DURABILITY

StuDy measURing the durABility of the PROTÉGÉ EverFlex stent In Leslons of the Superficial Femoral ArTerY

On behalf of the DURABILITY Investigators:

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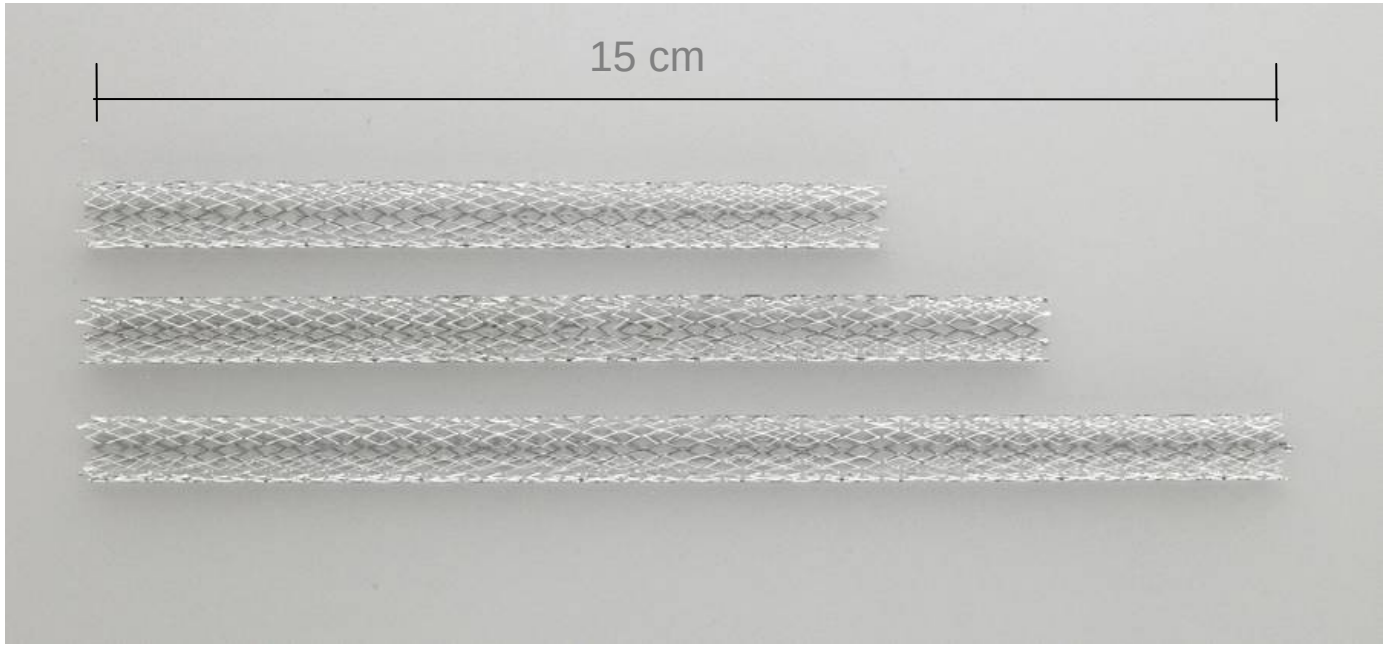
Purpose

DURABILITY I

Study measuRing the durAbility of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral ArTery

- to evaluate the long term efficacy and integrity of the long PROTÉGÉ™ EverFlex™ stent (10-15cm) in long SFA lesions



Study Design

DURABILITY I

Study measuRing the durABility of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral ArTery

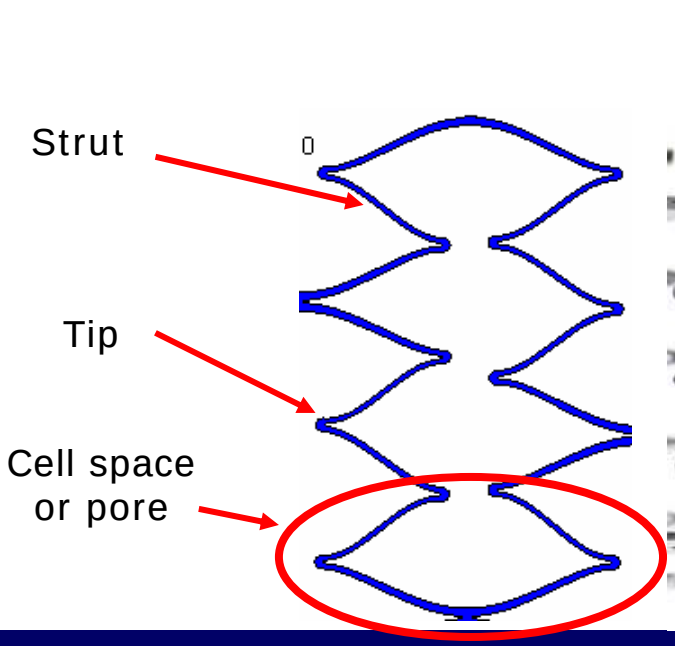
- Prospective
- 151 Patients (August 2006 – June 2007)
- 13 centres in Europe
- 6 & 12 months follow-up
- Core lab for Angio, Duplex, X-Ray

