

MEET 2008

Update in femoral angioplasty & stenting

Will extra-long stents be a solution
for SFA disease ?

PRO

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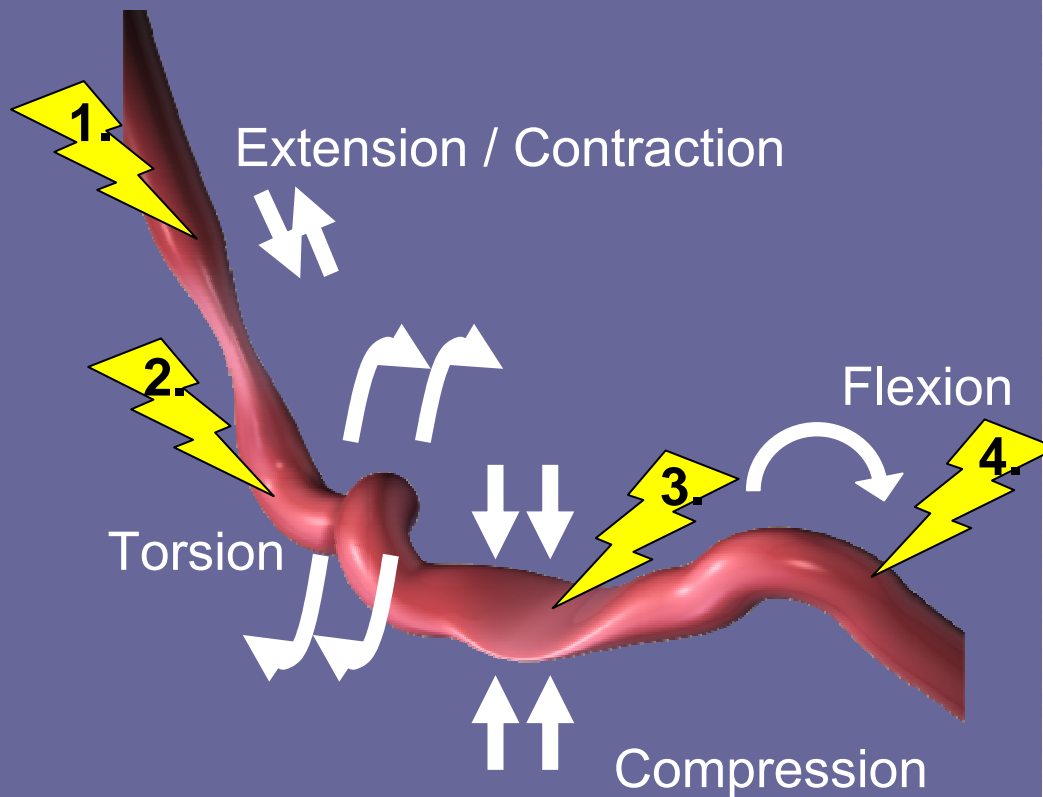
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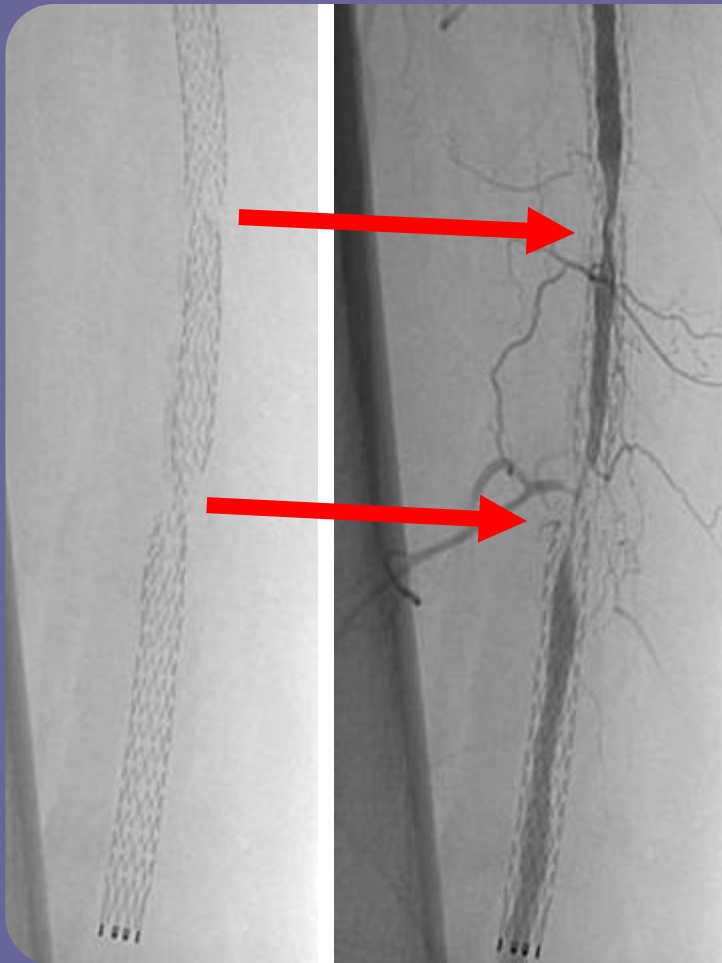
Disclosure statement of financial interest

- I have the following potential conflicts of interest to report:
 - Consulting
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s)
 - I do not have any potential conflict of interest

