Why use special devices: stents still work

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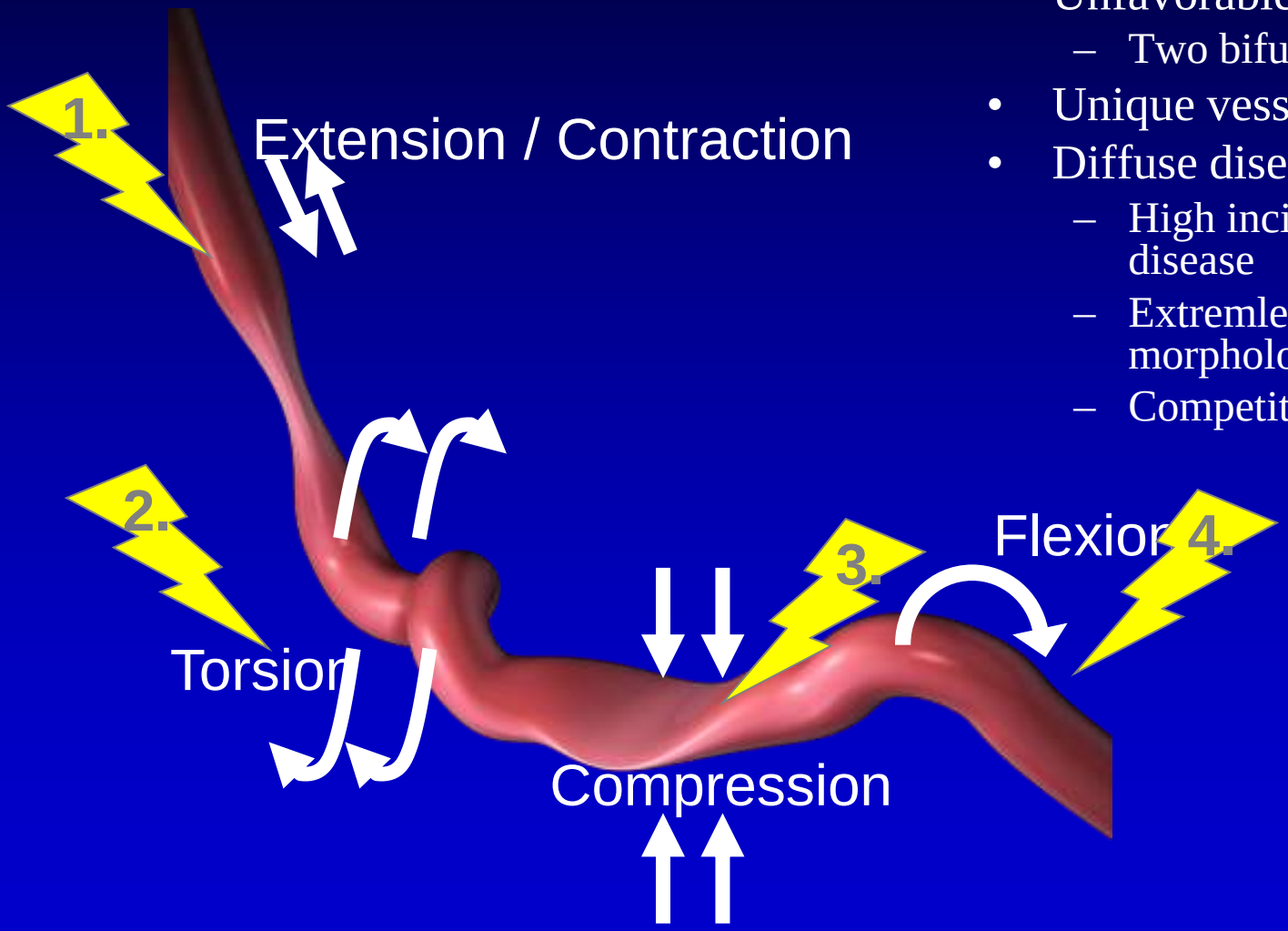
Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• iDev, Covidien/Medtronic
• Consulting Fees/Honoraria	• Covidien/Medtronic, Boston Scientific, Angiosculpt/Spectranetics
• Major Stock Shareholder/Equity	• Arsenal, Primacea, TissueGen, CV Ingenuity, Scion Cardiovascular, Spirox, Essential Medical
• Royalty Income	• None
• Ownership/Founder	• None
• Intellectual Property Rights	• None
• Other Financial Benefit	• None

Forces Exerted on the SFA

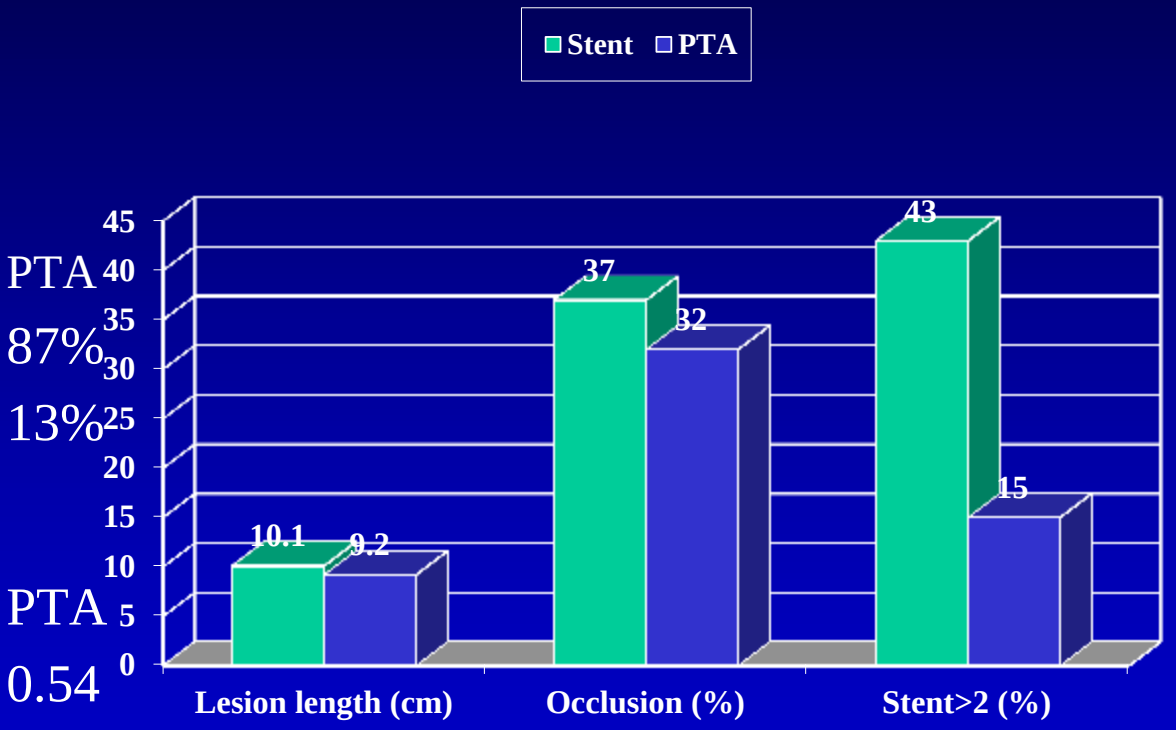


- Unfavorable anatomy
  - Two bifurcations/articulations
- Unique vessel forces
- Diffuse disease
  - High incidence of occlusive disease
  - Extremley complex lesion morphologies
  - Competitive flow via PFA

Balloon Angioplasty versus Implantation of Nitinol Stents in the Superficial Femoral Artery

Martin Schillinger, M.D., Schila Sabeti, M.D., Christian Loewe, M.D., Petra Dick, M.D., Jasmin Amighi, M.D., Wolfgang Mlekusch, M.D., Oliver Schlager, M.D., Manfred Cejna, M.D., Johannes Lammer, M.D., and Erich Minar, M.D.

