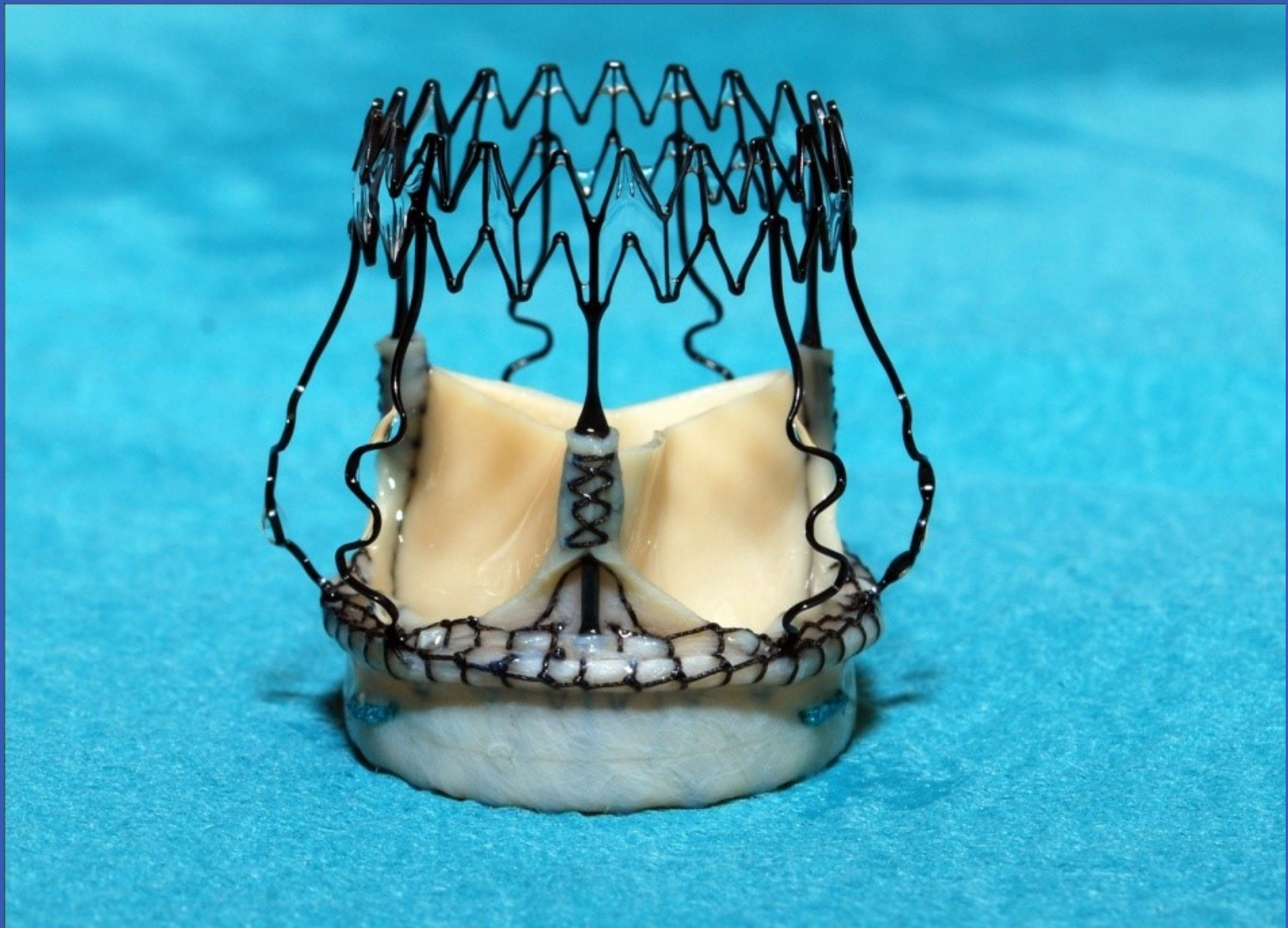


LATEST GENERATION OF SURGICAL VALVES:

THE SUTURELESS SOLUTION FOR AVR.



