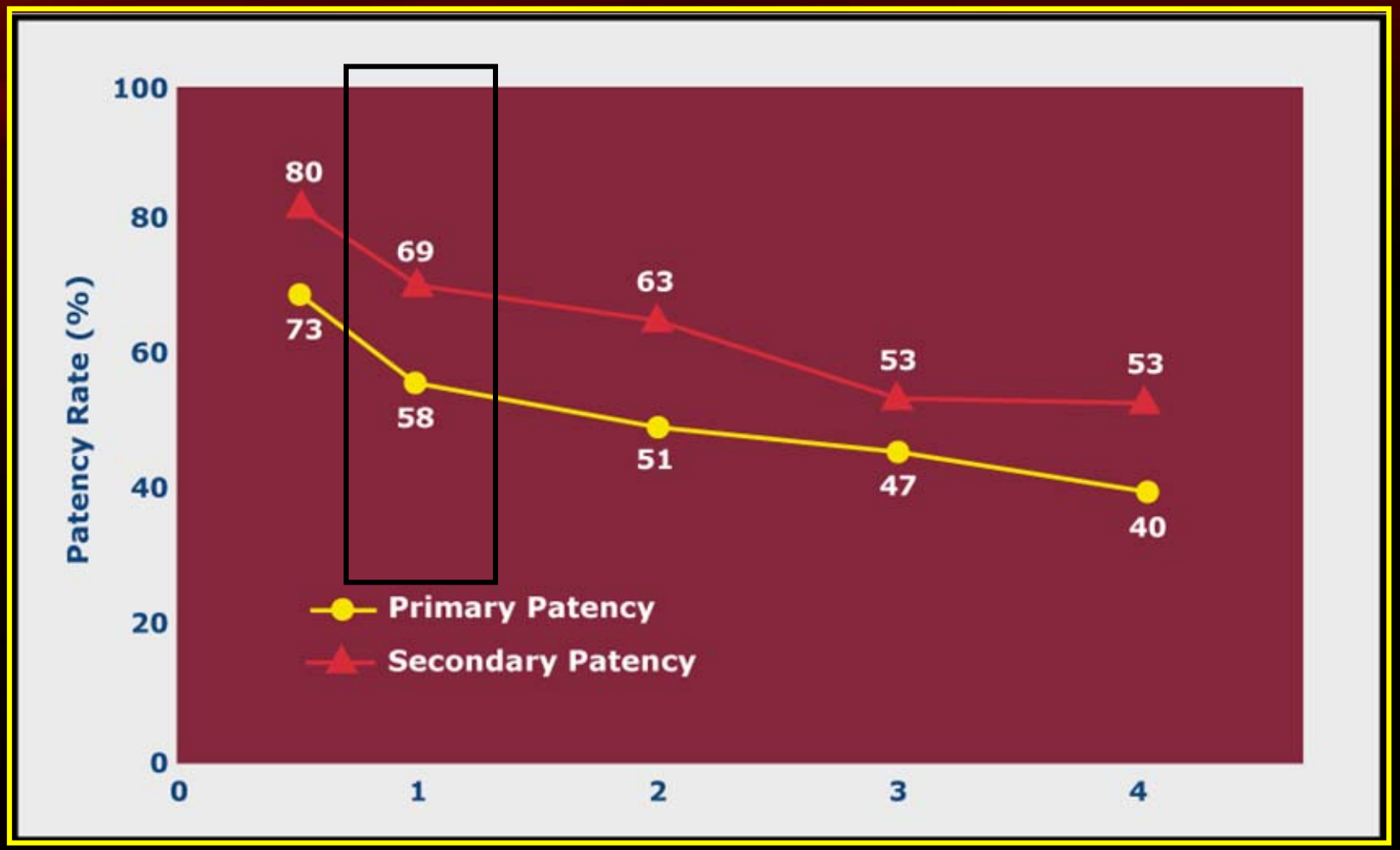


SFA Endovascular Options

Multiple stand-alone and adjunct therapies are used in the SFA



SFA Patency after PTA



Dorrucci ‘04

SFA PTA
Primary Patency

Meta-analysis (N = 1003)

Lesion Type:		Lesion Severity:	
Stenosis	64%	Claudication	65%
Occlusion	36%	Critical Ischemia	35%

% Primary Patency

1 Year	2 Years	3 Years	4 Years	5 Years
59	54	52	49	45

Kandarpa, *JVIR* 2001;12:683-695.