- 104 patients
- Claudicants/CLI
  - Stent PTA
  - RB<3 88% 87%
  - RB>4 12% 13%
- ABI
  - Stent PTA
  - 0.57 0.54



Schillinger *NEJM* 2006

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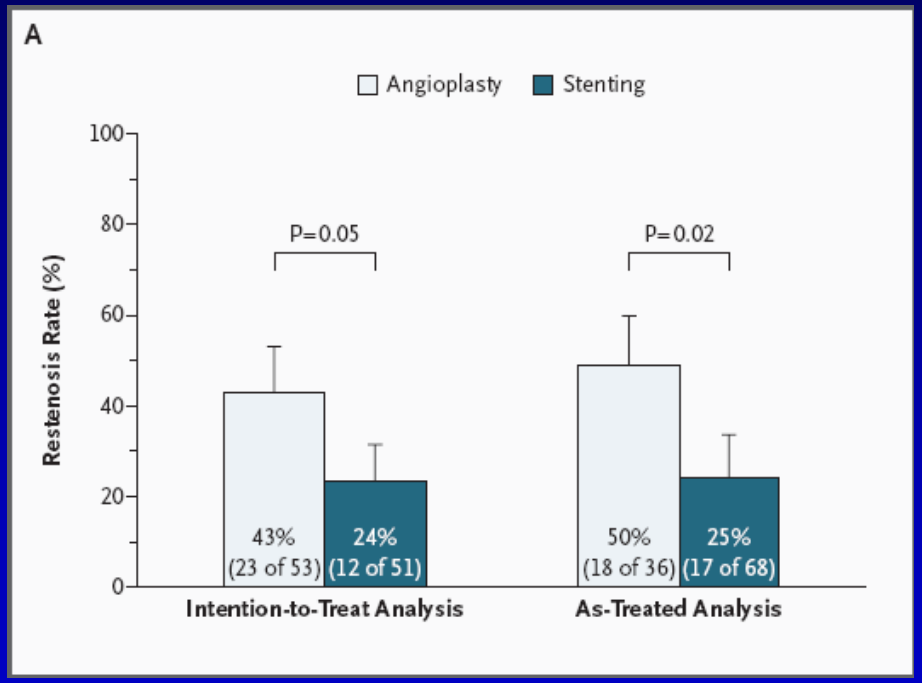
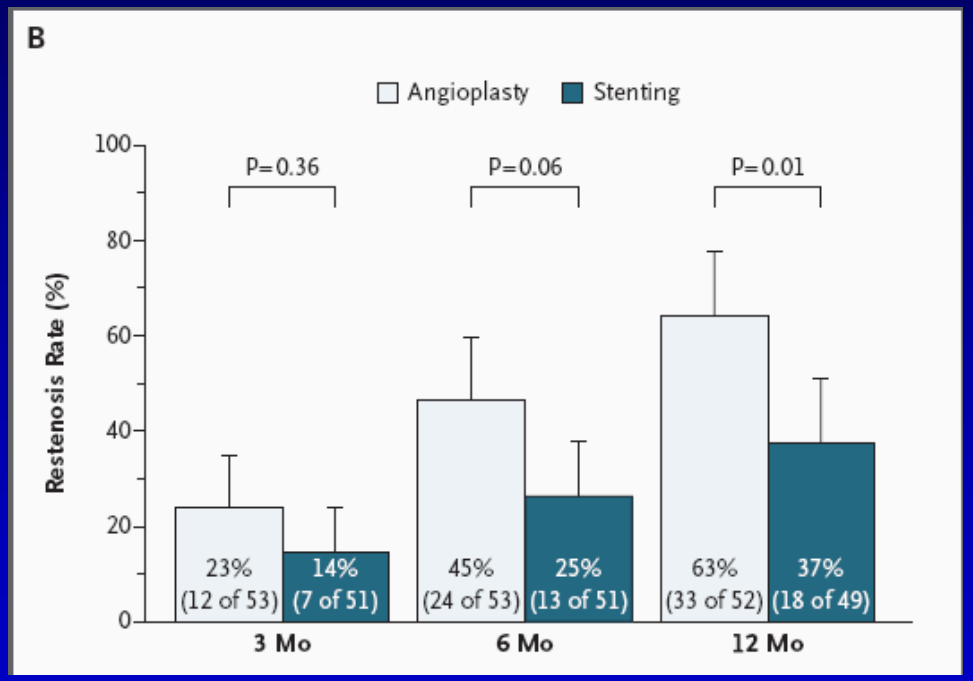
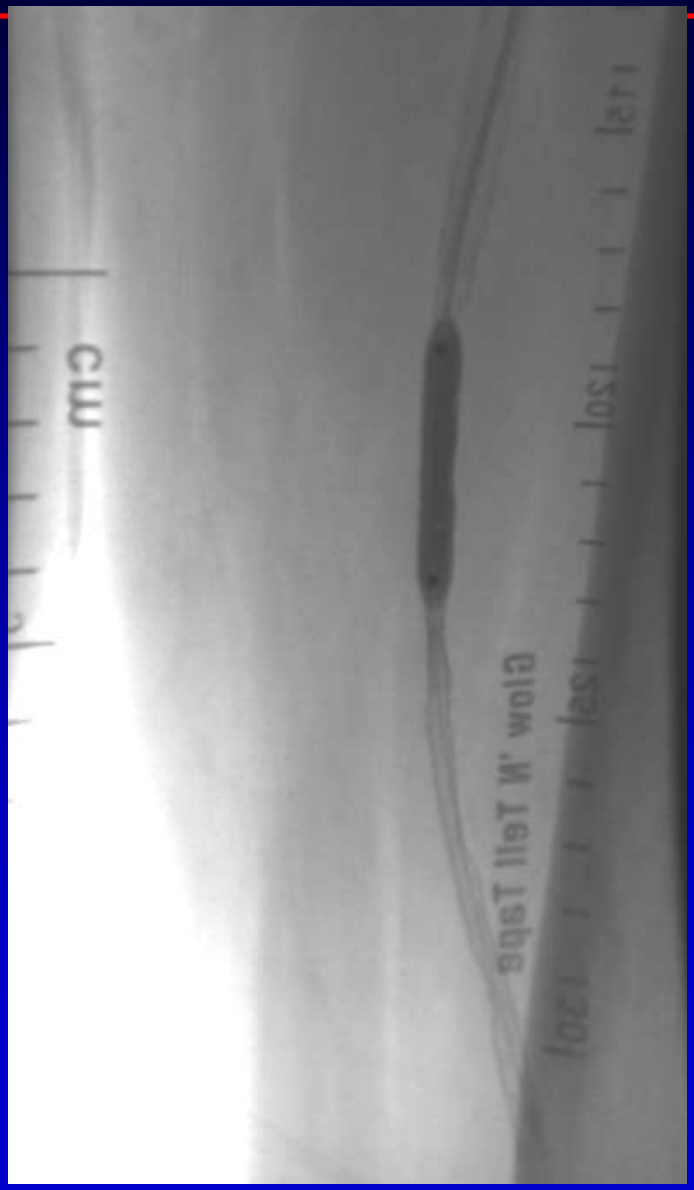