Bart Meuris, MD, PhD
University Hospitals Leuven, Belgium



First-in-man: 2007

Perceval - Clinical studies



Enrolment status

**Completed
2007 – 2008**

**Completed
2009 - 2010**

**Completed
2010 - 2013**

**Ongoing
2013**

**Ongoing
2011**

Patients and centers

30 pts

150 pts

658 pts

300 pts

>500 pts

3 EU centres

9 EU centres

26 EU centres

9 centers active

11 centers active

Follow-up

**5 years
completed**

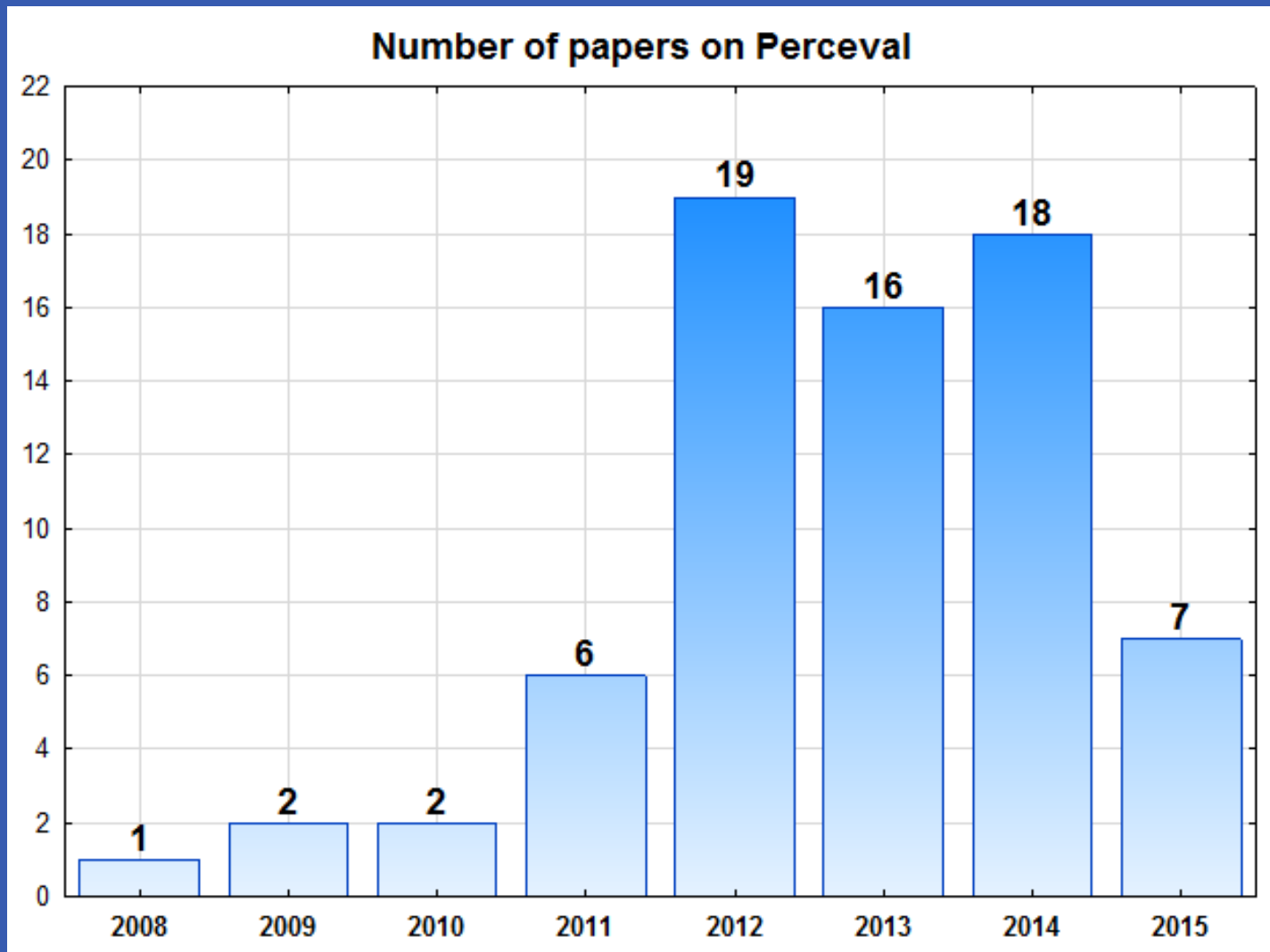
**3 years
completed
Up to 5 years
ongoing**

**Up to 5 years
ongoing**

**Up to 5 years
ongoing**

**Up to 3 years
ongoing**

Perceval - Literature



Perceval – Literature

European Journal of Cardio-Thoracic Surgery Advance Access published March 6, 2015

European Journal of Cardio-Thoracic Surgery (2015) 1–8
doi:10.1093/ejcts/ezv040

ORIGINAL ARTICLE

Cite this article as: Shrestha M, Fischlein T, Meuris B, Flameng W, Carrel T, Madonna F *et al.* European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients. *Eur J Cardiothorac Surg* 2015; doi:10.1093/ejcts/ezv040.

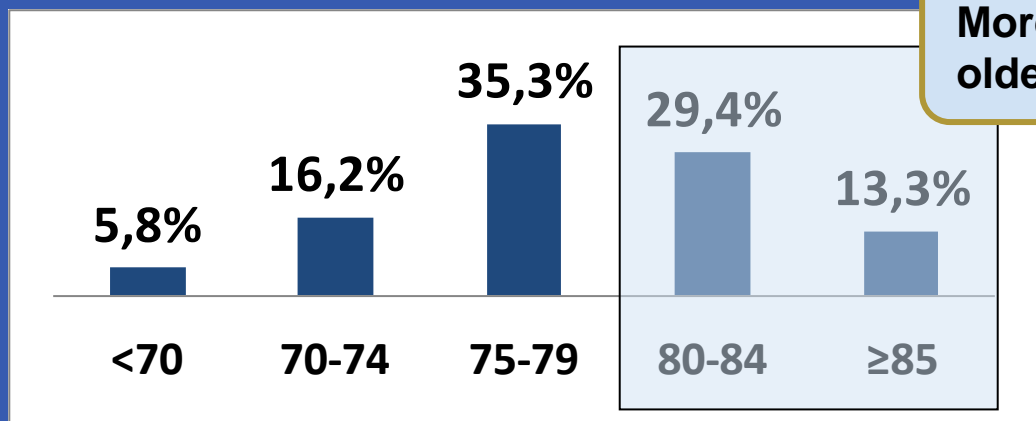
European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients[†]

**Malakh Shrestha^{a,*}, Theodore Fischlein^b, Bart Meuris^c, Willem Flameng^c, Thierry Carrel^d,
Francesco Madonna^e, Martin Misfeld^f, Thierry Folliguet^g, Axel Haverich^a and Francois Laborde^g**

Prospective study N=731

Demographic Data	
Implant period	April 2007 – September 2013
Mean age	78.9 ± 5.4
Gender (Female)	68.1%
EuroScore	10.9%
STS score	8.5%