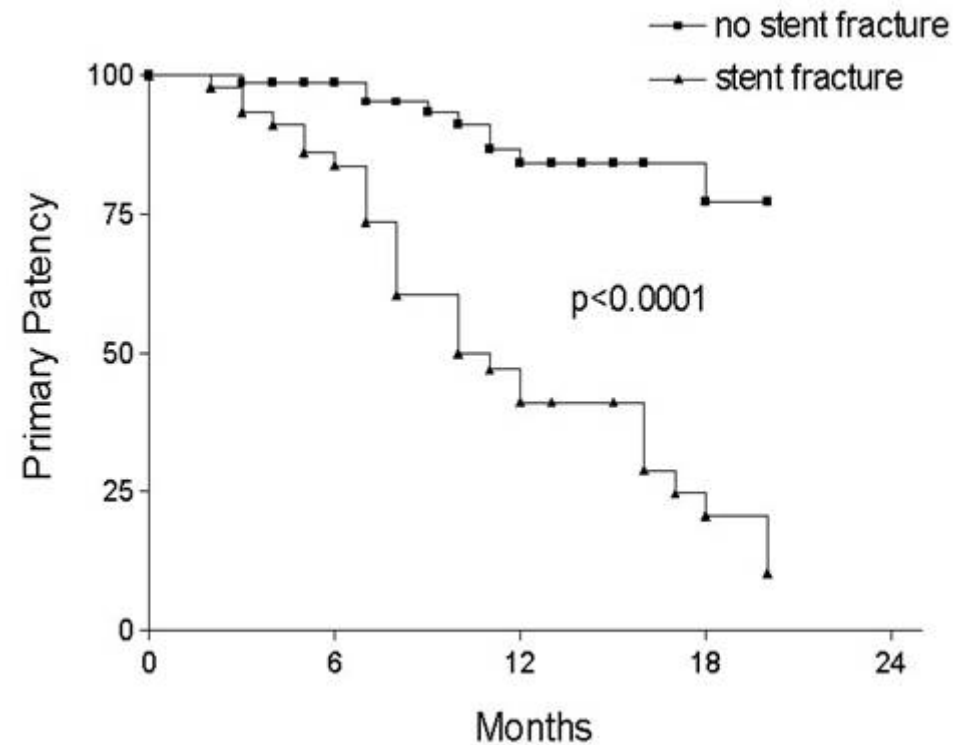
Repetitive motion → material fatigue



Clinical importance of stent fractures



- FESTO database



**We have to
make stents
more
crash-
resistant**

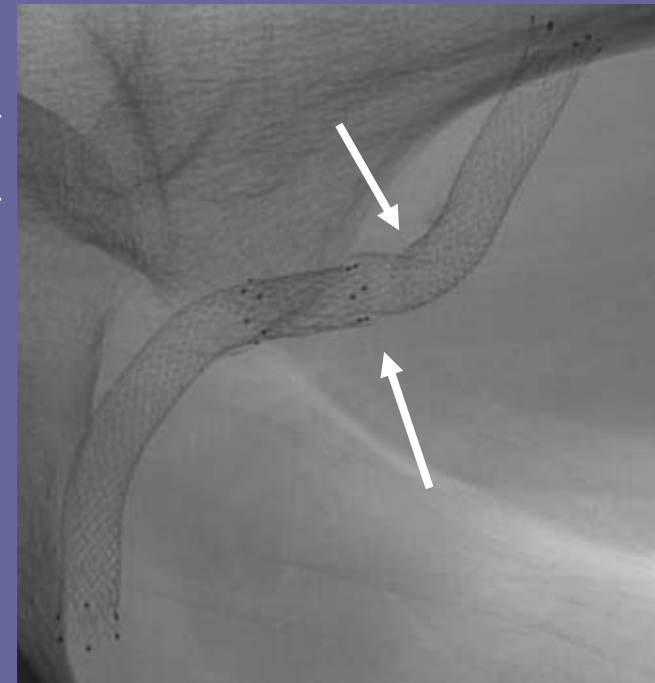


First generation stent design

Issue 1

- Relatively **short length stents**
 - Often stent overlap required to cover total lesion length
 - Increased stiffness + fracture risk at **stent overlap** area

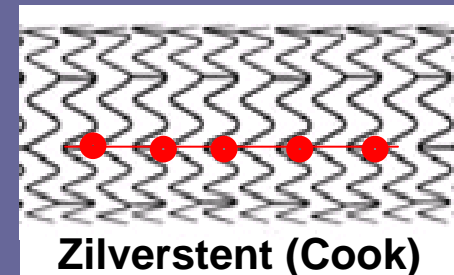
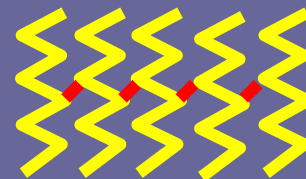
Stent fracture rate	@ 6 M	@ 12 M
SIROCCO I (max 3 stents)	19%	31%
SIROCCO II (max 2 stents)	9%	11%



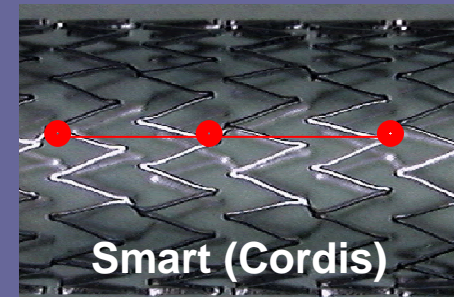
First generation stent design

Issue 2

- Linear stent bridge orientation
 - Stent rings connected with **longitudinally** oriented bridges



Zilverstent (Cook)



Smart (Cordis)



Luminexx (Bard)

PROBLEM 1: No torsion component
PROBLEM 2: All forces grouped on 1 single connection during flexion



weak spot for fracture

First generation stent design

Issue 2

- Linear stent bridge orientation
 - FESTO-trial**

12M data	Stent Fracture	Primary Patency
Smart	26.9%	78%
Self-X	29.2%	60%
Luminexx	53.3%	27%



FAST – Femoral Artery Stenting Trial

Study description

- Prospective, randomized, controlled
 - **PTA vs. Luminexx nitinol stent (Bard)**
- SFA lesions between 1 and 10cm in length
- Only 1 stent per treated lesion
- 91.8% (224/244) claudicants

