Novel laser-based atherectomy catheter: Results from the Eximo Medical B-Laser™ IDE+EU Study

Marianne Brodmann, MD

Division of Angiology, Medical University Graz, Austria

Disclosure

Speaker name:

Marianne Brodmann, MD

I have the following potential conflicts of interest to report:

☒ Consulting

Medtronic, BD BARD, Spectranetics, Intact Vascular, Soundbite Medical, Biotronik, Bayer, Daiichi Sankyo, Böhringer Ingelheim, Astra Zeneca

B-Laser™ Atherectomy System

- Small and light solid-state Nd:YAG laser
- No calibration and no warm-up time for laser system
- Indifferent to contrast media presence **(Safety!)**
- Three fold affinity to lesion type tissue vs artery's endothelium **(Safety!)**
- 355 nm wavelength
- Short pulses (~10 ns) **(Calcium!)**
- ATK and BTK including calcified lesions, ISR, CTO
- Four OTW (0.014") catheter sizes – 0.9mm, 1.5mm, 2.0mm and 2.35mm (fitting to 4F-7F sheaths)
- Aspiration capability (for the 2.0mm and 2.35 mm) to avoid emboli **(Safety!)**
- "Off-center" capability for large lumen creation and for non-concentric lesions (2.35mm)

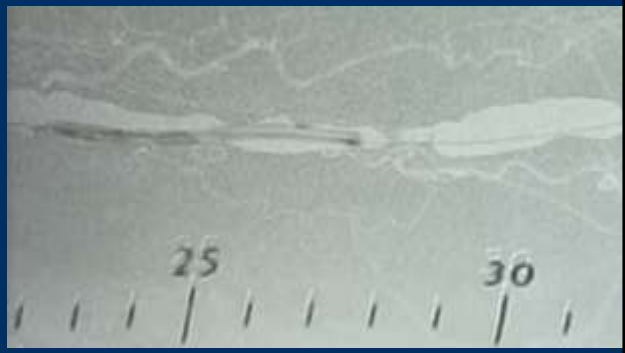
B-Laser™ Line of Catheters

EXIMO B-Laser™ offers a full line of laser catheters with unprecedented capabilities that open new market opportunities in PAD

B-Laser™ catheters come

in a range of diameters

from **0.9 to 2.35mm**



B-Laser™ Clinical Experience of IDE study and EU study (1)

- **Studies Subjects:** 147 subjects (160 lesions)
  6 (IDE study) and 12 (Pilot study) month follow-up
- **Sites** 13 sites | 31 physicians | Used in both Hospital and OBL settings in the U.S. and EU
- **Summarized Results** Excellent clinical performance and safety profile

- EU study results publication is underway
- IDE acute and 30 days results publication was accepted by CRM Journal
- IDE entire study up to 6 months FU will be submitted soon

