Vascular
therapies for living

angiolite BTK

Sirolimus eluting stent

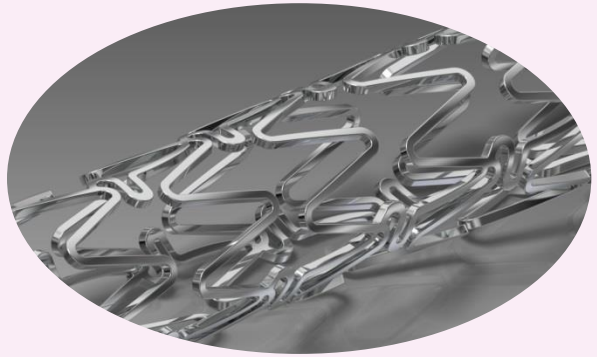
Elements of angiolite BTK DES

Delivery system
Balloon catheter

xperience

+

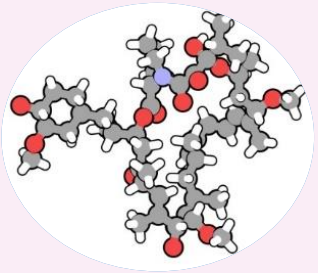
Scaffold
CoCr stent



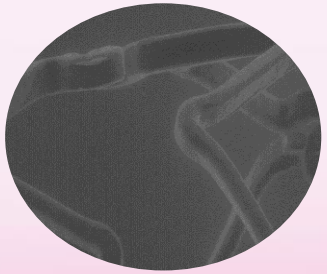
dedicated design

+

Pharmacological activity
Coating



sirolimus



Fluoro Acrylate

Balloon catheter

Rapid exchange catheter (RX) & **semi-compliant** balloon

Optimized Thermocrimping

- Compatible w/ **5F guiding catheters**
- Crossing profiles: 0,043" (3F) –0,051" (3,75F)

Conical wire transition

Optimal visibility / flexibility

Tip profile 0,017"

0.8 mm Platinum - Iridium markers

SS / PTFE hipotube

Trilayer balloon

1 **PEBAX**

Anti-dislodgement: Soft layer for **cushion effect**

2 3 **NYLON**

Anti-puncture: Reinforced inner layers

Hydrophillic coating

High durability proprietary formula

Super fast deflation < 3s

Stent CoCr

Specifically designed for DES.

