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12-month results of the PREVENT study

Investigating the Everolimus-Eluting stent in BTK lesions in CLI patients

Marc Bosiers, MD

Study design

- Prospective, non-randomized, multi-center study

- Study objective:

  To evaluate the immediate and long-term (up to 12 months) outcome of the PROMUS ELEMENT PLUS Everolimus-Eluting Stent System (Boston Scientific) in a controlled prospective investigation for **lesions no longer than 40mm.**

Device description

- PROMUS ELEMENT PLUS STENT SYSTEM

TABLE 1 : PROMUS ELEMENT PLUS STENT SYSTEM PRODUCT DESCRIPTION

Available stent Lengths (mm)	8, 12, 16, 20, 24, 28, 32, 38
Available stent Diameters (mm)	2.25*, 2.50, 2.75, 3.00, 3.50, 4.00
Stent Material	Platinum Chromium (PtCr) Alloy
Drug Product	A conformal coating of a polymer carrier with 100 µg/cm² everolimus applied to the stent with a maximum drug content of 241.8 µg of the largest stent (4.00 x 38 mm)
Delivery system effective length	144 cm
Delivery system Y-adaptor ports	Single access port to inflation lumen. Guidewire exit port is located approximately 26 cm from tip. Designed for guidewire ≤ 0.014 in (0.36 mm)
Average stent foreshortening at nominal diameter	2.25 - 4.00 mm: 0.1 - 1.5 mm
Stent delivery Balloon	A balloon, with two radiopaque markers nominally 0.4 mm longer than the stent at each end.
Balloon Inflation pressure	Nominal inflation pressure: 11 atm - 1117 kPa Rated Burst Pressure: 18 atm - 1827 kPa for stent diameters 2.25 - 2.75 (mm) and 16 atm - 1620 kPa for stent diameters 3.00 - 4.00 (mm) diameters
Guide Catheter Inner Diameter	≥ 5F (0.056 in) (1.42mm)
Catheter shaft outer Diameter	2.3F (≤ 0.80 mm) proximally and 2.7F (≤ 0.95 mm) distally
Guide Sheath Inner Diameter	4F (1.5 mm)
Stent strut thickness (Including coating)	2.25 - 3.50 mm: 0.093 mm, 4.00 mm: 0.098 mm

* 2.25 mm stent diameter not available in 38 mm length

Participating centers

- **BELGIUM**
  - M. Bosiers, K. Deloose, J. Callaert - AZ Sint-Blasius, Dendermonde
  - P. Peeters, J. Verbist - Imelda Hospital, Bonheiden
  - K. Keirse - RZ Heilig Hart, Tienen

- **GERMANY**
  - Prof. G. Torsello – St. Fransiskus Hospital, Münster
  - Prof. T. Zeller - Herzzentrum, Bad-Krözingen

Study design

Main inclusion criteria

- **Rutherford classification from 4 or 5**
- **Single or multiple lesions** or restenotic lesions after PTA in the infrapopliteal arteries, suitable for endovascular therapy
- Total target lesion length maximally **40mm** (covered with max 2 stents)

Primary endpoint

- **Primary patency at 12 months,** defined as:

  absence of restenosis (≥50% stenosis) or occlusion within the originally treated lesion based on **Angiography**

PREVENT study : Timetable

Patient demographics

	N=70
Male *(%)*	47 *(67.1%)*
Age *(min – max; ±SD)*	78.29 *(62.78 – 90.74 ±6.64)*
Nicotine abuse *(%)*	18 *(25.7%)*
Hypertension *(%)*	55 *(78.5%)*
Diabetes mellitus *(%)*	**38 *(54.3%)***
Renal insufficiency *(%)*	15 *(21.4%)*
Hypercholesterolemia *(%)*	41 *(58.6%)*
Obesity *(%)*	27 *(38.6%)*