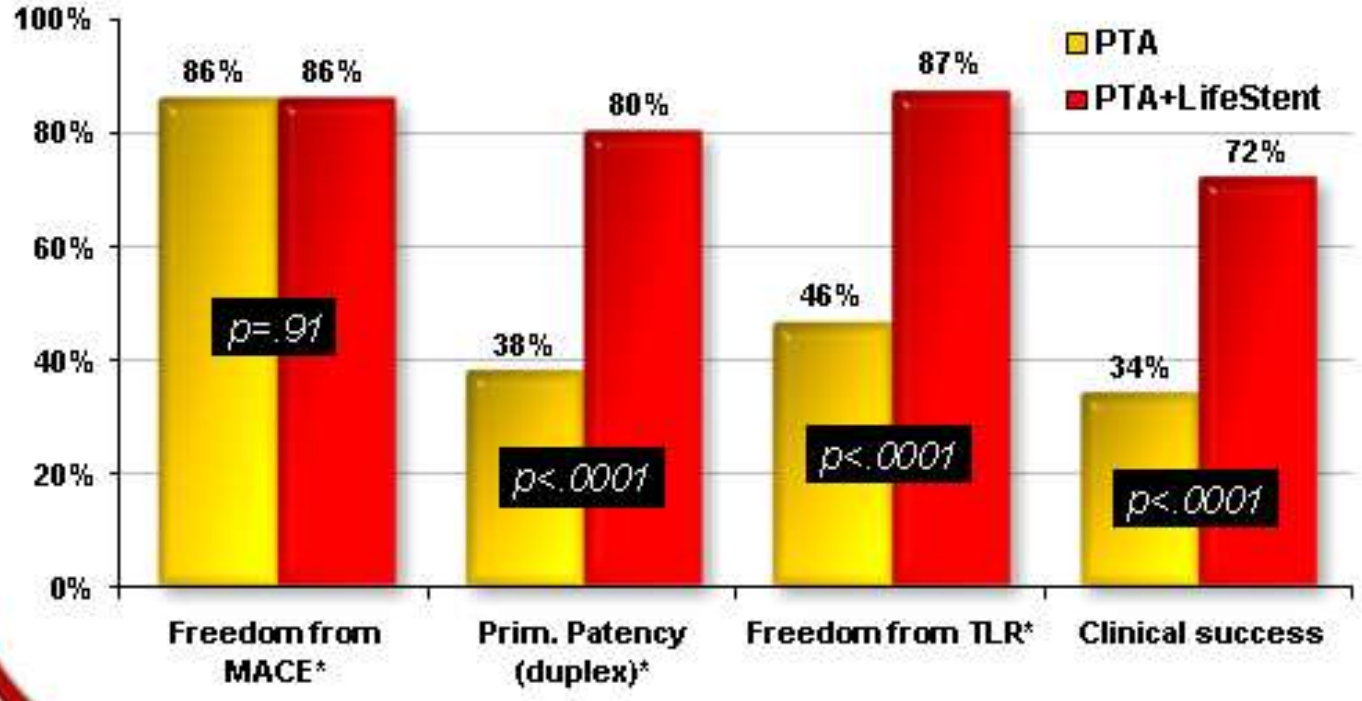


RESILIENT

- Lesion lengths up to 14 cm
- Lesions treated
  - PTA 5.7 cm (6.4 cm LL)
  - Stent 6.2 cm (7.0 cm LL)
- 2:1 randomization with PTA
  - PTA failure 40%
- Stent fractures
  - All stents imaged for SF
  - Fracture rate 2%



12-Month Results



*Data from Kaplan-Meier Survival Analysis

THE RESILIENT TRIAL

STROLL: Purpose and Study design

- Prospective, single arm, multicenter trial evaluating the SMART self-expanding nitinol stent in the superficial femoral/popliteal artery.
- Multi-center, single-arm, prospective trial
  - 250 patients, 39 study sites in the United States
  - Follow-up to 3 years
- Primary Endpoints:
  - Safety at 30 days
  - Primary Efficacy (patency) at 12 months
    - DUS 30 day, 6m, 12m, 24m and 36m
- Secondary Endpoint: Incidence of stent fractures.
  - Protocol-mandated X-ray of stents at 30 day, 6m,12m, 24m and 36m

Patient and lesion characteristics

STROLL S.M.A.R.T.®	(n=250)
Age	68 ± 10
Male (%)	61.6
Diabetes (%)	47.2
Hypertension (%)	88.8
Renal disease (%)	11.7
Previous MI (%)	22.5
Rutherford category (%) 2 3 4	 45.8 51.4 2.8
Lesion Length (mm ± SD)	77 ± 31
Total Occlusions (%)	23.6
Severe Calcification (%)	19.3

Results: Primary Patency

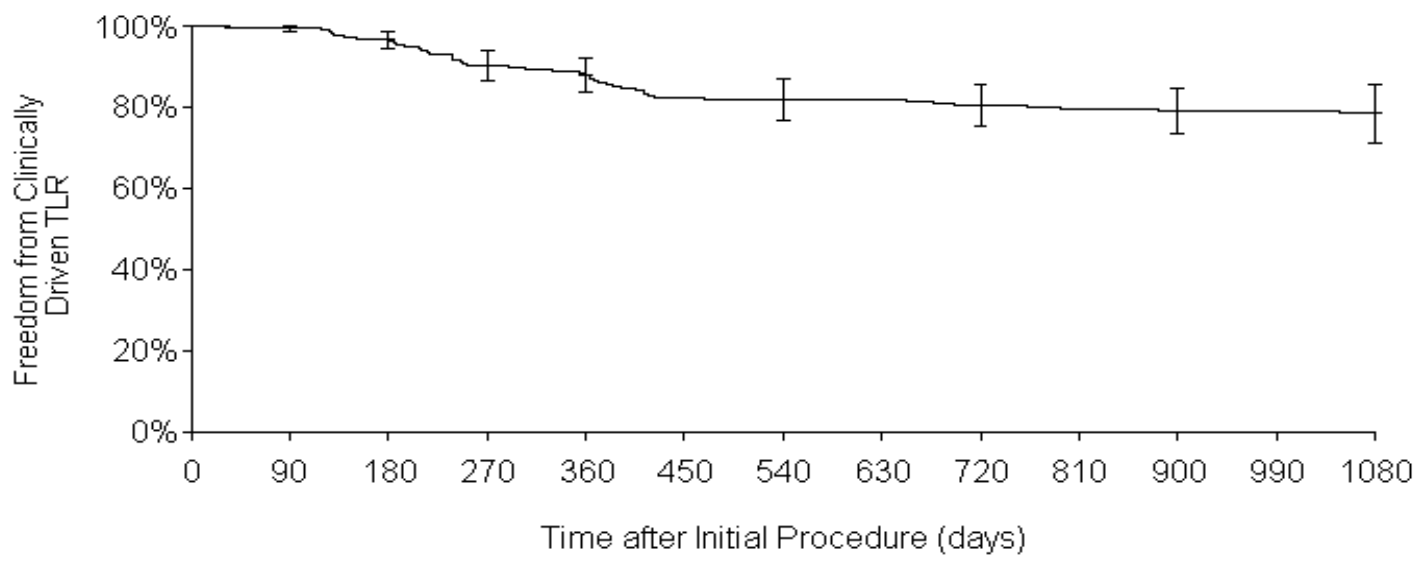
	12 months	24 months	36 months
Primary Patency (KM estimate) (PSVR < 2.5)	81.7%	74.9%	72.7%
DUS Patency (PSVR < 2.5)	81.1% (154/190)	83.5% (132/158)	83.9% (115/137)
Absence of Clinically Driven TLR	87.4% (202/231)	79.0% (173/219)	75.8% (157/207)

