Long Superficial Femoral Artery Stenting With SuperA® Interwoven Nitinol Stents

STELLA SuperA trial one-year clinical outcome

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ClinicalTrials.gov Identifier: NCT03020290
PI: Prof. Yann Gouëffic

Disclosure

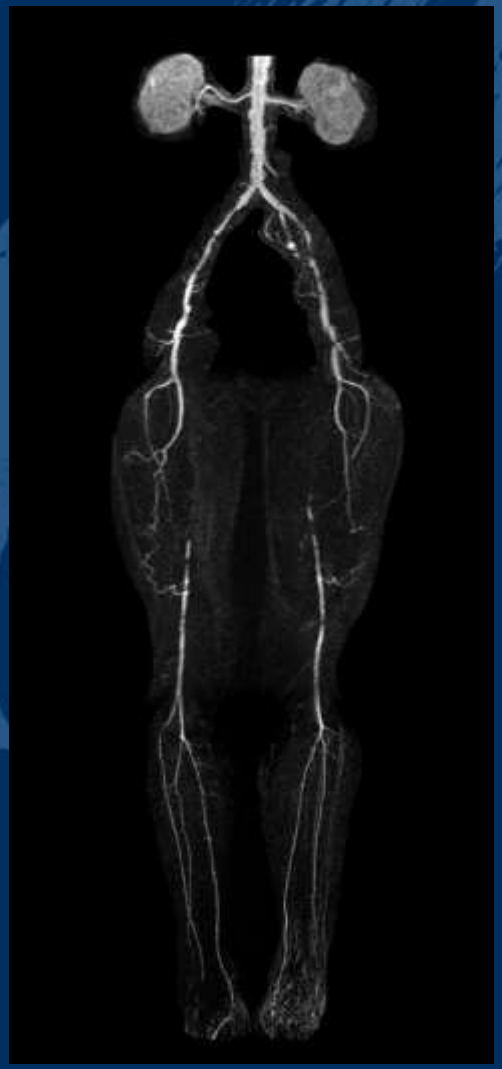
Speaker name: Yann Gouëffic

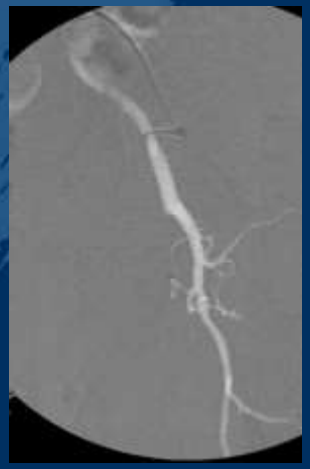
Y. Gouëffic reports:

- **Research funding** from Bard, Medtronic, Terumo, WL Gore

- **Personal fees and grants** from Abbott, Bard, Biotronik, Boston Scientific, Medtronic, Terumo, Vygon, WL Gore (medical advisory board, educational course, speaking)

Long femoropopliteal lesions: challenging cases





>15-cm
Popliteal involvement
De novo - restenosis
Calcifications

CLI by alteration of the re-entry

Entry / Re-entry
Intra and subintimal
Long balloons - stents

ESC-ESVS guidelines

Recommendations	Class[a]	Level[b]
In patients who are not at high risk for surgery, bypass surgery is indicated for long (i.e. ≥25 cm) superficial femoral artery lesions when an autologous vein is available and life expectancy is >2 years.[314]	I	B
The autologous saphenous vein is the conduit of choice for femoro-popliteal bypass.[284,315]	I	A
When above-the-knee bypass is indicated, the use of a prosthetic conduit should be considered in the absence of any autologous saphenous vein.[284]	IIa	A
In patients unfit for surgery, endovascular therapy may be considered in long (i.e. >25 cm) femoro-popliteal lesions.[312]	IIb	C

[a] Class of recommendation.
[b] Level of evidence.
[c] These recommendations apply for patients with intermittent claudication and severe chronic limb ischaemia.