Age distribution



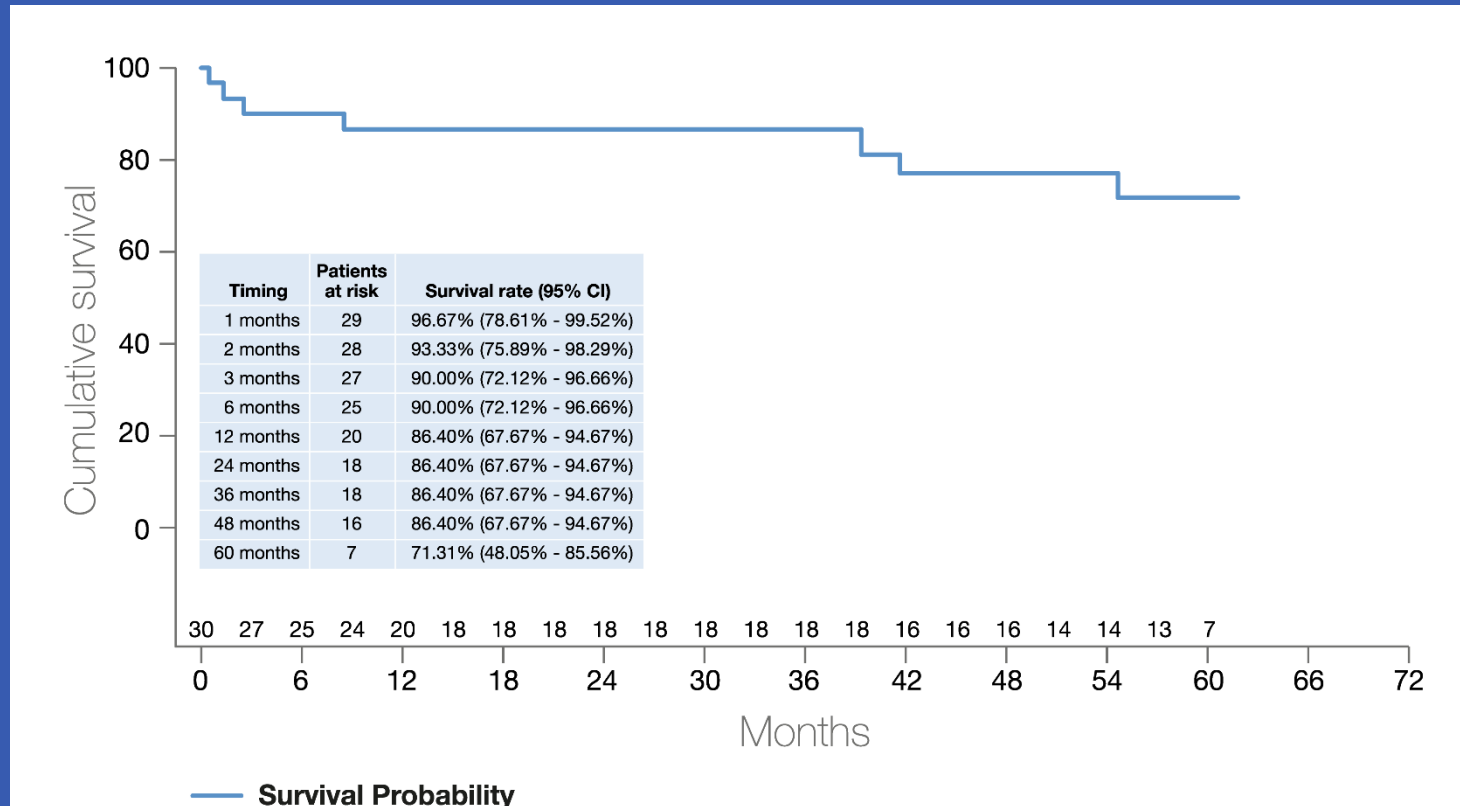
More than 40% of pts. older than 80 years

Prospective study N=731

✓ Mortality:

✓ 30-day, all-cause: 3.3%

✓ Survival @5 years: 74.7%



Prospective study N=731

- ✓ Data from 5-year follow-up
 - ✓ No thrombosis
 - ✓ No post-operative migrations
 - ✓ No structural valve degeneration
 - ✓ Explants N= 21