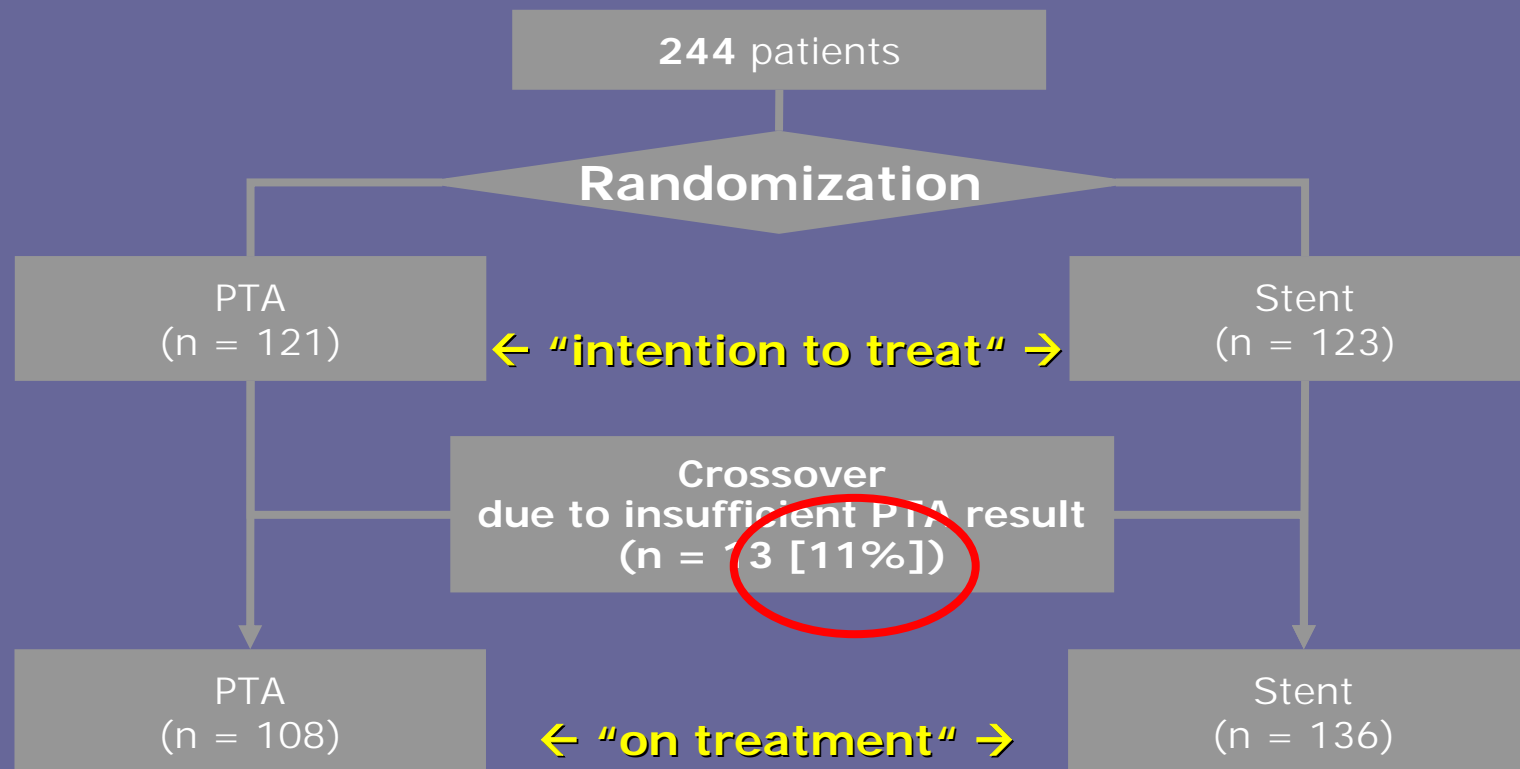


Luminexx stent

	PTA	Luminexx stent	
Average lesion length	4.5cm	4.5cm	not significant
Occlusions	25%	37%	not significant

FAST – Femoral Artery Stenting Trial

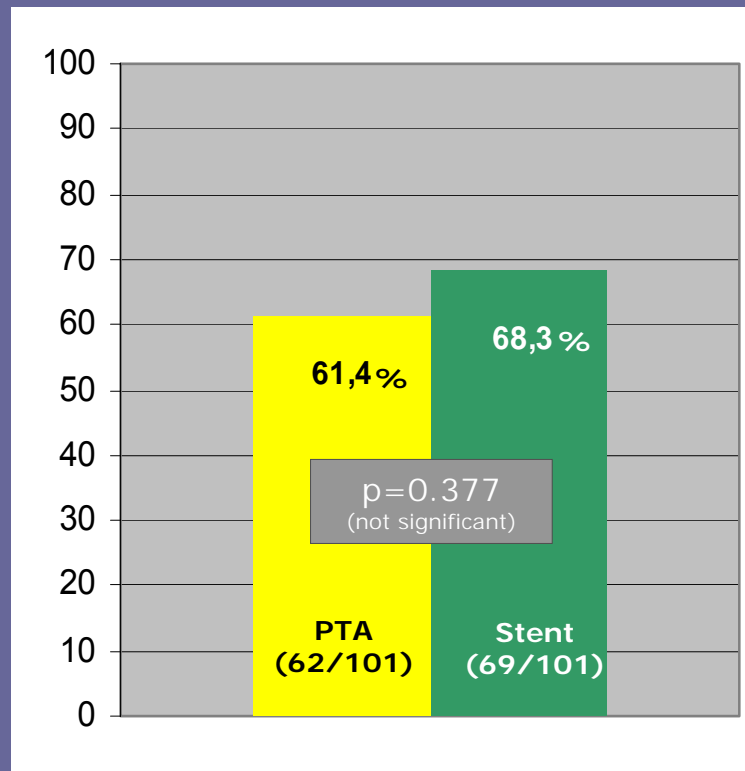
Randomization scheme



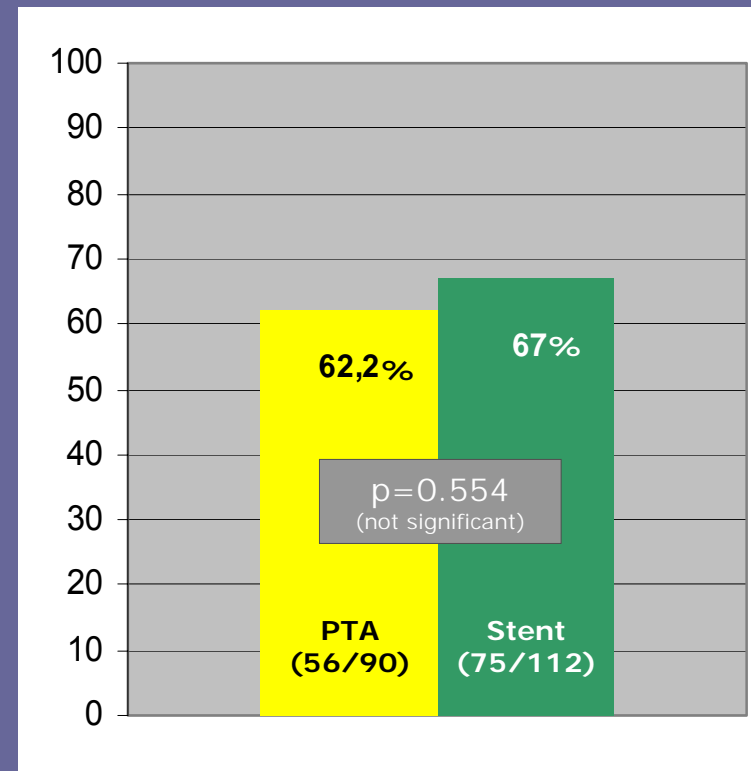
FAST – Femoral Artery Stenting Trial

Primary patency @ 12 months

“intention to treat”



“on treatment”

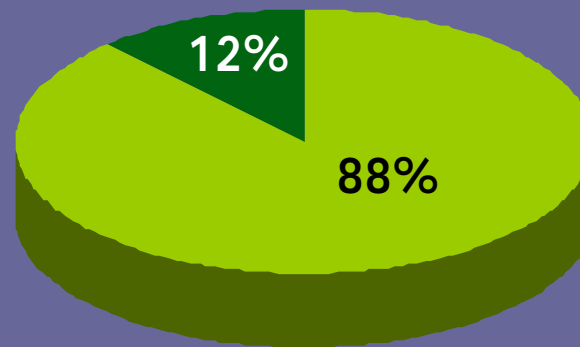


FAST – Femoral Artery Stenting Trial

Stent fracture rate @ 12 months

- Of 101 stent patients remaining after 12M, X-ray performed in 83

Stent Integrity



■ OK (n=73)

■ Fracture (n=10)

Latest generation stent design *Solutions*

**Safety
first**



Latest generation stent design

Solution 1

- Longer stents → less overlapping stents

Everflex
ev3

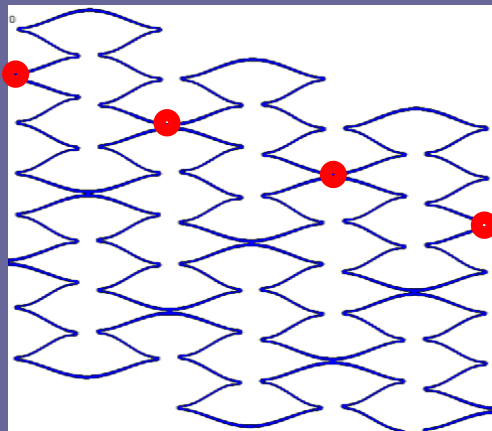
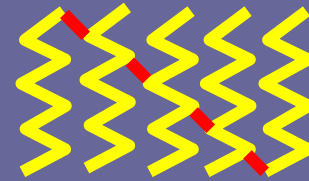