Primary Patency: *composite endpoint of absence of clinically driven TLR and DUS assessed binary restenosis defined as diameter stenosis >50% (non-patent).*

DUS patency: *stent non-patency defined as a diameter stenosis >50% with a specific a peak systolic velocity ratio as measured by Duplex Ultrasonography*

Clinically driven TLR: *any intervention in the stented target lesion following documented recurrent symptomatic leg ischemia by Rutherford/Becker Classification (2,3,4) with a resting or exercise ABI <0.8 and >50% diameter in-lesion stenosis by angiography. Or >70% in-lesion diameter stenosis by angiography in the absence of ischemic signs and symptoms.*

Freedom from Clinically-Driven TLR:1080 days



Clinically Driven TLR	0	30	90	180	270	360	540	720	900	1080
# Entered	250	250	247	244	235	213	206	184	175	161
# Censored	0	3	1	1	5	0	5	4	8	53
# Incomplete	0	0	1	1	2	1	3	2	3	7
# At Risk	250	249	246	243	232	213	202	181	170	131
# Events	0	0	1	7	15	6	14	3	3	1
# Events/Month	--	0.0	0.5	2.3	5.0	2.0	2.3	0.5	0.5	0.2
% Survived	100.00%	100.00%	99.60%	96.73%	90.47%	87.91%	81.87%	80.50%	79.07%	78.50%
SE	0.00%	0.00%	0.41%	1.15%	1.92%	2.14%	2.57%	2.69%	2.85%	3.64%

Cumulative stent fracture rate

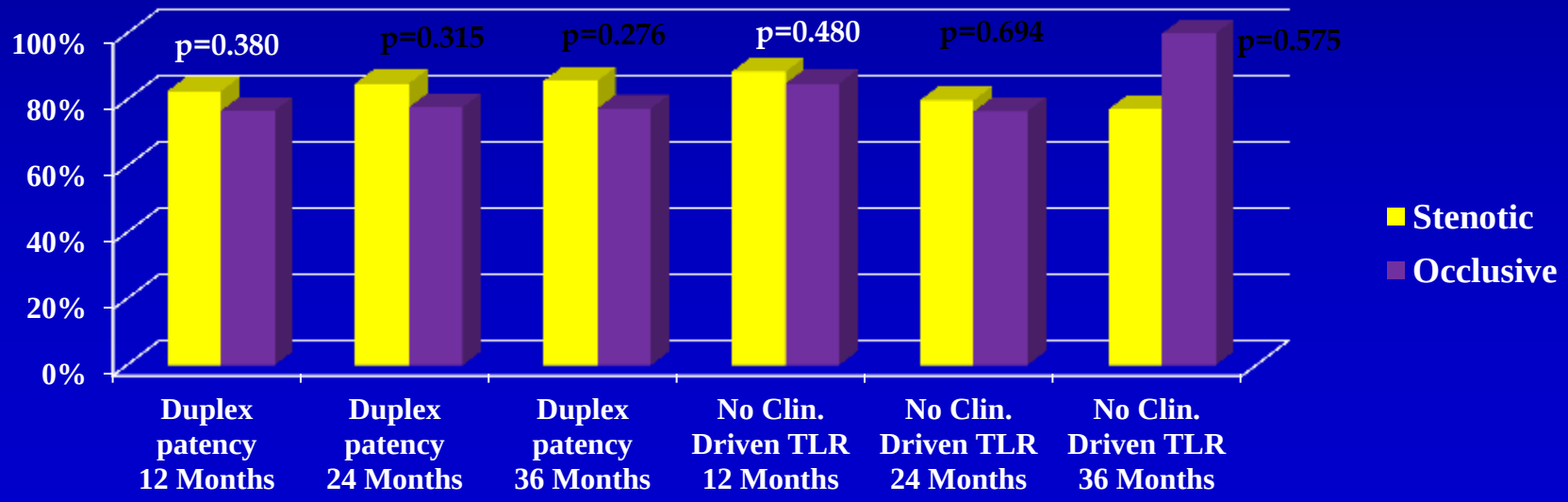
Stent Fracture	6-month	12-month	24-Month	36-Month
Type I	1.49% (3/202)	2.03% (4/197)	2.3% (4/177)	3.6% (6/169)
Type II	0.0% (0/202)	0.0% (0/197)	0.0% (0/177)	0.0% (0/169)
Type III	0.0% (0/202)	0.0% (0/197)	0.0% (0/177)	0.0% (0/169)
Type IV	0.0% (0/202)	0.0% (0/197)	0.0% (0/177)	0.0% (0/169)
Type V	0.0% (0/202)	0.0% (0/197)	0.0% (0/177)	0.0% (0/169)
Any Stent Fracture	1.49% (3/202)	2.03% (4/197)	2.3% (4/177)	3.6% (6/169)

Only Type I Fractures

Type I Single Strut fracture
Type II Multiple single Strut fracture
Type III Complete transverse linear separation without stent displacement
Type IV Complete transverse linear fracture with stent displacement
Type V Spiral dissection of stent

Efficacy in Total Occlusions

	Stenotic			Occlusive		
	12 Month	24 Month	36 Month	12 Month	24 Month	36 Month
Duplex patency (PSVR < 2.5)	82.6% (119/144)	85.0% (102/120)	85.7% (90/105)	76.7% (33/43)	77.8% (28/36)	77.4% (24/31)
Absence of Clinically Driven TLR	88.5% (154/174)	79.9% (131/164)	77.1% (118/153)	84.9% (45/53)	76.5% (39/51)	73.1% (38/52)

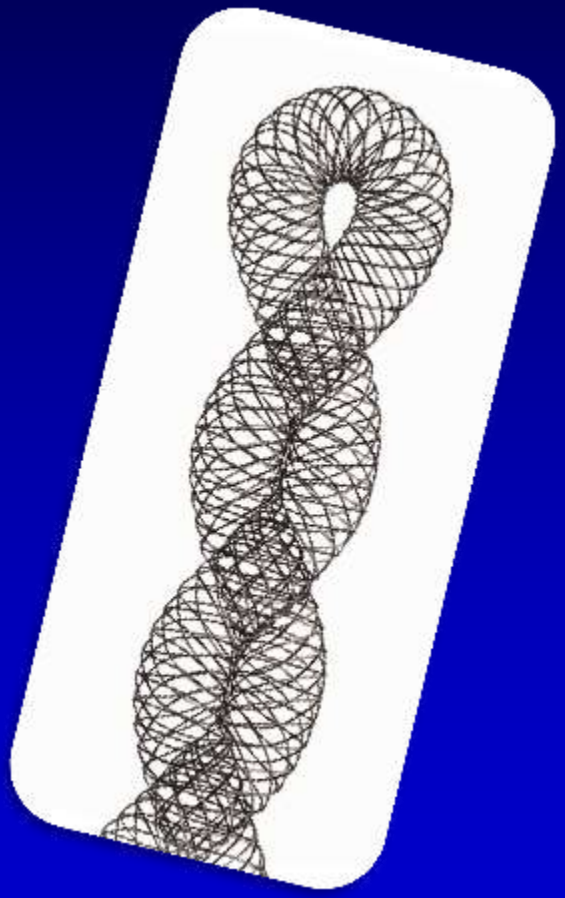


New Class of Stent

- Biomimetic products are:
  - Biologically inspired
  - Engineered in harmony with the structure and function of biological systems
  - "Abstraction of good designs from nature"