Eur J Vasc Endovasc Surg, 2017

Evidence for long femoropopliteal lesions

	DURABILITY 200	STELLA	STELLA ptx	Zilver ptx registry	DCB vs DES	DEB-SFA-LONG	DES-SFA-IONG	VIASTAR	SUPERB
Devices	BMS Everflex*	BMS Lifestent£	DES Zilver PTX&	DES Zilver PTX&	DCB v.DES In.Pact Admiral* v Zilver ptx&	DCB In.Pact Admiral *	DES Eluvia° (Bosto Sc)	CS v. BMS Viabhan#	CS v bypass Viabhan#
Design	PR	PR	PR	PR	RR (propensity score)	PR	PR	RCT	RCT
Treated limbs, (n)	100	62	48	135	131/97	105	62	72/69	63/62
Claudicant, (%)	71	40.3	58	NA	81/91.7	89.5	52	86/82	67.7/61.9
Mean treated lenght, (cm)	24.2±	22±16	25.2±9	22.6	19.4±8.6 19.5±6.4	25.1±7.1	20±12 cm	18.9.8±6.3 17.32±6.6	23.6±7.1 23.3±8.3

*Medtronic; £ Bard; ° Boston Scientific; # WL Gore; $ Supera; PR: prospective registry, RR: retrospective registry; RCT: randomized clinical trial; BMS: bare metal stent; DES: drug eluting stent; DCB: drug coating balloon; CS: covered stent

Bosiers, J Vasc Surg, 2011; Davaine, Eur J Vasc Endovasc Surg, 2012 ; Davaine, Eur J Vasc Endovasc Surg, 2012; Bosiers, J Cardiovasc Surg, 2013; Zeller, J Endovasc Ther 2014; Micari, A JACC interv, 2015; Lammer, JACC, 2013; Reijnen, JACC interv , 2017; Bisdas, Jacc Interv 2018

STELLA trials

	STELLA	STELLA ptx
Devices	BMS Lifestent[£]	DES Zilver PTX[&]
Design	PR	PR
Treated limbs, (n)	62	48
Claudicant, (%)	40.3	58
Mean treated lenght, (cm)	22±16	25.2±9

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Treated limbs, (n)	62	48
Claudicant, (%)	40.3	58
Mean treated lenght, (cm)	22±16	25.2±9
Patency rate at 1-year (%)	66	52.5
CD-TLR at 1 year (%)	18.2	36.4

Davaine, Eur J Vasc Endovasc Surg, 2012 ; Davaine, Eur J Vasc Endovasc Surg, 2012;

£ Bard; & Cook; PR: prospective registry, BMS: bare metal stent; DES: drug eluting stent; CD-TLR: clinically driven target lesion revascularization stent

STELLA SuperA®

Prospective single center registry for long superficial femoral artery stenting with SuperA® Interwoven nitinol stents

Nantes University hospital

PI: Prof. Yann Gouëffic

From December 2016 to October 2018

Patients were asked to give their oral authorization to participate in the study by their surgeon.

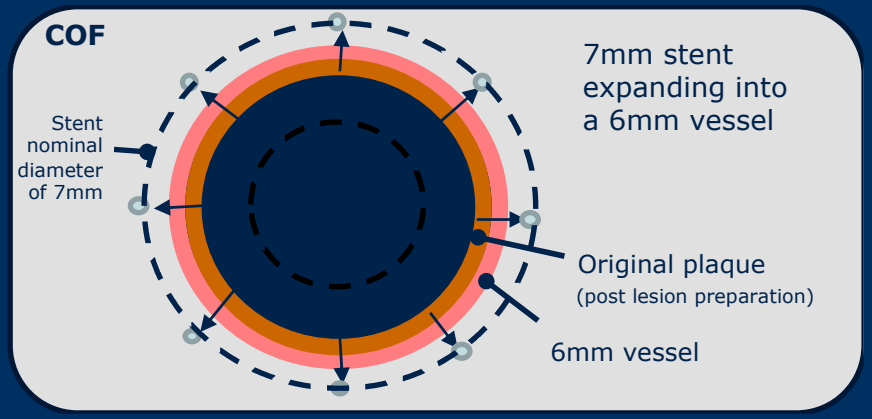
Pre-operative exams were collected

Patient were followed in the study during 2 years.

Sponsor Nantes university hospital
STELLA SuperA® ClinicalTrials.gov number, NCT03020290

SuperA® stent (Abbott)

The SuperA® bio-mimetic vascular stent incorporates a wire interwoven nitinol biomimetic stent



SuperA®, a low COF stent*, could decrease in-stent restenosis and improve patentcy rate ?