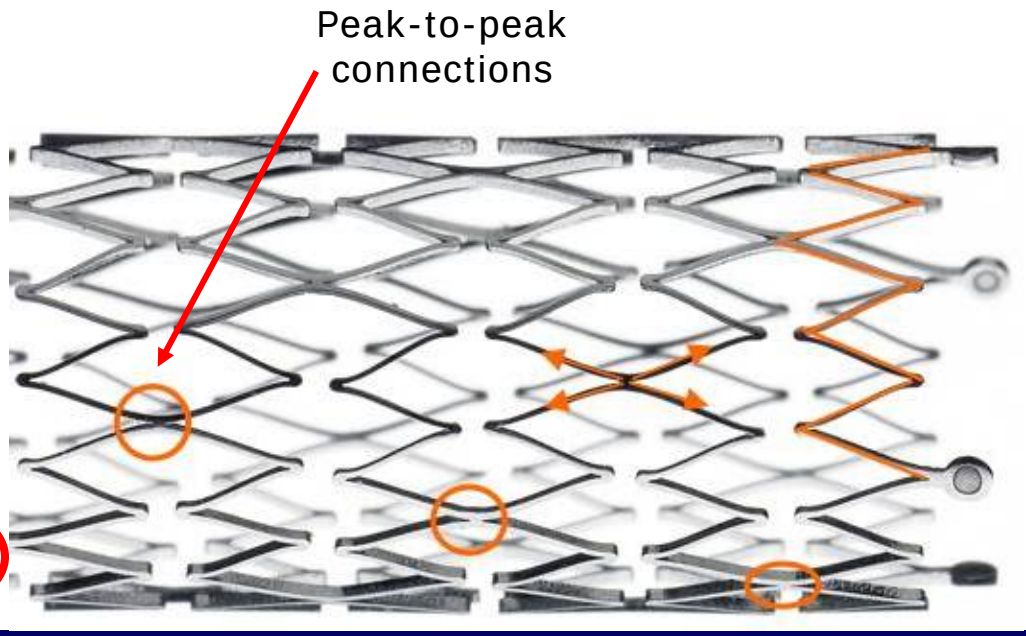
Study Device

DURABILITY I

Study measuRing the durAbility of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral ArTery

- ev3 PROTÉGÉ EverFlex Stent System
  - Self-expanding Nitinol stent
  - Spiral cell interconnection
  - GPS tantalum markers
  - EX.P.R.T. Release Technology
- Stent Diameters 6,7,8 mm
- Stent Lengths 100, 120, 150 mm
- Now available in 200mm





Endpoints

DURABILITY I

Study measuRing the durABility of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral Artery

- Primary Primary patency at 12 months

  Target vessel with <50% diameter stenosis determined by Duplex ultrasound (PSV>2.5)

- Secondary

  Technical success

  Initial arteriographic success

  Follow up clinical success

  Primary Patency at 6 months

  Secondary Patency at 6 and 12 months

  Fracture rate as determined by X-ray at 6 and 12 months

  Major Adverse Clinical Events

Patient Population

DURABILITY I

Study measURing the durABility of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral ArTery

- De-novo or restenotic lesions
- Max. lesion length **140** mm
- Stent lengths **100**, **120** and **150** mm
- Only one stent allowed
- Rutherford classification **2** to **4**
- Target lesion located within the native SFA: Distal point 3 cm above knee joint and 1 cm below origin of profunda femoralis
- Angiographic evidence of at least one vessel runoff to the foot

Demographics (n=151)

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Study measuRing the durABIlity of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral ArTerY