Latest generation stent design

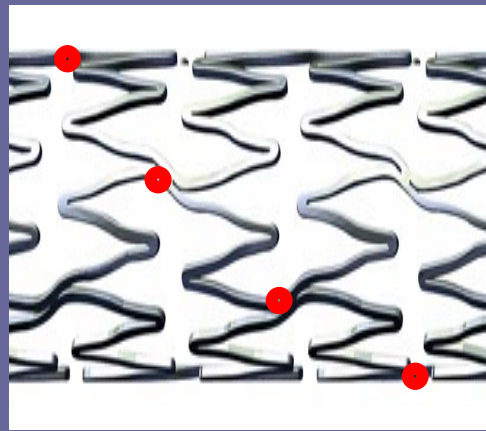
Solution 2

- Helical stent bridge orientation

→ Stent rings connected with **helically** oriented bridges



Everflex
ev3



Astron Pulsar
Biotronik

**Improved
torsion
component**

**In case of
flexion,
improved
force
distribution**

**Where do current SFA studies
lead us to ?**



TASC 2007

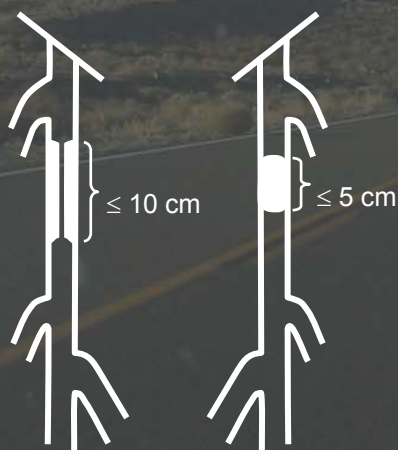
endovascular
therapy

A

=
treatment of choice

lesions

1. Single stenosis ≤ 10 cm in length
2. Single occlusion ≤ 5 cm in length



TASC 2007

endovascular therapy

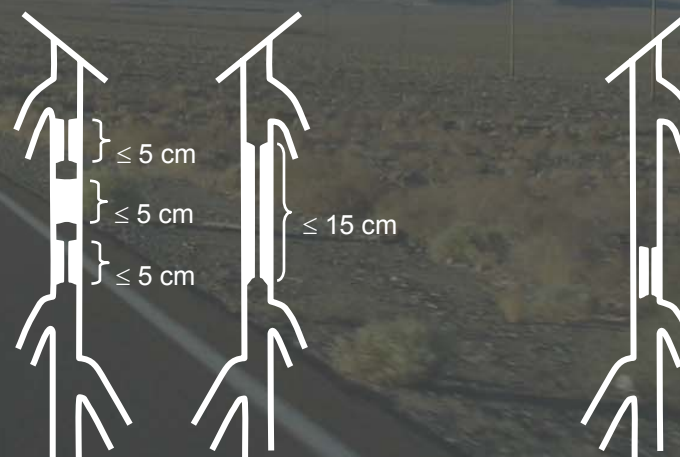
B

=
preferred treatment

*co-morbidities, informed patient preference
and local operator's long-term success
rates must be considered*

lesions

3. Multiple lesions each ≤ 5 cm
4. Single stenosis or occlusion ≤ 15 cm
not involving the infra geniculate popliteal artery
5. Single or multiple lesions
in the absence of continuous tibial vessel €
to improve inflow for a distal bypass
6. Heavily **calcified** occlusion ≤ 5 cm long
7. **Single popliteal stenosis**



Resilient trial

Study description

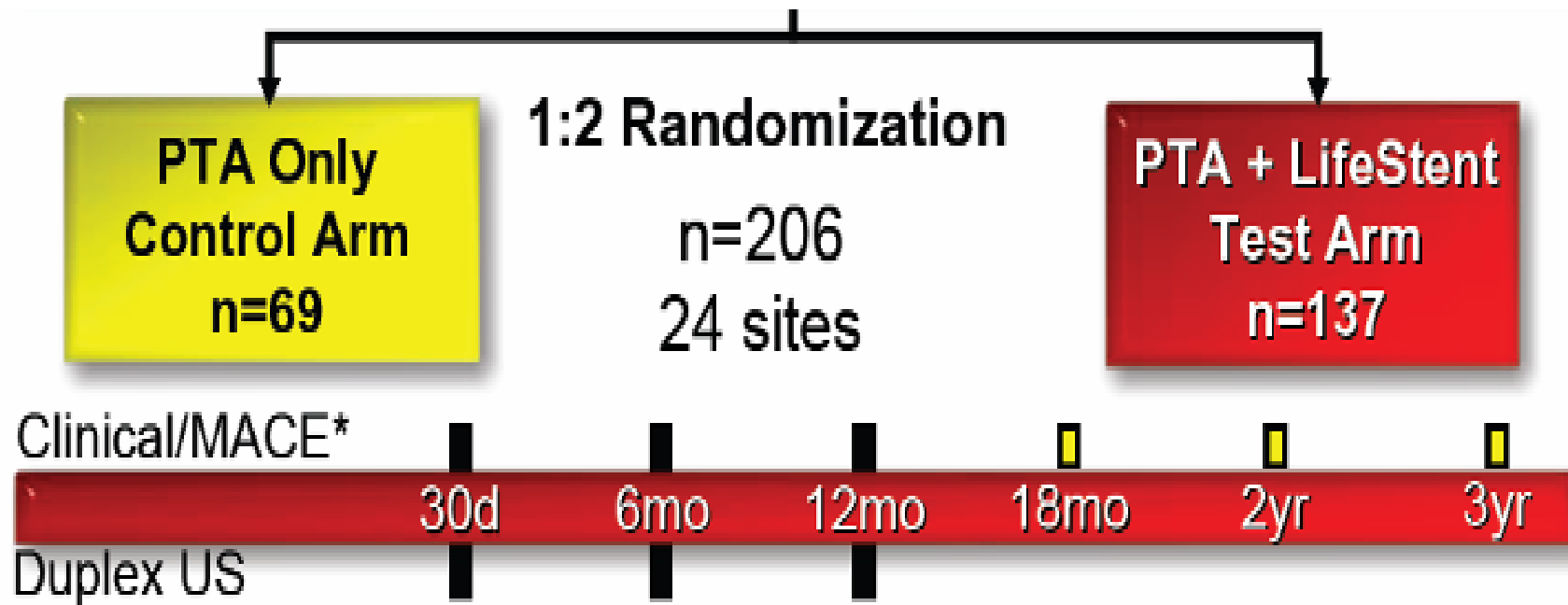
- Prospective, randomized, controlled
 - **PTA vs. triple helix nitinol Lifestent**
(Edwards - Bard)
- Femoro-popliteal lesions with length <150mm
- Only claudicants (Rutherford 1-3)