*Test(s) performed by and data on file at Abbott.

Objectives

To evaluate safety and efficacy of implantation of SuperA® Interwoven nitinol stents for TASC C and D SFA atherosclerotic lesions at 12 months in a prospective single center registry for long superficial femoral artery stenting with

Primary endopoint

Primary sustained clinical improvement @ 12mo

(improvement by at least 1 Rutherford stage or healing of all skin lesions and resolution of ischemic rest pain + no need of repeated TLR in surviving patients)

Secondary endpoints

Morbi-mortality rates, MACE, Major amputations, ABI, ISR, TLR, TER, Stent fracture

Patients

Inc. criteria

- Age > 50 yo
- De novo atheromatous stenosis
- Rutherford stages 2,3,4,5 and 6
- TASC C-D lesions
- Guidewire had passed through the target lesion
- Written informed consent

Ex. criteria

- Restenosis
- No atheromatous disease
- Asymptomatic lesion
- Life expectancy < 1 year
- Pregnancy
- Patient involved in another trial
- Refusing patient
- No written informed consent

Follow - up

- Clinical research agents

- Clinical and duplex scan examinations

(1, 3, 6, 9 and 12 months)

- Bi-plane X-ray @ 12 months

Procedures

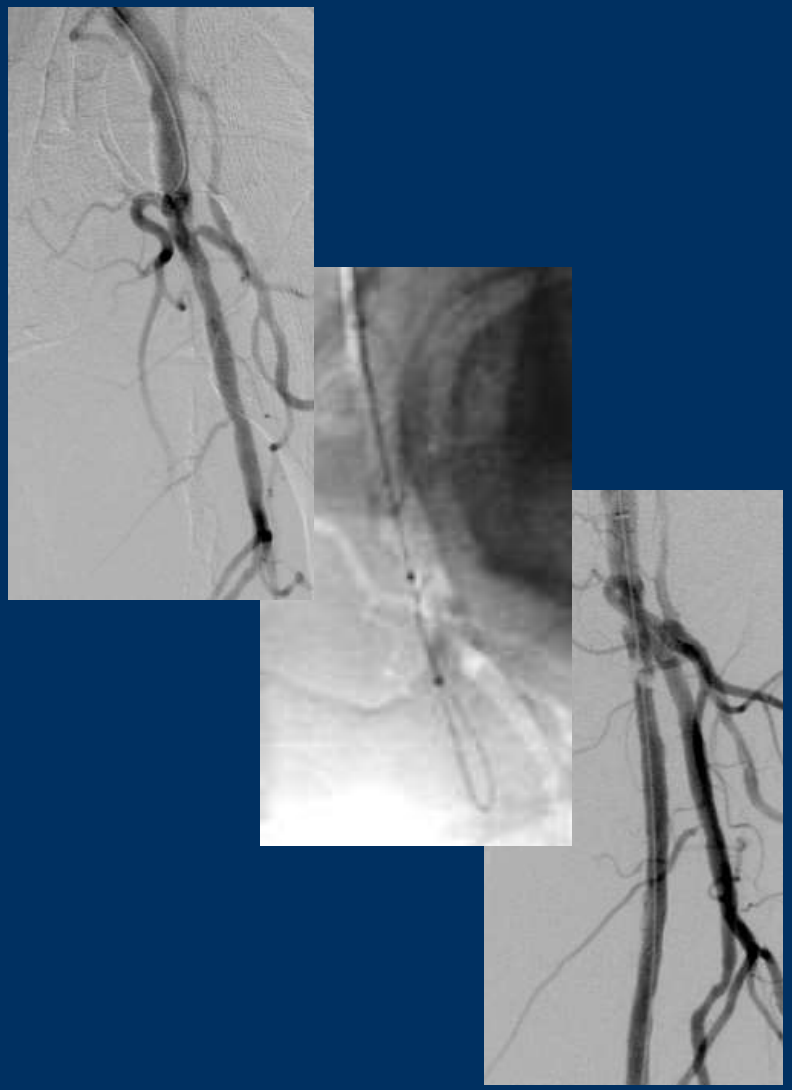
Local anaesthesia + sedation

Antegrade/cross over approach

Vessel preparation (3mn with a balloon of 0.5mm diameter more than the SuperA to be implanted)