Homogeneous arterial coverage

Allows recrossing

Open cell

Alternative links

Optimized dimensions

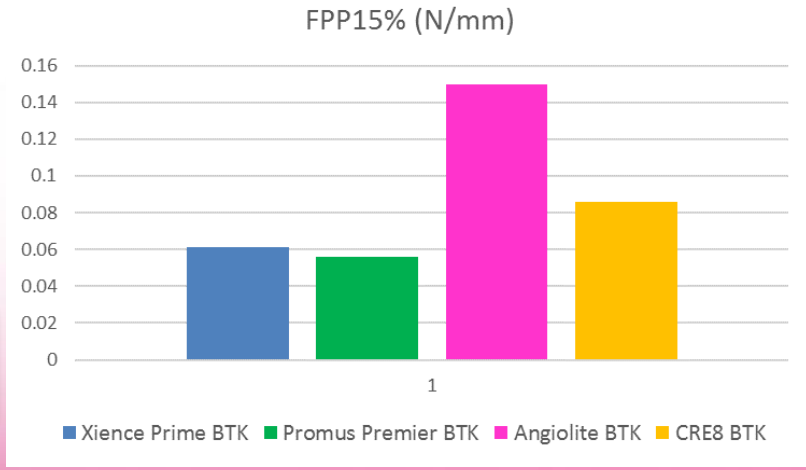
New opening angles

Optimal Radial Force

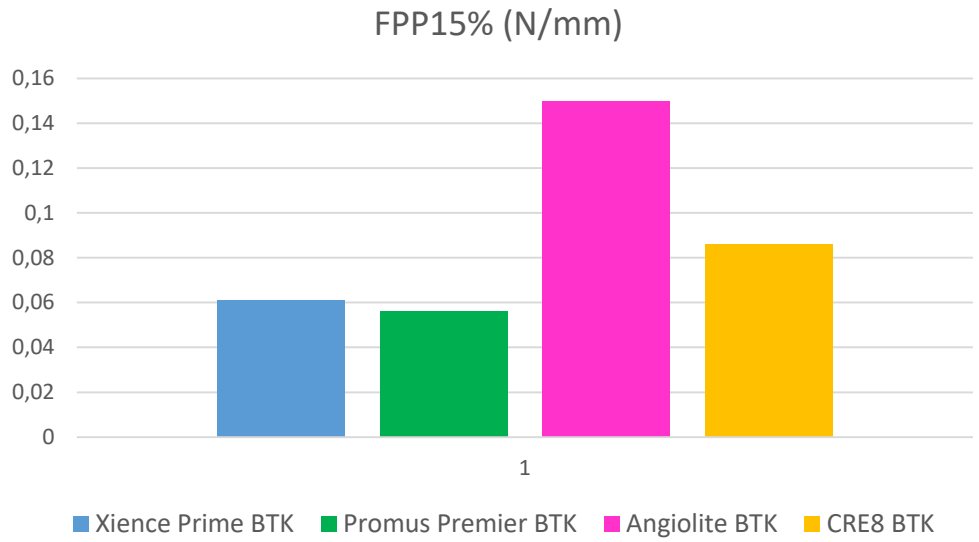
Lower stress on the coating

Outstanding arterial support

Stent diameter /mm	2,00 2,25 2,50	2,75 3,00 3,50	4,00 4,50
Design	S	M	L
# zigzag x turn	6	8	9
# cells x turn	3	3	3
# zigzag x cell	2-2-2	2-3-3	3-3-3
Strut thickness / µm	75	80	85
Link thickness / µm	70	70	70