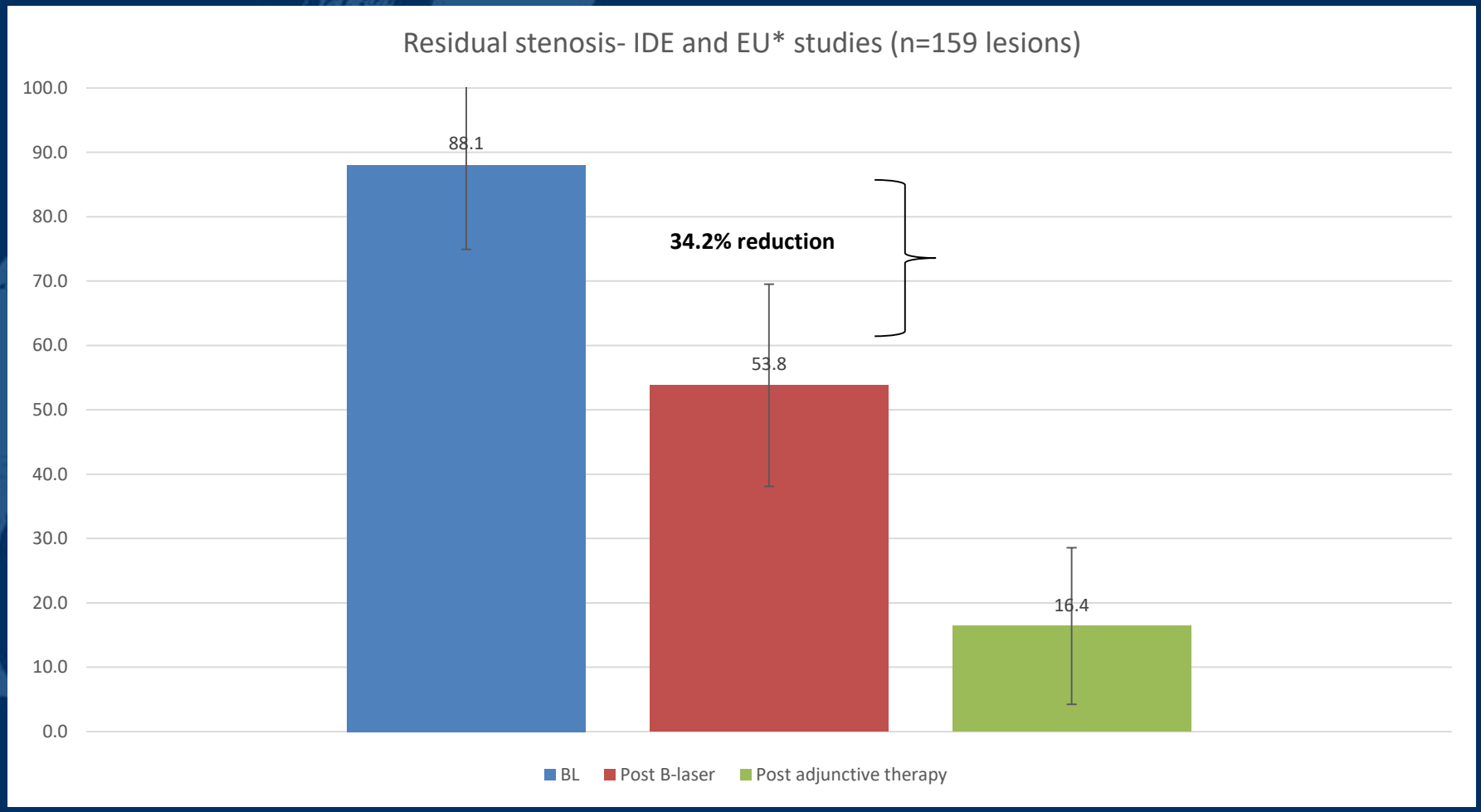
B-Laser™ Clinical Experience of IDE study and EU study (2)

- Studies were performed with a real world case mix including various lesion types, ATK and BTK, including ISR.
- B-Laser™ performance not impacted by calcification severity
  - EU Study:88% of subjects had some level of calcification; >60% were moderate-severely calcified
  - IDE Study:77% of subjects had some level of calcification; >25% were severely calcified
- Proven efficacy with subjects who suffered from Chronic Total Occlusion
  - EU Study: 79% had CTO lesions
  - IDE Study: 34.6% had CTO lesions & sub-total occlusions

B-Laser™ Clinical Experience of IDE study and EU study (3)

- None of the147 study subjects (97 IDE + 50 EU) experienced device-related complications that required intervention (zero perforation and no flow-limiting dissections), by CoreLab.
- None of the147subjects experienced perioperative distal embolization (by CoreLab) with only 8 EPD used.
- TLR at 6 months- **3 / 141** subjects (2.1%)
- TLR at 12 months- **2 / 46** (4.3%)
- Bailout stenting – **1 / 147** (0.7%) (not device related)
- MAE at 30 days- **1 / 147** (0.7%) (not device related)