Stenting (SuperA®)

DAPT for 6 months



Flow chart

48 patients

- 3 deaths
- 2 withdrawal consent

43 Visits M12

No patient was lost of follow-up

48 patients - 49 limbs

Age (y):	71.9 ± 10 yo
Sex ♂ n (%)	39(81.2%)
Dyslipidemia n (%)	25 (52.1%)
BMI (kg/m²)	25.8 ± 4.1
Renal insufficiency n (%)	6(12.5%)

Critical limb ischemia: 29%

Intermitent claudication: 71%

Lesions and intraoperative results

Cross over: 93.9%

SUPER A stent: n=94

Other stents: n=10

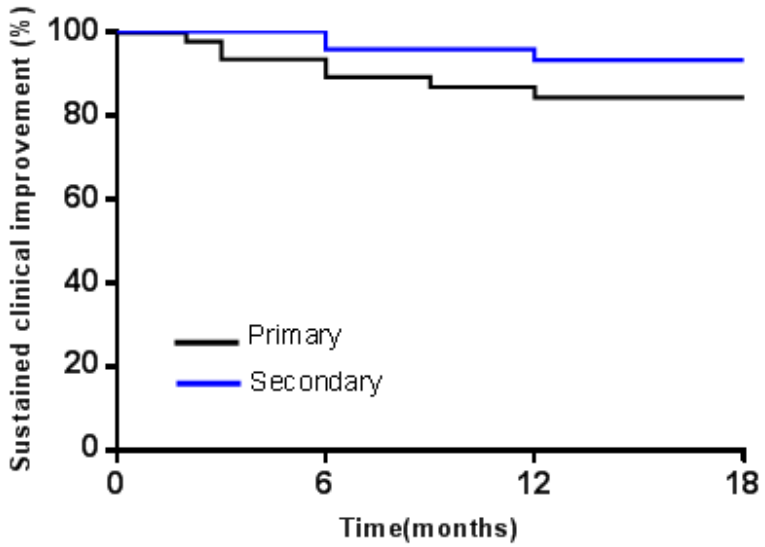
Median stents per lesion: 2

Median diameter: 5.5mm

Mean total length of stented segment:

277± 128 mm

Sustained clinical improvement @ 1 year

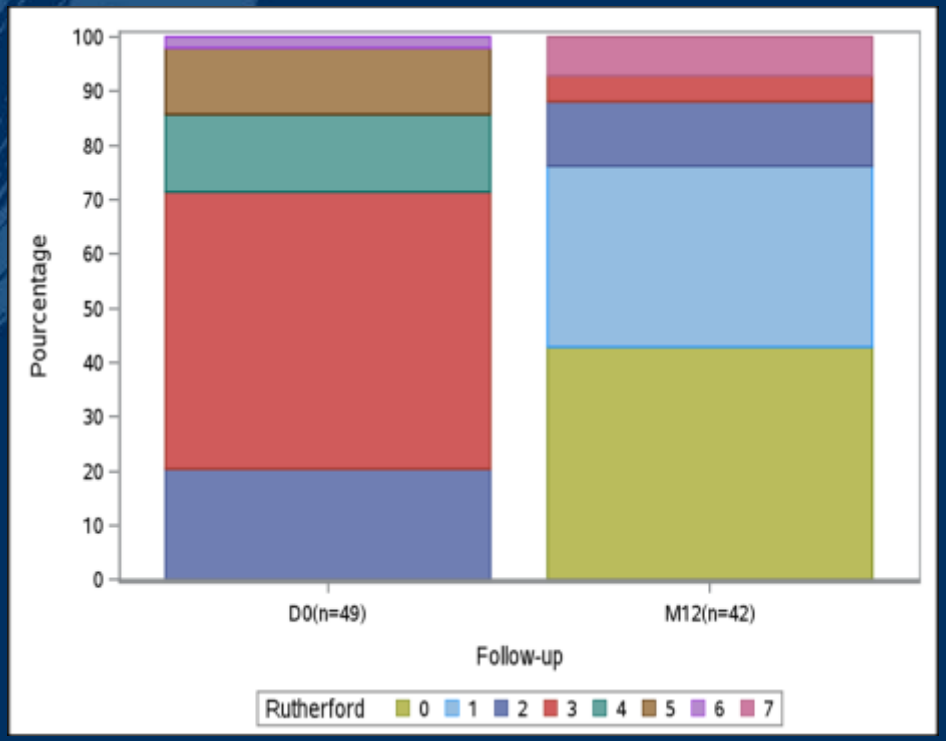


nb a t risk	1	6	12
primary	49	44	35**(84,6+/-5,4)**
secondary	49	47	38**(93,2+/-3,8)**

