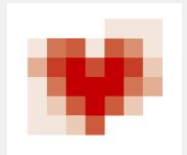


# Intra Stent Restenosis: POBA, DEB, DES or Covered Stent?

Hans Krankenberg, MD

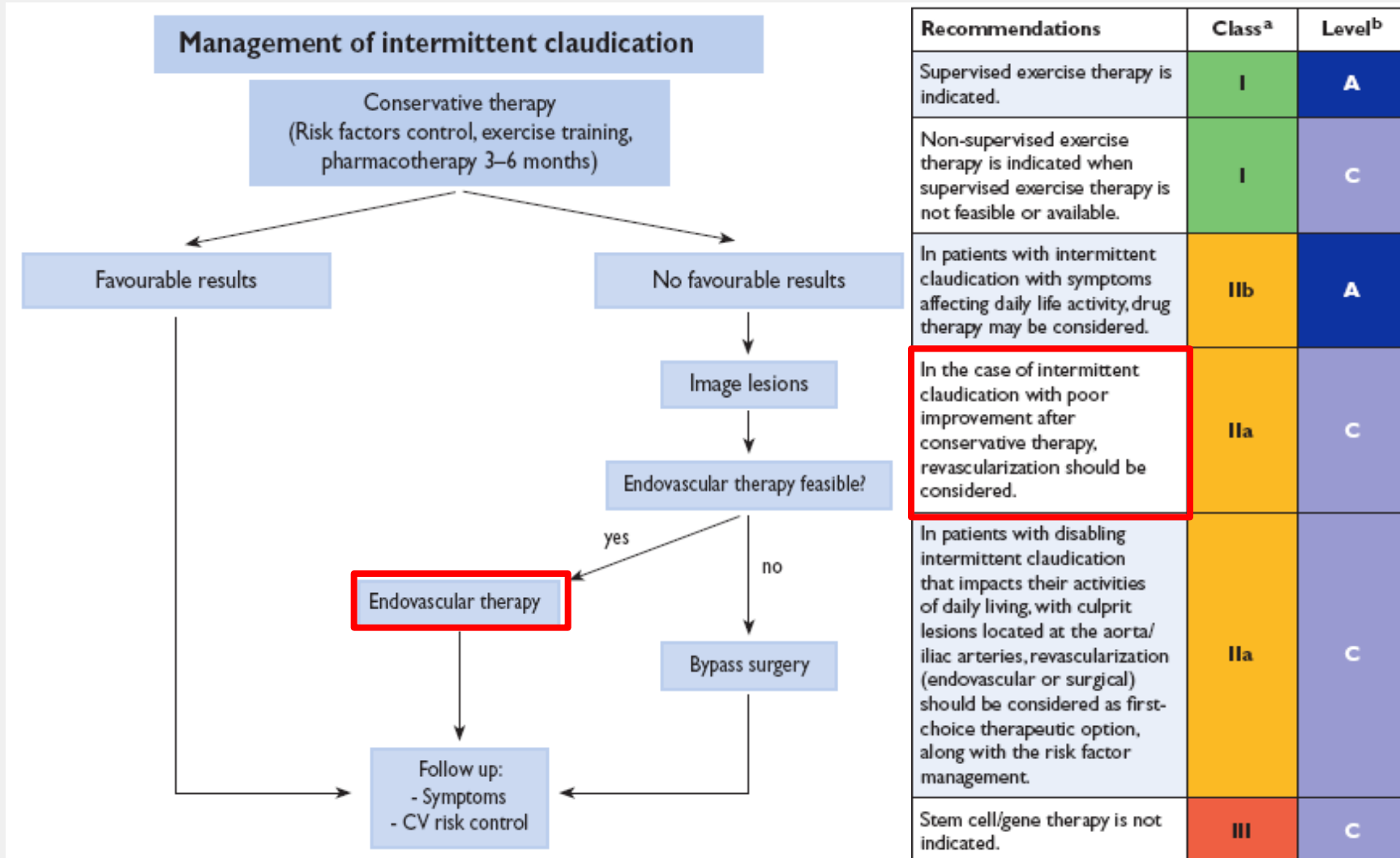
*Klinik für Angiologie*

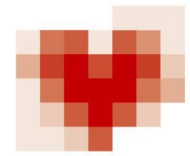
*Herz- und Gefäßzentrum Bad Bevensen*



# ESC-Guidelines

## Intermittent claudication

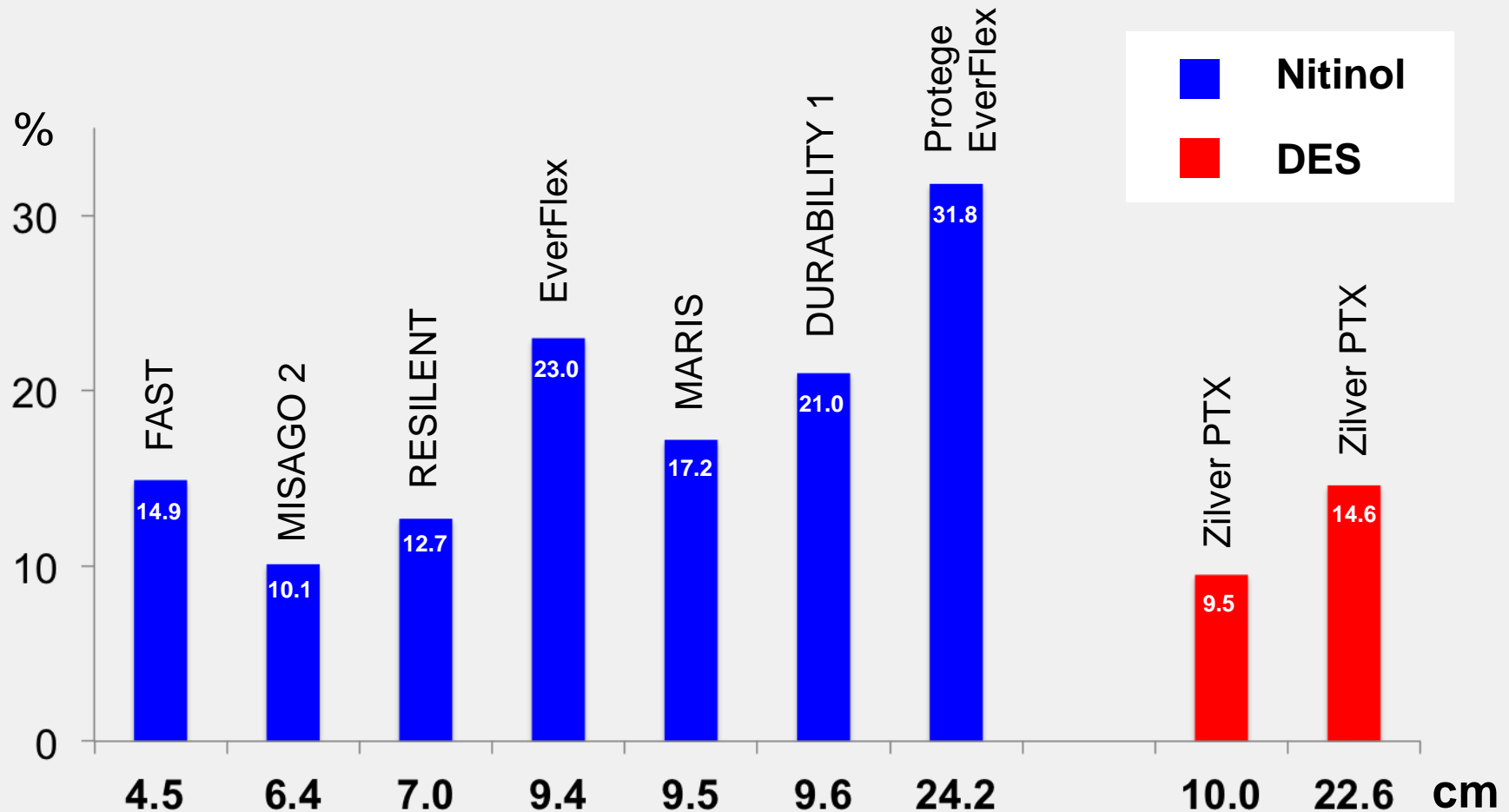
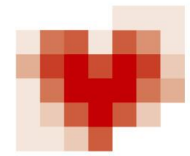




