

Long term results from the LegDeb registry

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

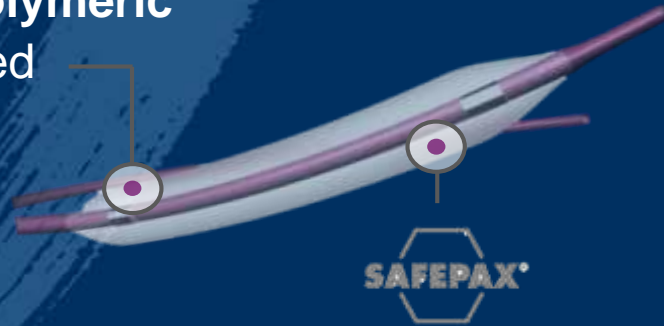
- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

LEGFLOW — Drug-Coated Balloon

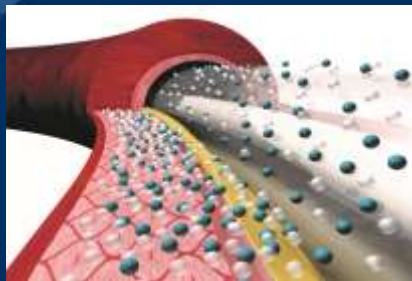
Excipient

-- **lipophilic** and **polymeric**
ammonium-salt-based

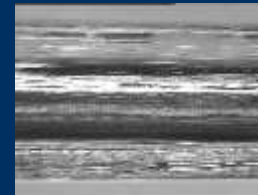


Paclitaxel

-- 3.0 $\mu\text{g}/\text{mm}^2$



Optical Imaging (100x)



LEGFLOW DCB
Homogeneous,
smooth
amorphous
coating



Hydrophilic Coating DCB
White powder of brittle
crystalline coating

The 'SAFEPAx' drug coating technology should provides a proper protection from low mass-related risk for distal embolization and prothrombotic effects

LegDeb Registry Design

- Prospective
- Multicenter
- Femoropopliteal lesions
- PTA according to local standard practices



FOLLOW-UP

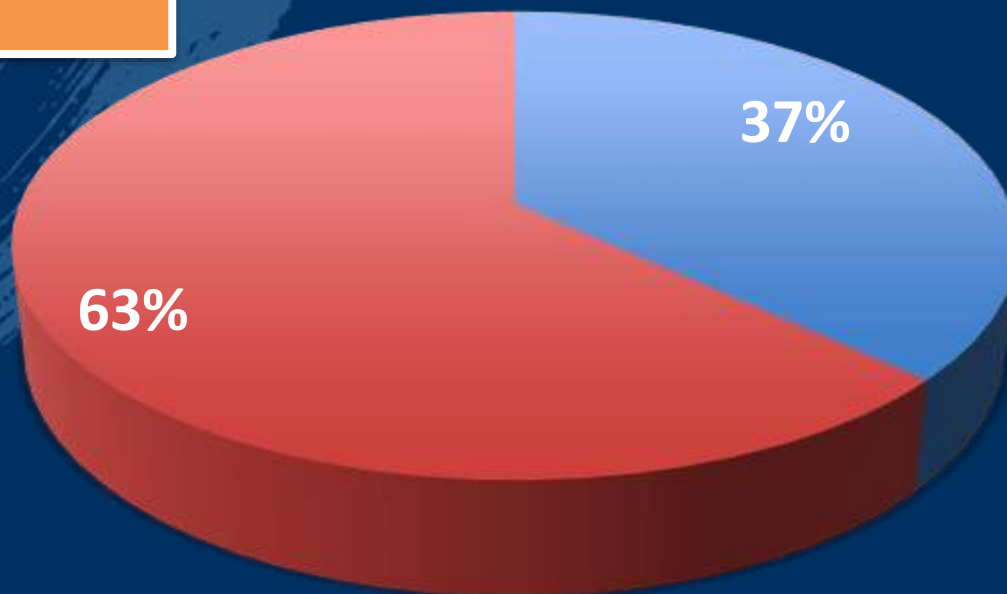
- Clinical examinations
- Duplex US
- Repeated angio in presence of intermediate or severe restenosis

ASSESSMENTS

- **Primary end point:** freedom from restenosis at 12 and 24 months
- **Secondary end point:** freedom from CD-TLR