Primary sustained clinical improvement : 84.6%

Secondary sustained clinical improvement : 93.2%

Clinical Outcome @ 1year

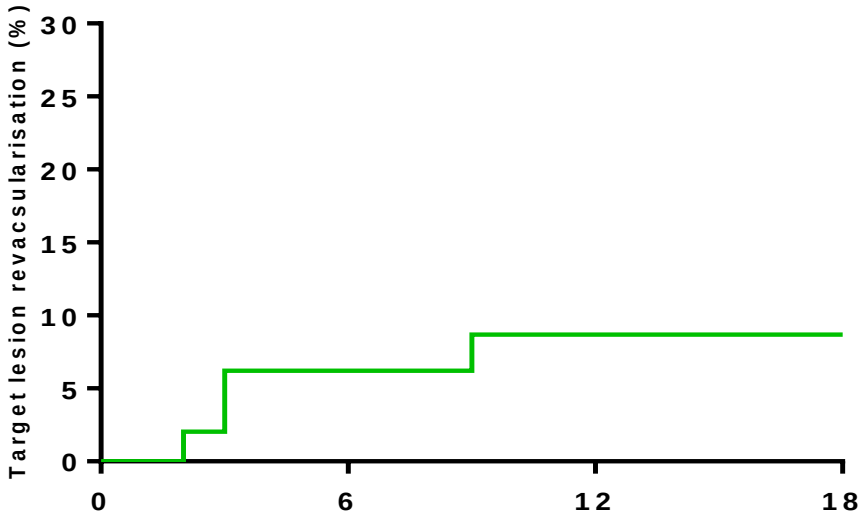


p= 0.0168

Death: 3 (6.3%)

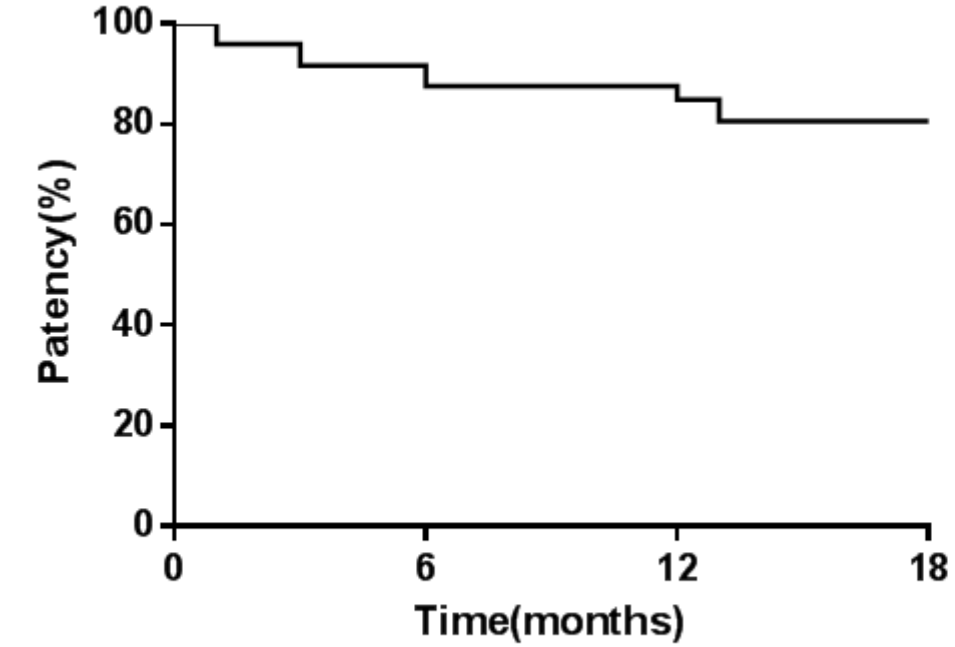
Major amputations: 0 (0%)