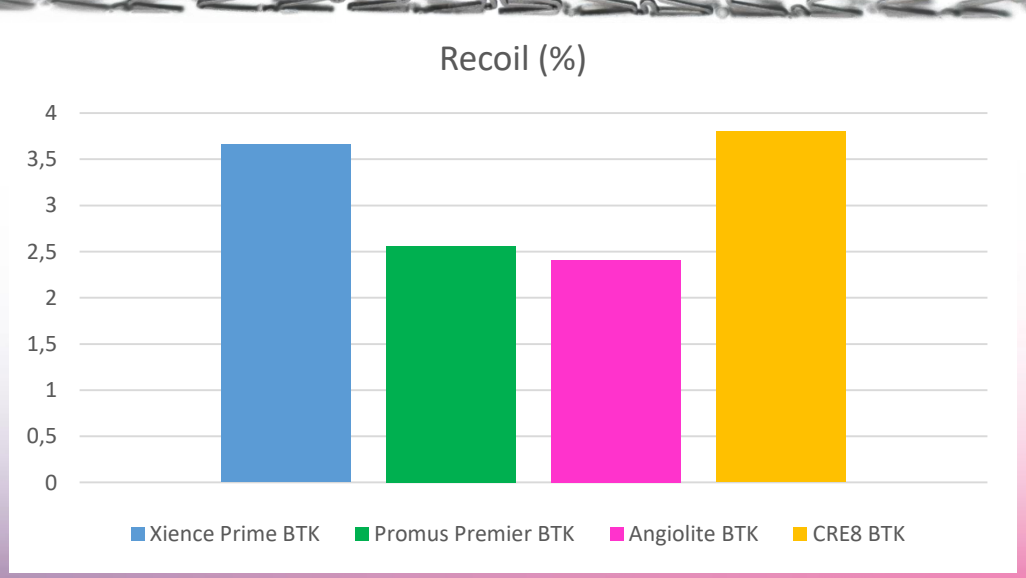


Big Radial Force

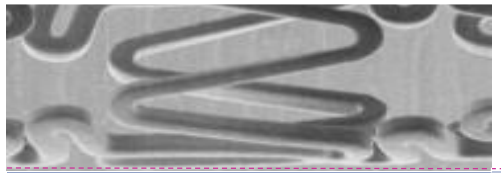


Benchmark

Minimum recoil



Coating

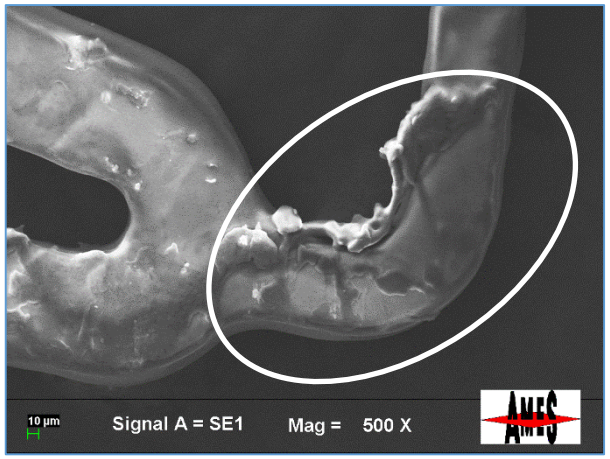


3 layers

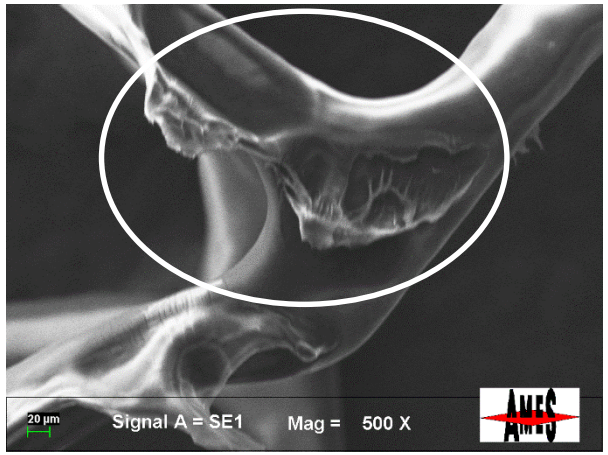
Acrylate	1. Primer • Assures adhesion to BMS
Fluoropolymer + Sirolimus	2. Matrix • Integrity, elasticity, cohesion
Fluoropolymer	3. Top • Controls elution kinetics