### Recommendations for revascularization in patients with femoropopliteal lesions

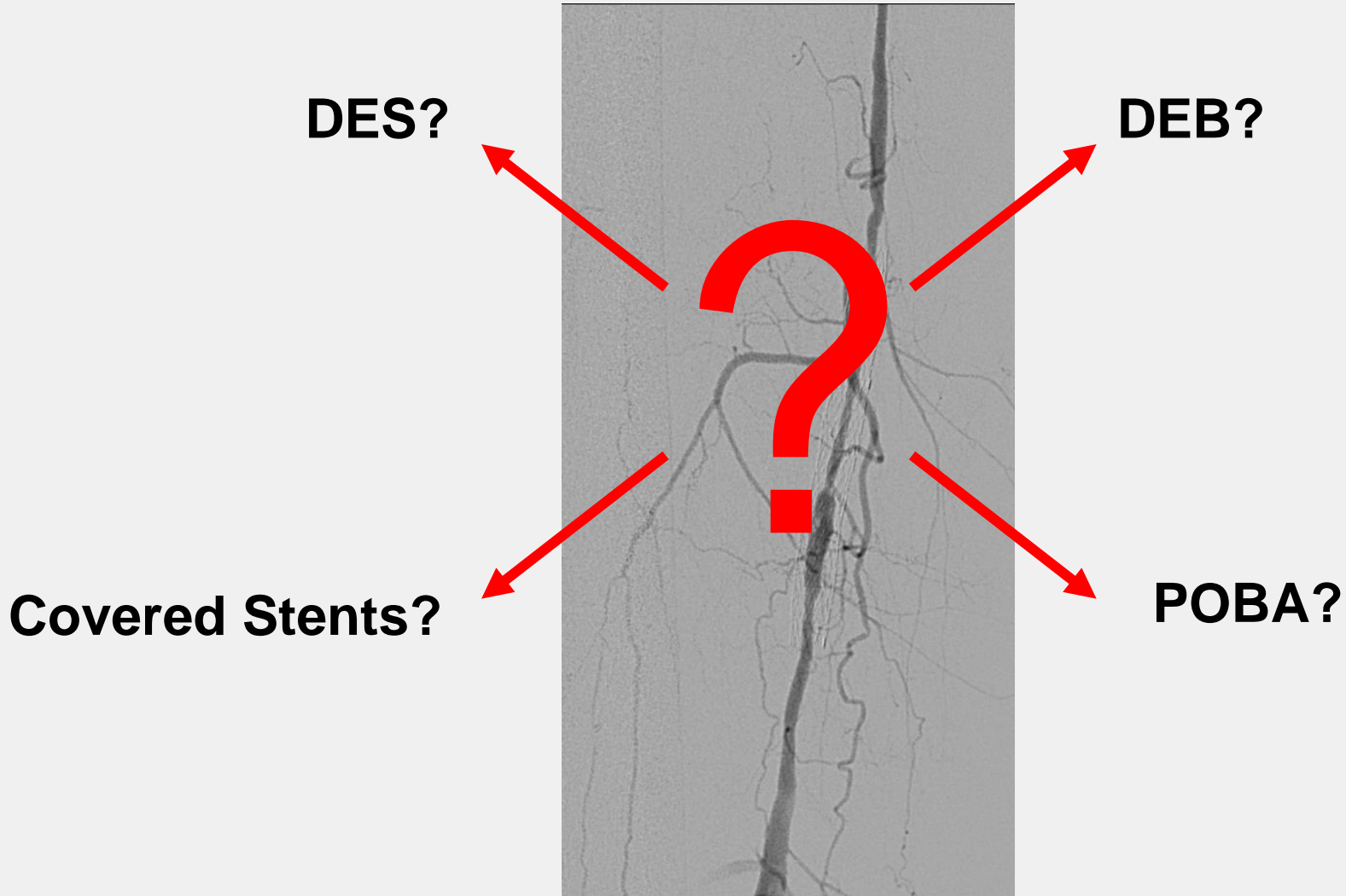
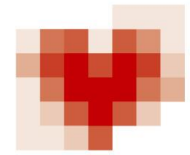
Recommendations	Class <sup>a</sup>	Level <sup>b</sup>	Ref <sup>c</sup>
When revascularization is indicated, an <b>endovascular-first</b> strategy is recommended in all femoropopliteal TASC A–C lesions.	I	C	-
<b>Primary stent implantation</b> should be considered in femoropopliteal TASC B lesions.	IIa	A	285, 286, 291
A <b>primary endovascular approach</b> may also be considered in TASC D lesions in patients with severe comorbidities and the availability of an experienced interventionist.	IIb	C	-