B-Laser™ Clinical Experience of IDE and EU studies

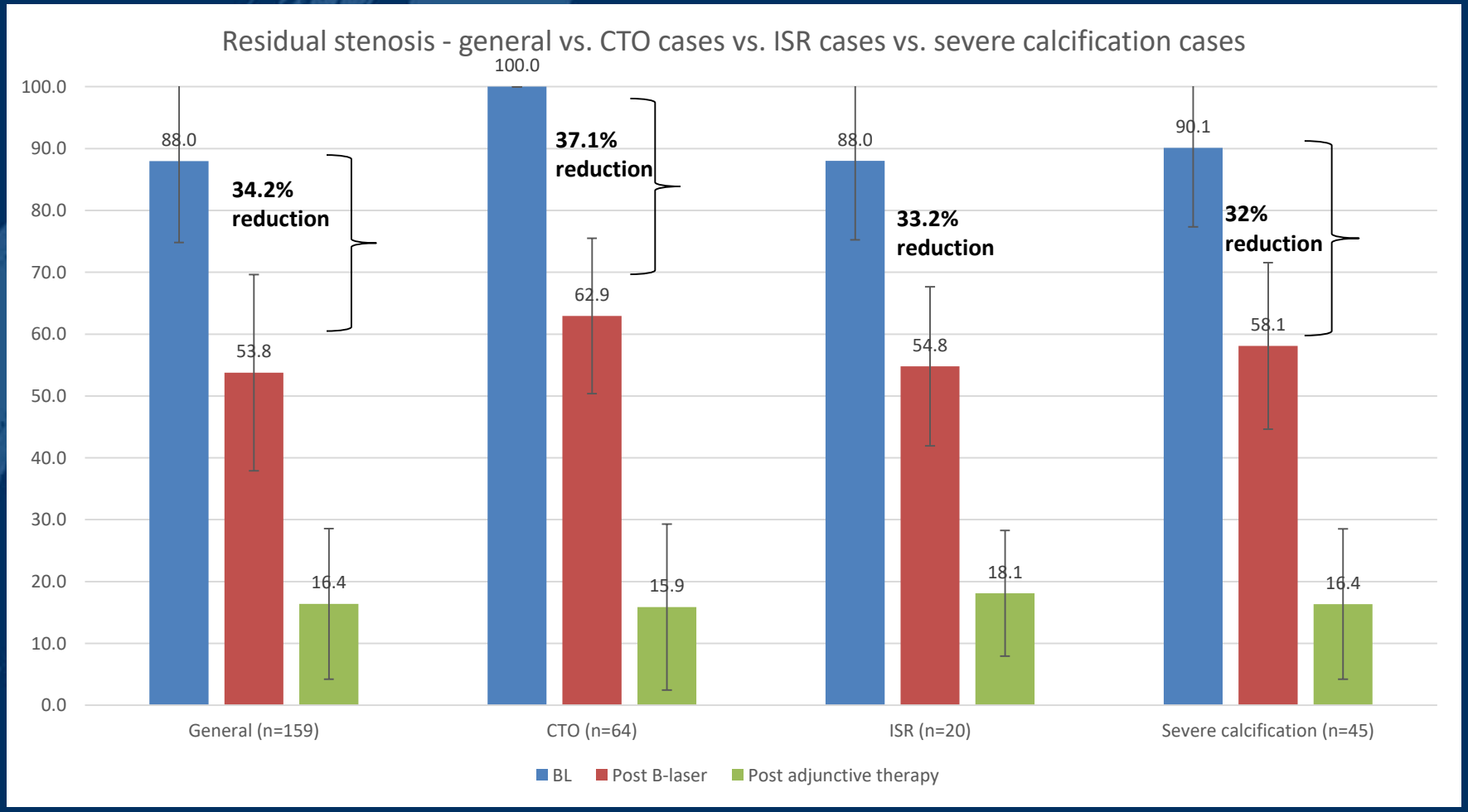


*For EU study:

(1) Post adjunctive therapy was evaluated per the investigator and not per corelab.

(2) 2nd lesions (in 3 cases) were evaluated per the investigator and not per corelab.