Coating Integrity

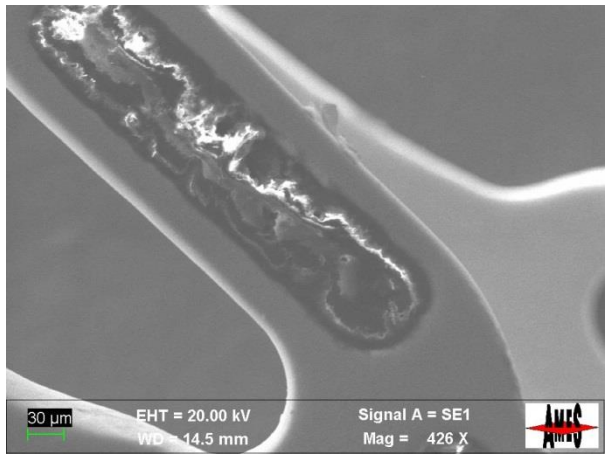
Xience Prime BTK



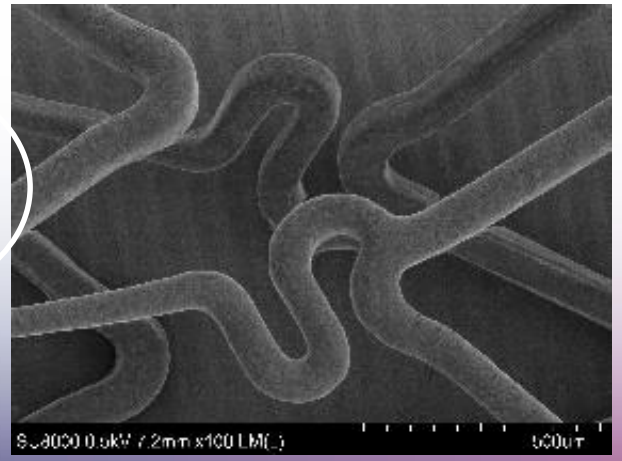
Promus Premier BTK



CRE8 BTK



Angiolite BTK



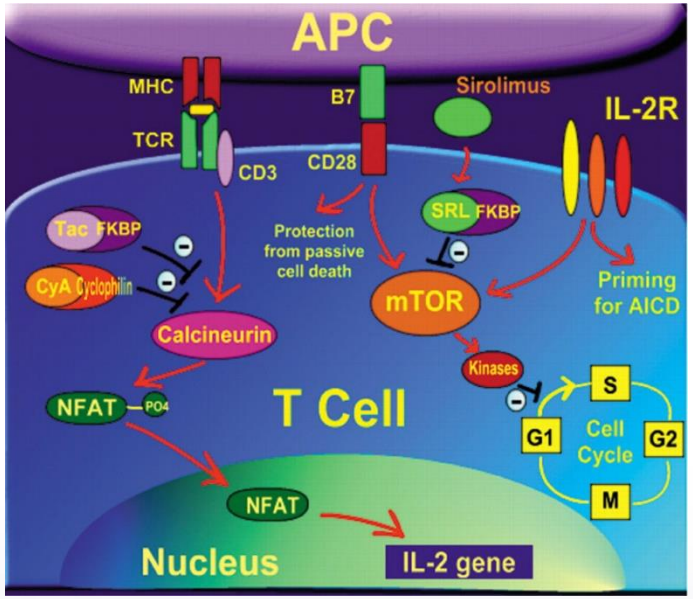
Innovative coating technology

Flexible formula

Durable

Coating

Sirolimus



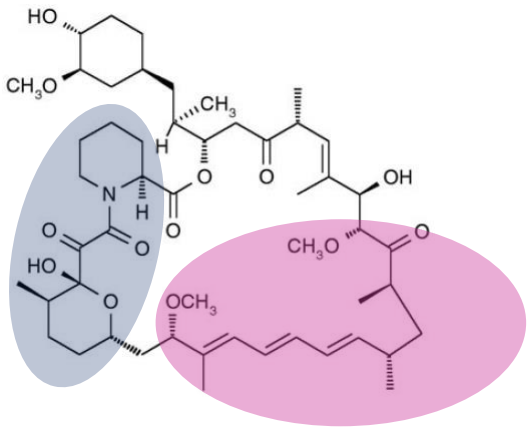
Powerful inhibitor of neo-intimal proliferation: blocks the growth, proliferation and mobility of smooth muscle cells

Multiple studies endorse **efficacy** and **safety** of sirolimus-DES

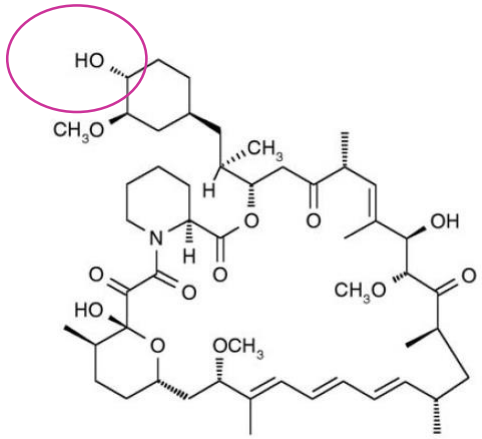
Coating
Sirolimus

Higher pharmacologycal activity

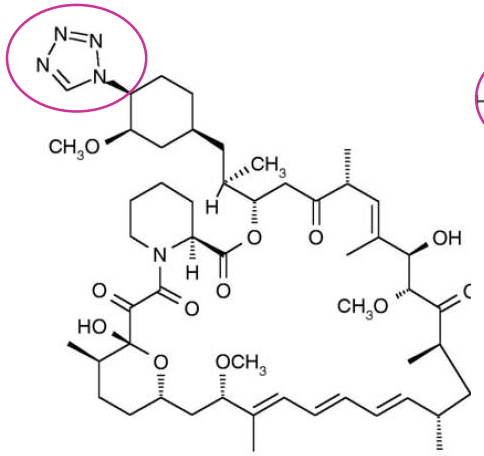
Binding to FKBP12



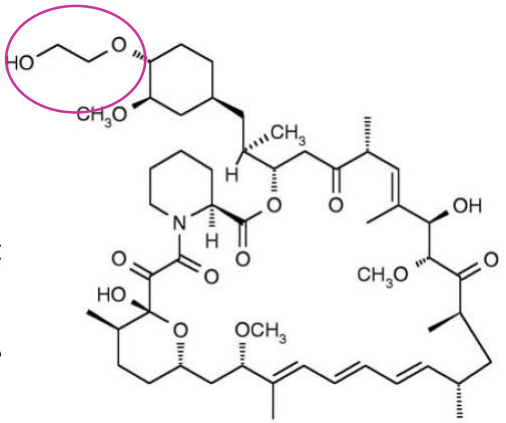
Binding to mTOR



Sirolimus



Zotarolimus



Everolimus

Drug	Solubility/ (log P)	$FKBP_{12}$ / Bond (nM)
Sirolimus	5,50	0,4-0,9
Everolimus	5,42	1,8-2,6
Zotarolimus	5,39	2,6-3,0