LEGDEB Registry 24-months analysis

70 patients initially enrolled



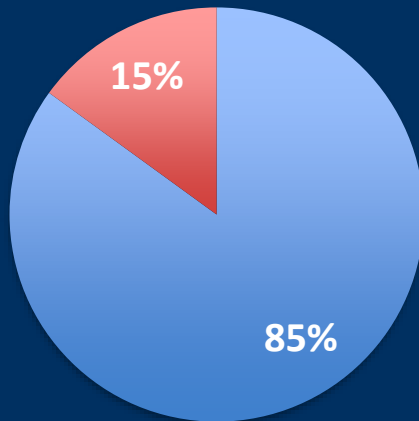
■ University of Napoli "Federico II" (26)

■ Vascular Clinica ZNA Hospital Stuivenberg, Antwerp (44)

77.1% available for
24-months analysis (n:54)

Baseline Characteristics

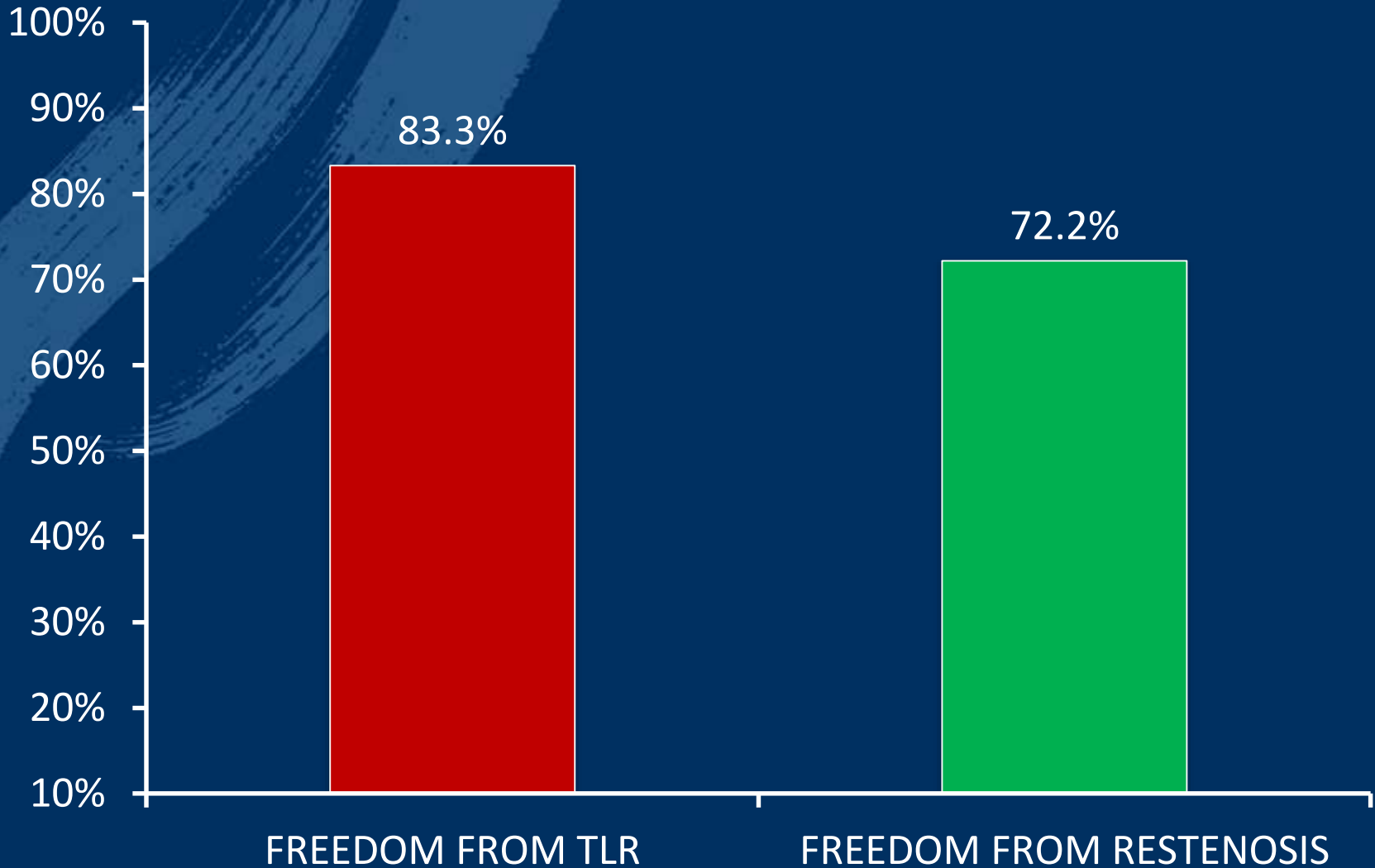
Number of patients	70
Male	78%
Age	66 ± 11
Diabetes	50%
Hypertension	77%
Hypercholesterolaemia	57%
Smoking history	56%