TLR @ 1 year: 8.5%



Nb at risk	1	6	12
TLR	49	45	37 **(8,5+/-4,1)**

Patency @ 1 year: 85.1%

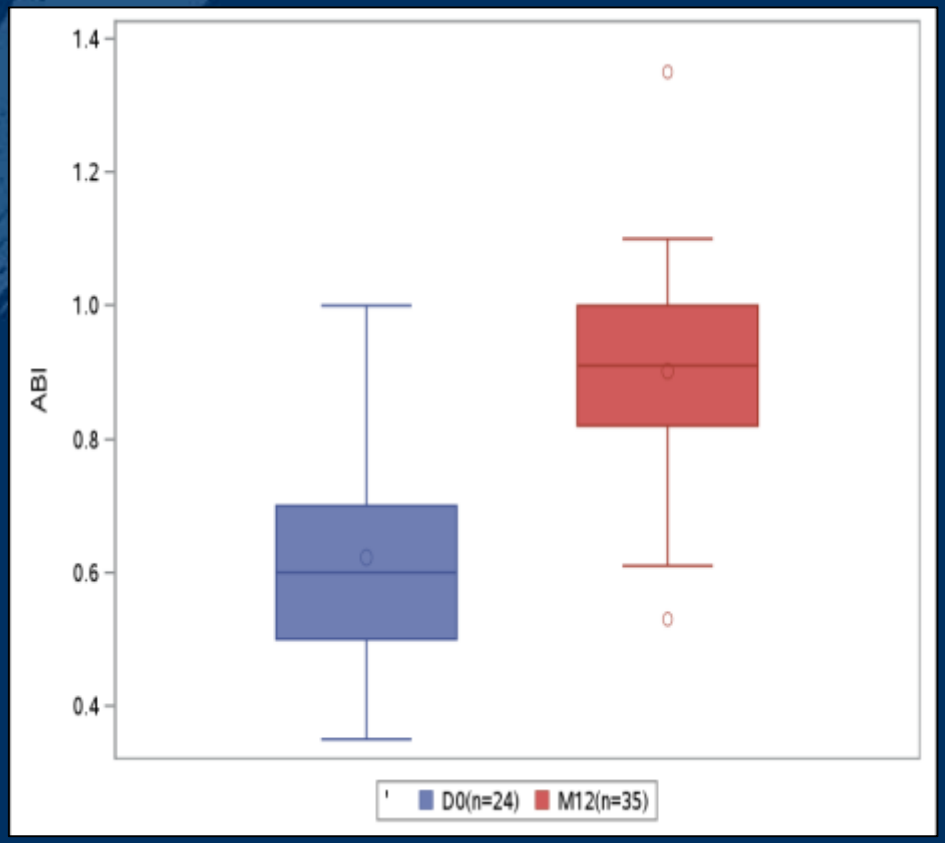


Nb at risk	1	6	12
Patency	49	44	35 **(85,1+/-5,2)**

In-stent restenosis : 12% (6/49)

In-stent thrombosis : 6% (3/49)