In vitro efficacy

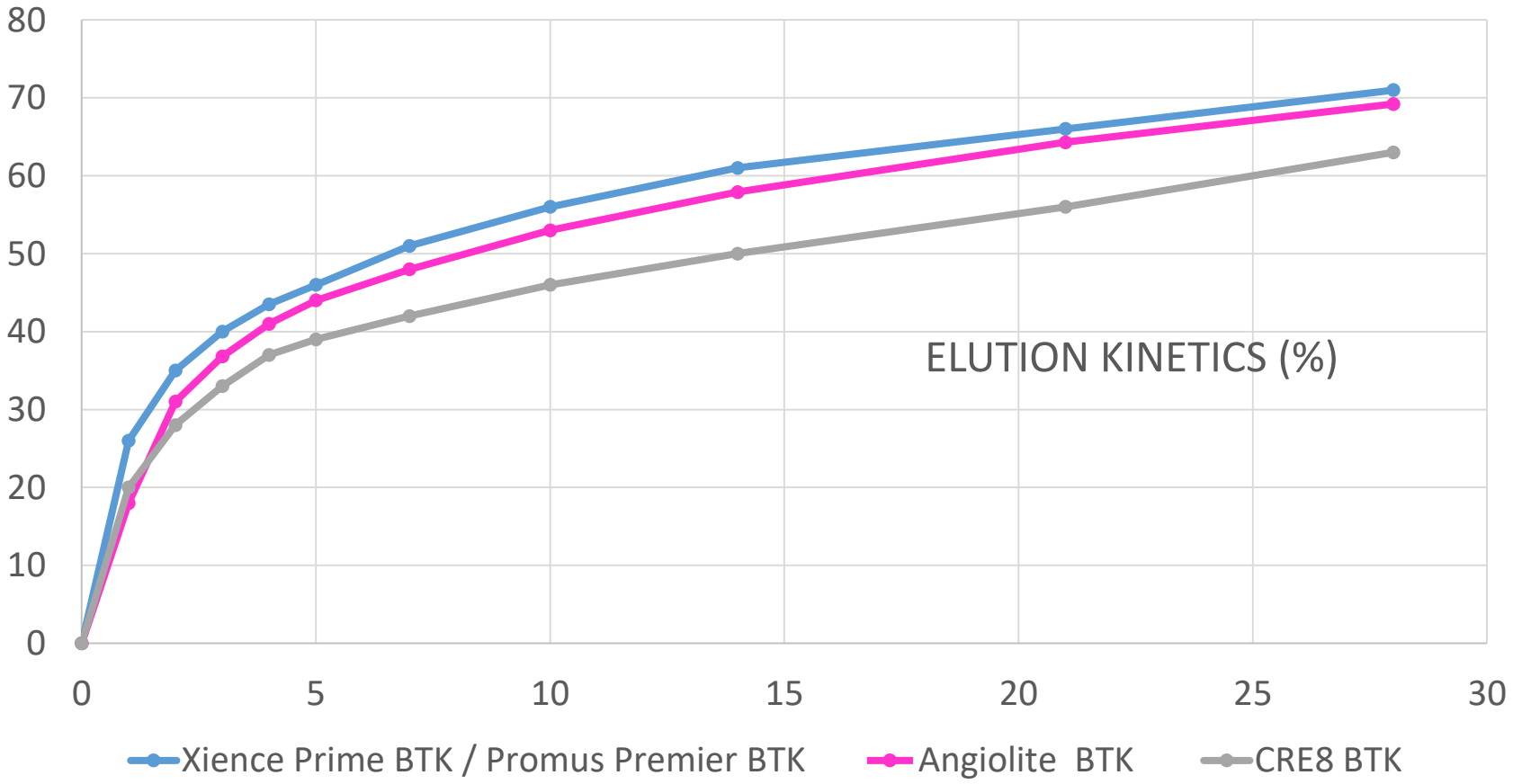
SIROLIMUS SHOWS HIGER ACTIVITY

Transp. Proced. 30, 2192-2194 (1998), Expert Opin. Invest. Drugs 11, (2002), Eur Heart J. 27, 988-993 (2006)