B-Laser™ Clinical Experience of IDE and EU studies

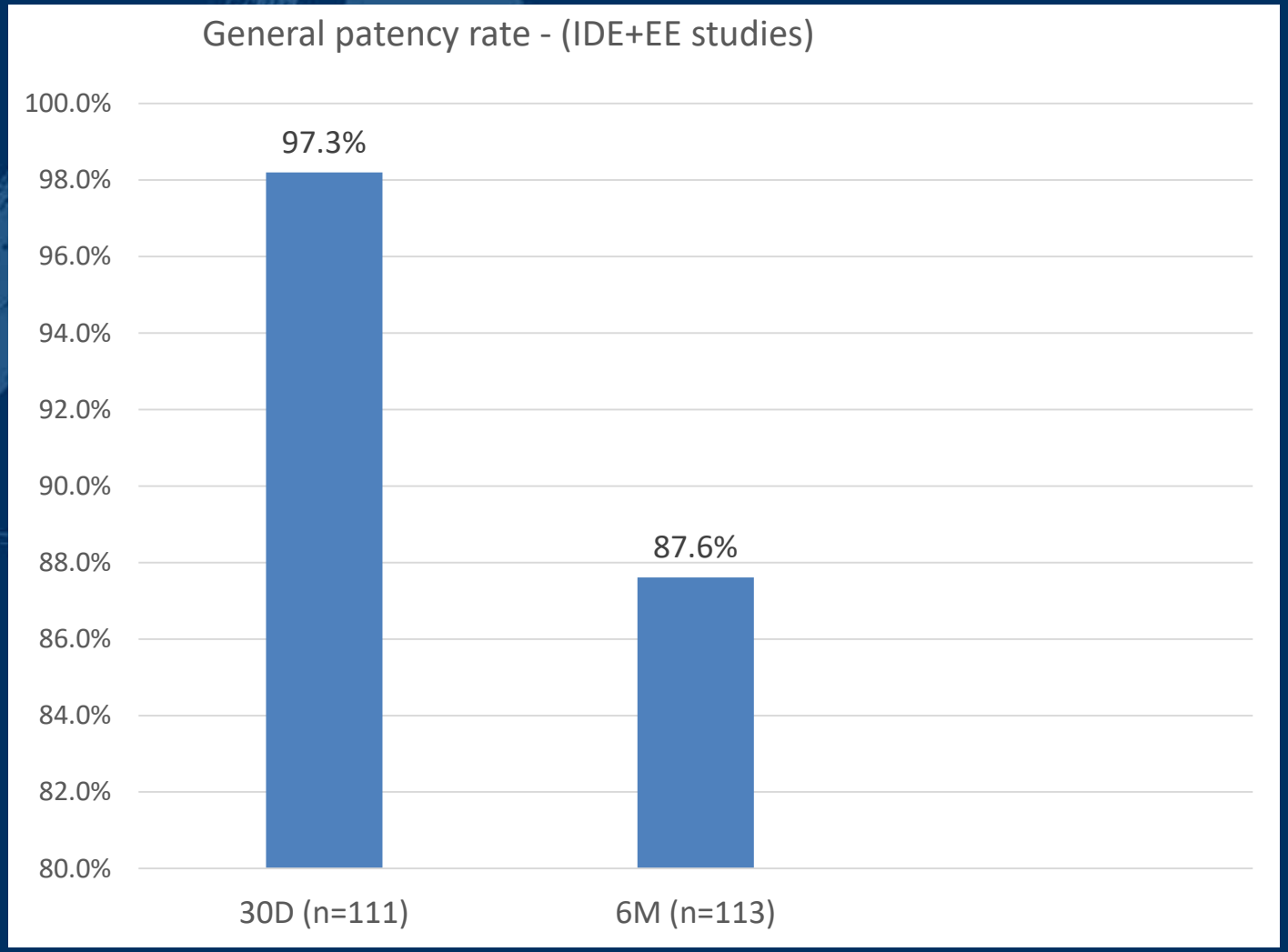


*For EU study:

(1) Post adjunctive therapy was evaluated per the investigator and not per corelab.