# 12-month TLR following SFA-stenting



➔ With stenting increasingly performed in the SFA, an increasing number of patients will require repeat treatment for **in-stent restenosis**

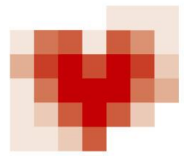
# In-Stent Restenosis (ISR)



# In-Stent Restenosis (ISR)

HGZ

HERZ- UND GEFÄSSZENTRUM BAD BEVENSEN  
AKADEMISCHES LEHRKRANKENHAUS  
DER MEDIZINISCHEN HOCHSCHULE HANNOVER



## Covered Stents

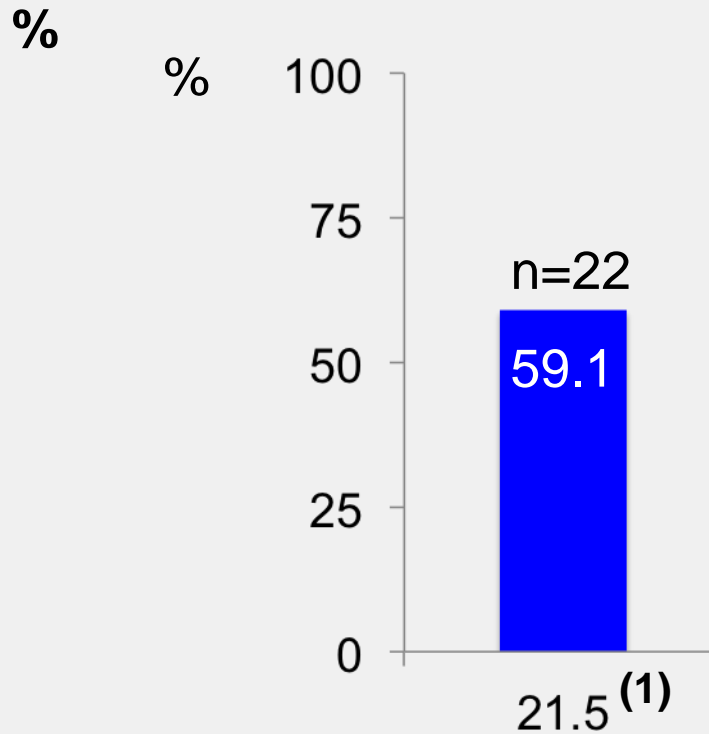
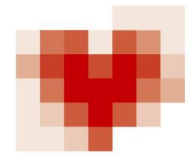


# Covered Stents\* in SFA-ISR

## Primary patency at 12 months

HGZ

HERZ- UND GEFÄSSZENTRUM BAD BEVENSEN  
AKADEMISCHES LEHRKRANKENHAUS  
DER MEDIZINISCHEN HOCHSCHULE HANNOVER



Mean lesion length (cm)

Mean lesion length (cm)

(1) Gorgani F et al. *J Invasive Cardiol* 2013

(2) Laird JR et al. *Cath Cardiovasc Interv* 2012

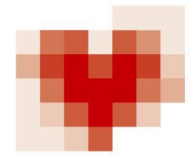
(3) Al Shammeri et al. *Ann Saudi Med* 2012

\*GORE VIABAHN Endoprosthesis

# In-Stent Restenosis (ISR)

HGZ

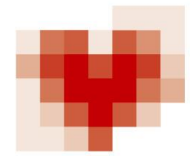
HERZ- UND GEFÄSSZENTRUM BAD BEVENSEN  
AKADEMISCHES LEHRKRANKENHAUS  
DER MEDIZINISCHEN HOCHSCHULE HANNOVER