Hemodynamic outcomes @ 12 months



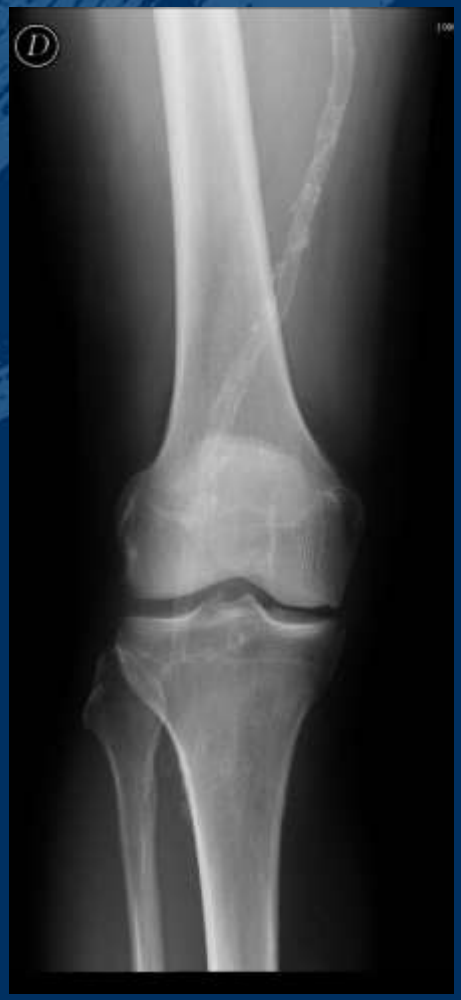
p< 0.0001

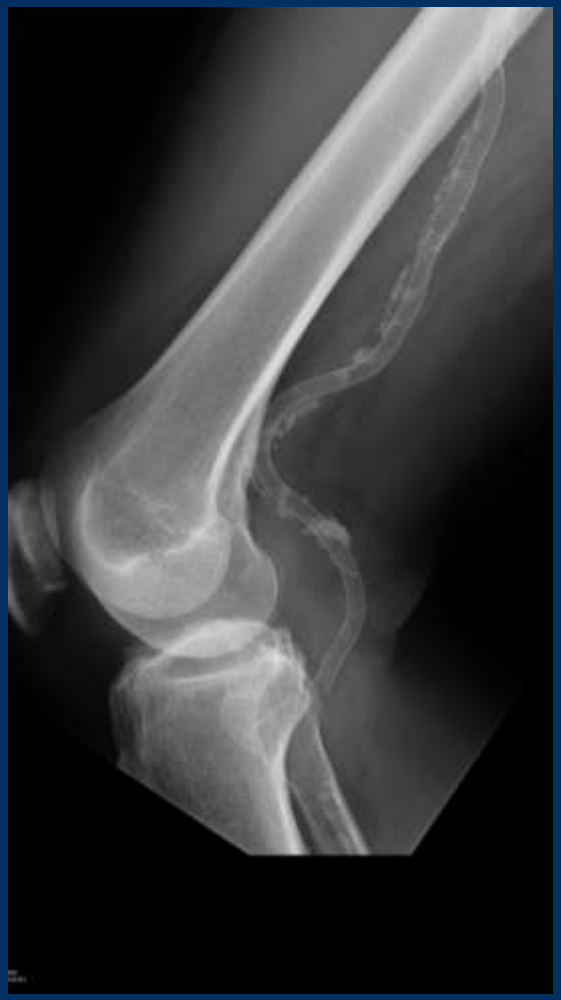
At baseline :
Median: 0.62 ± 0.15

At M12:
Median: 0.91 ± 0.17

Stent fractures

No fracture were observed





Update of evidence for long femoropopliteal lesions

	DURABILITY 200	STELLA	STELLA ptx	Zilver ptx registry	DCB vs DES	DEB-SFA-Long lesion	DES-SFA-long lesion	VIASTAR	SUPERB	STELLA SUPERA
Devices	BMS Everflex*	BMS Lifestent£	DES Zilver PTX&	DES Zilver PTX&	DCB vs DES In.Pact Admiral* v Zilver ptx&	DCB In.Pact Admiral*	DES Eluvia° (Bosto Sc)	CS vs BMS Viabhan#	CS vs bypass Viabhan#	**BMS Supera$**
Treated limbs, (n)	100	62	48	135	131/97	105	62	72/69	63/62	**49**
Claudicant, (%)	71	40.3	58	NA	81/91.7	89.5	52	86/82	67.7/61.9	**71**
Mean treated lenght, (cm)	24.2±	22±16	25.2±9	22.6	19.4±8.6 19.5±6.4	25.1±7.1	20±12 cm	18.9.8±6.3 17.32±6.6	23.6±7.1 23.3±8.3	**23.3±12**
Patency rate at 1-year (%)	64.8	66	52.5	77.6	76.1 vs 69.6	83.2	87	71.3 vs 36.8	64.8 vs 63.6	**84.8**
CD-TLR at 1 year (%)	37.8	18.2	36.4	16.4	15.6 vs 19	4	13	15.4 vs 23	27.9 vs 29	**8.7**

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Take home message

SuperA® (Abbott) is safe and efficient for long femoropopliteal lesions

In a non-controlled study, SuperA® achieves high primary patency rate and low TLR

SuperA® stent could be an alternative to open surgery treatment for femoropopliteal lesions superior to 25cm.