	PTA	Lifestent	
Average lesion length	6.4cm	7.1cm	not significant

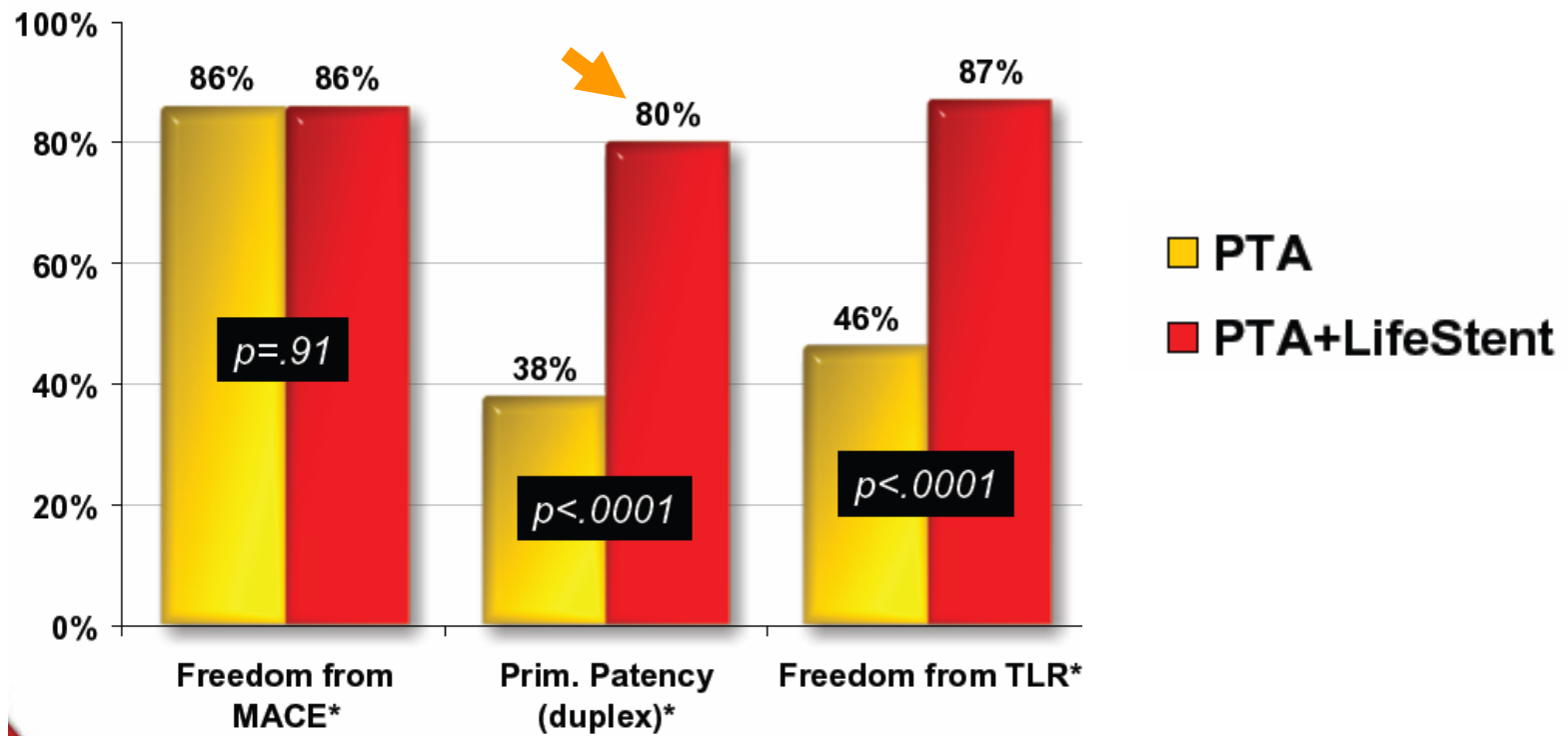
Resilient trial

Randomization scheme



Resilient trial

12-month results



MACE = major adverse coronary event / TLR = target lesion revascularisation

Resilient trial

Stent fracture rate @ 12-month

Fracture Type	Total 0-12 months	2 or more overlapping stents	Stent Elongation at deployment
Type I	4	1 of 4	1 of 4
Type II	-	-	-
Type III	-	-	-
Type IV	5	4 of 5	5 of 5