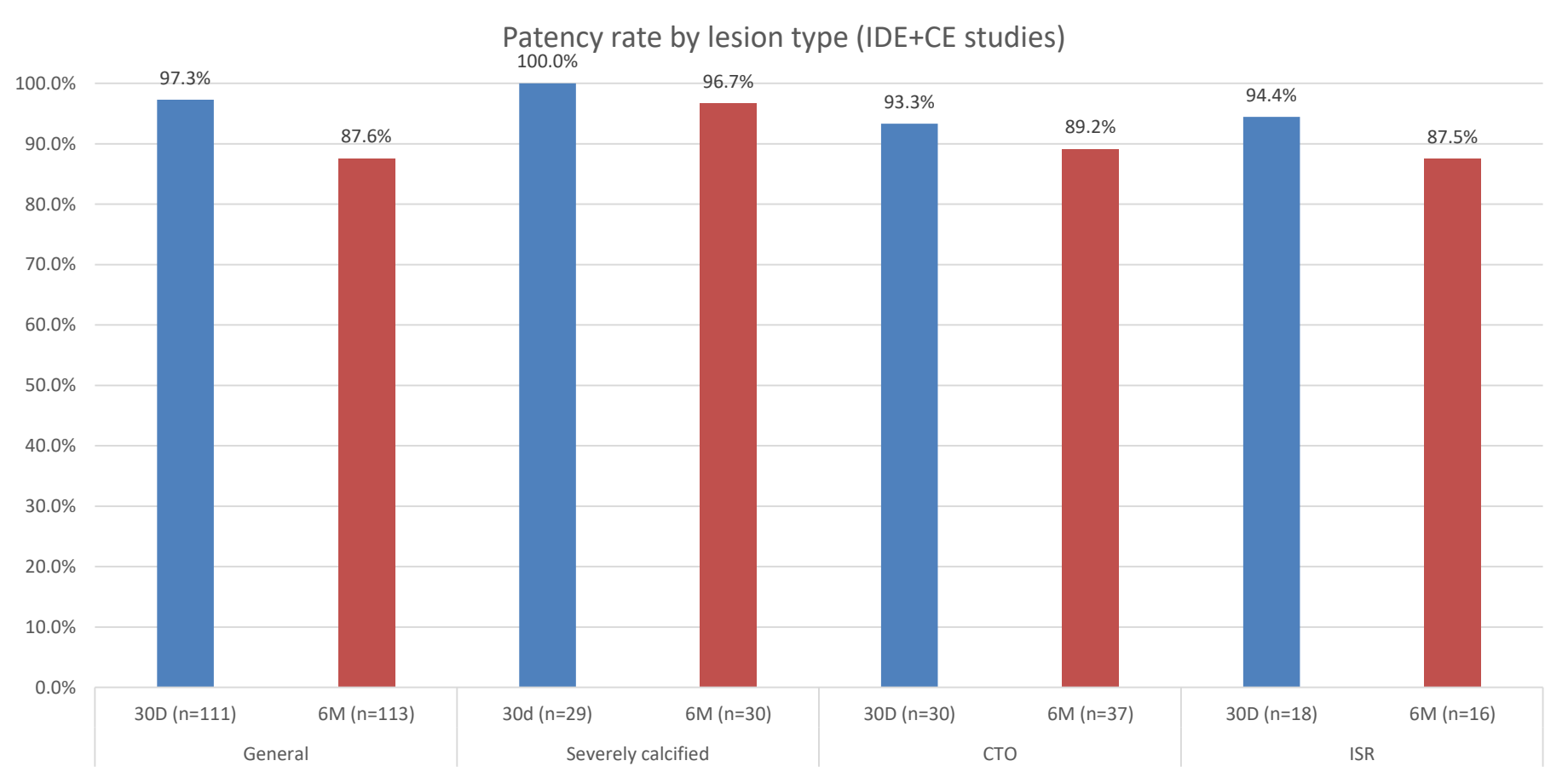
(2) 2nd lesions (in 3 cases) were evaluated per the investigator and not per corelab.

