First-in-Human Report: Initial Experience with a Stentless and Retrievable Percutaneous Aortic Valve Prosthesis

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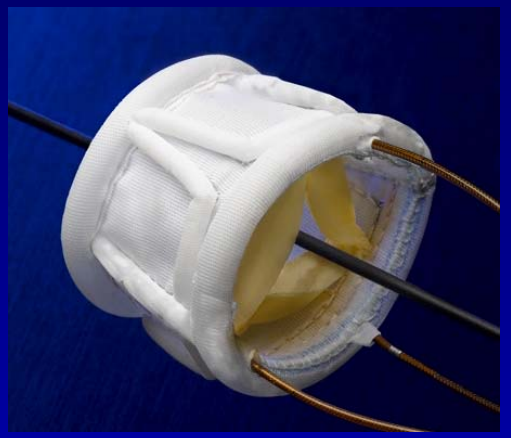
The Direct Flow Medical (DFM) Aortic Valve Prosthesis



- Consists of
  - a trileaflet valve made of bovine pericardium

    encased in
  - a slightly tapered, conformable polyester fabric cuff
  - Independently inflatable balloon rings constitute the upper (aortic) and lower (ventricular) margins of the cuff
- Transfemoral implantation

Investigational device currently in European clinical trial. Not available for sale in or outside the United States.

The DFM AV Prosthesis
European Clinical Trial

Intention-to-treat population
n = 31

Sites:
- **Hamburg**, Germany (n=25)
- **Siegburg**, Germany (n=6)

→ No iliac access (n=2)
→ Functionally bicuspid valve (n=2)
→ Excessive LVOT calcification (n=3)
→ Annular Ø ↑↑, excessive calcification (n=1)
→ Excessive valvular calcification (n=1)

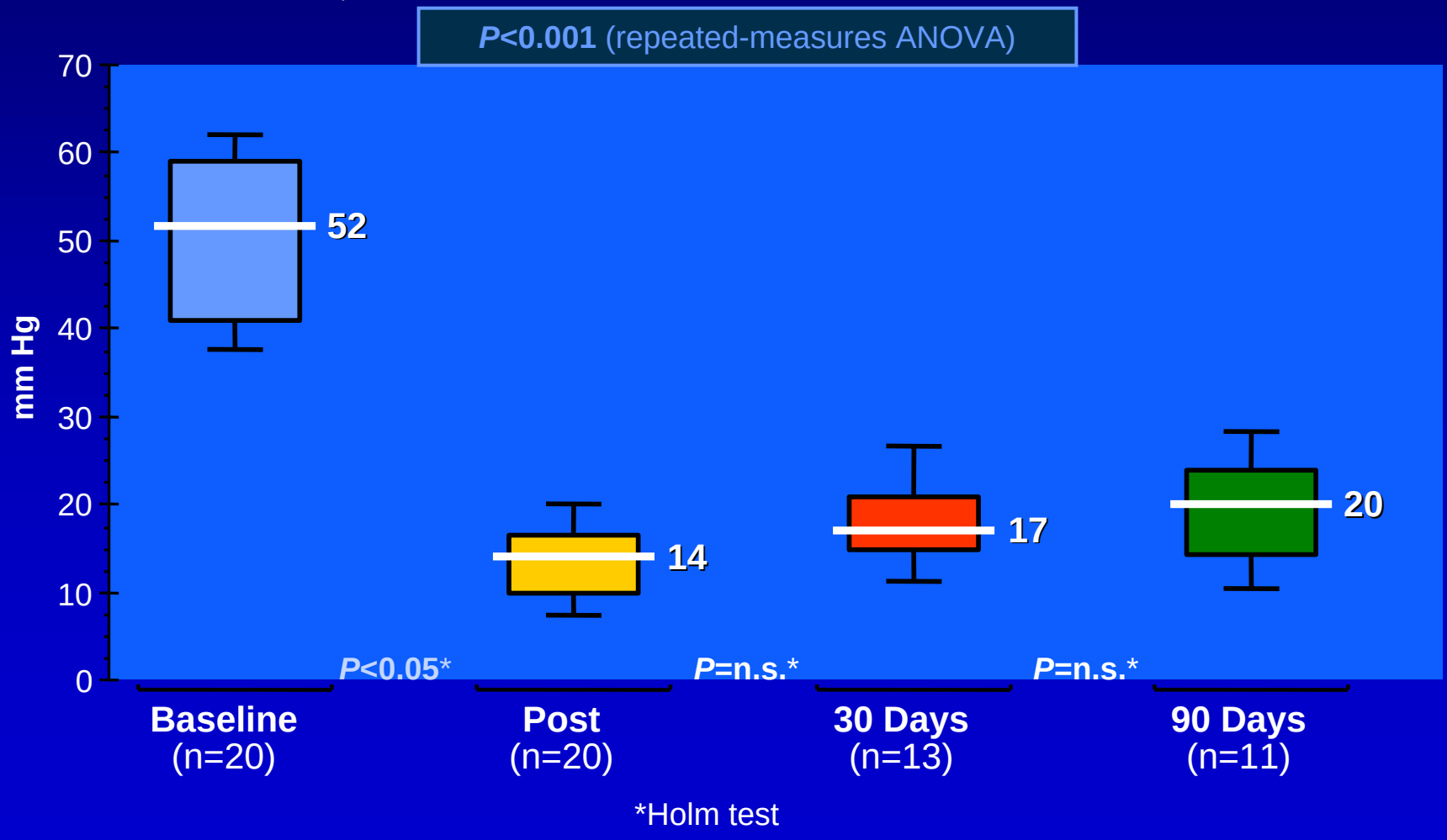
Device implanted
n = 22 (71%)