**Drug eluting stents**

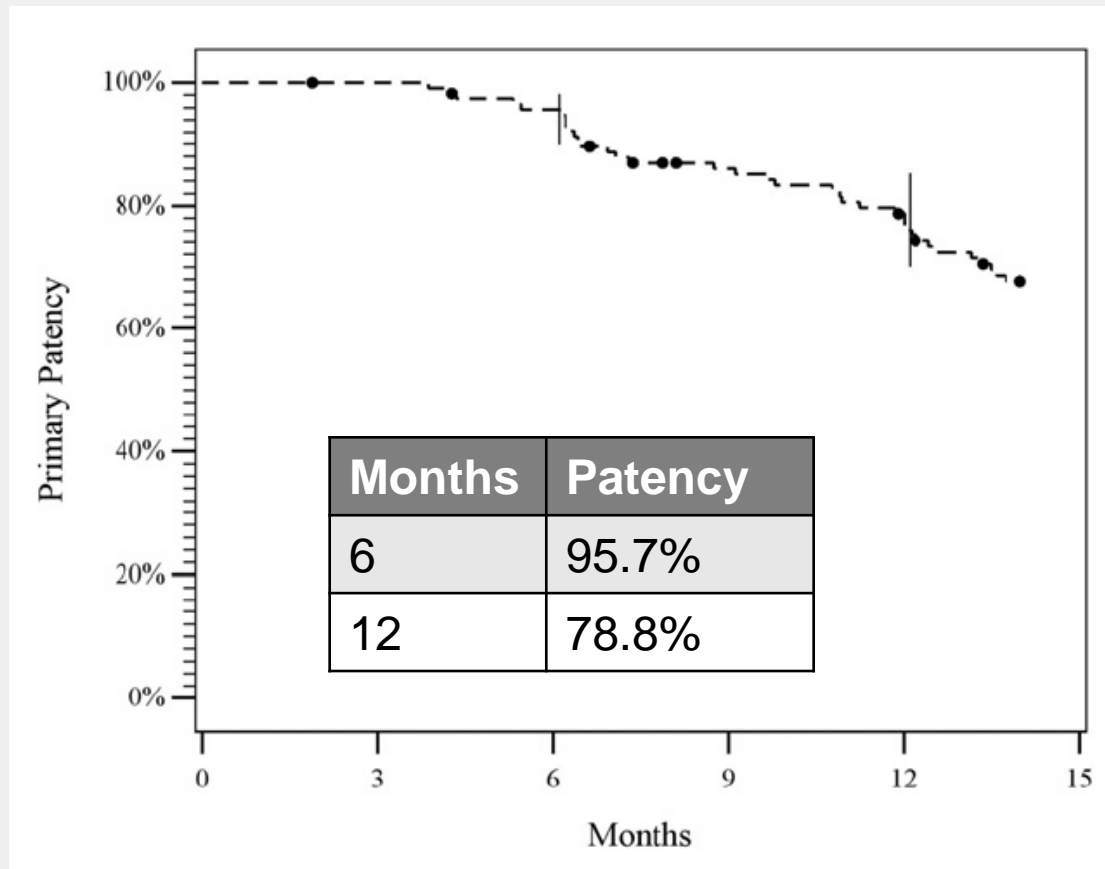


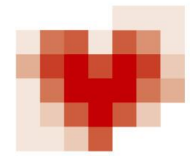




### Primary Patency

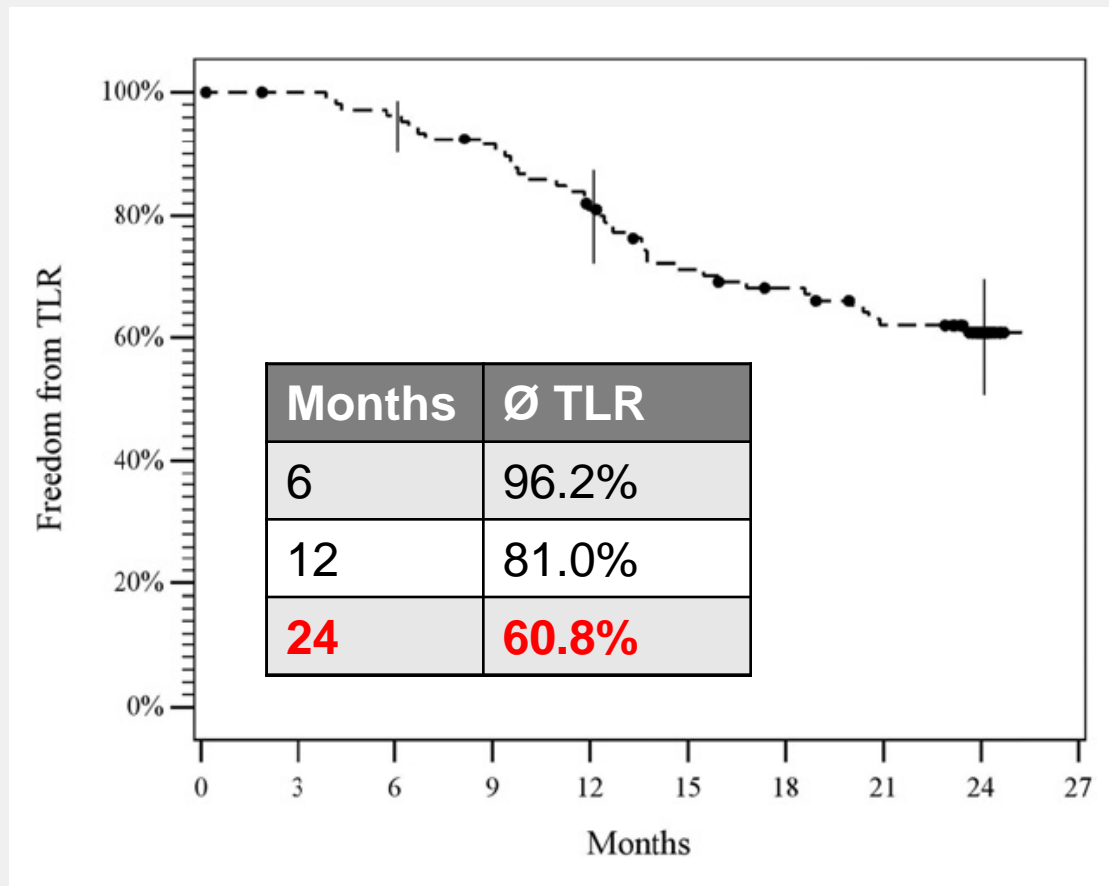
108/787 patients, 119 lesions, mean lesion length 13.3 cm





### Freedom from TLR

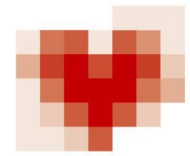
108/787 patients, 119 lesions, mean lesion length 13.3 cm



# In-Stent Restenosis (ISR)

HGZ

HERZ- UND GEFÄSSZENTRUM BAD BEVENSEN  
AKADEMISCHES LEHRKRANKENHAUS  
DER MEDIZINISCHEN HOCHSCHULE HANNOVER

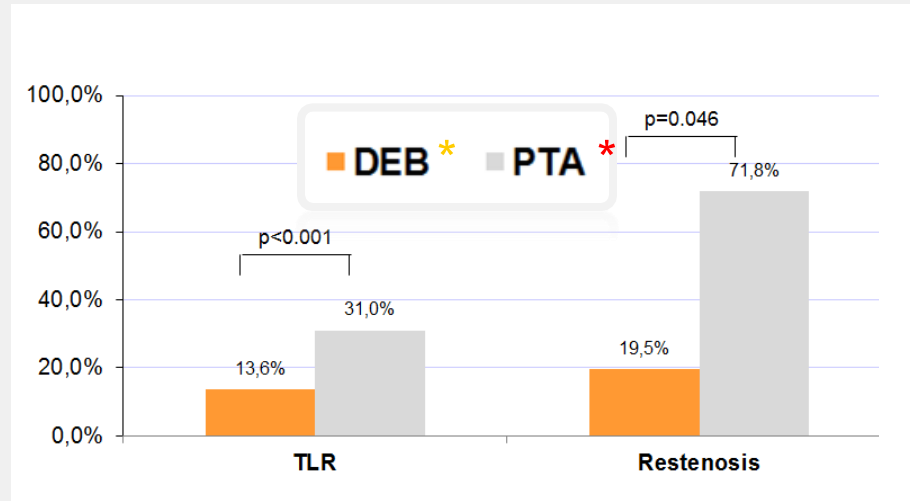
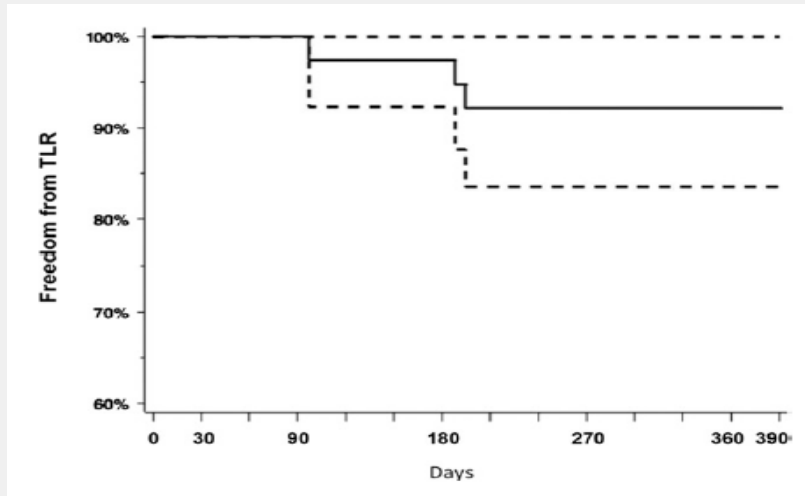
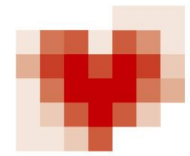