Coating

Elution Kinetics

Therapeutical dosage



1 month : 75% drug released

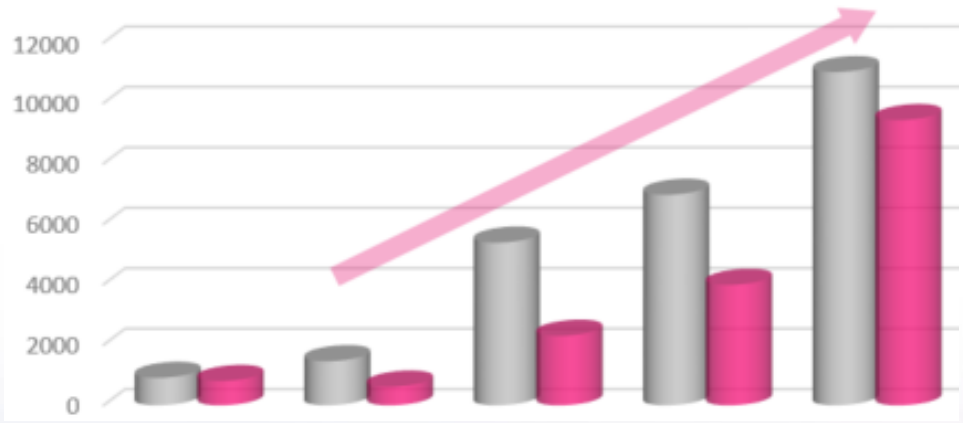
2 months : 100% drug released

Coating

Fluoropolymer

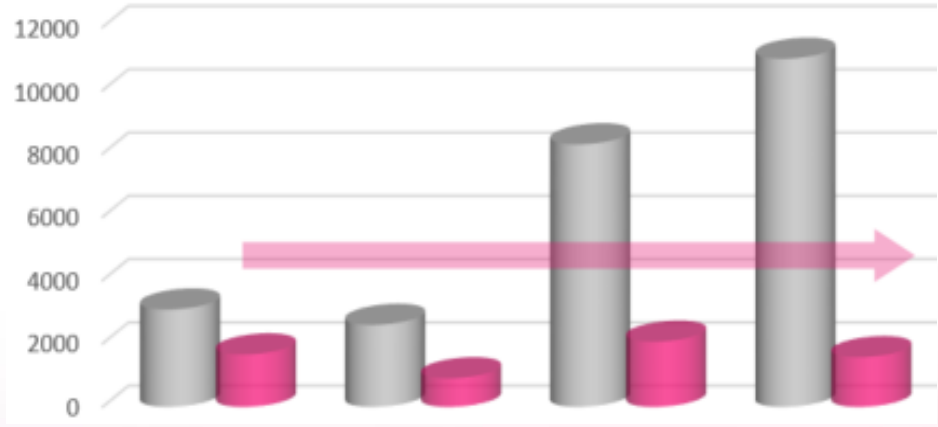
Selective cellular activity

Allows endothelialization



Proliferation of
endothelial cells

Inhibits re-stenosis



Reduces proliferation of
smooth muscle cells

- Positive control (polystyrene)
- Fluoroacrylate angiolite

Benchmark

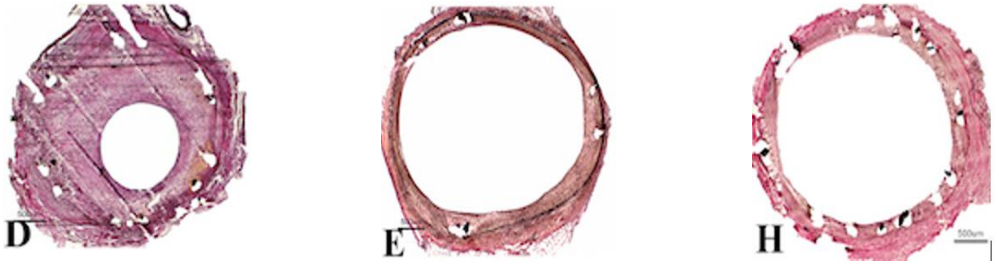
Elements specially designed for DES

	Alloy	Strut	Drug	Polymer	Nb of Crowns	Connectors	BMS
Xience Prime BTK	CoCr (L605)	81 mm	Everolimus (1,0 mg/mm2)	Fluorinated Polymer	Ø2.25-3.0:6 Ø3.5-4.0:9	3	Multilink 8
Promus Premier BTK	PtCr	81 mm	Everolimus (1,0 mg/mm2)	Fluorinated Polymer	Ø2.25:6 Ø2.5-2.75:8 Ø3.0-3.5:8 Ø4.0:10	2 on body, 4 on ends	Premier
CRE8 BTK	CoCr (L605)	80 mm	Sirolimus (0,9 mg/mm2)		Ø2.25 – 2.75: 4 Ø3.0-3.5:5 Ø4.0 – 4.5:6	4 5 6	Chrono
Angiolite BTK	CoCr (L605)	75 mm	Sirolimus (1,4 mg/mm2)	Fluorinated Polymer	Ø2.25-2.5:6 Ø2.75-3.5:8 Ø4.0-4.5:9	3	Specific