Due to endocarditis N= 14

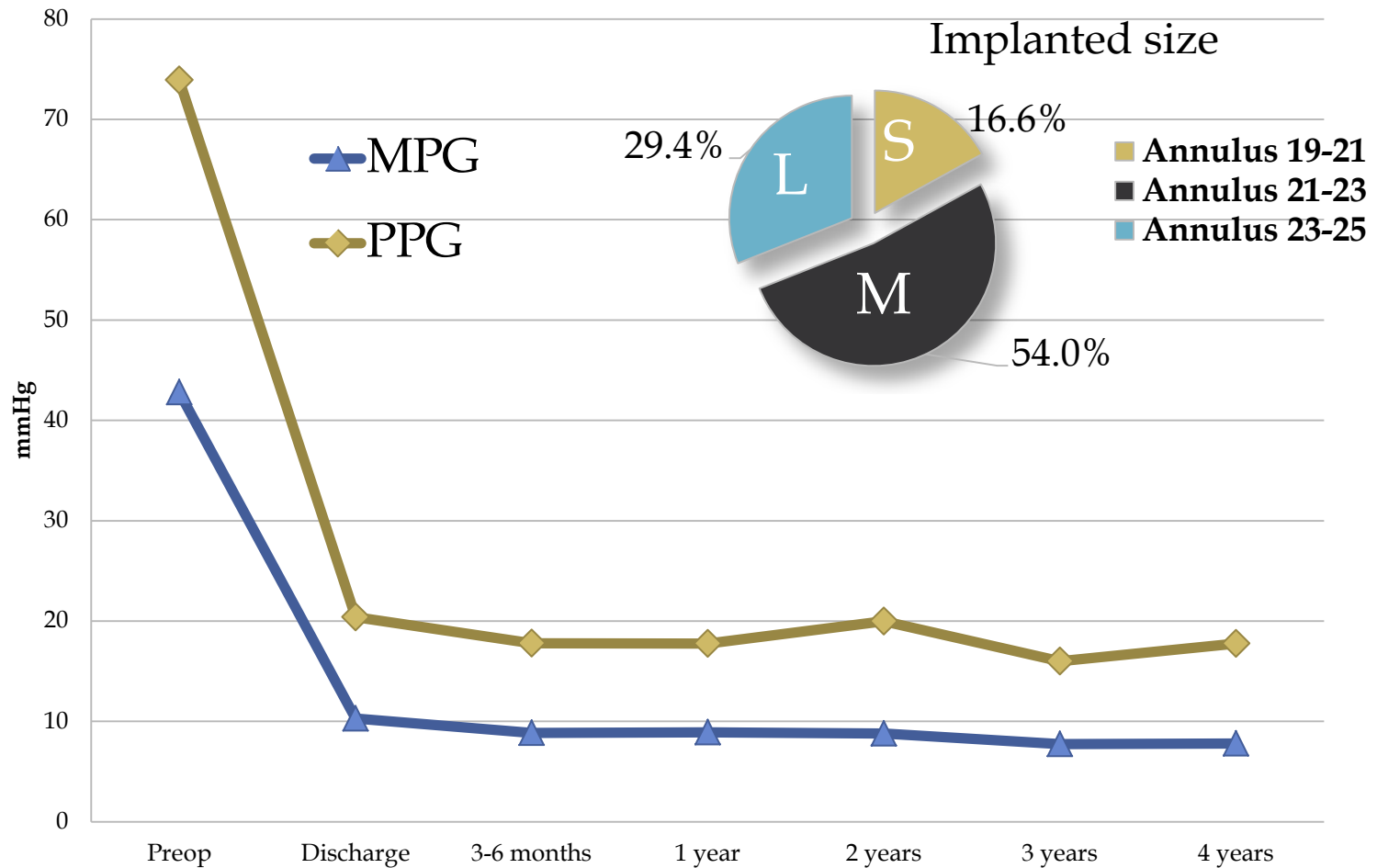
Due to major paravalvular leak N= 7

Prospective study N=731

- ✓ Key to successful implant
 - ✓ good patient selection
 - ✓ good decalcification
 - ✓ stable and adequate positioning
 - ✓ adequate TEE control intra-operative

Hemodynamic performance

Pressure Gradients



Perceval – Key benefits

- ▣ Speed of implantation
- ▣ Minimal manipulation in aortic root
- ▣ Flexible stent design

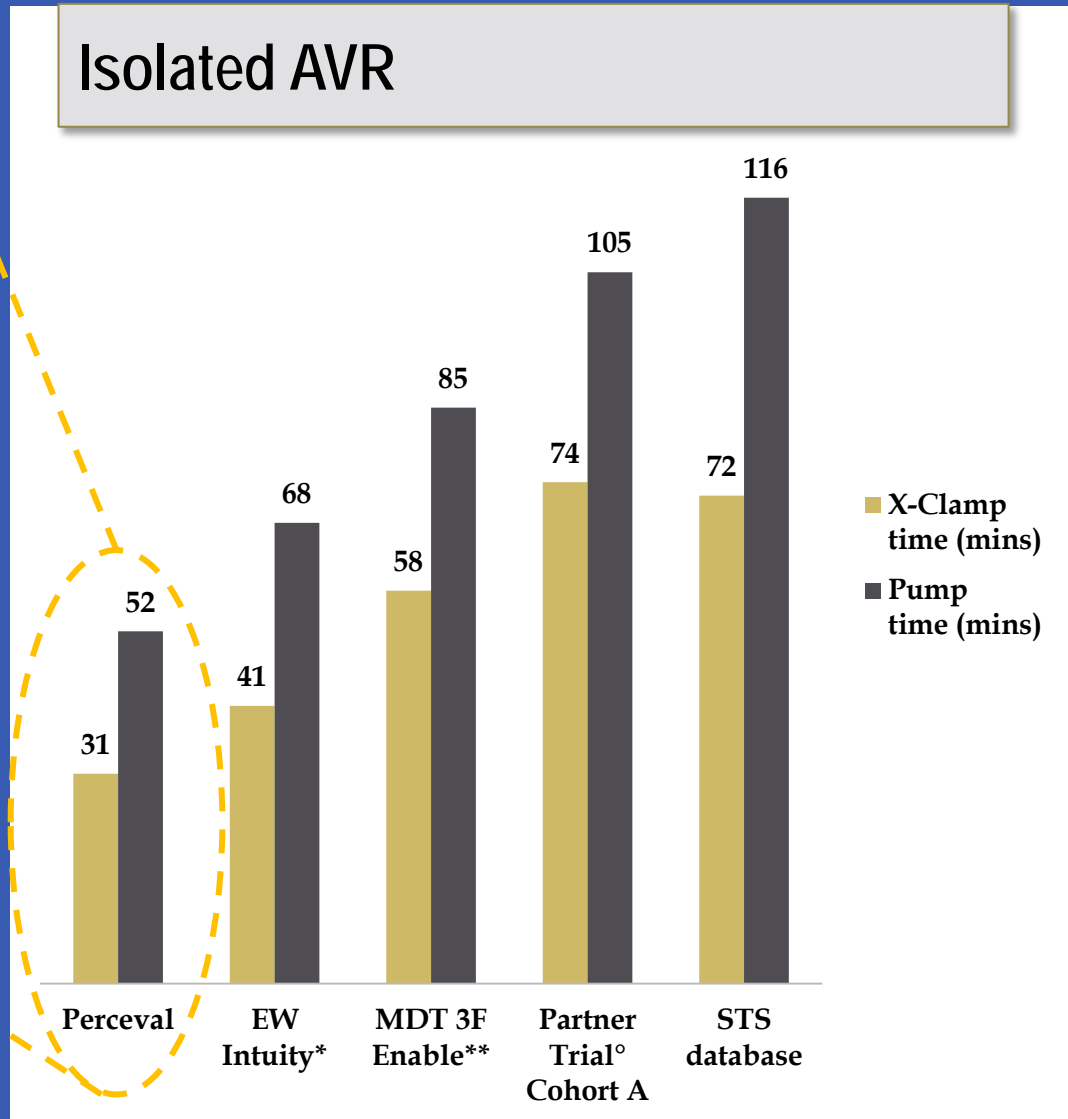
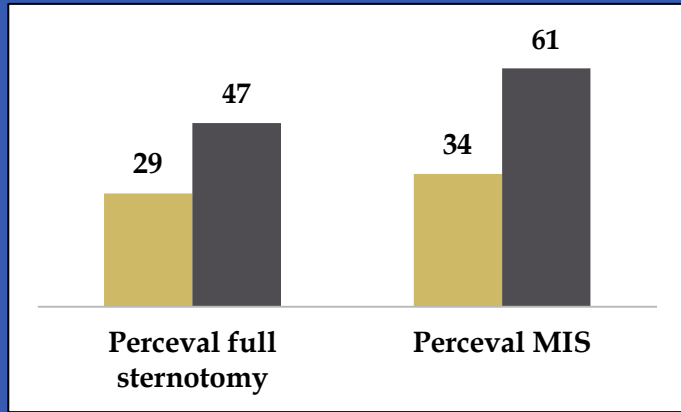
Leuven experience

Effect of sutureless implantation of the Perceval S aortic valve bioprosthesis on intraoperative and early postoperative outcomes.