**Drug eluting balloon**



# DEB in SFA-ISR

12-month primary patency 80-90%



n = 39  
ISR 8.3 cm

Recurrent restenosis **7.9%**  
12-month TLR **7.9%**

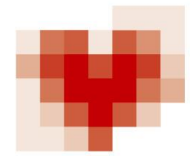
\* Stabile E et al. *JACC* 2012;60:1739-42

n = 42  
ISR 13.2 cm

Recurrent restenosis **19.5%**  
12-month TLR **13.6%**

\*\* Liistro F et al. *J Endovasc Ther* 2013

\* IN.PACT DEB (Medtronic) \* historical comparison group



## **Drug Eluting Balloon vs. PTA for Superficial Femoral Artery In-Stent Restenosis**

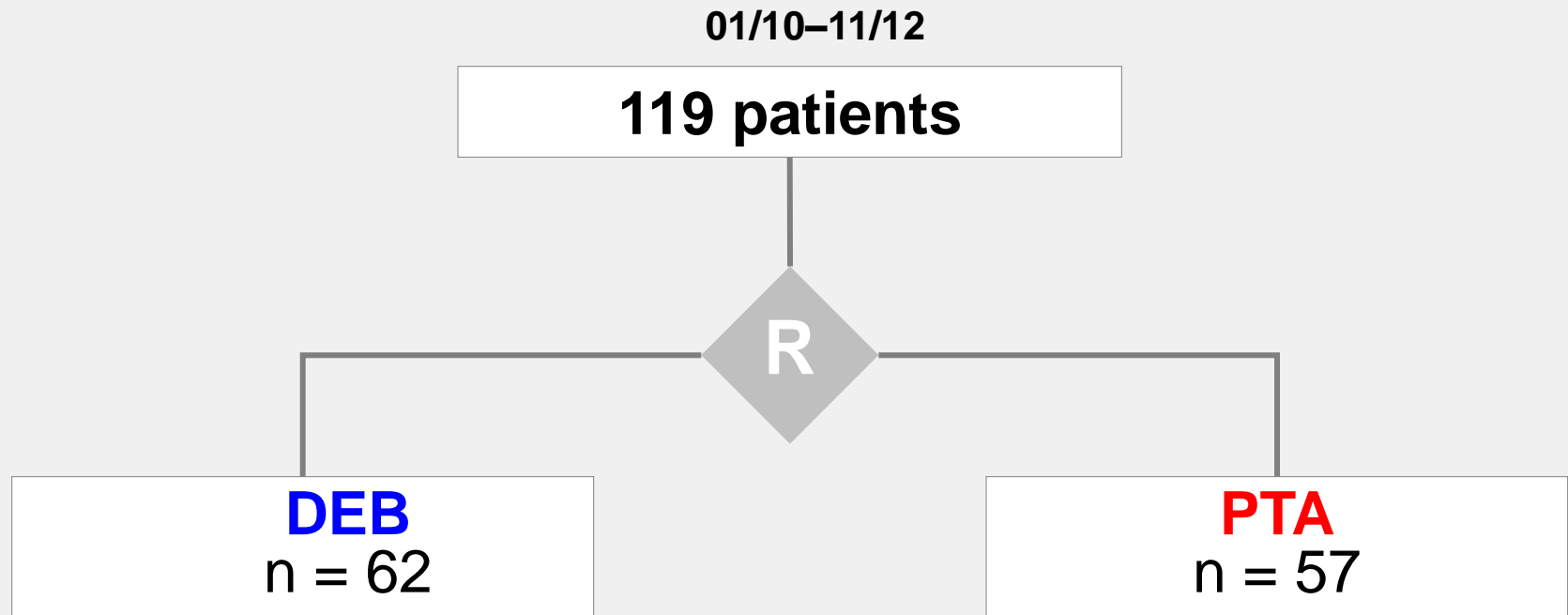
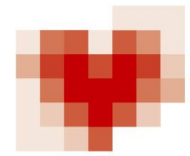
Investigator initiated, corelab adjudicated, prospective,  
multicenter, randomized trial

**Objective:** to assess safety and efficacy of PTA with drug-eluting balloon (IN.PACT Admiral, Medtronic) vs. standard PTA for the treatment of symptomatic SFA-ISR

**Primary Endpoint:** Binary ( $\geq 50\%$ ) restenosis rate at 6 months by duplex ultrasound corelab adjudication (PSVR  $\geq 2.4$ )