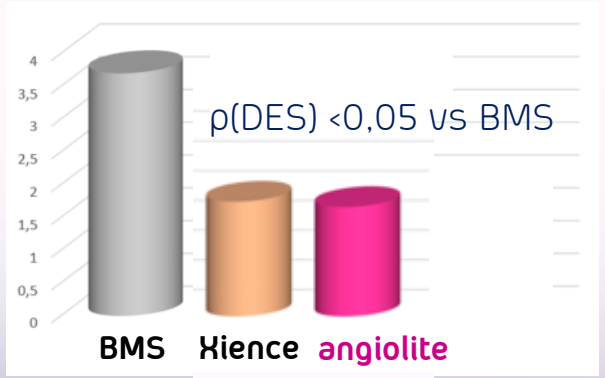
Pre-clinical data

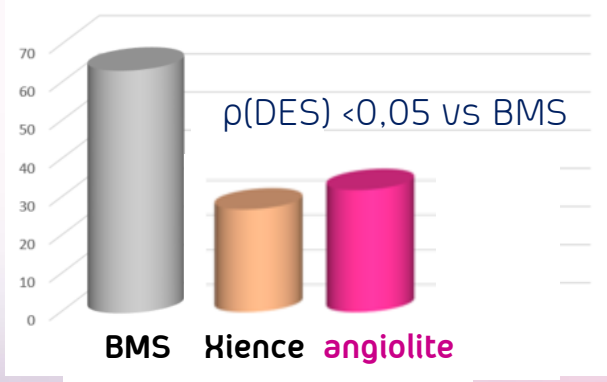
EFFICACY

- ✓ Swine model
- ✓ Protocol: 1,2 : 1 over-expansion
- ✓ Follow –up: 28 day histology



BMS | Xience® | angiolite®



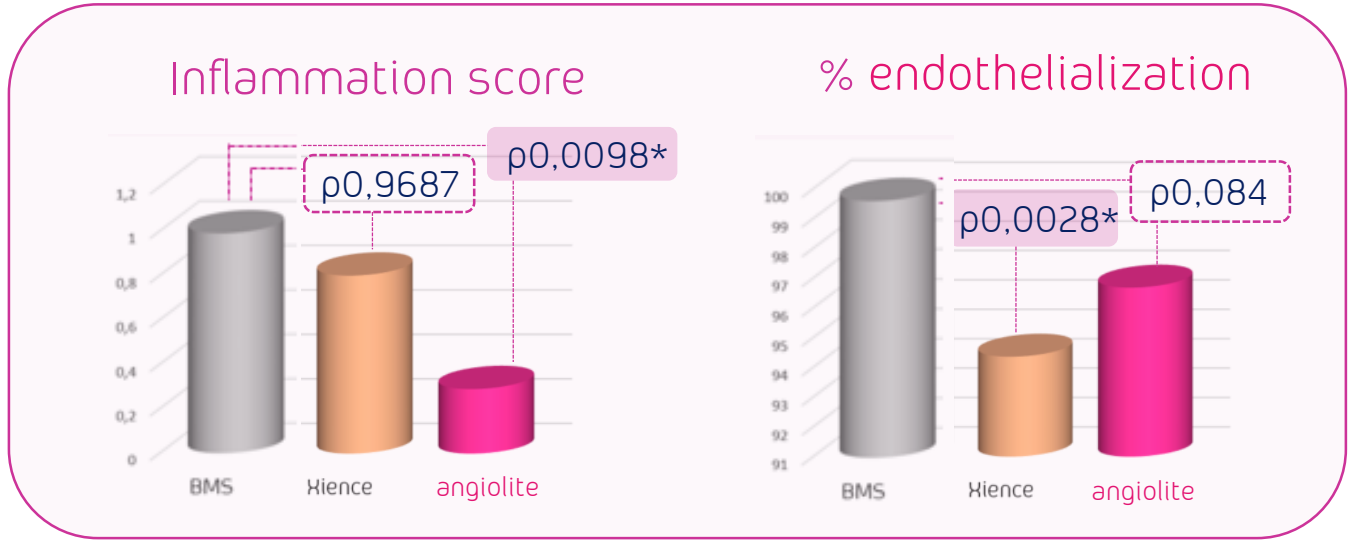


28-day stenosis is equivalent to Xience

Pre-clinical data

SAFETY

Angiolite® improves endothelialization and reduces inflammation compared to Xience



Angiolite shows comparable performance to Xience®

References

Wide size range

Catheter length 150 cm		Length/ mm						
		9	14	19	24	29	34	39
Diameter / mm	2.00	✔	✔	✔	✔	✔	✔	✔
	2.25	✔	✔	✔	✔	✔	✔	✔
	2.50	✔	✔	✔	✔	✔	✔	✔
	2.75	✔	✔	✔	✔	✔	✔	✔
	3.00	✔	✔	✔	✔	✔	✔	✔
	3.50	✔	✔	✔	✔	✔	✔	✔
	4.00	✔	✔	✔	✔	✔	✔	✔
	4.50		✔	✔	✔	✔	✔	✔