- SUPERA was designed to be highly fracture resistant and dynamically conformable to closely mimic vascular anatomy and maintain optimal patency

- Vascular mimetic stent design has characteristics to promote maximal flow and resist kinking and fracture



Angiographic Core Lab Analysis

Baseline Characteristics	N= 266 Lesions
Mean lesion length	
Core lab*	77.7 mm
(Site)**	(83.2mm)
Calcification	
Moderate	27.9%
Severe	44.9%
Occlusions	24.7%

72.8%

Lesion Location

Proximal SFA
12.4%

Mid SFA
53.8%

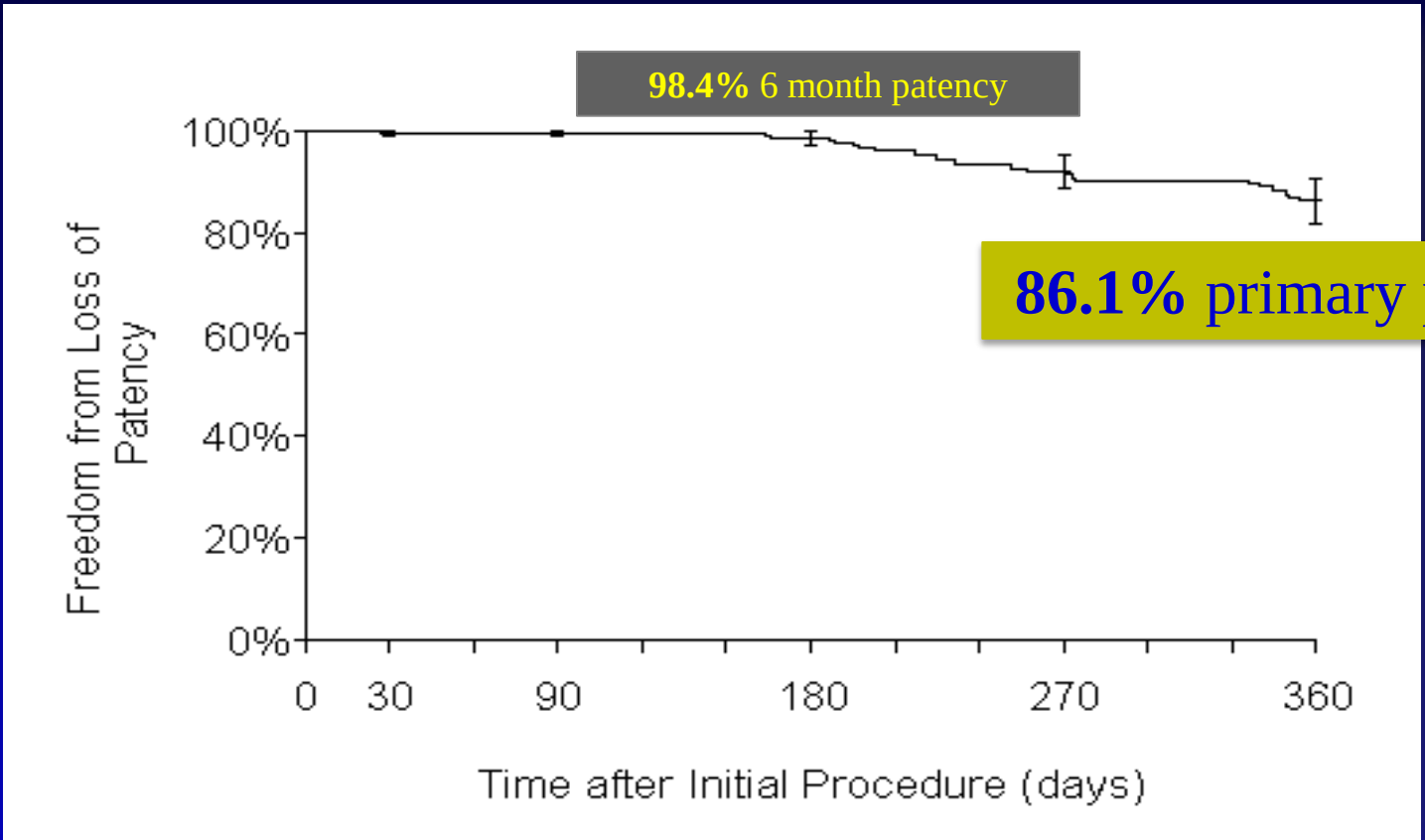
*Distal SFA****
31.9%

*Popliteal****
1.9%

* *Core lab assessed length from 20% DS to 20% DS*
** *Site measurement as normal to normal*

*** *A total of 10.9% of lesions were popliteal artery only, or lesions extending from distal SFA into the proximal popliteal artery*