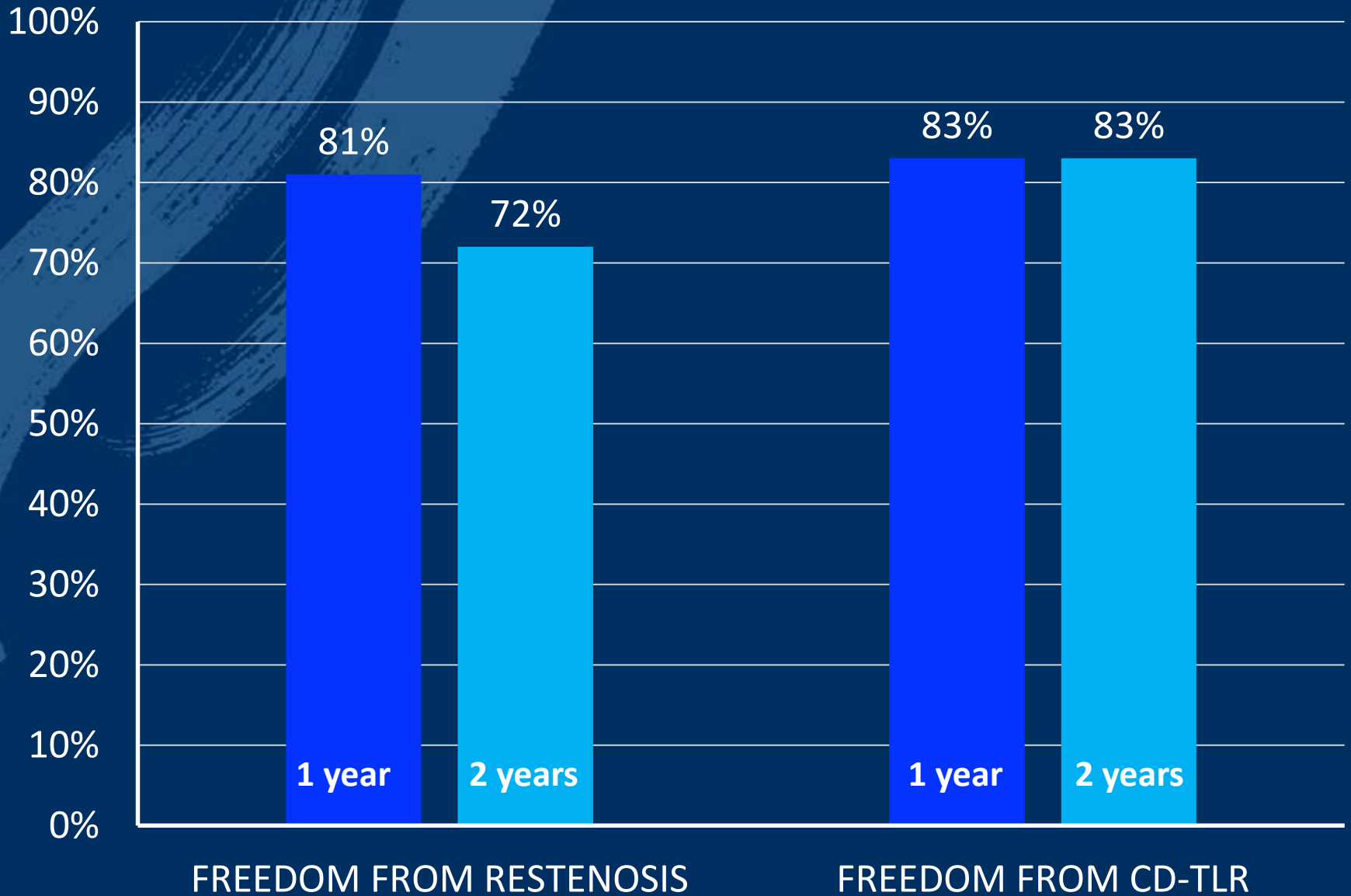
■ SFA ■ FEM / POP

CLI (Rutherford Class ≥ 4)	31%
Rutherford Class	3.2 ± 0.8
<i>de novo</i> lesions	49%
Restenosis	18%
In-stent restenosis	33%
Lesion length (overall)	99 ± 37
<i>de novo</i> lesion length	90 ± 41
In-stent restenosis lesion length	120 ± 17
Restenosis lesion length	86 ± 36