# DEB vs. PTA in SFA-ISR

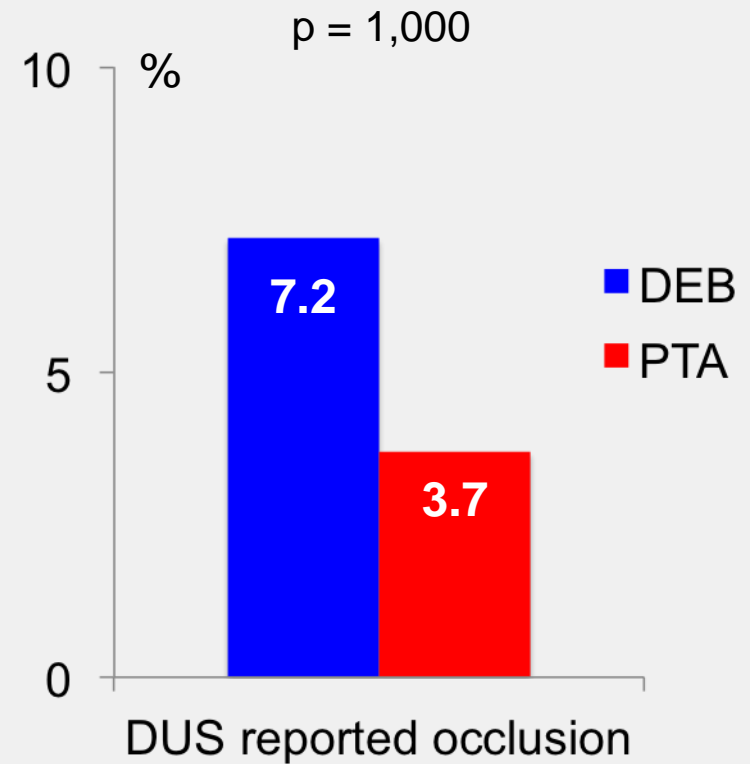
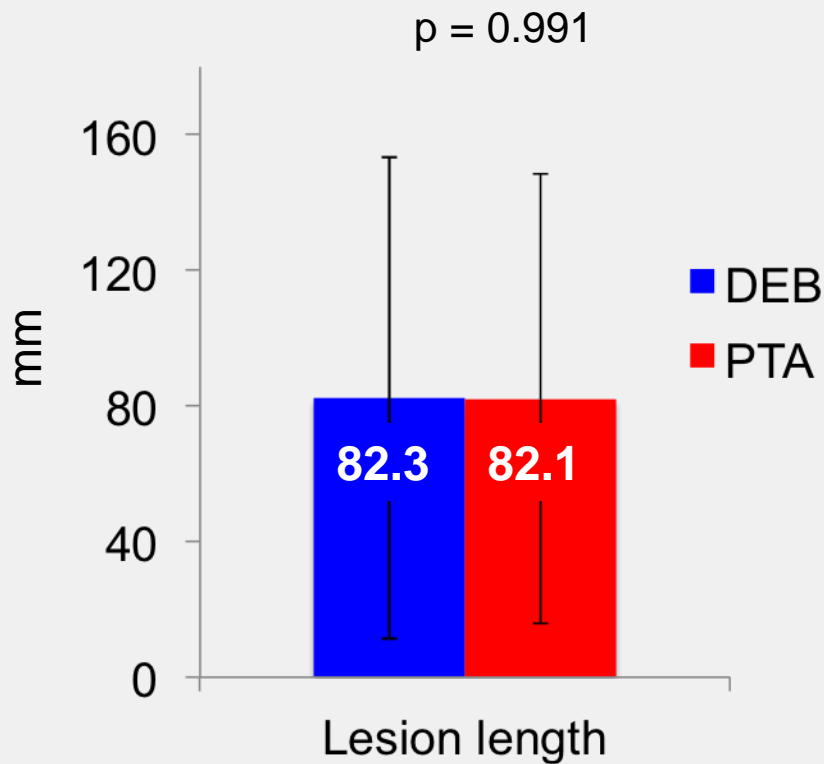
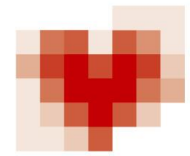
## FAIR – Trial profile



<b>Follow-up</b>	
<b>Clinical/Functional:</b>	at 1, 6, and 12 months
<b>Duplex US:</b>	at 6, and 12 months