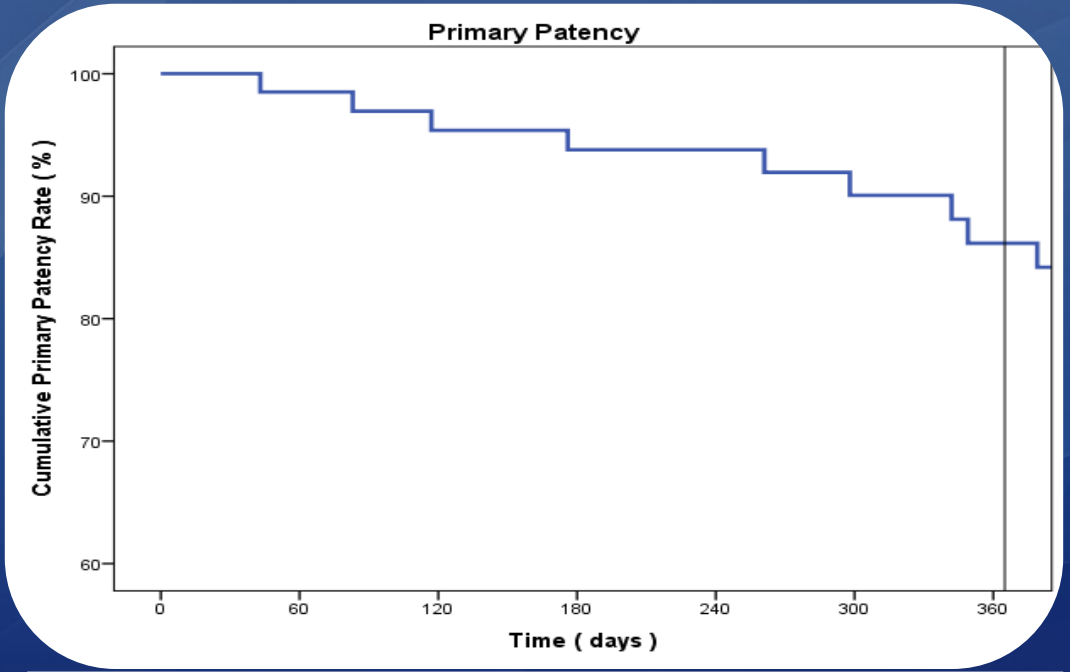
Indications + Procedural characteristics

	N=70
Rutherford 4 *(%)*	33 *(47.1%)*
Rutherford 5 *(%)*	37 *(52.9%)*
Duration *(minutes)*	52.2 *(13.00 – 261.00 ; ±33.89)*
Access side: - Left Common Femoral Artery *(%)* - Right Common Femoral Artery *(%)*	 36 *(51.4%)* 34 *(48.6%)*
Cross-over performed *(%)*	62 *(88.6%)*
Scopy time *(minutes)*	15.99 *(5.00 – 56.00 ; ±10.89)*
Contrast dose *(ml)*	98.19 *(45.00 – 320.00 ; ±40.52)*

Lesion characteristics

	N=70
Left/Right limb *(%)*	32 *(45.7%)* / *38 (54.3%)*
Lesion length *(min – max; ±SD)*	**22.83 mm** *(5.0 – 40.0; ±8.78)*
Reference vessel diameter	3.06 mm *(2.5 – 4.0; ±0.40)*
Mean lumen diameter	0.39 mm *(0.0 0– 1.05; ±0.32)*
Occlusion *(%)*	14 *(20.0%)*
Calcified lesion *(%)*	35 *(50.0%)*