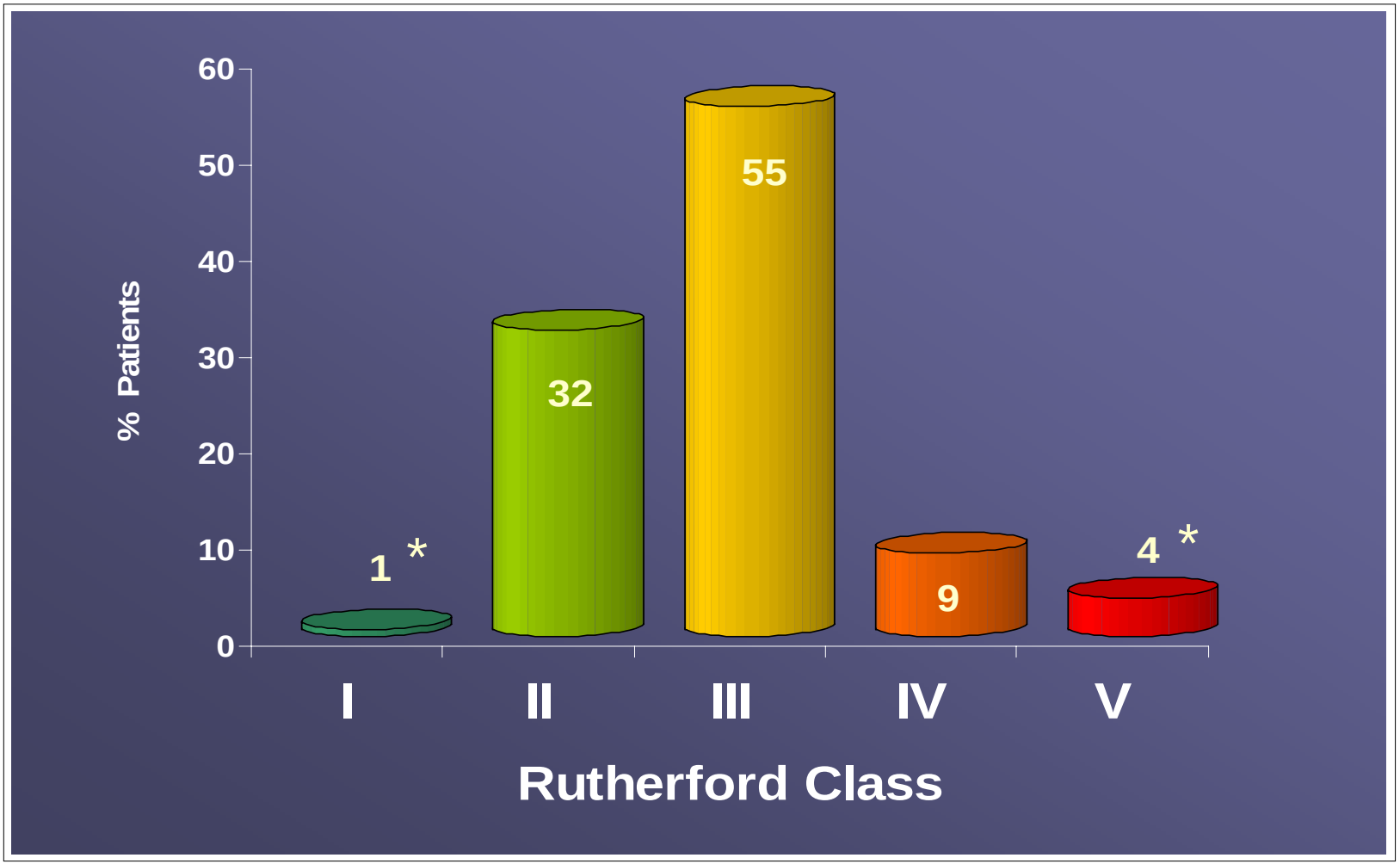
Age	68 ± 8
Body Mass Index	27 ± 4.3
Male / Female	74% / 26%
Diabetes	46%
Smoking	56%
Hypertension	80%
Hyperlipidemia	67%
Angina	25%
Stroke	9%
MI	23%

Target Lesion Characteristics

DURABILITY I
Study measURing the durABility of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral ArTerY