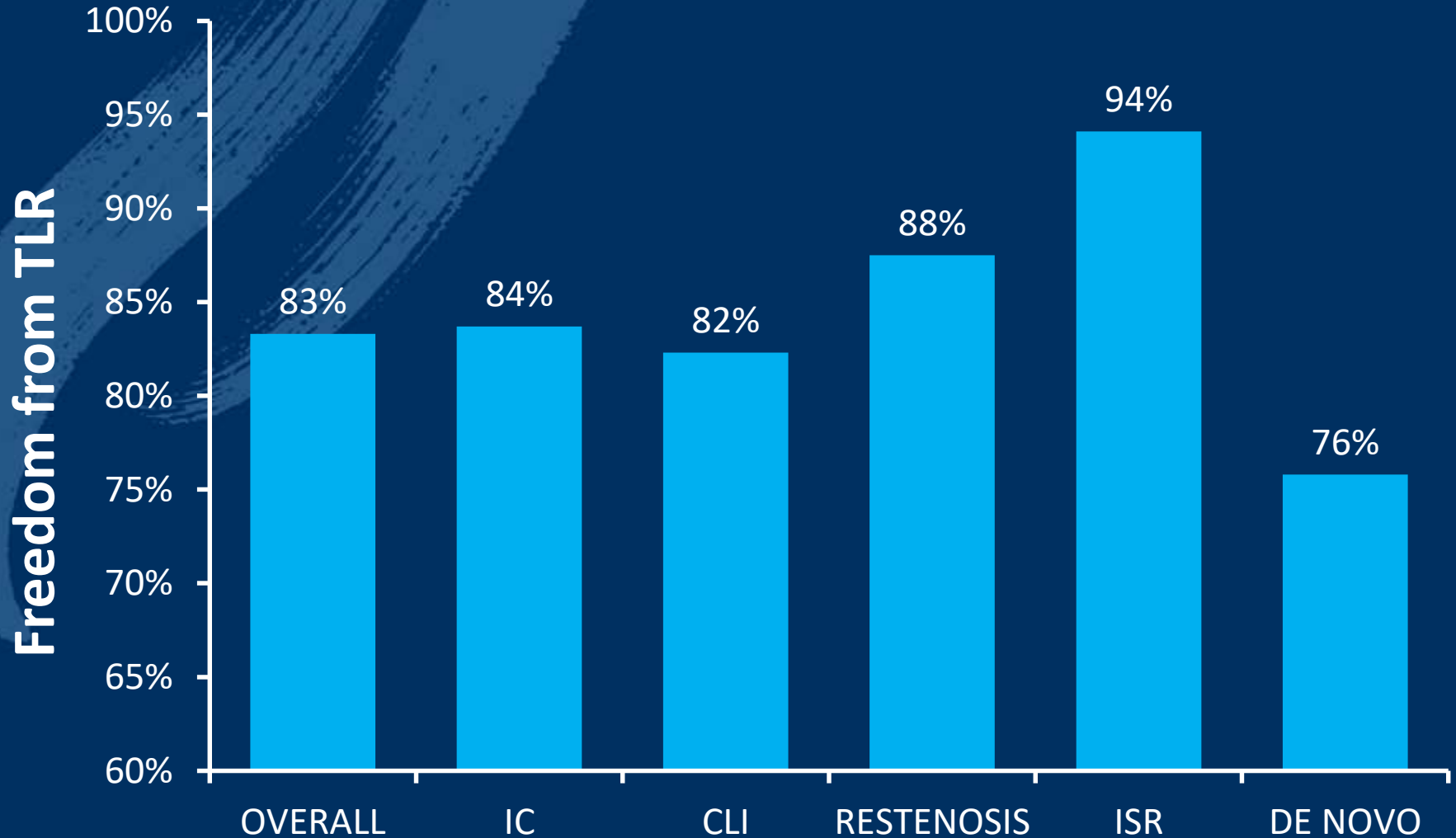
LegDeb Registry Results at 24-months



LegDeb Registry Results at 24-months

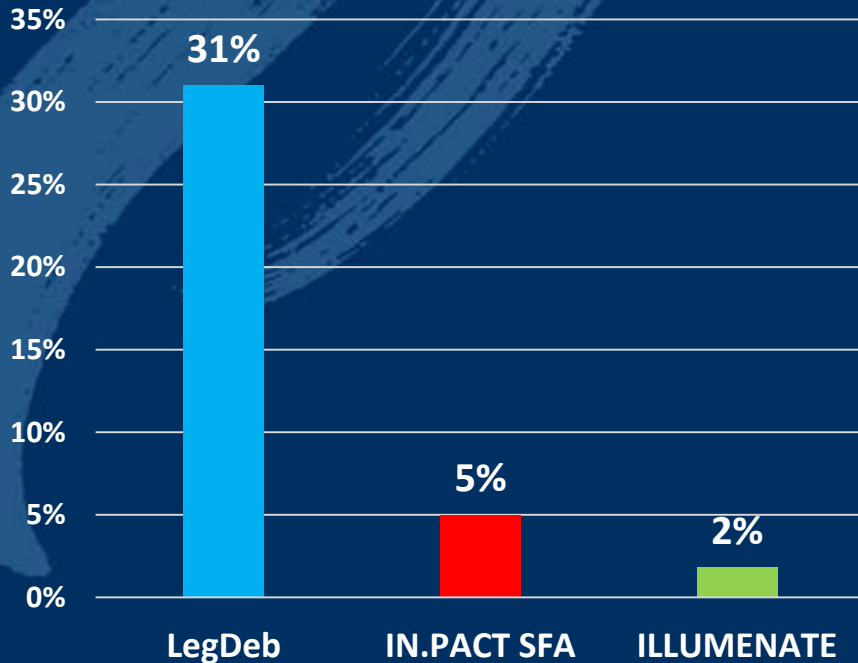


LegDeb Registry Results at 24-months

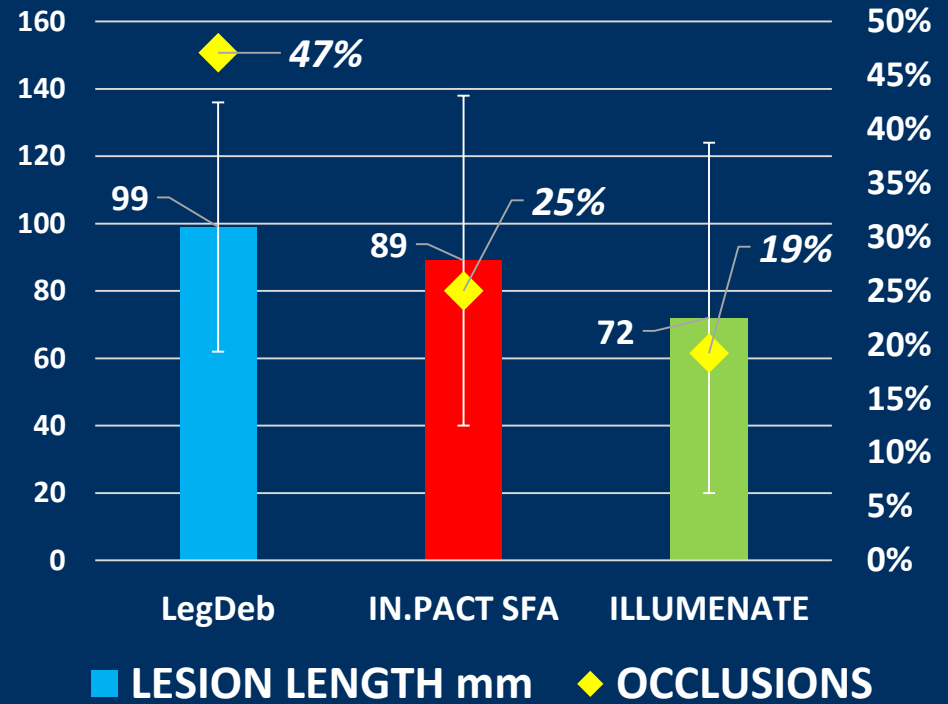


LegDeb Peculiarities

CLI %*