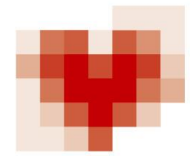
# DEB vs. PTA in SFA-ISR

## FAIR – Baseline lesion characteristics

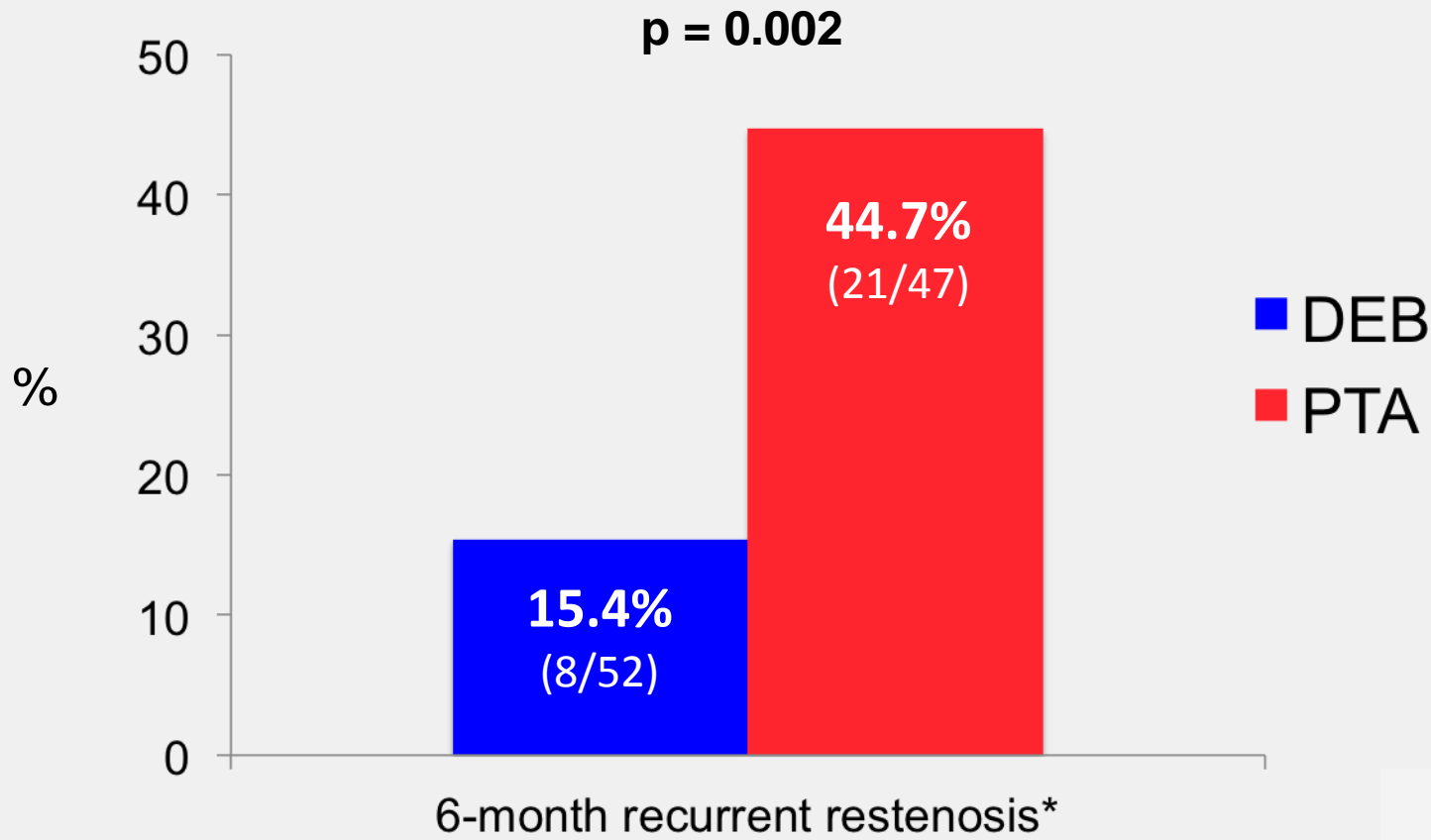


# DEB vs. PTA in SFA-ISR

FAIR – 6-month recurrent restenosis



## Primary endpoint

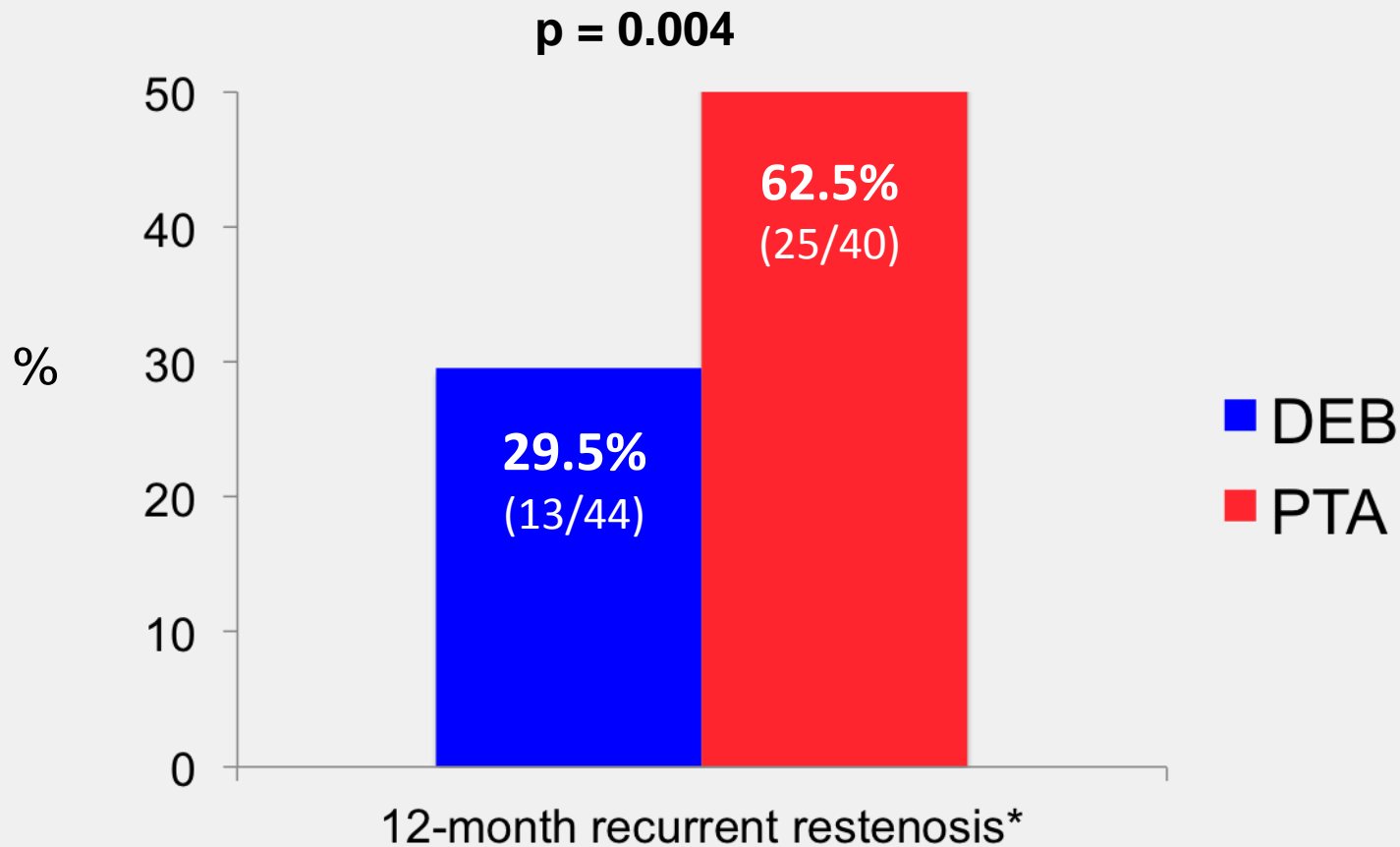
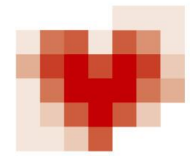


\* Site reported binary restenosis  $\geq$  50%



# DEB vs. PTA in SFA-ISR

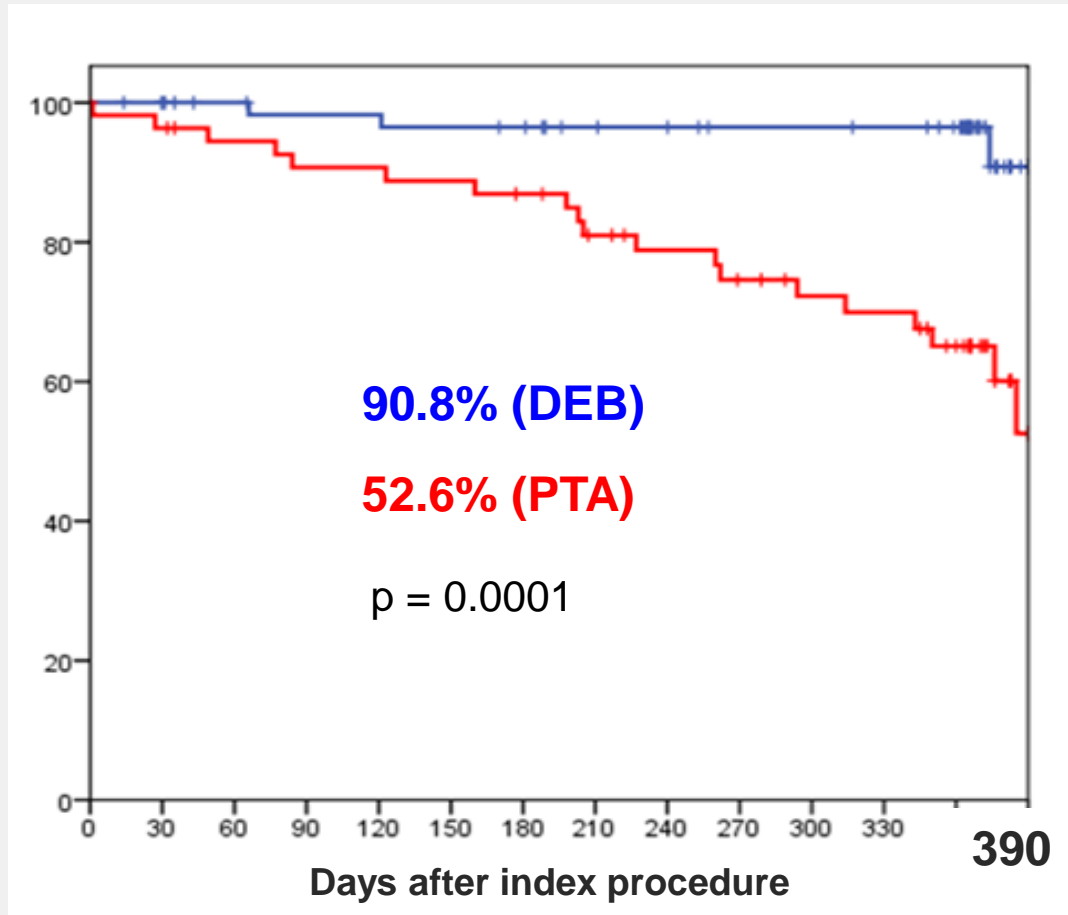
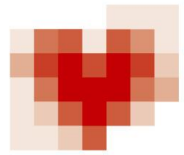
FAIR – 12-month recurrent restenosis