→ Surgical conversion (n=2)

Permanent implant
n = 20 (65%)

The DFM AV Prosthesis
European Clinical Trial

- Mean transvalvular pressure gradient in patients with a pe rmanent implant



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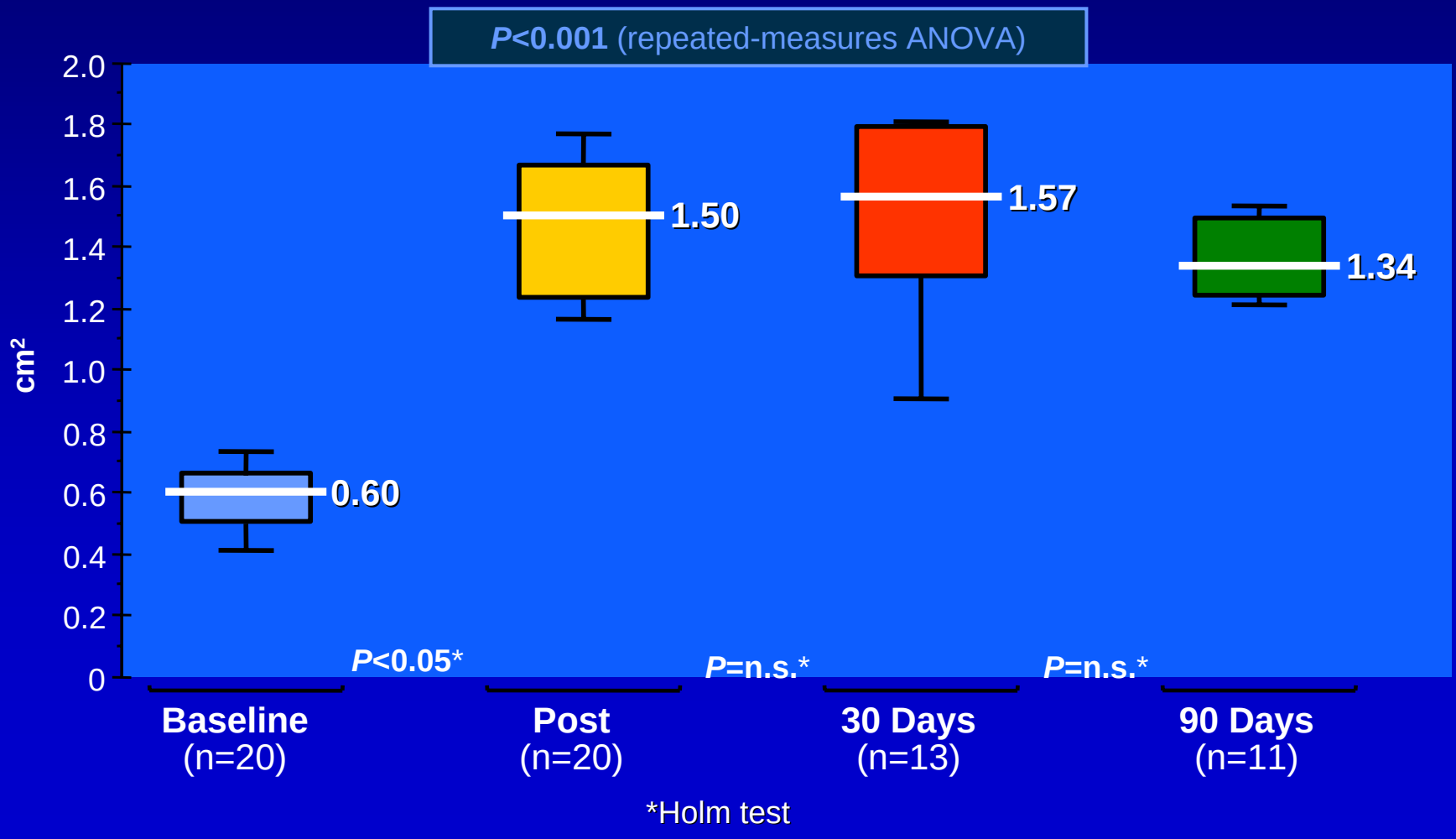
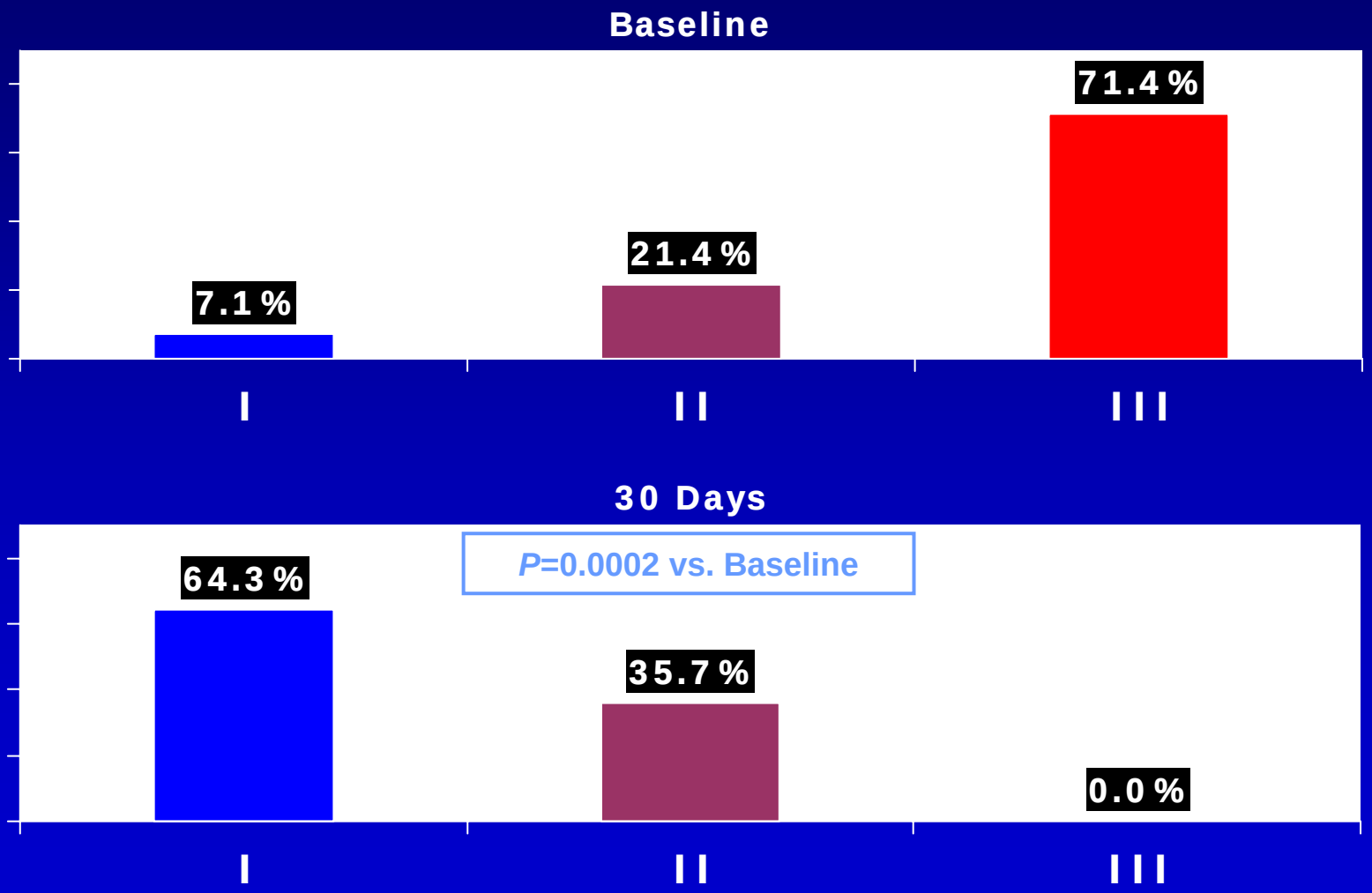
- Aortic orifice area in patients with a permanent implant