J Thorac Cardiovasc Surg 2011

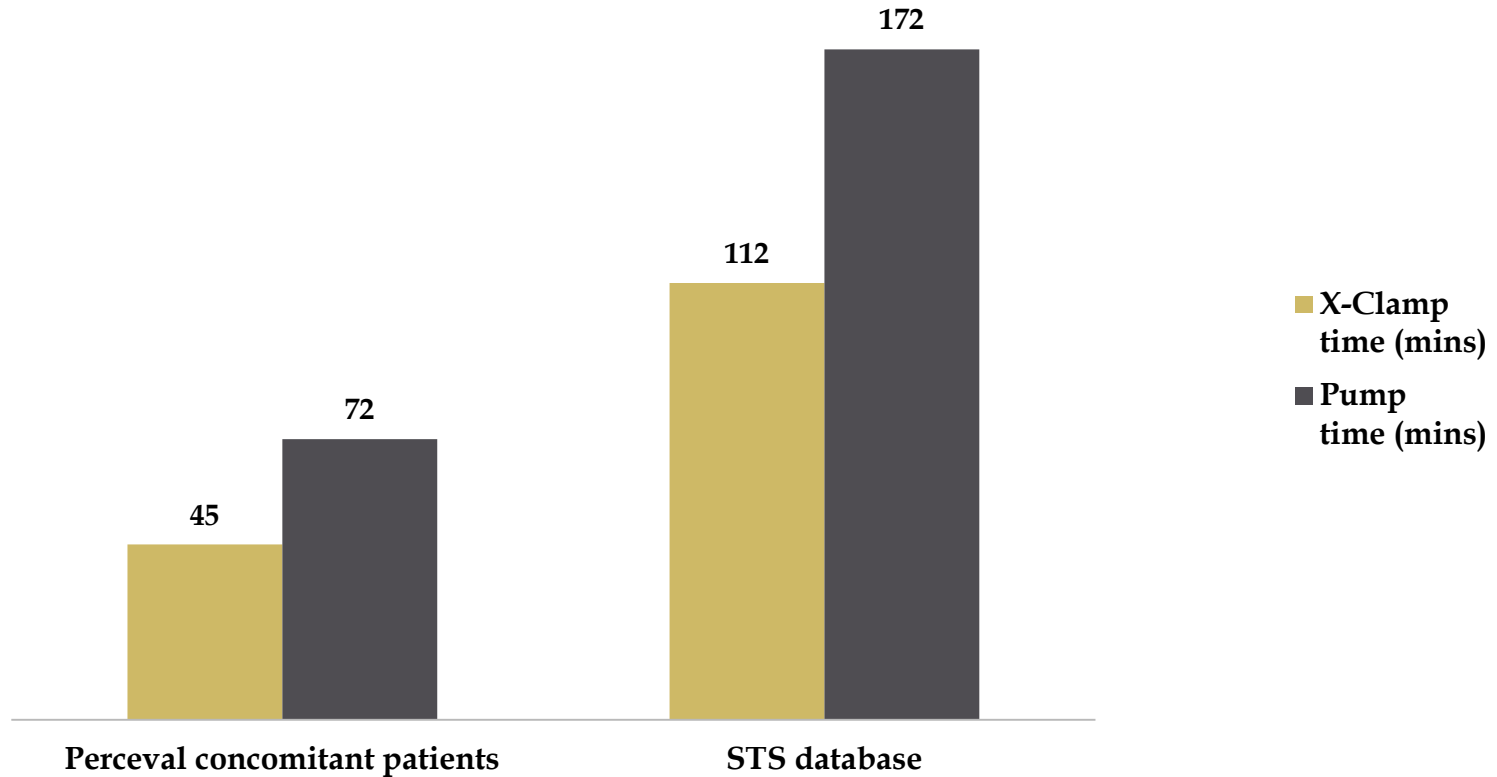
- 55 patients: Mean age : 78 y (75-87y)
Log EuroSCORE: 10% (6-35)
- Hospital mortality : 0%
- Cross-clamp in single AVR: 17min (range 12-34min)