B-Laser™ Clinical Experience of IDE and EU studies- DUS

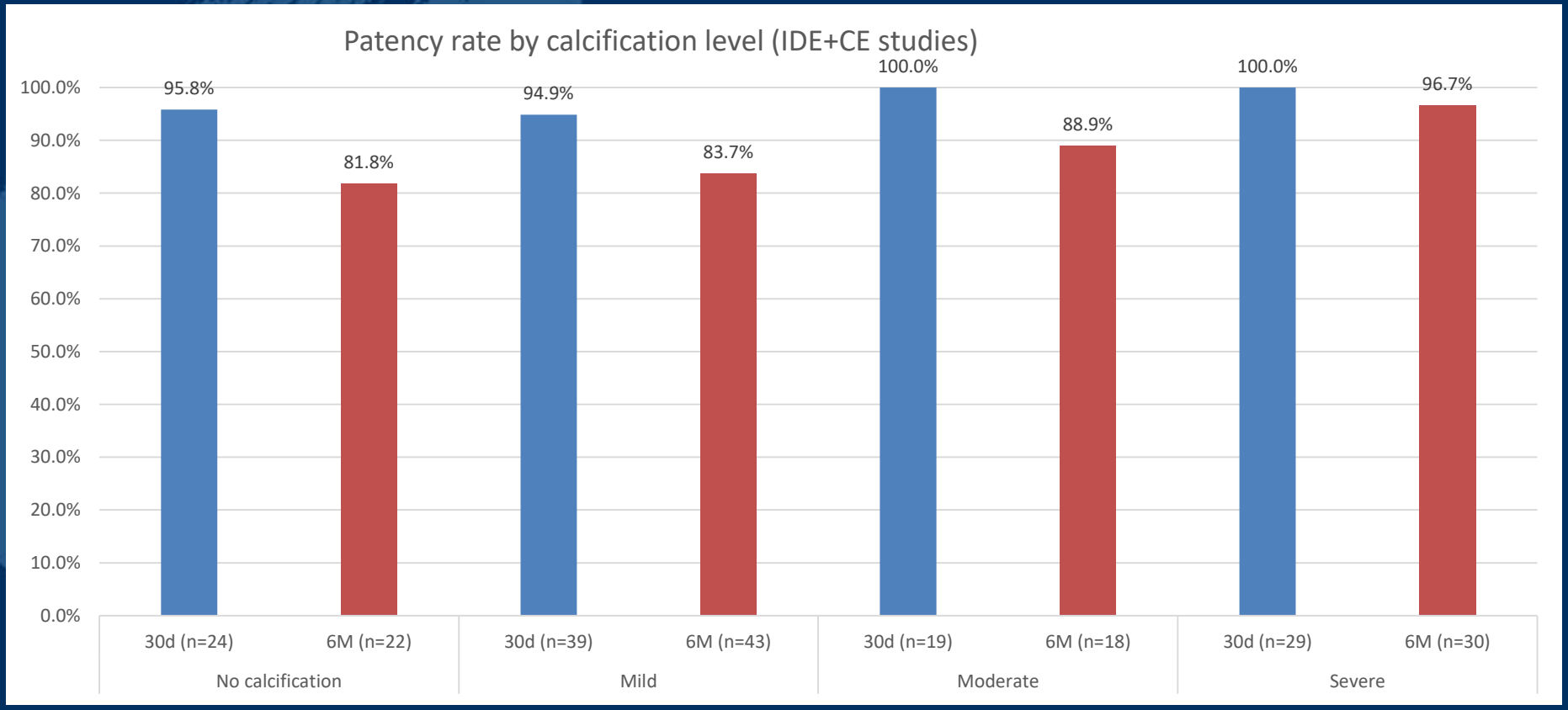


Note: Patency is defined by PSVR <2.5. For IDE it was determined by the CoreLab, and for EU it was determined by site ultra-sonographers

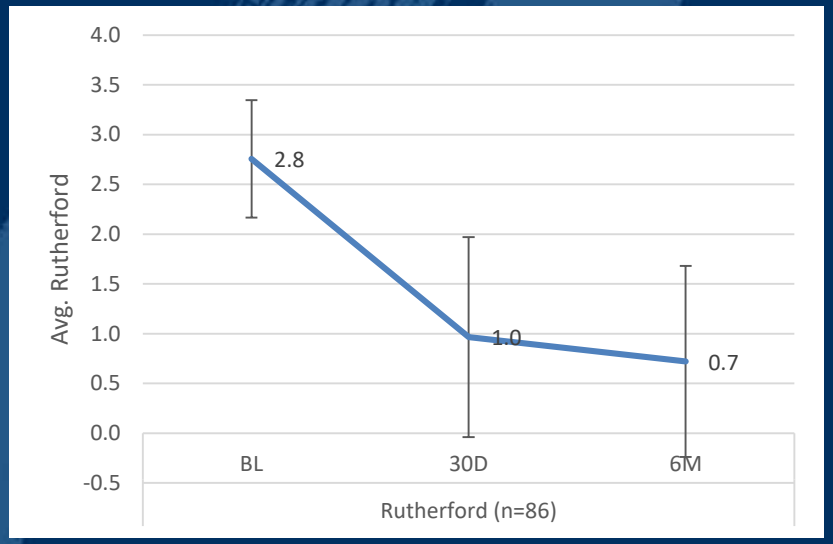
Patency rates at 30D and 6 Months- Lesion type