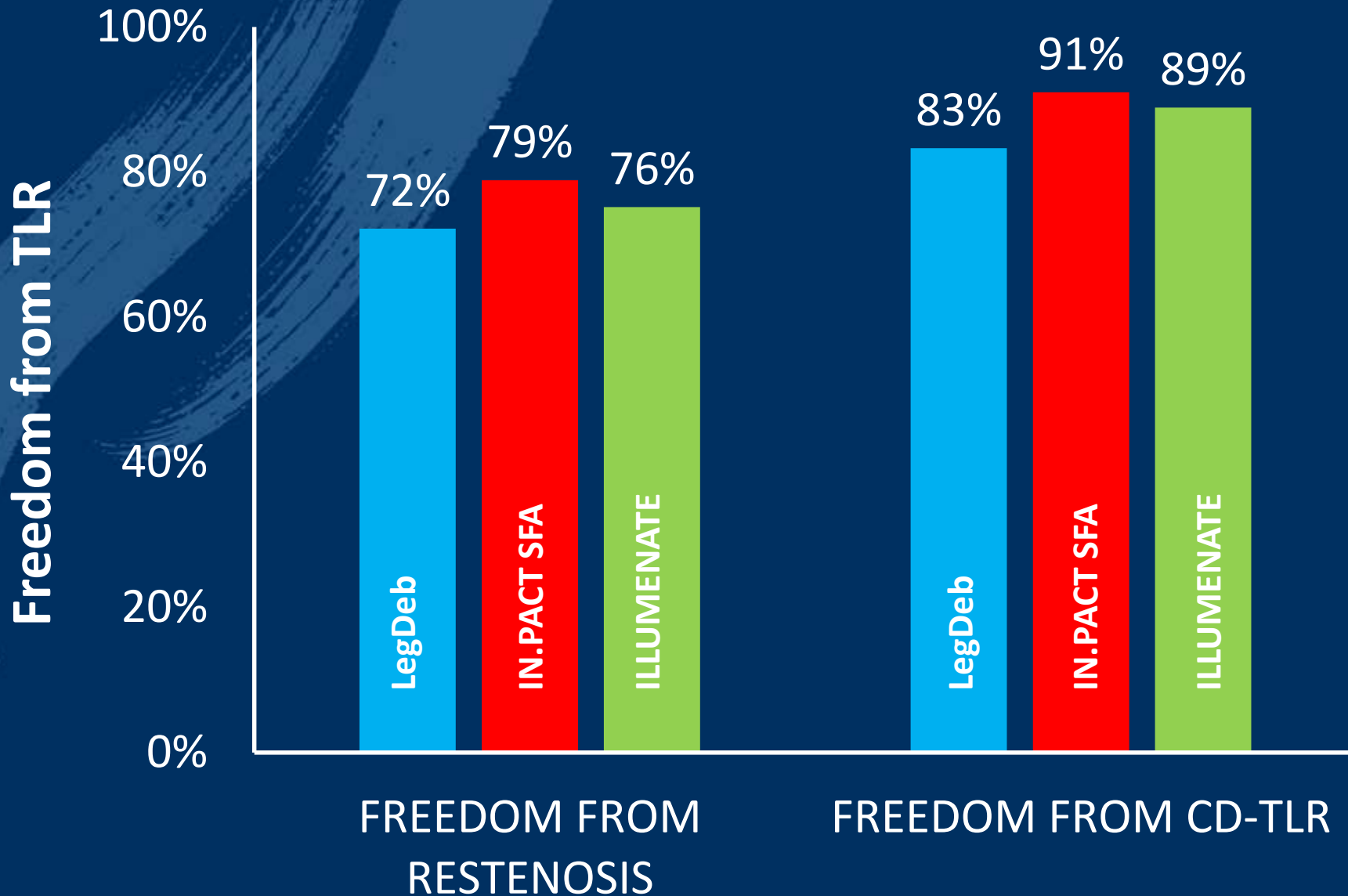


LESION CHARACTERISTICS



* No patients enrolled in Rutherford class ≥ 4

DCB 24-month outcome



Summary and conclusions

In a real-world population with SFA, Legflow achieved favourable outcomes:

100% procedural and technical success rates

83.3% freedom from TLR at 24 months

This was achieved in a population with worse clinical status than in most clinical trials:

31% had CLI

Average lesion: 99 mm

Legflow is a safe and effective treatment option in this challenging population

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