Prospective trial (N=731): X-clamp and CPB times



Use in combined procedures

Concomitant AVR

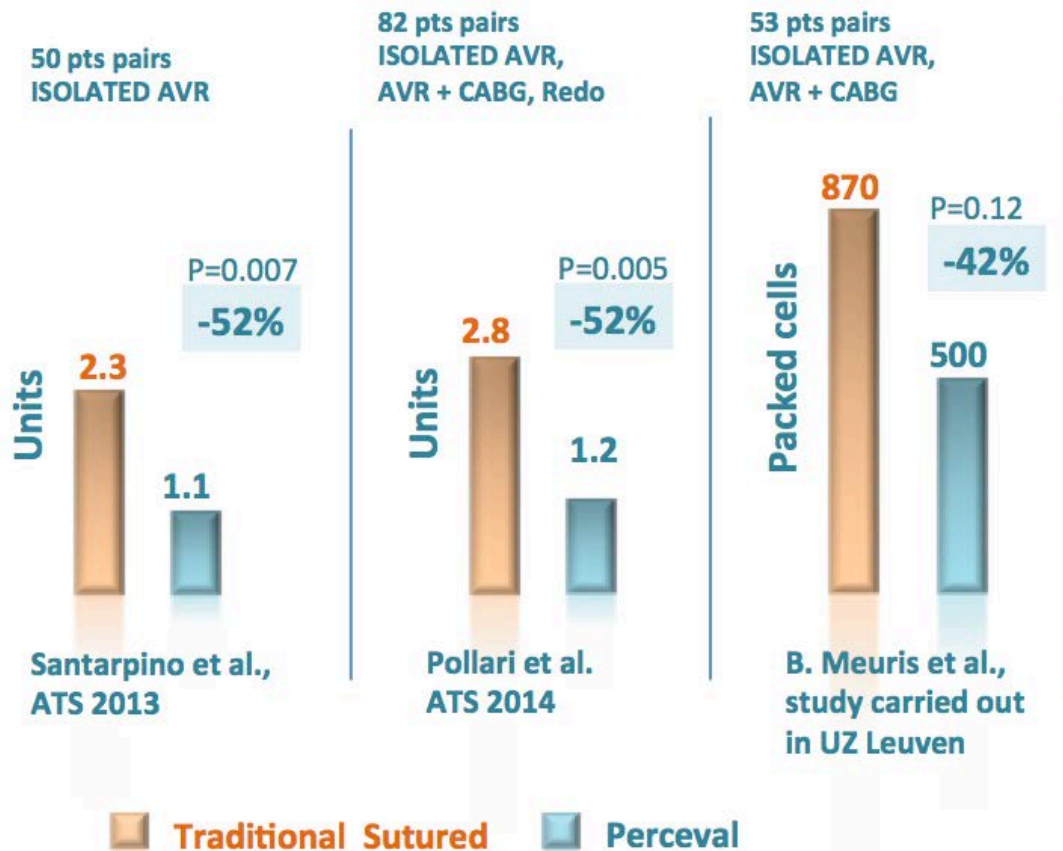


Perceval – Comparisons to stented valves

Author, Study/Publication	Patients Cohort Procedure	Prosthesis/ approach
Santarpino et al., ATS 2013	50 pts pairs ISOLATED AVR	Perceval VS biological Stented and stentless and Mechanical J sternotomy
Pollari et al. ATS 2014	82 pts pairs ISOLATED AVR, AVR + CABG, Redo	Perceval VS Biological Stented and Partial or full sternotomy
Laborde et al SFCTCV 2014	65 pts pairs ISOLATED AVR	Perceval VS Traditional valve Sternotomy (gathering more info)
B. Meuris et al., study carried out in UZ Leuven	53 pts pairs ISOLATED AVR, AVR + CABG	Perceval VS Perimount stented biological valve Partial or full sternotomy

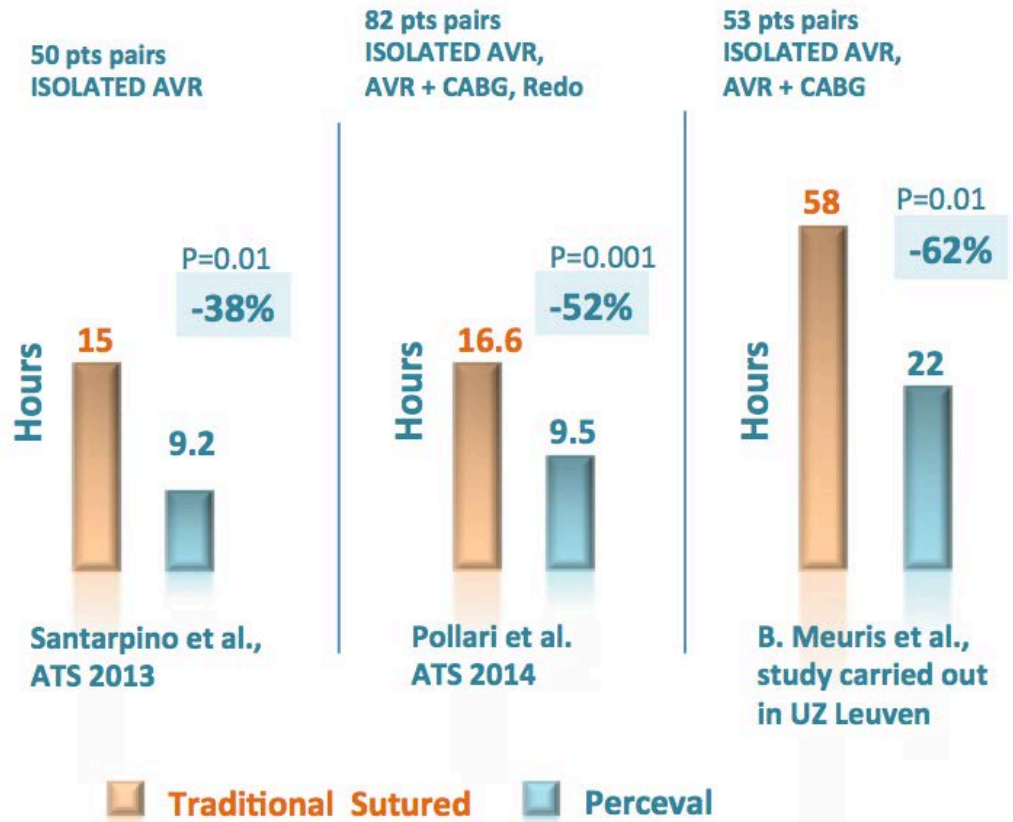
Perceval – Comparisons to stented valves