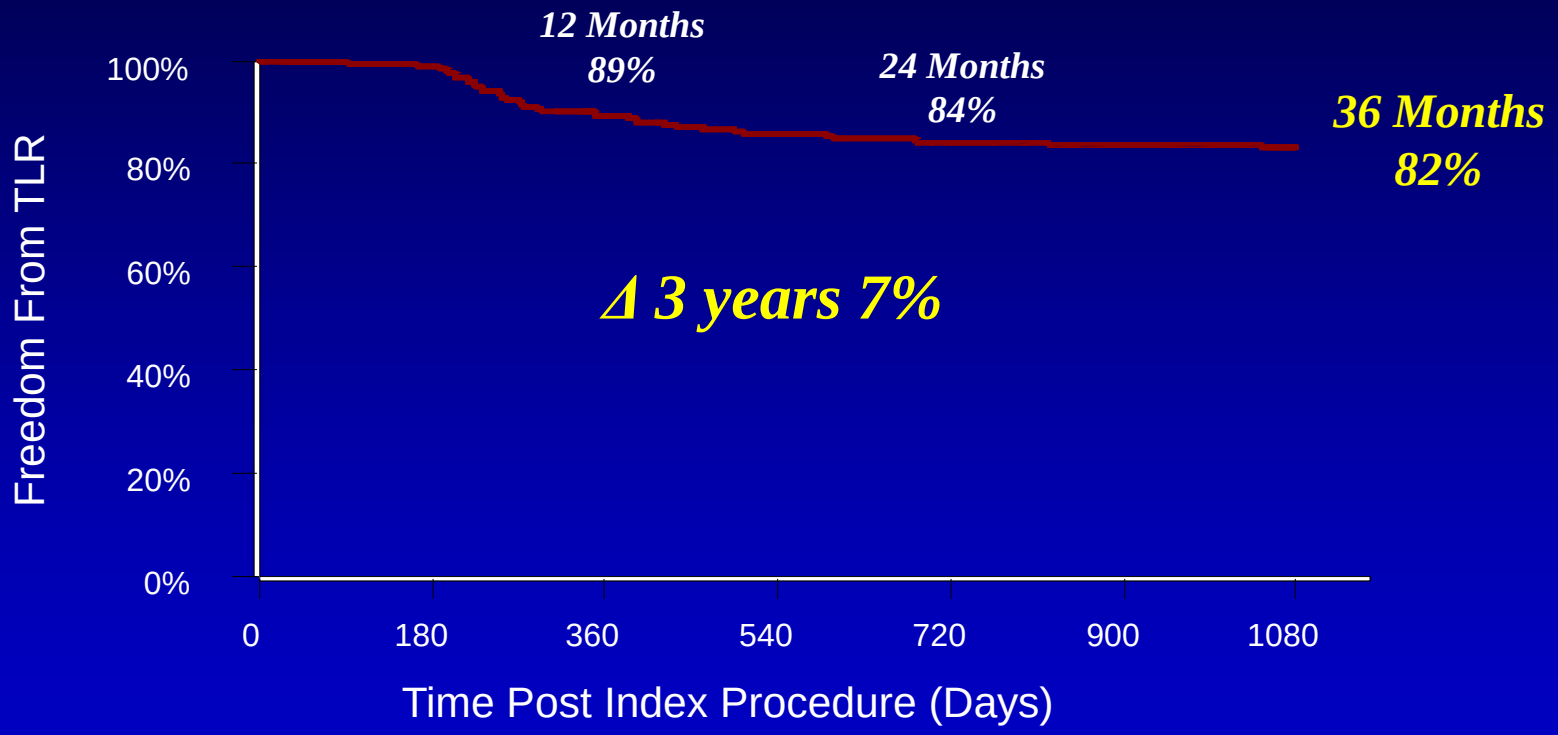
Freedom from Loss of Primary Patency at 1 Year (PSVR < 2.0)