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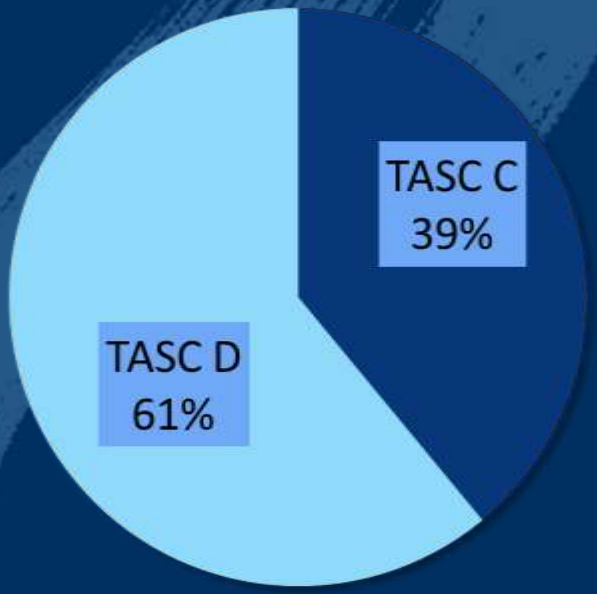
Lesions and intraoperative results



Over the bifurcation: ??

SAFARI : ??

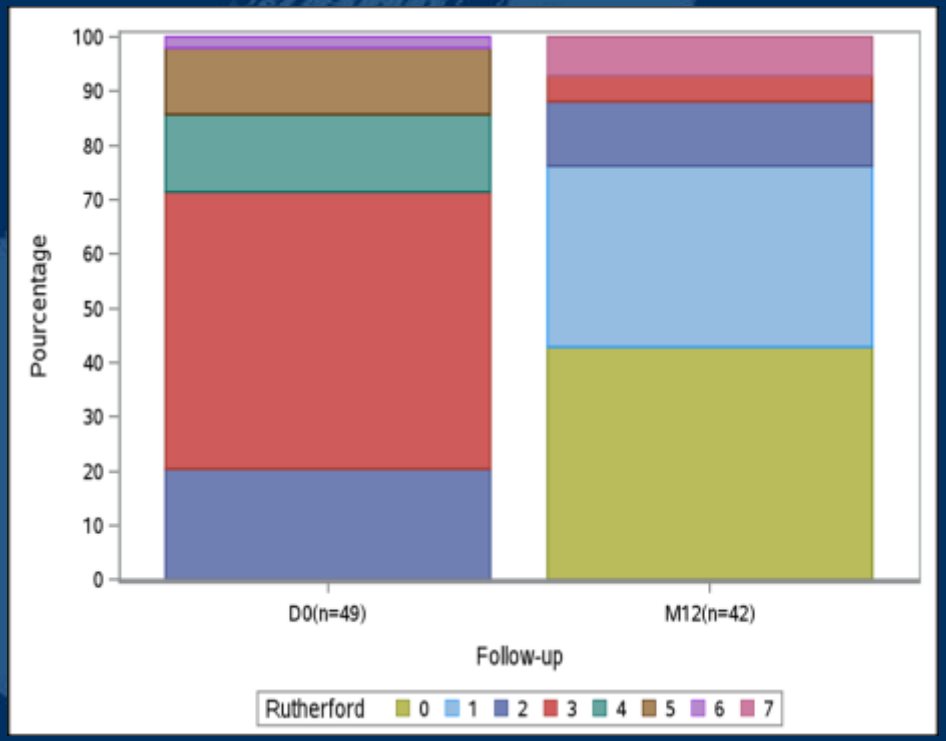
Stents SUPER A (Abbott), n=94

Median stents SUPER A per lesion: 2[min=1;max=4]

Mean total length of stented segment(n=104):

277± 128 mm

Clinical Outcome @ 1year



	MISAGO® (n= 85)
MACEs, n [1]	2
All-cause Death, n	2
Limb salvage, %[2]	100
Device- or Procedure-related Death, n	0
Mean hospitalization length, days ± SD	1.0 ± 1.1
Rehospitalization (%)	26 (31)

Death: 3 (6,3%)

Major amputations: 0 (0%)

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