Blood transfusion reduction



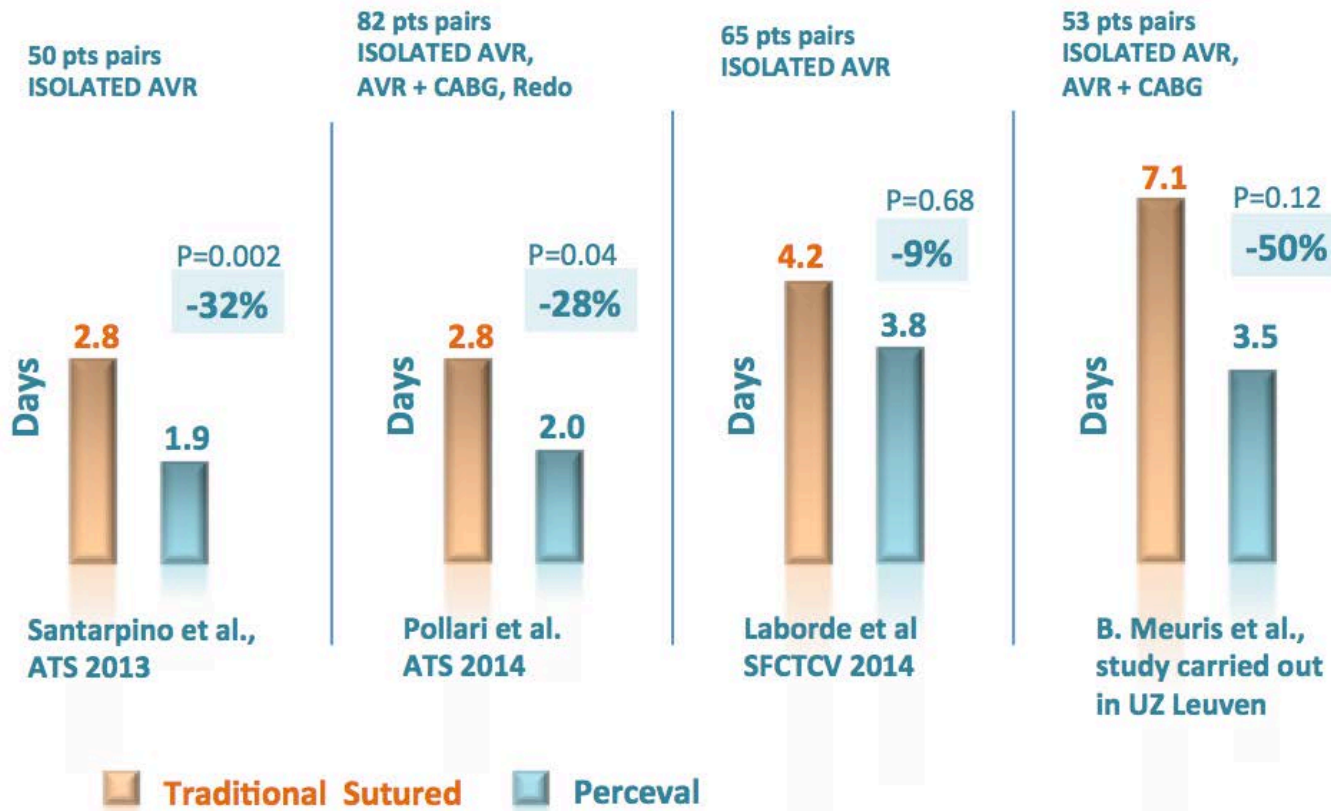
Perceval – Comparisons to stented valves

Ventilation time reduction



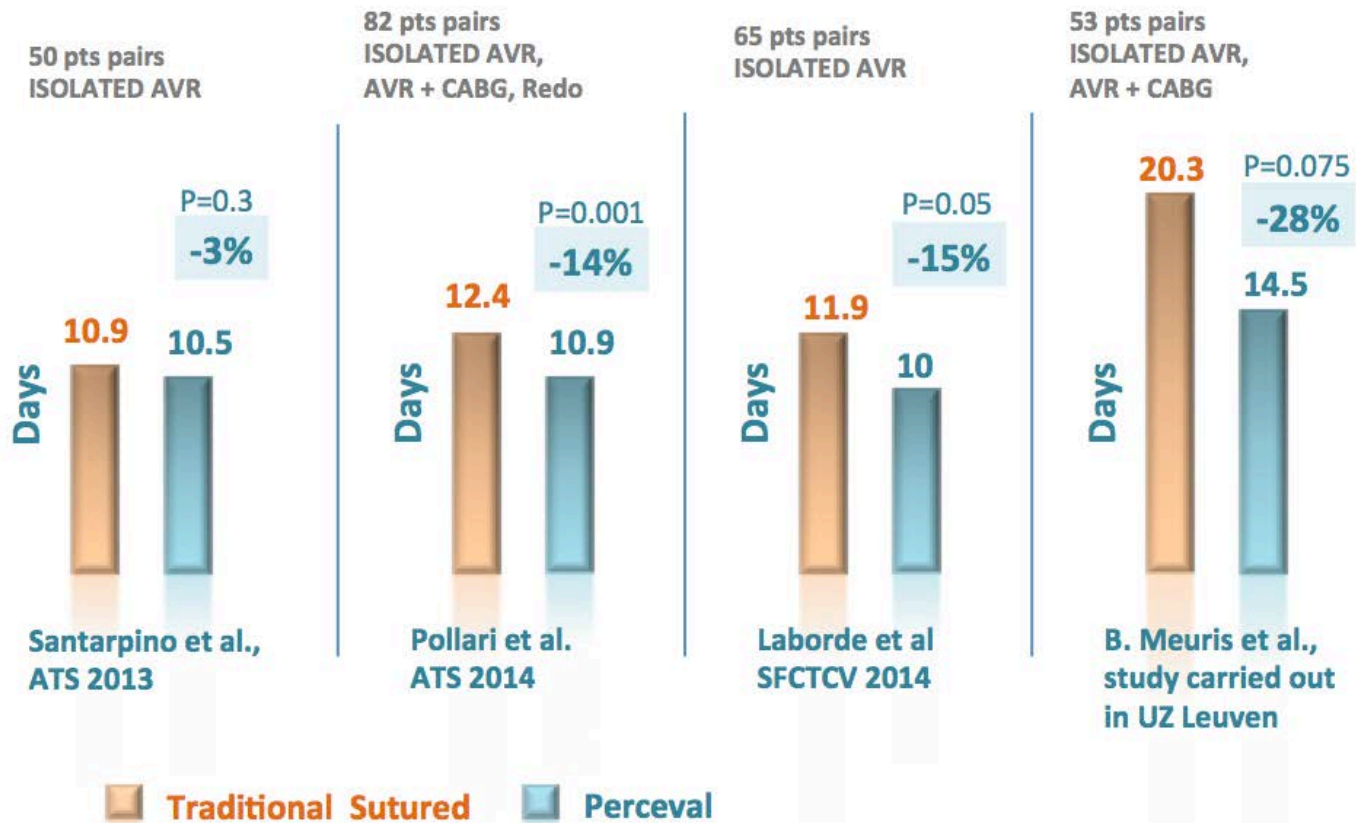
Perceval – Comparisons to stented valves