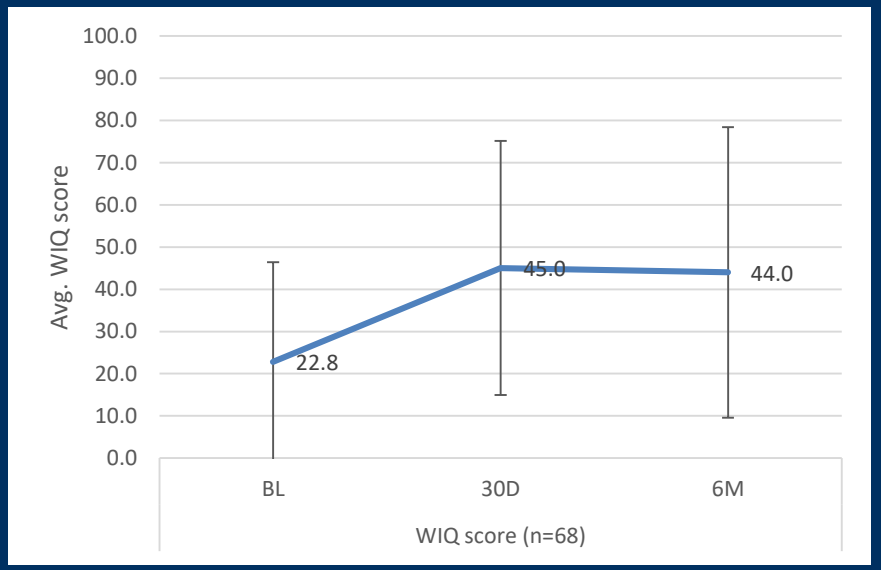


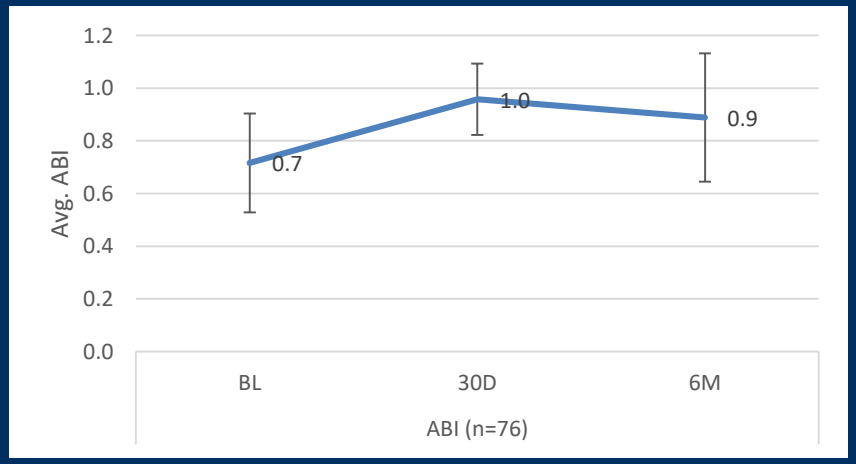
Patency rates at 30D and 6 Months- Calcification level



IDE- Clinical Outcome (ABI, Rutherford, WIQ n= number of the same subjects that have BL, 30D and 6M clinical outcome data)



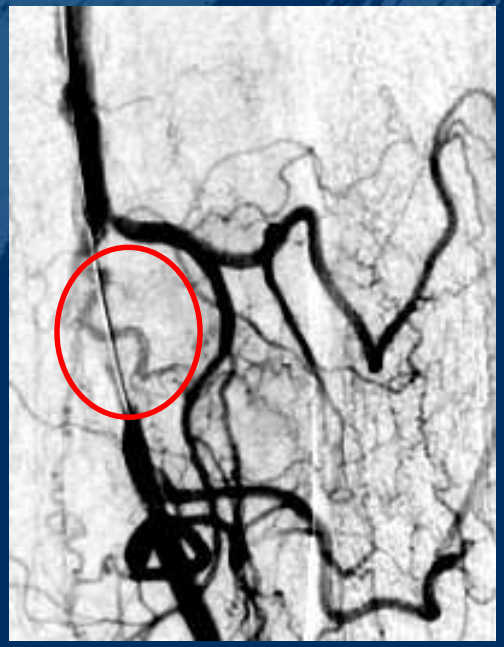




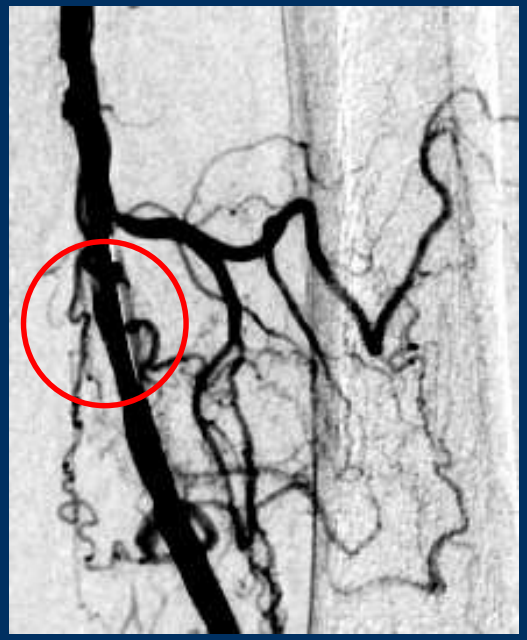
B-Laser™ Clinical Experience- Typical angiograph with “off -Centering”

5cm CTO in SFA, 2.35mm with “off-centering”