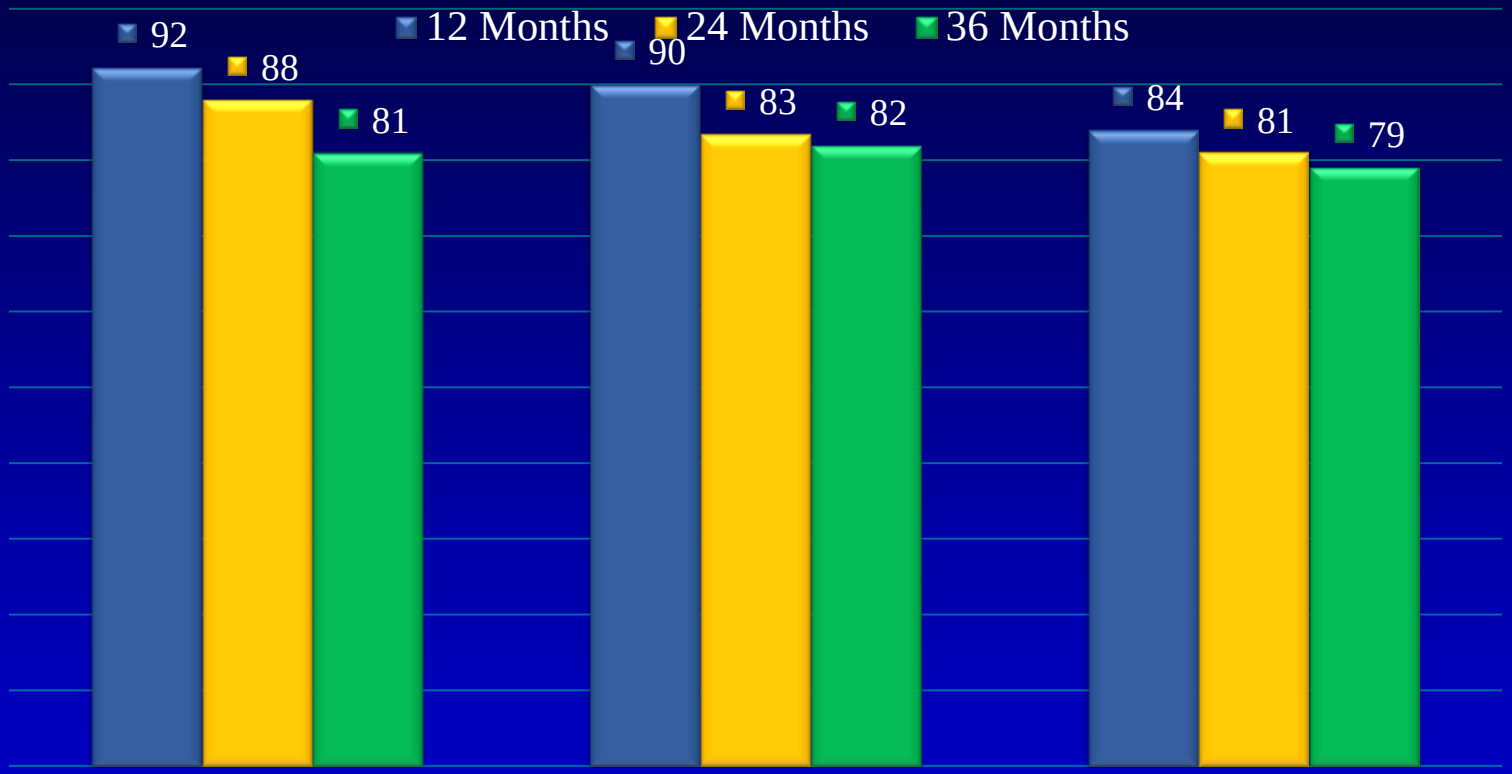
Freedom from TLR = 90%

Survival Analysis conducted by HCRI

Freedom From TLR Through 3 Years

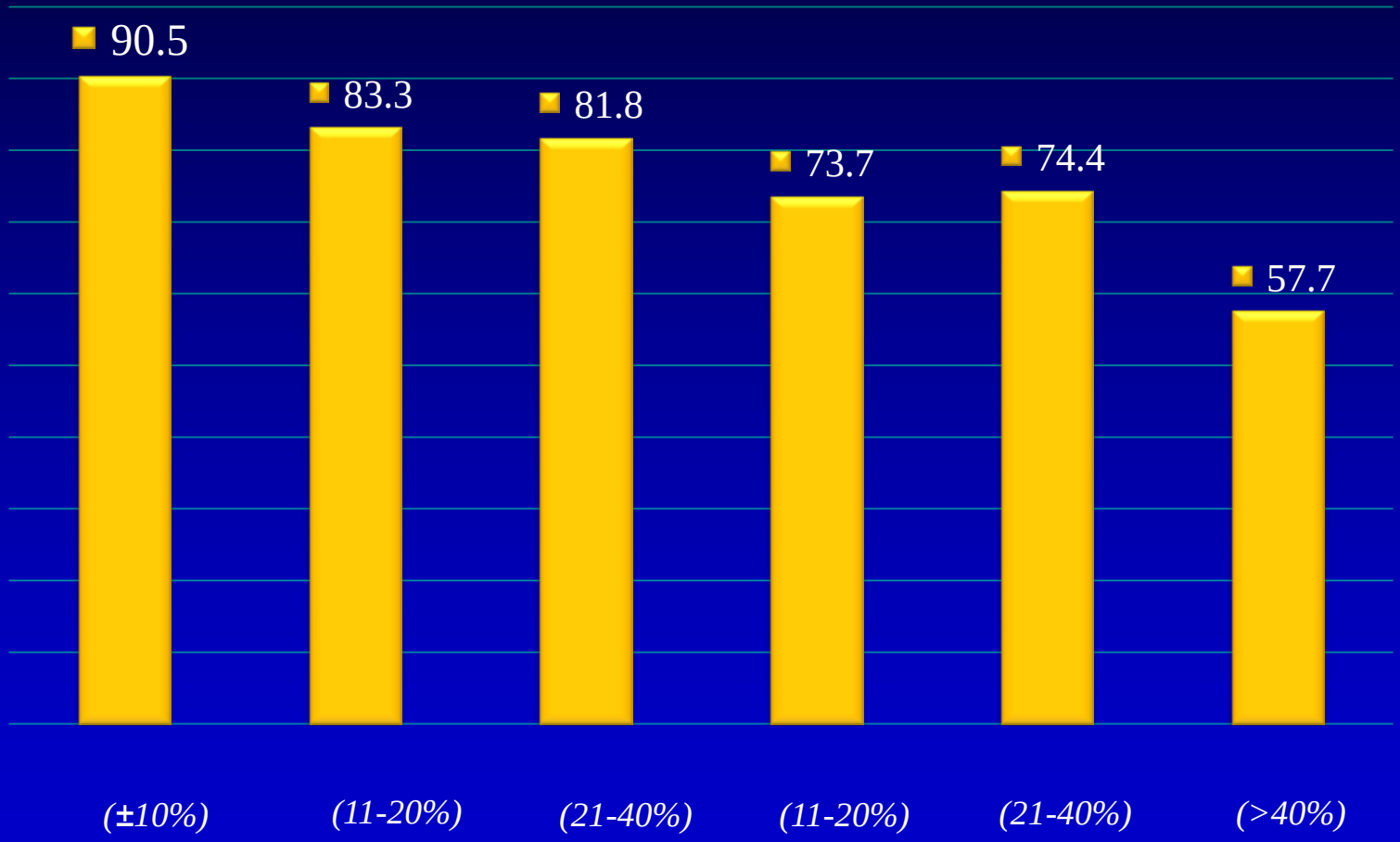


Freedom From TLR Across Lesion Lengths

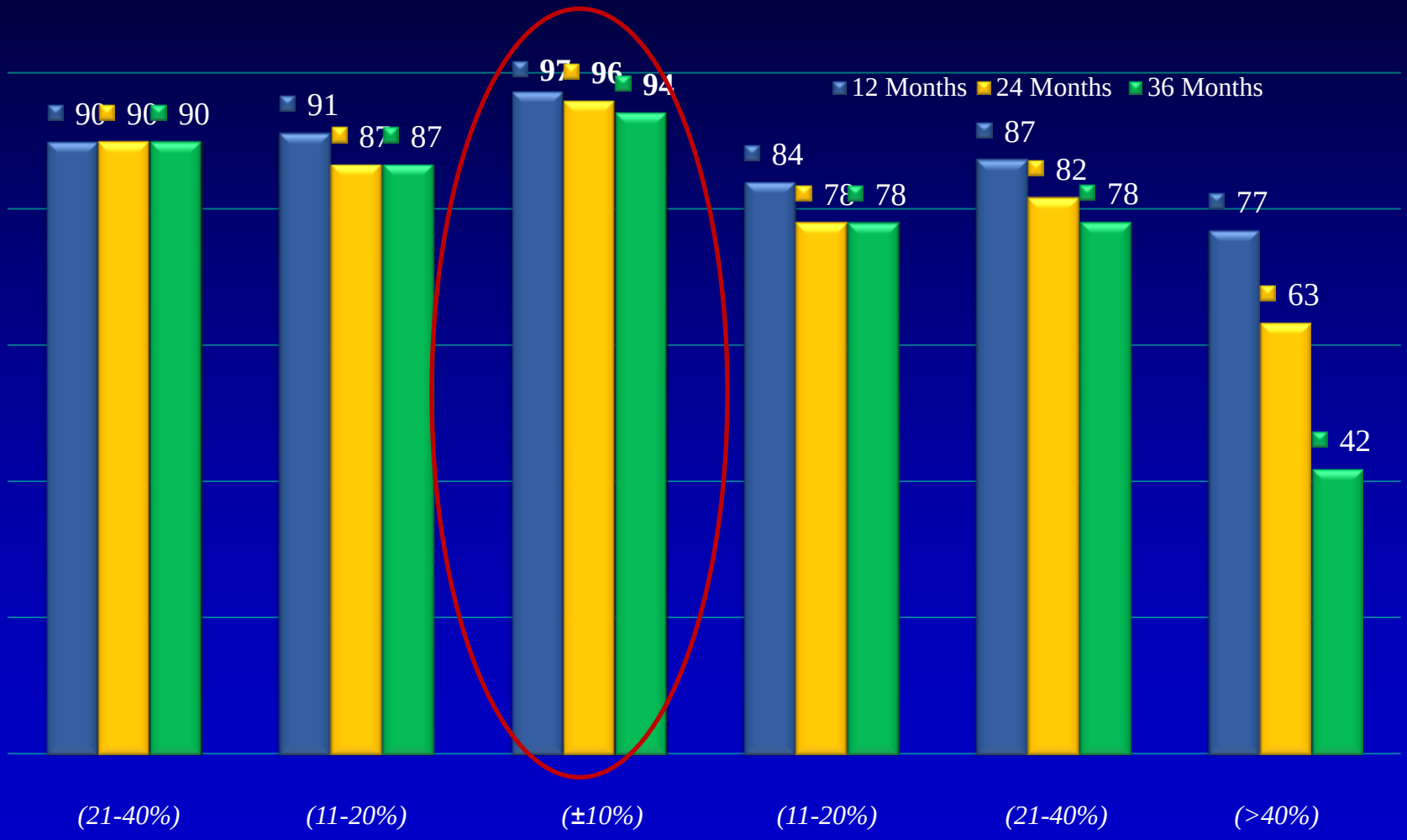


Mean Lesion Length	*35.4 mm*	*73.5mm*	*126.1 mm*
Min, Max Lesion Length	*8.5, 55.0 mm*	*55.5, 91.5 mm*	*96.1, 236.4 mm*