\* Site reported binary restenosis  $\geq 50\%$

# DEB vs. PTA in SFA-ISR

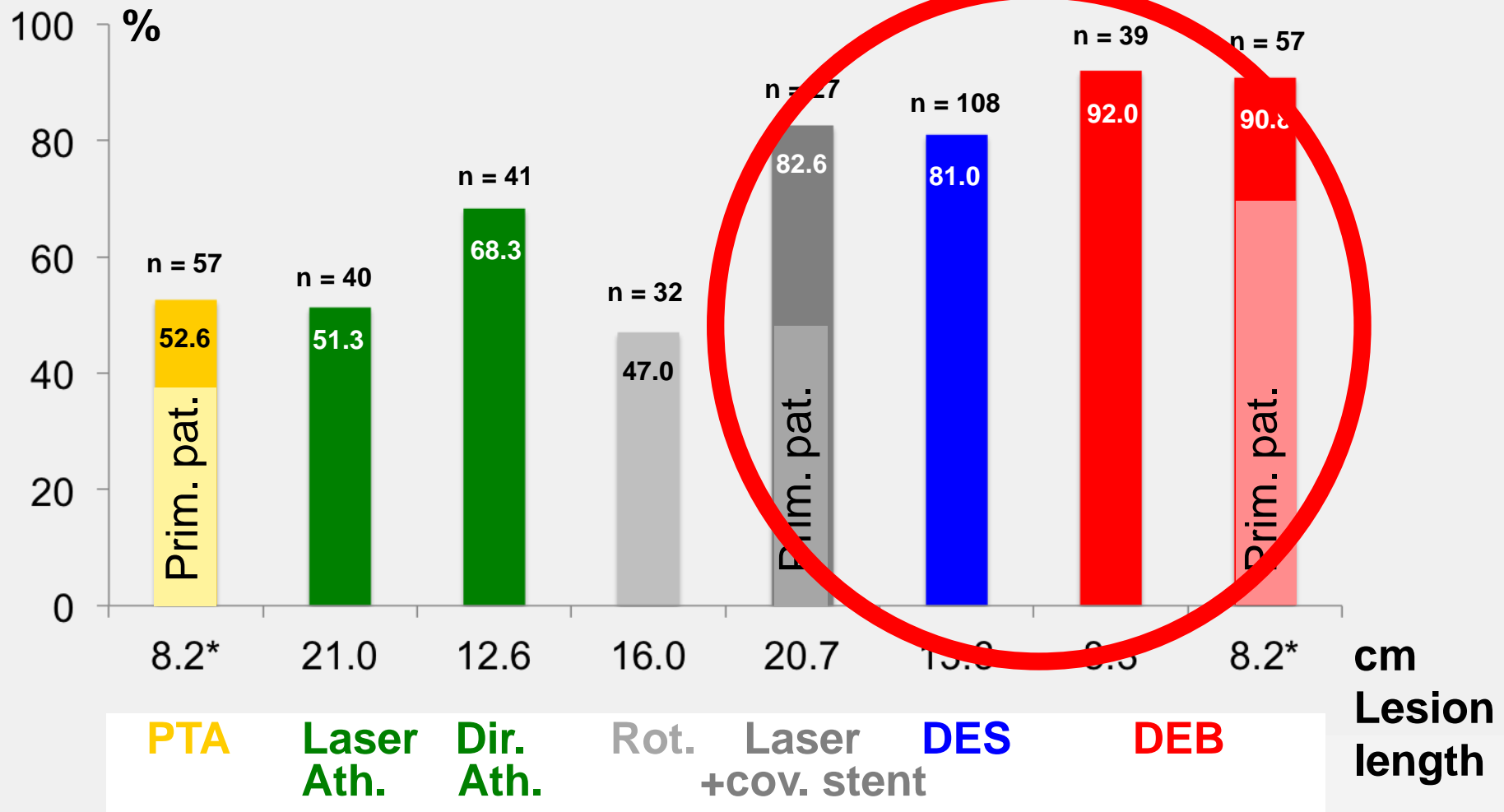
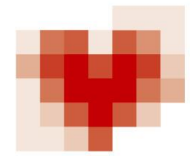
## FAIR – Freedom from TLR



\* on grounds of restenosis/reocclusion and symptoms

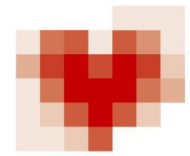
# Freedom from TLR at 12 months

## Following treatment for SFA-ISR



\* at 390 days

- A few small trials show promising results for **covered stents** (GORE VIABAHN) in SFA-ISR. A larger, randomized study is ongoing (GORE VIABAHN vs. POBA, Bosier M, NCT01108861).
- **DES** (Zilver PTX) in SFA-ISR resulted in a similar 12-month TLR rate compared to DEB and promising 24-month clinical outcomes.
- **DEB** (IN.PACT) in SFA-ISR is associated with less binary restenoses and clinically driven TLR through 6 +12 months than POBA.



# Intra stent restenosis: POBA, DEB, DES or covered stent?

Hans Krankenberg

[h.krankenberg@hgz-bb.de](mailto:h.krankenberg@hgz-bb.de)