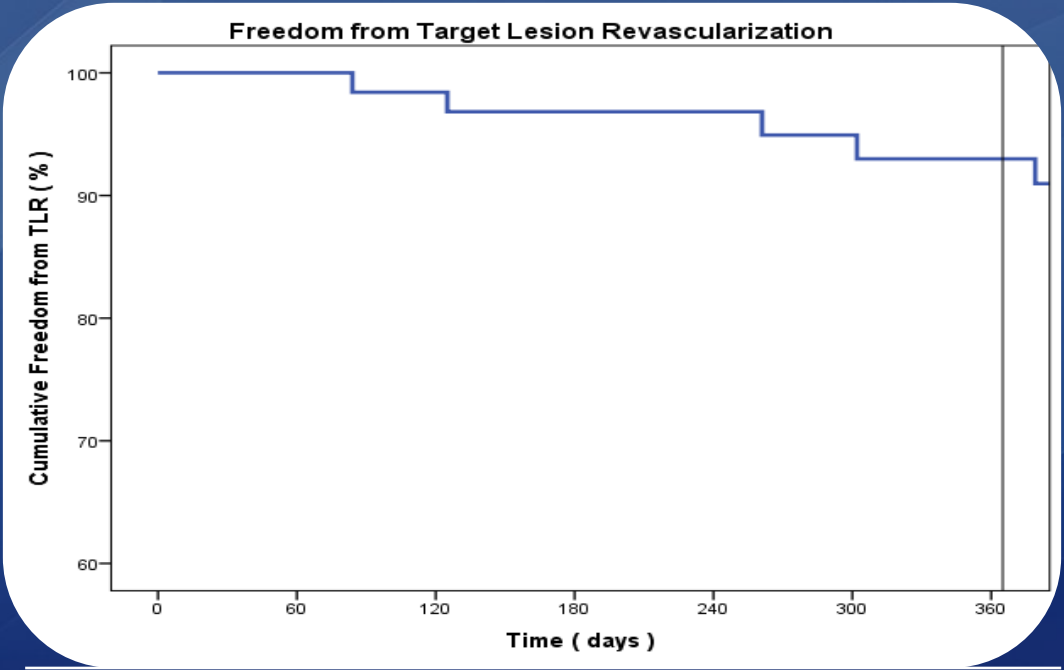
12 Month Primary Patency



86.2 %

time	baseline	1MFU	6MFU	12MFU
at risk	70	67	58	44
%	100	100	93.8	86.2

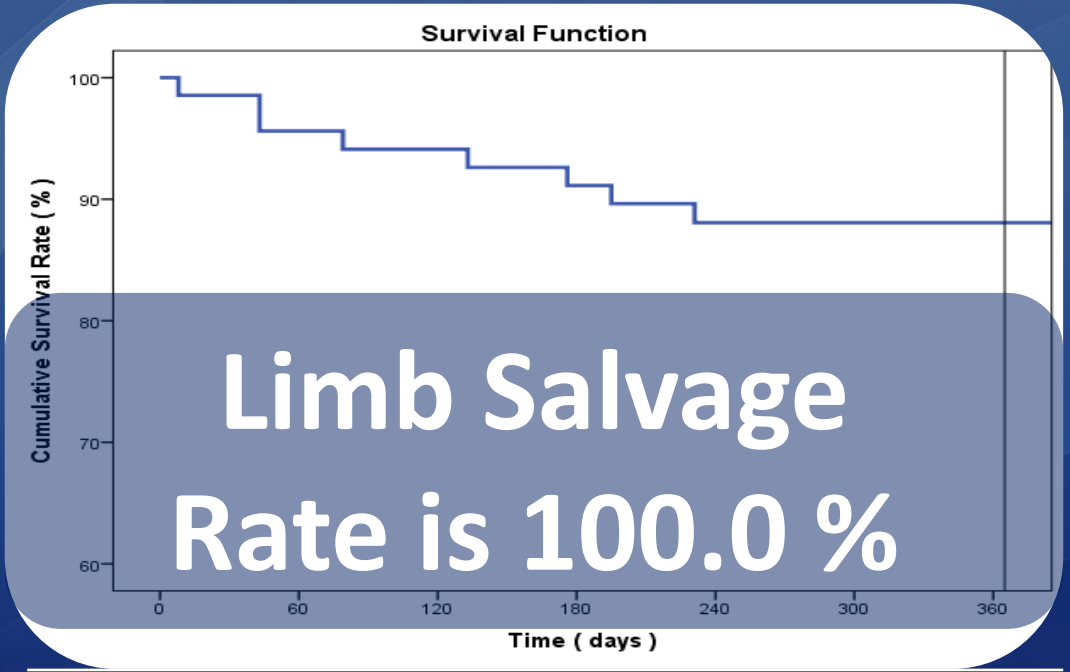
12 Month Freedom from TLR



93.0 %

time	baseline	1MFU	6MFU	12MFU
at risk	70	67	59	46
%	100	98	96.8	93.0

12 Month Survival & Limb Salvage