FRACTURE RATE
2.9%

MACE = major adverse coronary event / TLR = target lesion revascularisation

Absolute Vienna trial

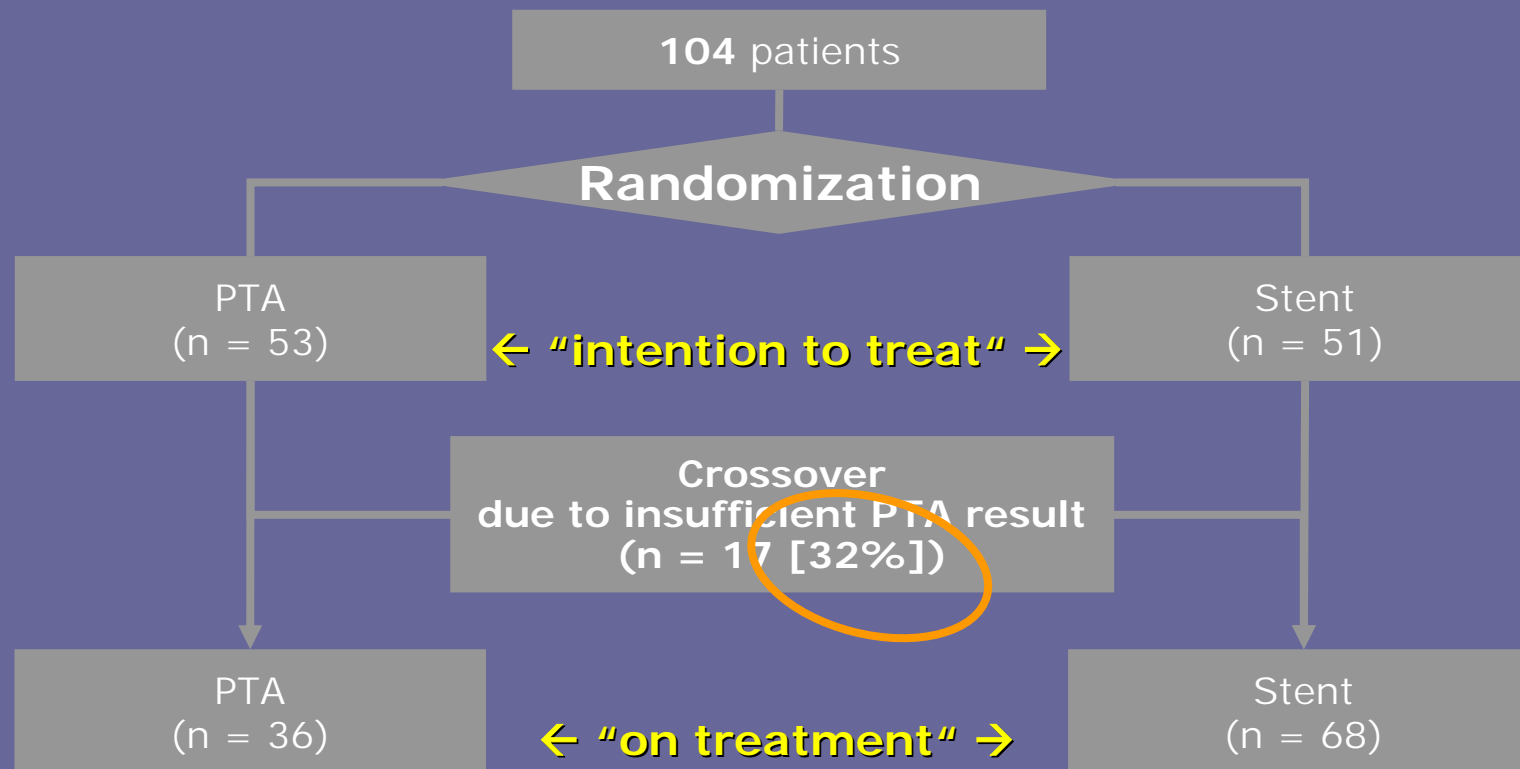
Study description

- Prospective, randomized, controlled
 - **PTA vs. Absolute nitinol stent (Abbott Vascular)**
- SFA lesions <150mm
- 87.5% (91/104) claudicants (Rutherford 3)

	PTA	Absolute	
Average lesion length	12.7cm	13.2cm	not significant
Occlusions	32%	37%	not significant

Absolute Vienna trial

Randomization scheme



Absolute Vienna trial

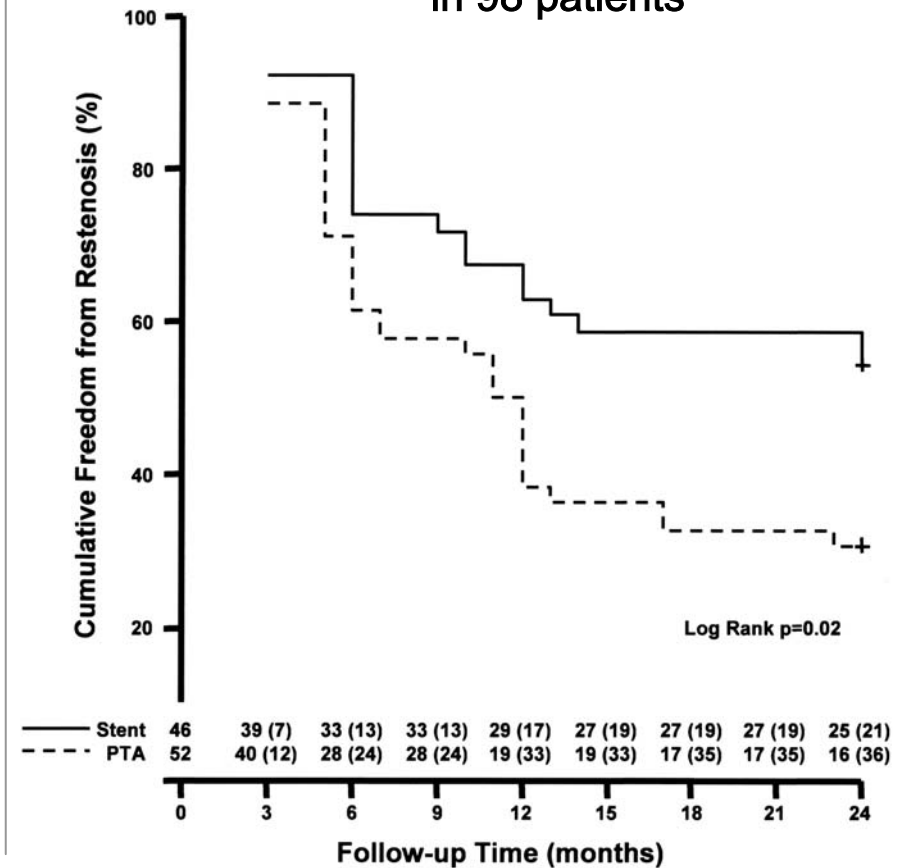
2-YEAR RESULTS

(intention-to-treat)

- Patency rates
 - Stent : 54.3%
 - PTA : 30.8%

$P=0.03$
- Fracture rate : 2.0%

Freedom from restenosis (>50%)
in 98 patients

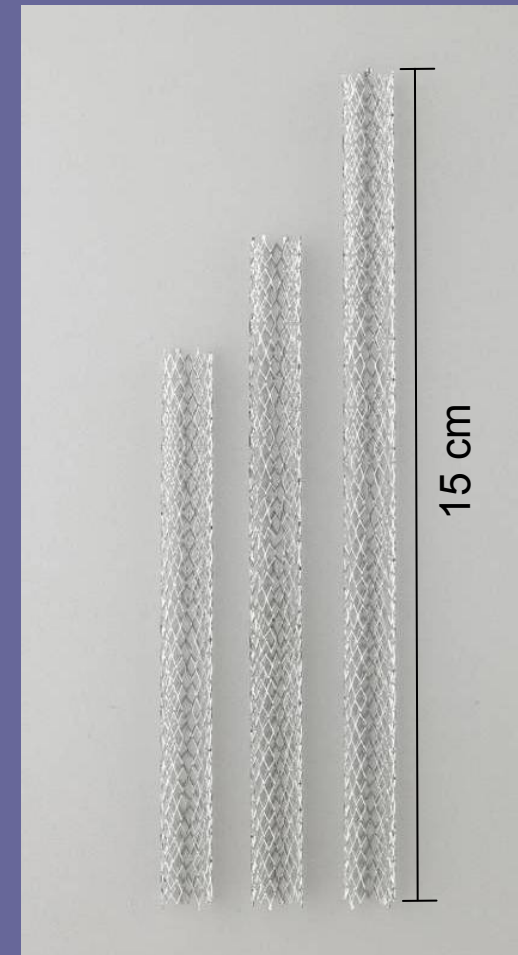


Durability trial

Study description

- Prospective, non-randomized, controlled
 - **Protégé Everflex stent (ev3)**
- FIRST TRIAL WITH LONG STENTS (100 – 120 – 150 mm)
- SFA lesions <140mm
- 86.1% claudicants