Deployment Technique Impact on 12-Month Patency



Deployment Technique Impact on Freedom From TLR

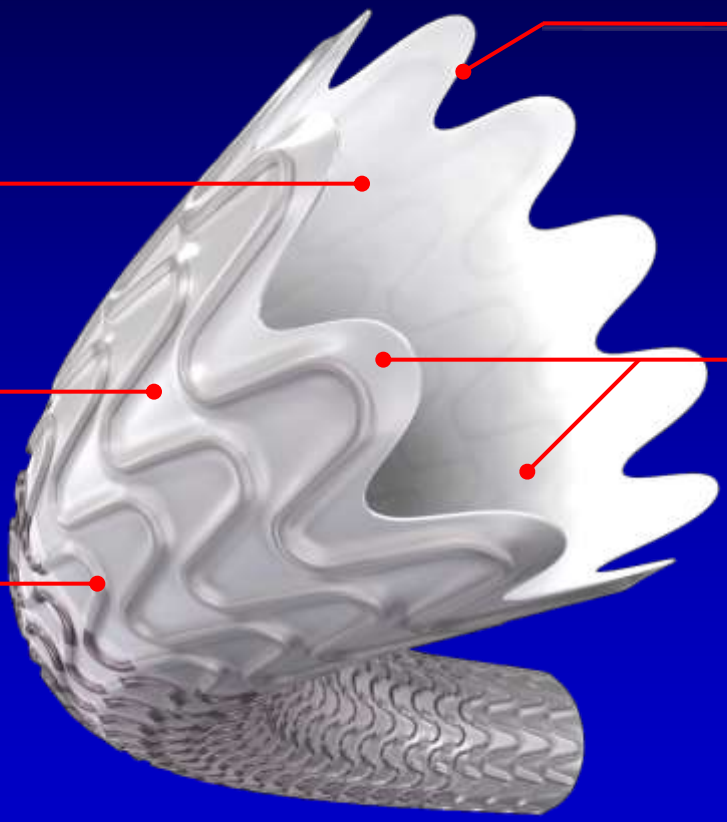


Stent Fracture

Stent Fracture	12 Months 0.0% (0/236)	24 Months 0.5% (1/196)	36 Months 0.6% (1/162)
Single Strut	0.0%	0.0%	0.0%
Multiple Strut	0.0%	0.0%	0.0%
Complete Fracture/Fragments Aligned	0.0%	0.5%*	0.6%*
Complete Fracture/Fragments Malaligned	0.0%	0.0%	0.0%
Spiral Fracture	0.0%	0.0%	0.0%

** One subject experienced a Type III fracture at 24 months after 3 directional atherectomy procedures to treat in-stent restenosis.*

Endoprosthesis Description



Contoured proximal edge

CARMEDA® Bioactive Surface (CBAS® Surface)

Ultra-thin wall ePTFE tube

Unique, durable bonding film

Polished nitinol support

Lengths: 2.5, 5, 10, 15 cm

Diameters: 5–8 mm

VIPER Lesion Characteristics

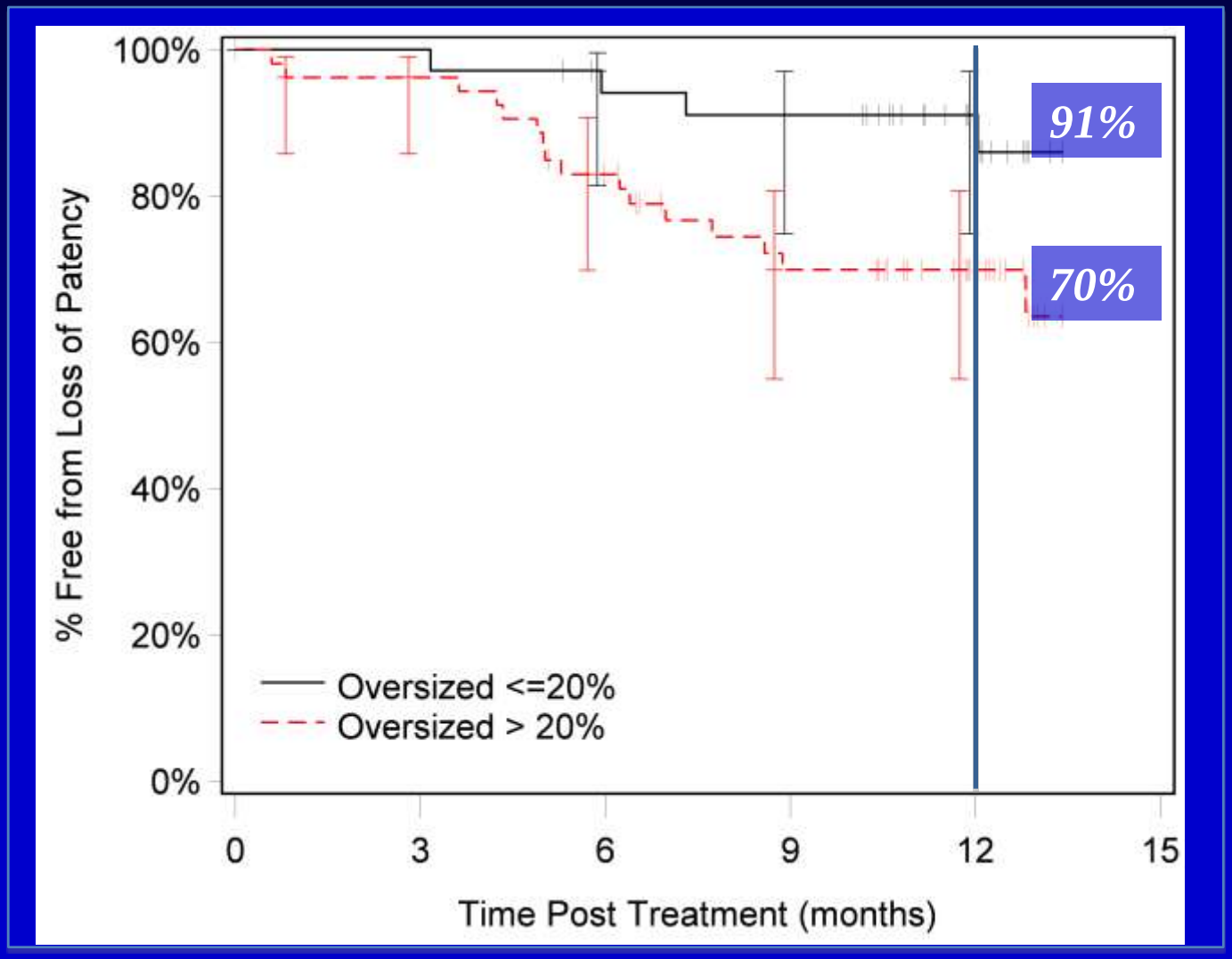
	Gore VIPER Clinical Study
Patients Enrolled	**119**
Treated Occlusions	**56%**
Lesion Length	**19 cm**
Lesion Calcification	
none-mild	**39%**
moderate-severe	**61%**
Tibial Runoff	
1 vessel	**21%**
2 vessel	**33%**
3 vessel	**46%**
Patients Enrolled	**119**

One patient excluded for treatment with device without heparin

One-Year Primary Patency by Subgroup

	Primary Patency
Overall	74%
Device Diameter	
5 mm (n= 23)	79%
6 mm (n= 85)	70%
7 mm (n= 8)	100%
Lesion Length	
≤ 20 cm (n= 68)	75%
> 20 cm (n= 51)	72%
Vessel Diameter at Landing Zone ≥ 4.0 mm by Core Lab (n= 53)	87%

Effects of Device Sizing: Proximal



Evidence based conclusions

- Currently many devices on the market
  - Primary approach for vast majority of patients is endovascular
- PTA/stenting remains the “gold” standard for endovascular therapy of 10-15 cm SFA lesions
  - Current studies tested 5-10 cm
    - SUPERA best in class primary patency at 86%
    - Stroll 3 year patency on par with DES
  - Covered stents at 20cm are >70% primary patency
  - TLR rates in the 90%’s
- Only direct comparator studies will either validate or impugn one device from another
  - All combinations need scientific validation and cost benefit analysis