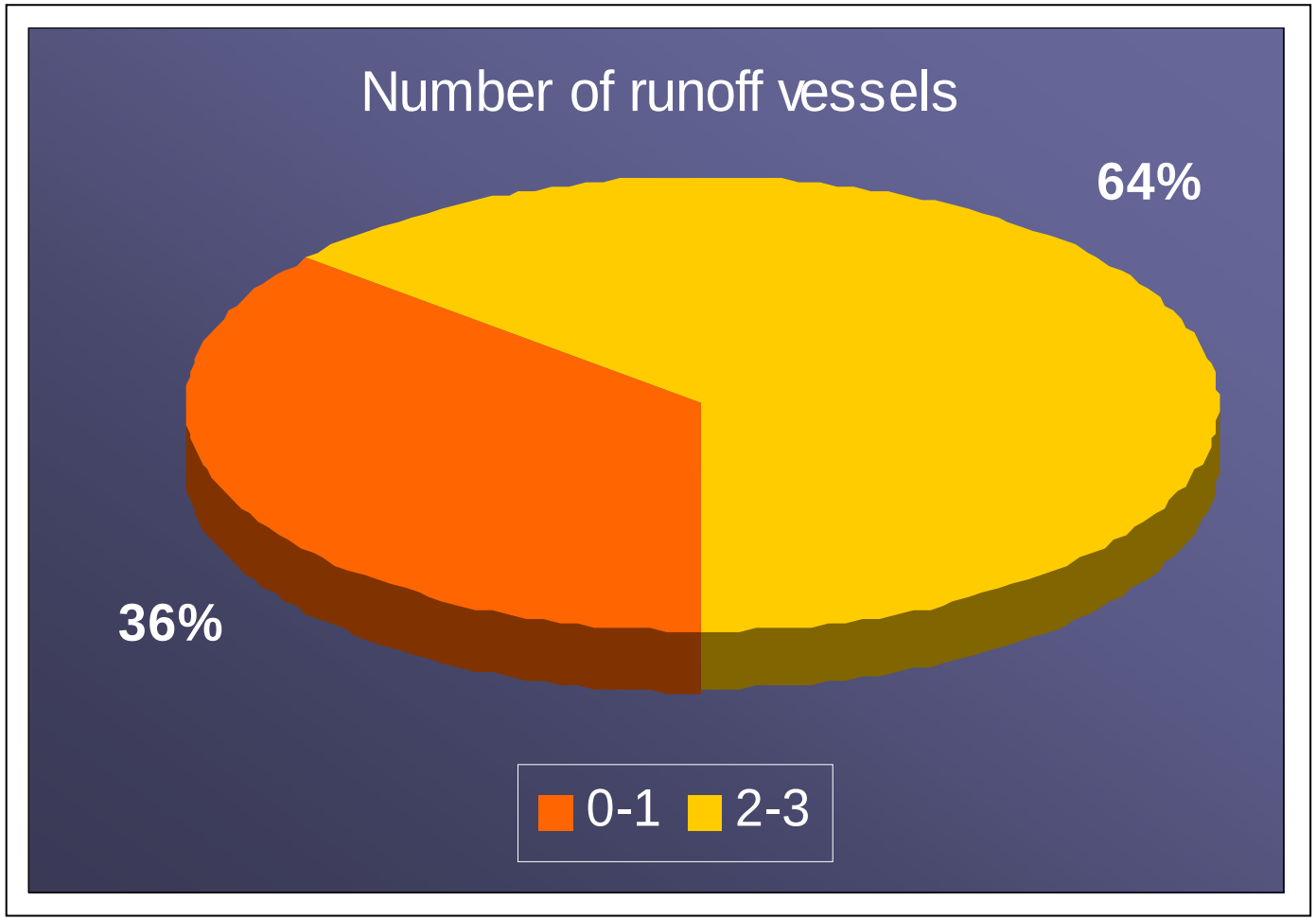
Mean Lesion Length (mm)		96.4 ± 26.8
Lesion Diameter Stenosis (%)		92.7 ± 10.1
MLD (mm)		0.56 ± 0.83
RVD (mm)		5.5 ± 0.70
Total Occlusions (% of lesions)		46%
Diffuse Disease		80%
Eccentric Lesion		55%
Calcified Lesion	*Moderate*	29%
	None	56%
	Not Evaluable	15%

Rutherford Class



* Protocol violation

Run-off



Procedure Details

DURABILITY I
Study measURing the durABility of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral ArTerY

- 151 patients, 161 stents
- Stented length 134 ± 29 (mm)
- 100% technical success
  Ability to cross target lesion with device and deploy the stent as intended
- Single stent in 141 patients (93%)
  - 100 mm: 28%
  - 120 mm: 18%
  - 150 mm: 47%
- Second stent in 10 patients (7%)

Dissection	4
Residual stenosis proximal or distal to stent	3
Protocol violation	3
Stented length range 160-240 mm	