- Mean lesion length : 96.4mm
- Occlusions : 46% of lesions



Durability trial

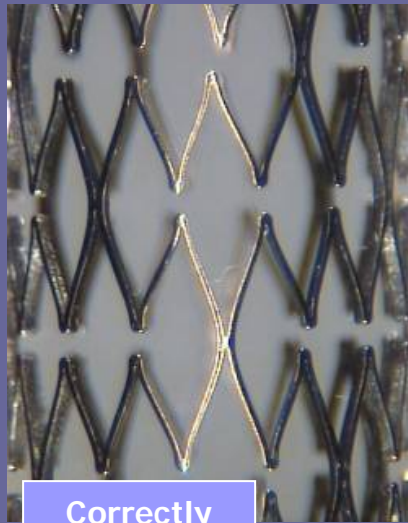
Results @ 6 months

	Stent
6M patency (duplex)	91%
6M fracture rate	6%

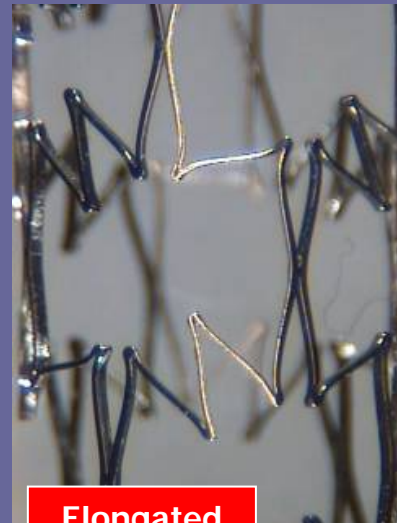
7 out of 8 (88%) fractures occurred in stents elongated at deployment

Durability trial

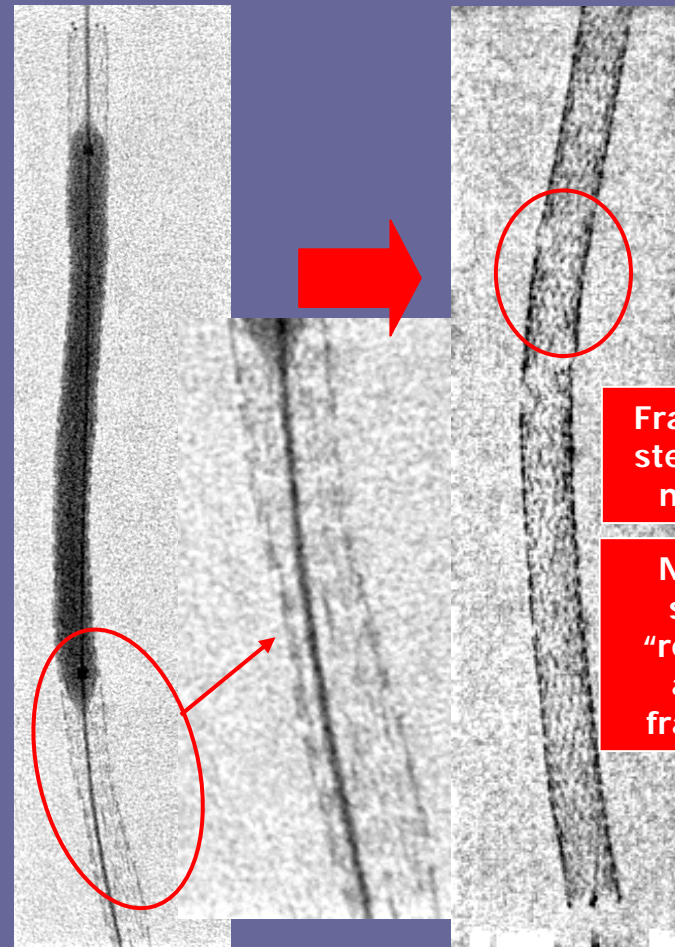
Stent Elongation/Fracture



Correctly
deployed
Stent



Elongated
stent at
implant



Fractured
stent at 6
month

Notice
stent
"recoils"
after
fracture

Lessons learned on stent fractures

- Single long stent +++
- Helical oriented design +++
- Stent elongation during deployment ---



TASC 2007

C

lesions

surgery =
preferred for good
risk patients

*co-morbidities, informed patient preference
and the local operator's long-term success
rates must be considered*

- Multiple stenoses or occlusions totaling **> 15 cm** in length, with or without heavy calcification
- Recurrent stenoses or occlusions that need treatment after two endovascular interventions



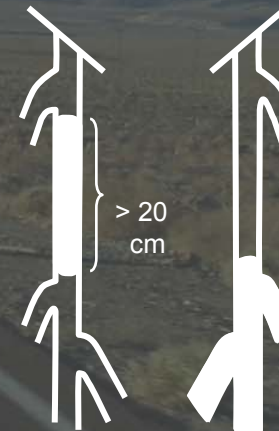
TASC 2007

D

lesions

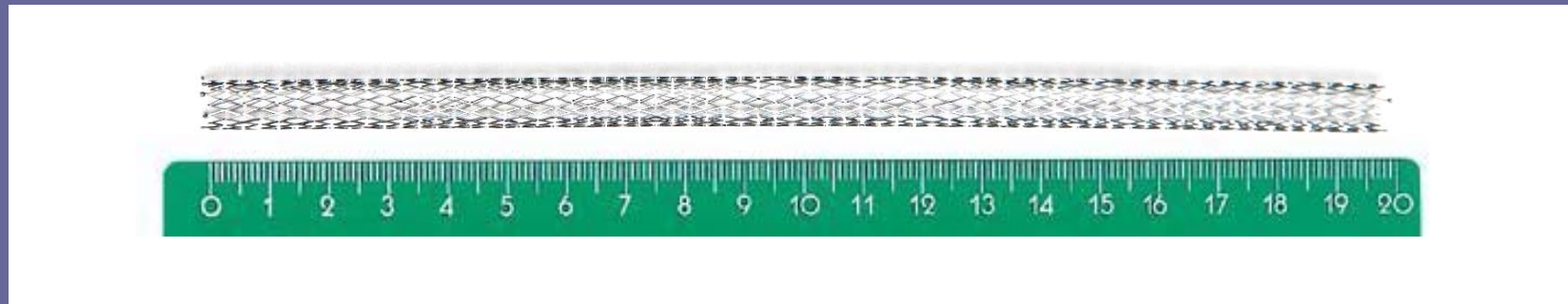
surgery
=
treatment of choice

- Chronic total occlusion of the CFA or SFA > 20 cm, involving the popliteal artery
- Chronic total occlusion of popliteal artery and proximal trifurcation vessels



Upcoming trial : Durability-200

- Phase 2, non-randomized European trial
- 100 patients
- Fempop lesions above 150mm
- 20cm long Everflex Protégé stents (ev3)
- Rationale : less overlap zones will improve results



Upcoming trial : Cook Zilver PTX



To evaluate safety and effectiveness of DES (**paclitaxel** coated stent) technology versus PTA

Clinical Trial

- Over 1000 patients in 89 sites in USA, Asia, Latin America, Canada & Europe
 - Randomized arm : 240 PTA vs. 240 DES (enrollement ongoing)
 - Non-randomized arm : 550 DES (enrollment complete)
- Lesion length up to 28cm