Preliminary results of real-life use of the latest generation of balloon expandable DES in below-the-knee treatment

Goverde P., Helsloot L., Taeymans K., Lauwers K., Verbruggen P.
Vascular Clinic ZNA, Antwerp, Belgium

Vascular Clinic ZNA

iVascular
therapies for living

1 Objective:

To evaluate if the latest generation of drug eluting balloon expandable stents like Angiolite could reduce the risk of major amputation and extend the primary patency rate.

2 Methodology:

Investigator initiated ongoing, single-center prospective follow-up study included all CLI patients of the last 6 months that were treated for limb threating arterial stenotic or occlusive lesions in below the knee area with drug eluting stents. We used the latest coronary Angiolite balloon expandable DES (iVascular, Spain) for the treatment.

3 Results:

More than 20 patients were treated with DES (80% diabetic, 75% cardiovascular comorbidity). Average stent amount was 1.2 per artery. Technical success rate was 100%. In case of ostial lesions and in case of heavy focal calcifications we preferred primary stenting with DES (70%). Preliminary 6-months primary patency rate is 90%. Compared with our balloon angioplasty group we saw improvement in wound healing and reduction in major amputation rate.

Baseline Patient Demographics: n = 26/50	
Male Gender	22
Mean Age (years ± SD)	74.76 ± 8.34
Mean BMI (± SD)	29,67 ± 4.67
Nicotine abuse (%)	73
Hypertension (%)	76
Hypercholesterolemia (%)	73
Diabetes (type 1=2) (%)	65
Vascular History (%)	69
Recurrent disease (%)	61
Coronary History (%)	61
Cerebrovascular History (%)	30
Renal insufficiency (%)	54

Rutherford Classification	
4	10
5	12
6	4
LESION TYPE	N = 29
Tibioperoneal Trunk	11
Anterior Tibial Artery	8
Peroneal Artery	6
Posterior Tibial Artery	4

	30 days
Primary Patency	100%
Secondary Patency	100%
Freedom from TLR	100%
Freedom from major amputation	100%
Freedom from minor amputation / surgical debridement	73%

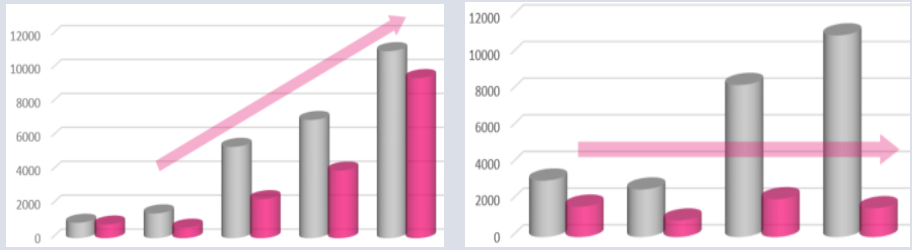
4 Conclusion:

The Angiolite balloon expandable DES can be safely used for below-the-knee treatment. The promising short term results need to be consolidated by longer follow-up. Further investigation is needed to see if the long term results can be sustained in the same way.

Key selling points

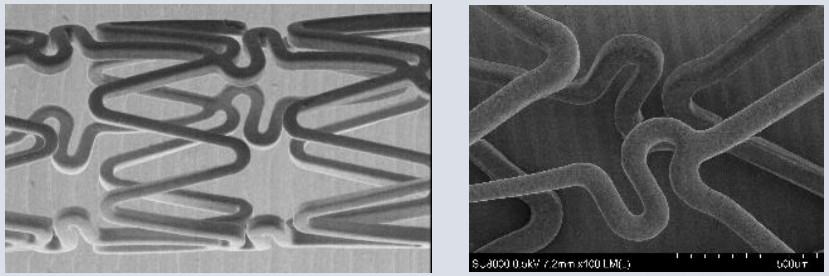
Quality of healing

Polymer choice for outstanding cellular behavior. Selective endothelial growth from restenosis



Coating Integrity

Outstanding mechanical properties: adhesion, elasticity, cohesion



Radial Force

Double radial force than competitors

Efficacy

Release kinetics equivalent to top competitors
Best ratio of safety and efficacy on swine model

FIM

Promising data demonstrating safety in BTK indications