6 Months Follow-up

DURABILITY I

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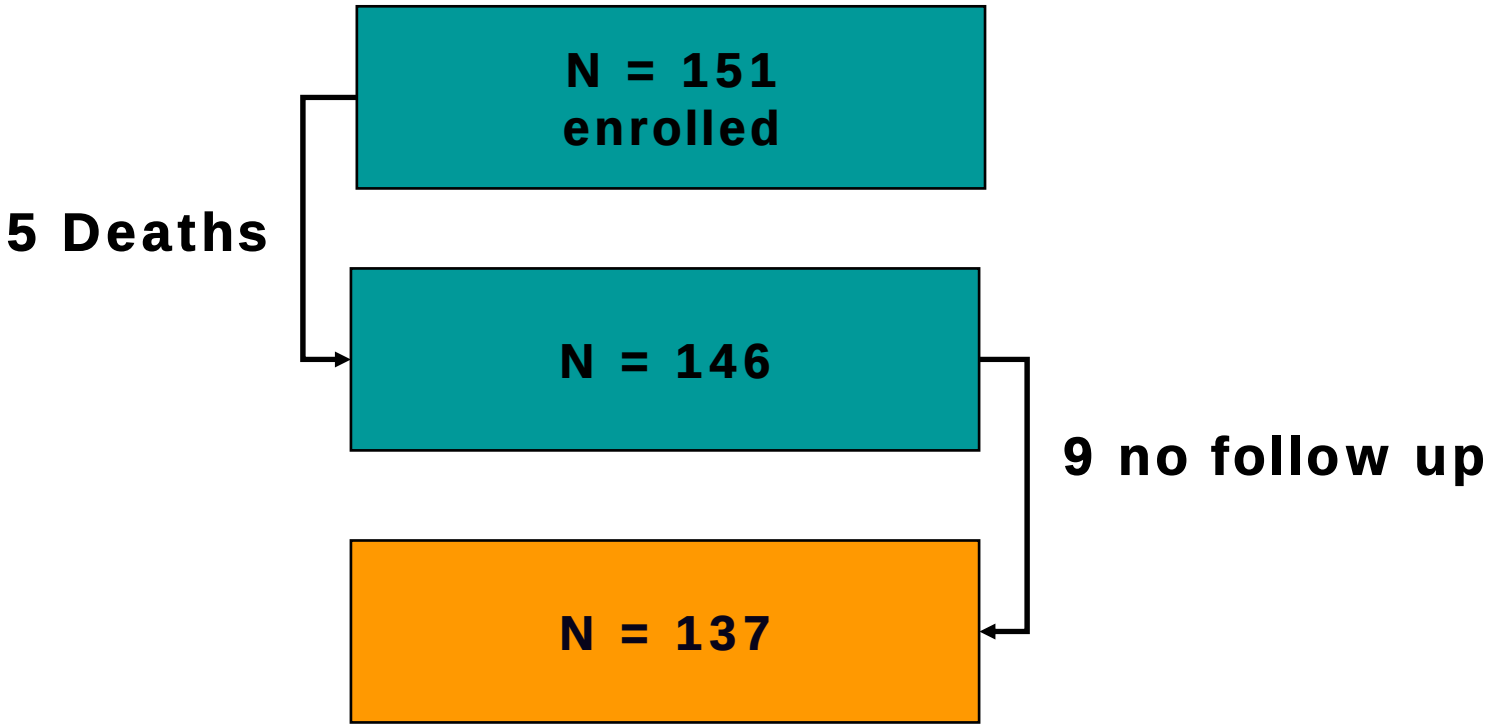


6 Months Results (n=137)

DURABILITY I

Study measuring the durability of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral Artery

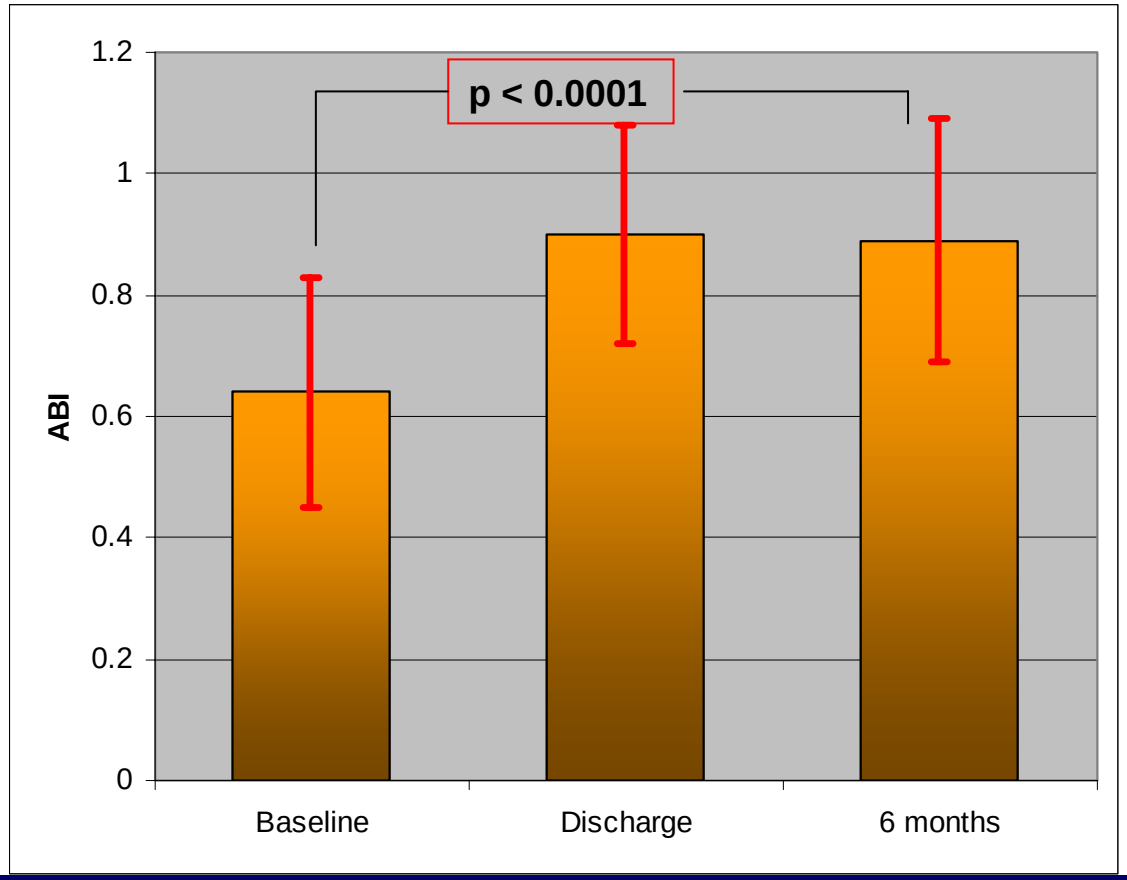
Primary Patency	91% [1]
Secondary Patency	100%
Freedom from TLR	94%
Freedom from TVR	93%