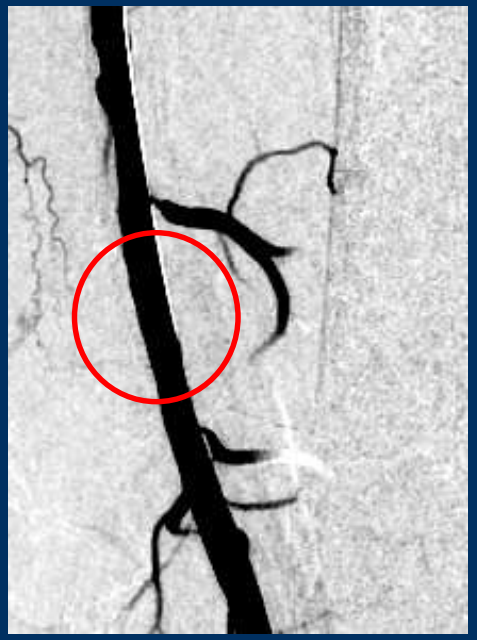
Before



After B-Laser™

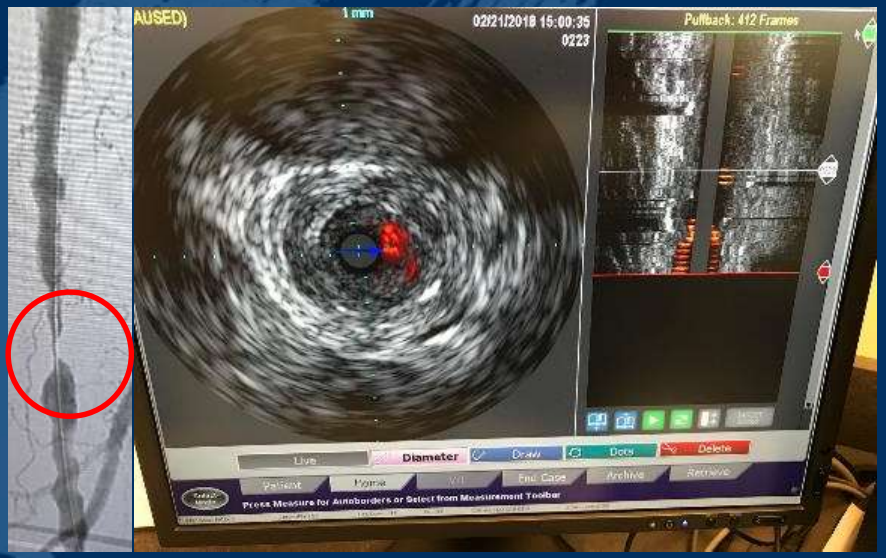


After B-Laser™ + Balloon

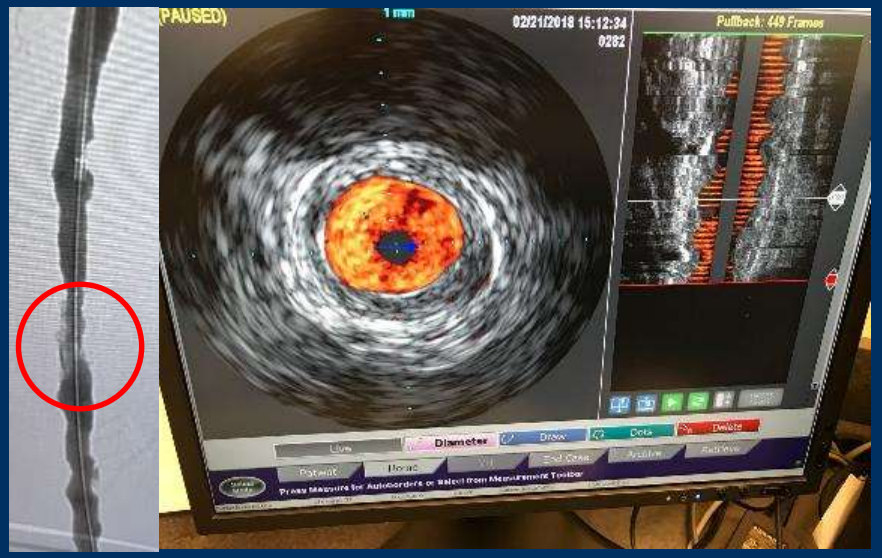


IVUS images (1.5mm in 5.5mm vessel)

Before Laser



After Laser



A lumen much larger than the nominal catheter diameter, was achieved

Thank You!

Novel laser-based atherectomy catheter: Results from the Eximo Medical B-Laser™ IDE+EU Study

Marianne Brodmann, MD

Division of Angiology, Medical University Graz, Austria