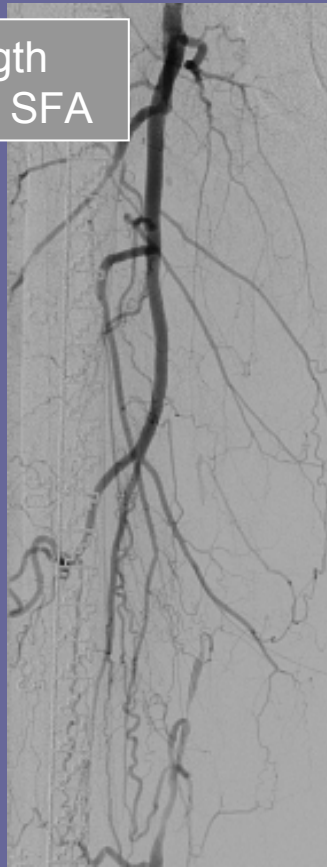
Preliminary results (DES patient group)

	@6M	@12M
Event-free survival rate	94%	84%
Freedom of TLR	96%	88%

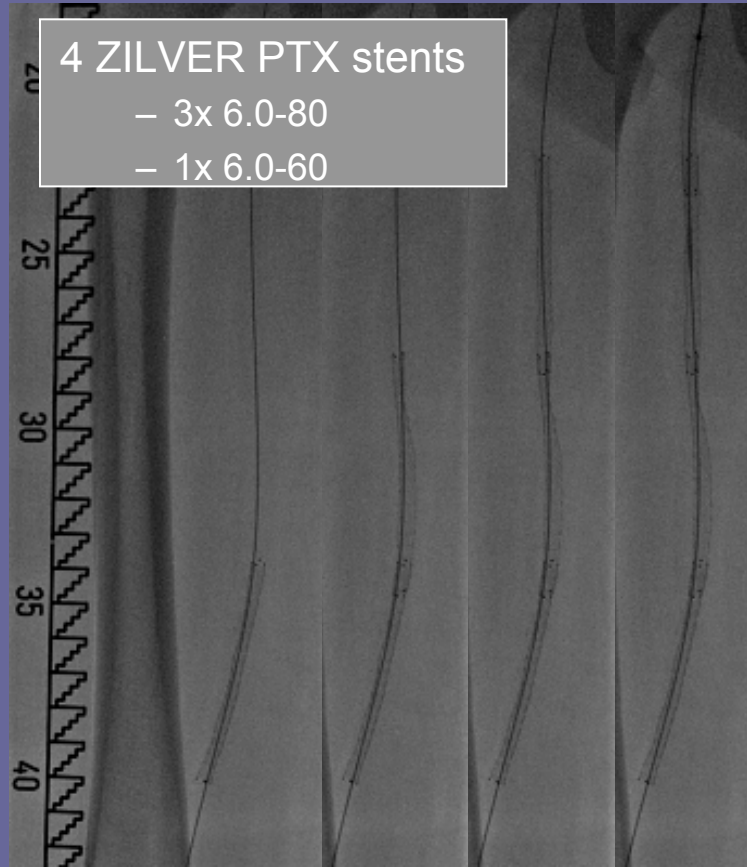
Upcoming trial : Cook Zilver PTX

Example case

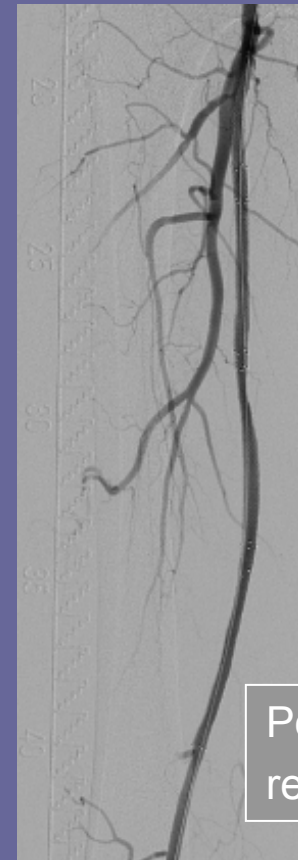
Pre-op full length
occlusion right SFA



4 ZILVER PTX stents
– 3x 6.0-80
– 1x 6.0-60



Post-op
result



Upcoming trials : Durability-200

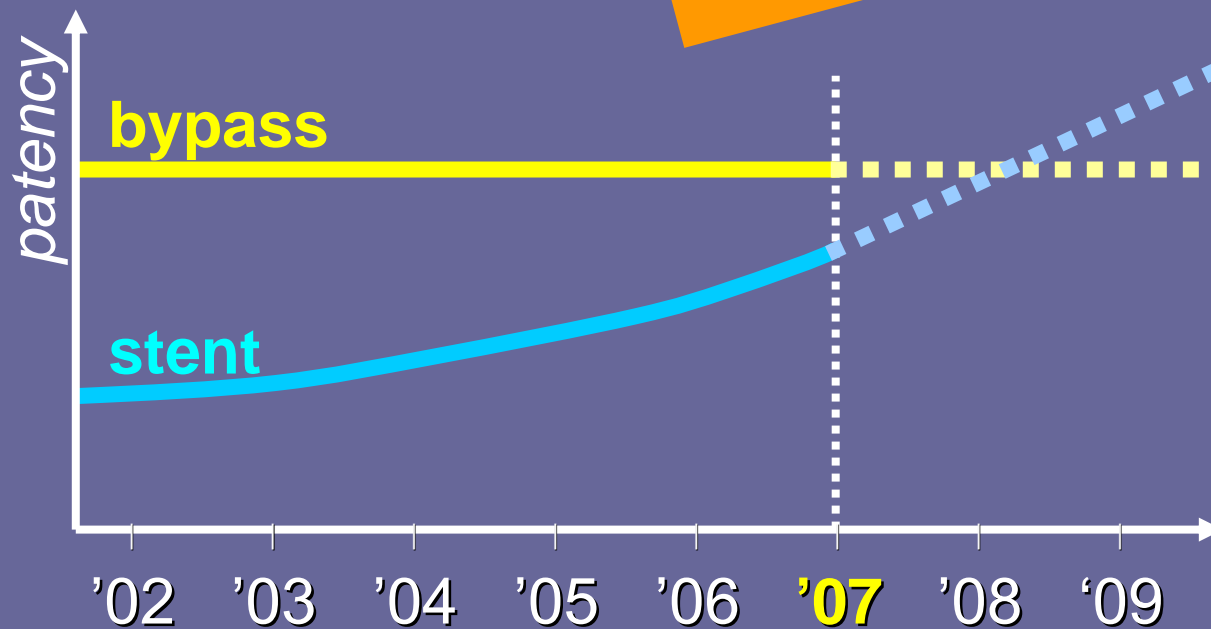
→ awaiting clinical evidence
FOR LONG LESIONS

Current treatment strategy
for long-segment SFA lesions (TASC C & D)
in the Imelda Hospital, Bonheiden, Belgium :

Conclusion

TASC A = PTA + bail-out
TASC B = Primary stenting
TASC C&D = SURGERY

New stent designs
&
active coatings



Conclusion

Will we be able
to treat
ALL SFA
lesions
endovascularly ?