[1] n=126 duplex images available for core lab evaluation

6 Months Results

DURABILITY I
Study measuRing the durAbility of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral ArTerY

	Baseline	Discharge	6-month	p-value
ABI	0.64 ± 0.19	0.90 ± 0.18	0.89 ± 0.20	P<0.0001



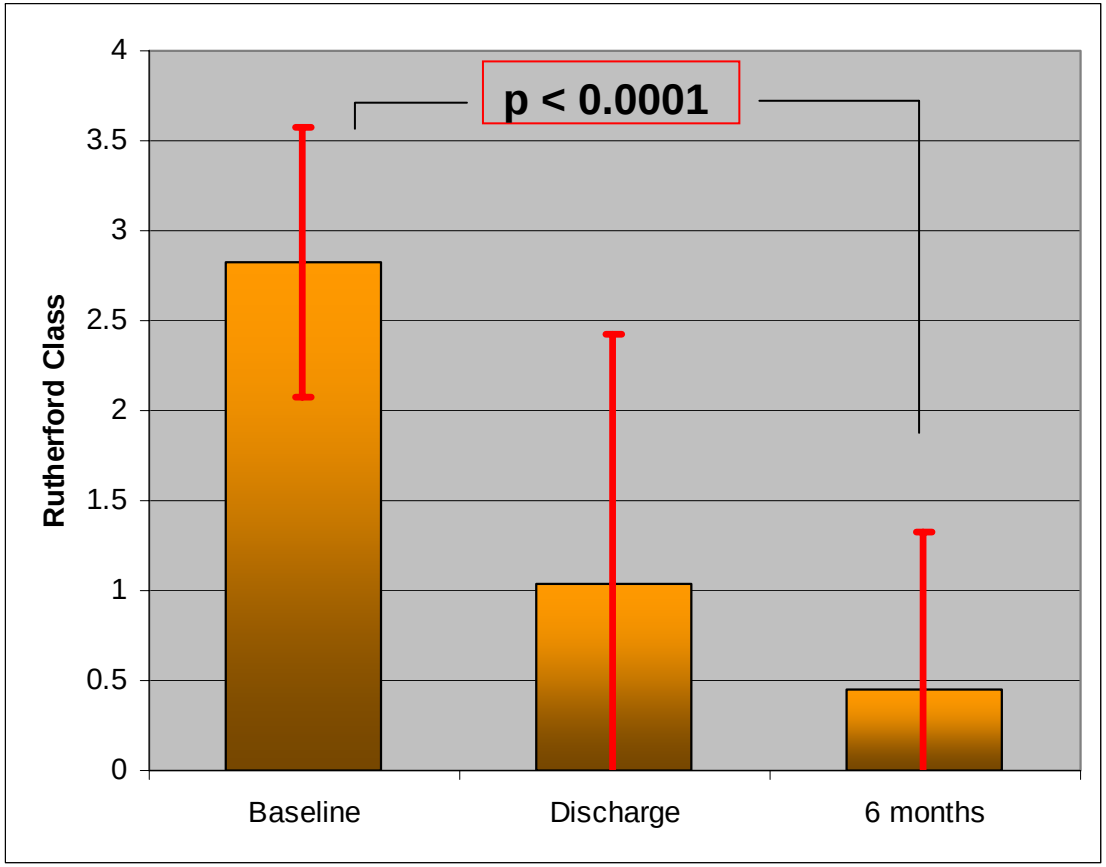
ABI improvement from baseline to 6 months

0.26 ± 0.22

6 Months Results

DURABILITY I
Study monitoring the durability of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral Artery

	Baseline	Discharge	6-month	p-value
Rutherford	2.83 ± 0.75	1.04 ± 1.38	0.45 ± 0.87	P<0.0001