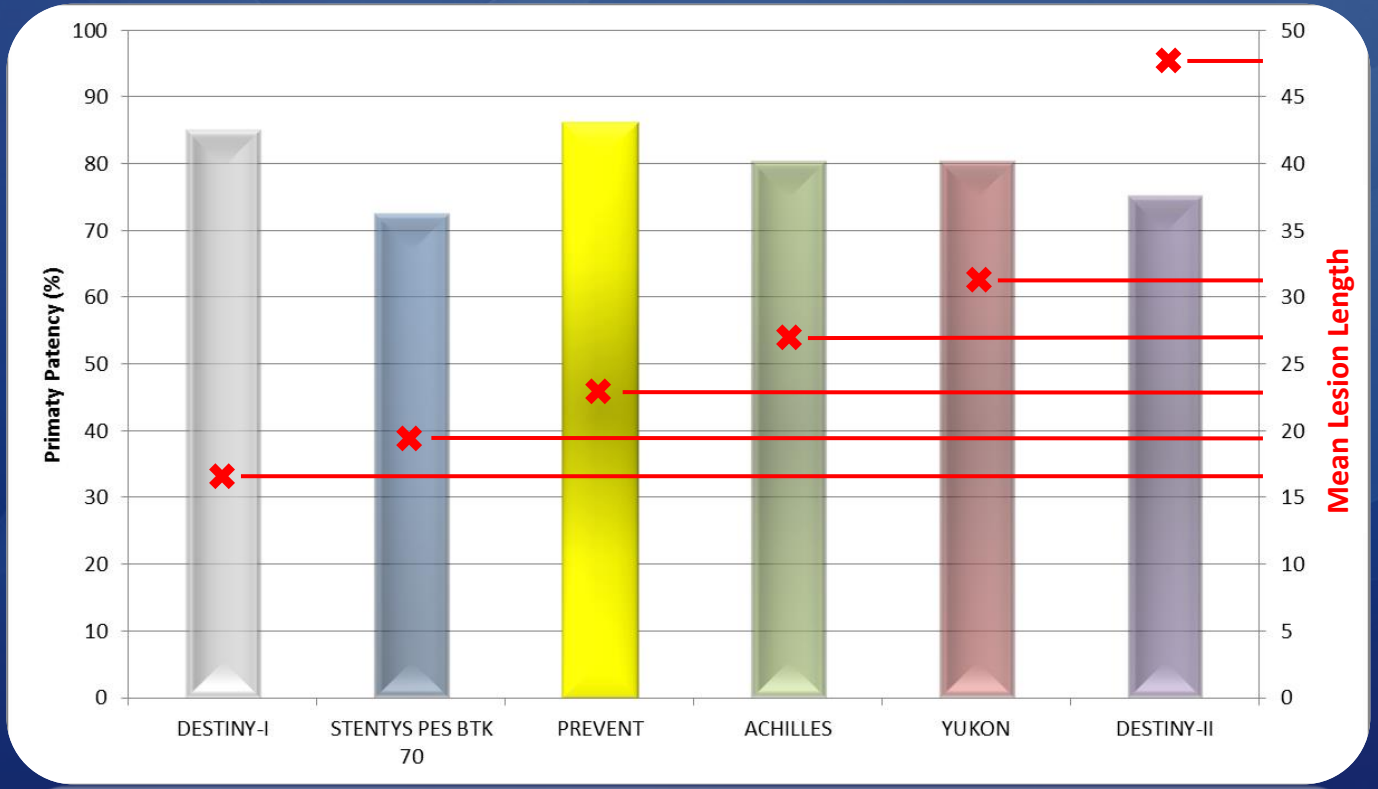


Limb Salvage Rate is 100.0 %

88.1 %

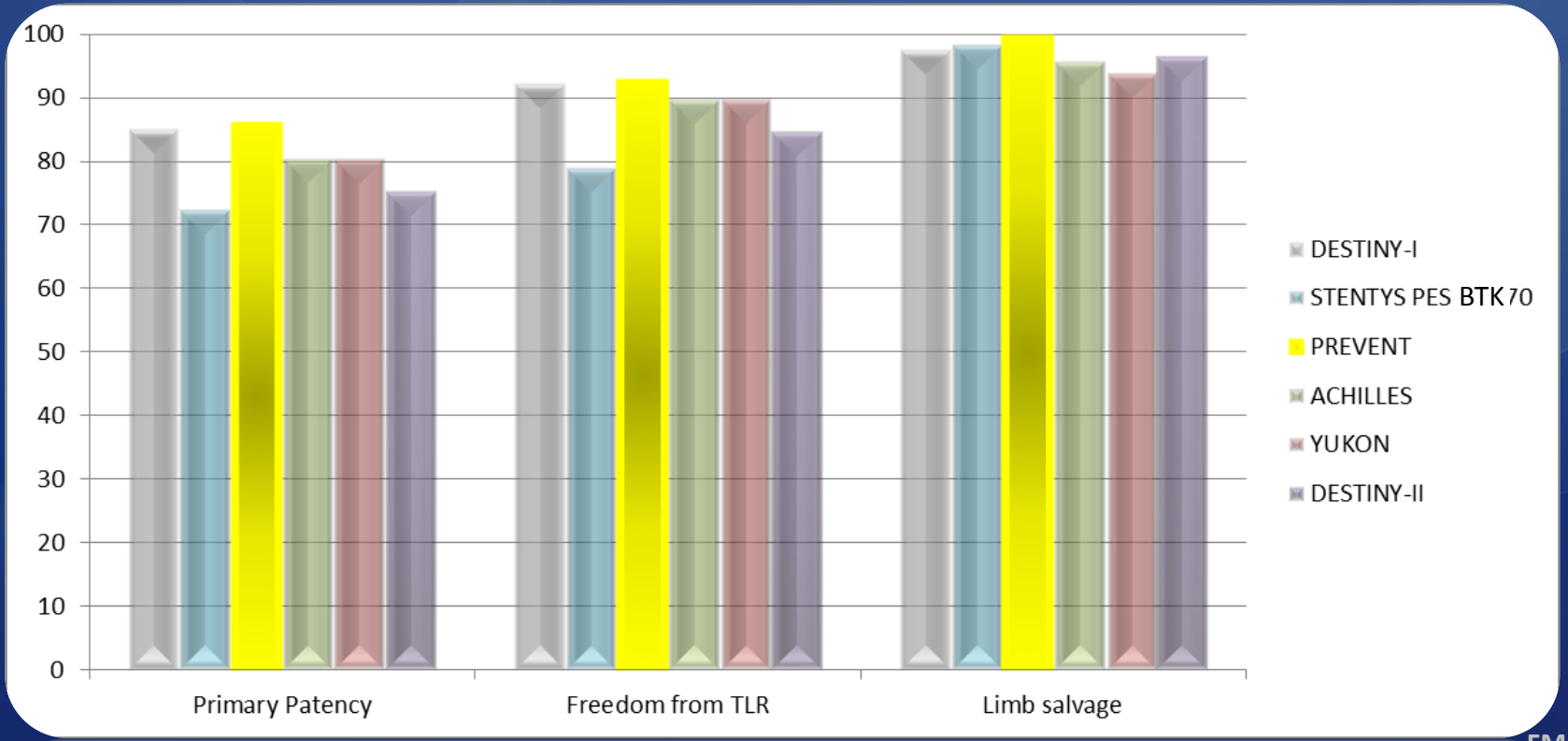
time	baseline	1MFU	6MFU	12MFU
at risk	70	67	61	52
%	100	98.6	91.1	88.1

Primary Patency Rate at 1 year



	Primary Patency	Lesion Length
DESTINY-I	85.2	15.9
STENTYS	72.6	19.7
PREVENT	86.2	22.8
ACHILLES	80.6	26.9
YUKON	80.6	31.0
DESTINY-II	75.4	47.4

Comparison – outcomes



Conclusion

There is definitely some evidence for
Drug / Everolimus Eluting Stents in the CLI-BTK area

The PROMUS ELEMENT PLUS seems a valid, safe and effective alternative to treat short focal lesions in BTK arteries in CLI patients.