Unanswered Questions: SFA PTA

- Impact of lesion length on patency?

These questions are best answered in randomized controlled trials

- Time point is patency assessment?
- What the clinical impact of patency?
- What about safety of PTA?

Why Have RCT in the SFA Been So Challenging?

- Balance between clinically relevant and doable trial v. ideal clinical design
- Physician bias/skepticism
- Trial design issues: Intention to Treat issues
- Heterogeneity of patient cohort

How Efficacious is PTA for SFA Disease?

- Uniform patient cohort

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- Uniform patient cohort
- Uniform endpoint

Development of PTA SFA Performance Goals

- Independent endpoint adjudication
- Safety assessment

PTA Performance Goals Requirements:

- Combination of peer-reviewed literature data **and** industry PTA control arm data from PMA device trials in the SFA

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- Uniform time point assessment

PTA Cohort Parameters

- Rutherford Class 2-4 patients
- Femoropopliteal lesion lengths 4-15 cm
  TASC C-D lesions
- **Efficacy:** Binary restenosis by DUS (PVS ratio >2)
- **Safety:** 30 day and 12 month death, amputation, TLR and change in Rutherford Class

Literature Review Requirements:

- Peer-reviewed literature 1990-2006
- PTA control arms of randomized trials (PTA v. stent, PTA v. brachytherapy, PTA v. bypass)
- Meet established safety and efficacy assessment endpoints

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How Good is PTA in Moderate SFA Disease?

Results from Literature RCTs

≥ 4-15 cm PTA Control Arm:

Pokrajac ‘04
Zdanowski ‘99
Minar ’00
van der Zaag ‘04
Schillinger ‘06

1º Patency
37%

Mostly Claudicants

12 mo. duplex Doppler PSV ratio >2.0
per patient analysis; n=201

Just How Good is PTA in Diffuse SFA Disease?

Results from 3 Industry SFA PMA Trials

≥ 4-15 cm PTA Control Arm:

Company A	(11.7cm)	12%
Company B	(6.8 cm)	14%
Company C	(8.2 cm)	39%
	(8.7 cm)	**28%**

12 mo. DUS ratio PSV >2.0
per patient analysis; n=135

Combined Literature and Industry PTA Data

Literature:	n=201	12 mo 1º patency	37%
Industry:	n=135	12 mo 1º patency	28%

Combined 12 mo 1º patency 33%

How Well Does SFA Nitinol Stenting Compare to PTA?

Early results from peer-reviewed RCTs of PTA v. stenting

RCT Trial /Stent	No. of Patients	Lesion Length	Primary Patency %
SIROCCOII/Cordis (6 mo. angio)	28	7.6 cm	92.3
BLASTER/Cordis (9 mo/DUS ≥ 2.5)	51	11.8	88
ABSOLUTE/Abbott	51	10.1	63
FAST*/Bard	123	4.5	77
RESILIENT*/Edwards (6 mo./ DUS ≥2.5)	172	6.2	89.7
ZILVER PTX*/Cook Bare stent (n=8)/9 mo. DUS)	8	3.6	75
TOTAL	*433*	*5.1 cm*	*80.0%*

**Not peer-reviewed*

PTA v. Viabahn Patency: 12 mo

Lesion Length	PTA	Viabahn	P value
ALL	40% (6.7cm)	62% (7.3 cm)	0.0003
3-6 cm	39%	56% →	0.0827
6-9 cm	28%	66%	0.0018
9-12 cm	38%	67%	0.07
>12 cm	17%	54%	0.0147

Viabahn® Instructions for Use

Is Nitinol Stenting the New Standard of Care in the SFA?

- Yes, ***BUT*** specific definitions of this standard are required:
  - Not in short lesions (4-5 cm)
  - Patency definition (DUS PSV)
  - Patient cohort
  - Clinical impact

Future Directions for Clinical Study

- Long Lesions (>10 cm)
- Durability (>1 yr)
- Clinical Impact
- Secondary Patency and treatment of ISR