Rutherford improvement from baseline to 6 months

2.16 ± 1.21

6 Months Results

DURABILITY I
Study measuRing the durABility of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral ArTery

Fracture Rate per patient [1]	**6.2%**	**8**/129 [2]
Mild	1.6%	2
Moderate	2.3%	3
Severe	2.3%	3

[1] Core Lab Analysis

[2] 151 patients; for 14 patients no x-ray done, 3 non-evaluable, 5 deaths

Stent Fracture Analysis

DURABILITY

Study measuRing the durABility of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral ArTery

Site	Number of fractures	% stents fractured vs. implanted	Elongated >20%
1	**0**	**0**	
2	**0**	**0**	
3	**0**	**0**	
4	**0**	**0**	
5	**0**	**0**	
6	**0**	**0**	
8	**0**	**0**	
9	**0**	**0**	
10	6	40	6
11	**0**	**0**	
12	1	**5**	1
13	1	**5**	0
TOTAL	8	6	7

75%

Stent Elongation/Fracture

DURABILITY I

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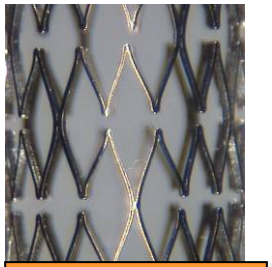
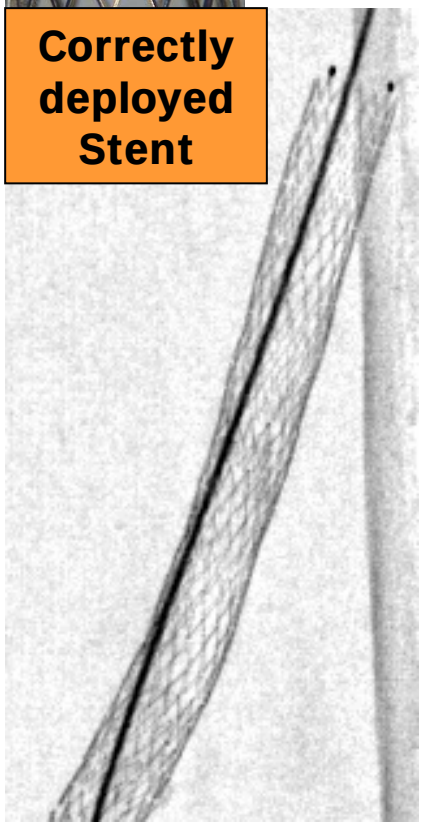
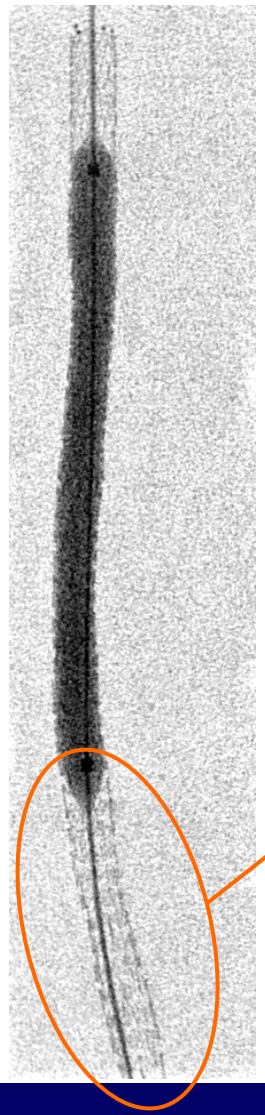
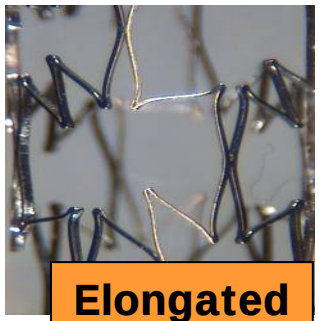