The DFM AV Prosthesis

European Clinical Trial

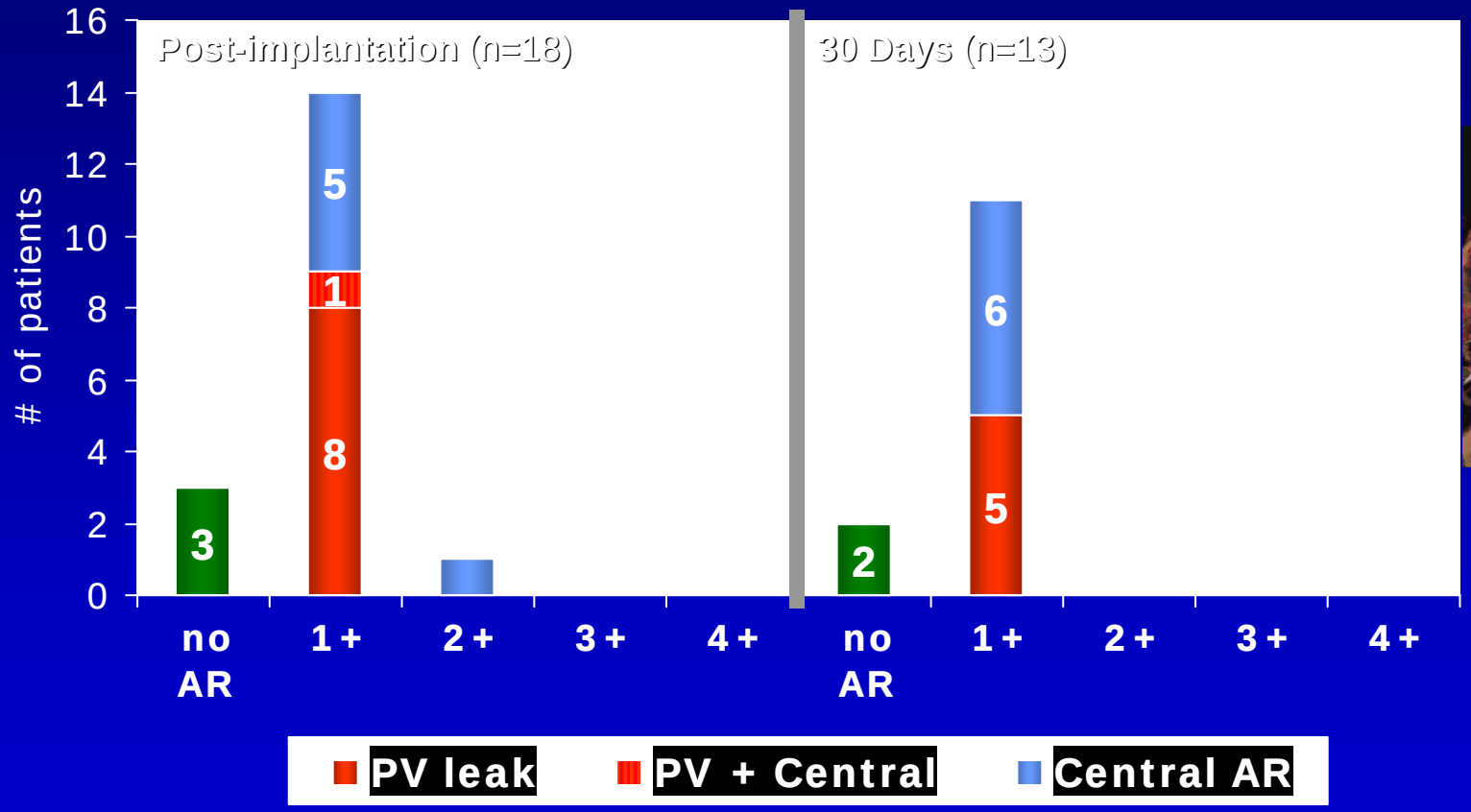
- NYHA class in 14 patients with permanent implant

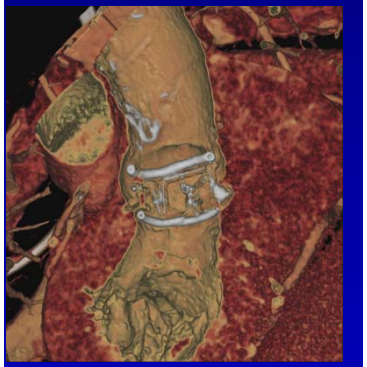


The DFM AV Prosthesis

European Clinical Trial – Outcomes

- Aortic regurgitation by echo (Hamburg patients)





03-01-008 @ 30d

The DFM AV Prosthesis
European Clinical Trial

- Major Adverse Events
  - Death — n = 4
    - ➔ 30-day mortality 13% [95% CI, 4%–30%]
      - Myocardial infarction @ day 2
      - Pulmonary embolism 1h after failed attempt at implantation
      - Septal rupture during valvuloplasty
      - Decompensated congestive heart failure
  - Major stroke (@ 12h) — n = 1
  - Surgical conversion — n = 2

  Total — n = 7 (23% [10%–41%])

  - AV conduction block 3° (1 after surgical conversion) — n = 3

The DFM AV Prosthesis
Conclusions

- The DFM aortic valve prosthesis gives the operator unpre cedented freedom of handling the device during implant ation
- In the FIM experience with 31 patients, permanent implan tation was achieved in 65% of patients with good hemod ynamic results (mean gradient ≤20 mmHg, excellent seal ing of native annulus)
- Despite the patients' high surgical risk profile, implantati on without hemodynamic compromise during the proced ure appears safe
- The amount and distribution of leaflet and LVOT calcifica tion impacts procedural outcome
- Patient selection is crucial!