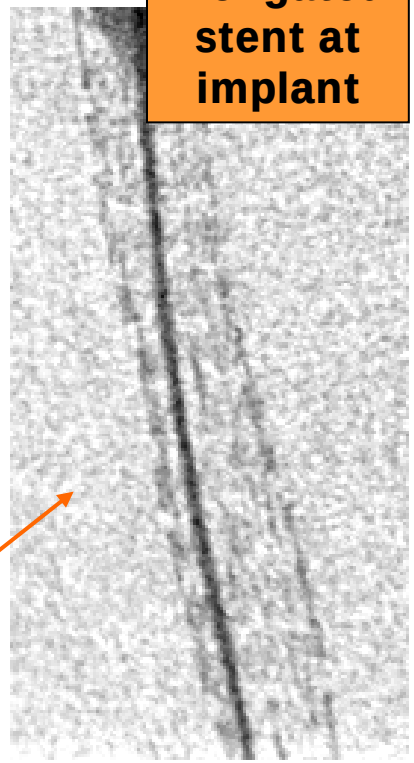
Correctly deployed Stent

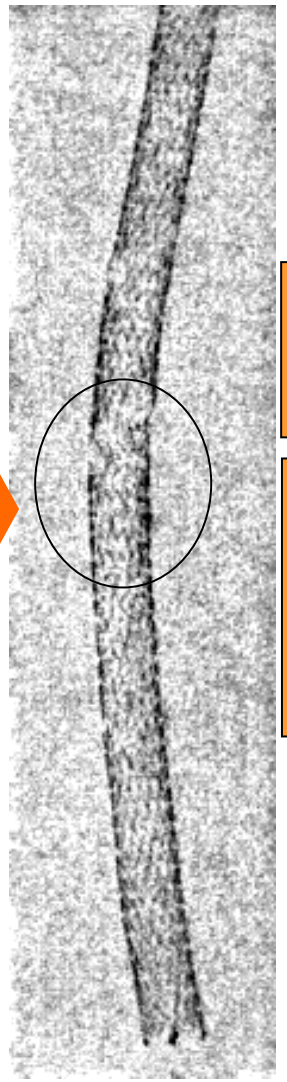






Elongated stent at implant





Fractured stent at 6 month

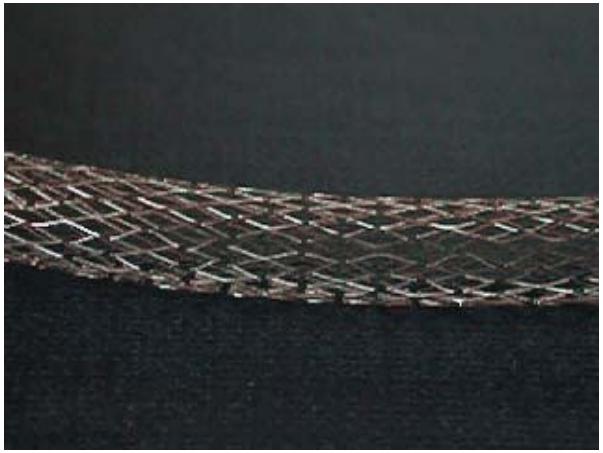
Notice stent “recoils” after fracture

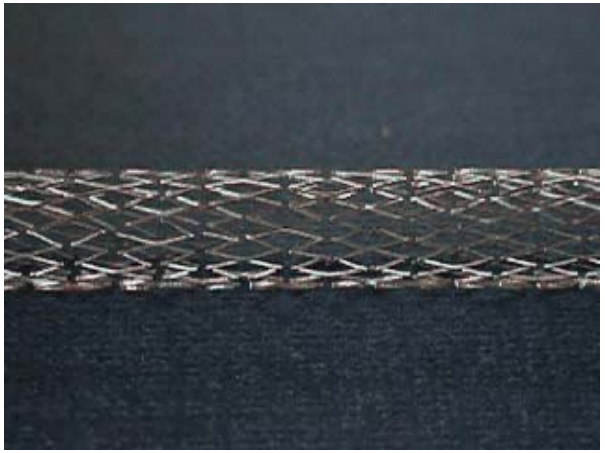
Fracture Analysis

DURABILITY I
Study measuRing the durABility of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral ArTerY

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

- 8 fractures
  - 5 patent (mild and moderate) — no TLR
  - 3 not patent (all severe) — 3 TLR





Testing Long Stents in Challenging Lesions

DURABILITY I
Study measuRing the durAbility of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral ArTerY

Parameter	DURABILITY I	RESILIENT	SCIROCCO	SCHILLINGER
Lesion length (mm)	96.4	61.8	81.4	96.4
Diabetics (%)	46	38	39	38
Rutherford 3 (%)	55	57	53	87
Rutherford 4 (%)	9	0		3
Rutherford 5 (%)	4	0	0	10
0 or 1 runoff vessels (%)	36	NA	NA	18
Total occlusions (%)	46	17	67	35
Stent lenghts (cm)	10-15	4-8	8	10

What have we learned?

DURABILITY

Study measuRing the durABility of the PROTÉGÉ EverFlex stent in Lesions of the Superficial Femoral Artery

- From SIROCCO and FESTO:
  - Correlation between overlap, fractures, patency, lesion length
  - Stent design matters
- From RESILIENT and DURABILITY
  - Elongation of stent at deployment compromises durability
- From DURABILITY
  - Single long stents are a viable alternative to multiple shorter stents

Conclusions

- The first evaluation of long stents in a challenging patient population shows that treatment with the EverFlex stent results in:
  - High patency rates 91%
  - Low fracture rates 6%
- Elongation during deployment needs to be avoided
- Long stents are a cost-effective treatment in the SFA