ICU stay reduction



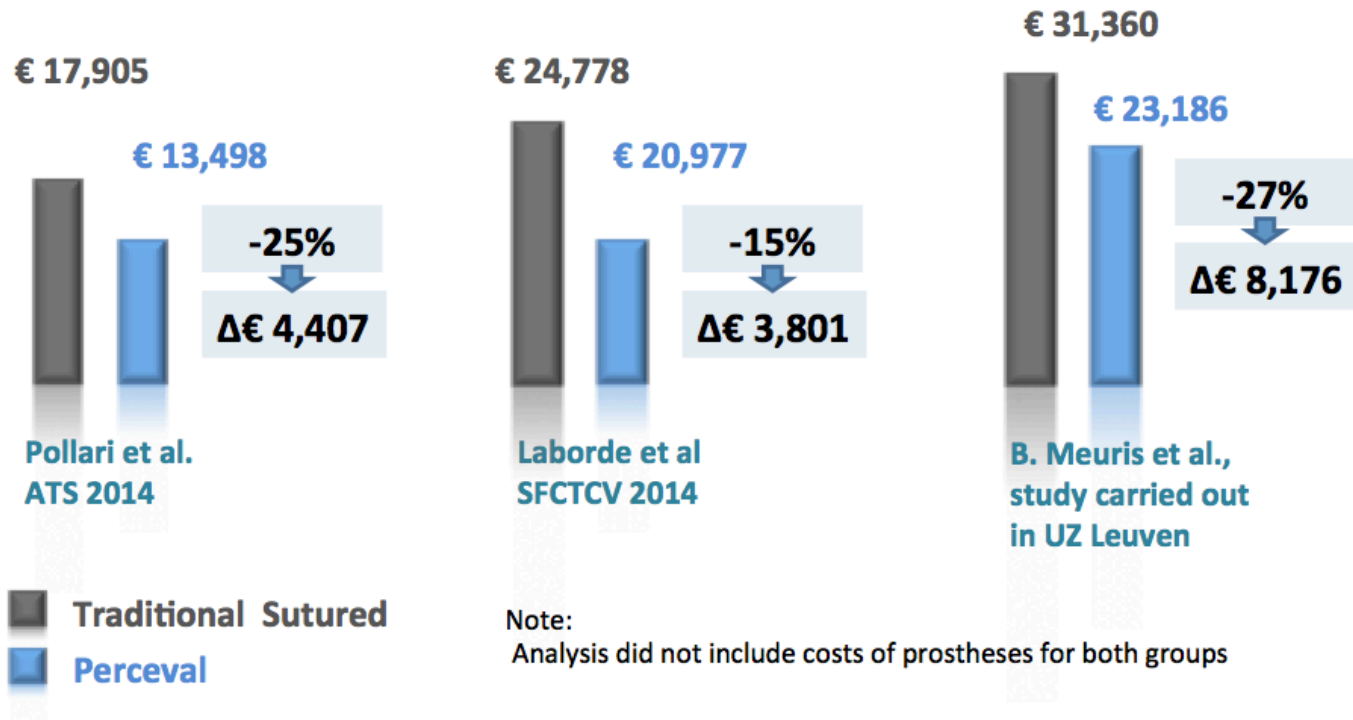
Perceval – Comparisons to stented valves

Hospital stay reduction



Perceval – Comparisons to stented valves

Optimizing Healthcare costs



Perceval – Key benefits

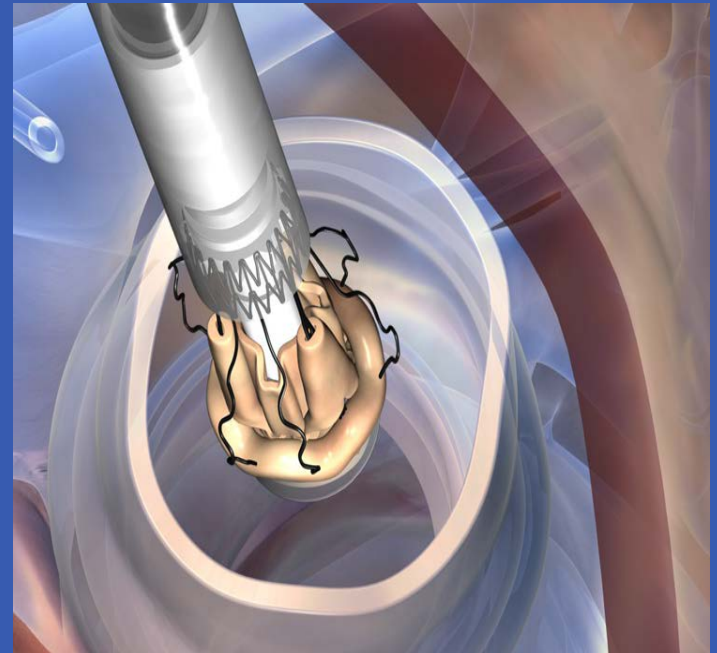
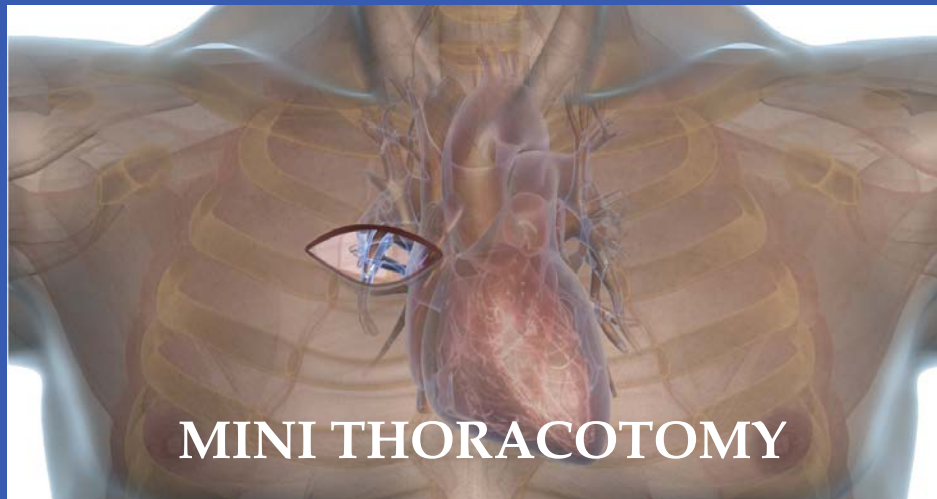
▣ Speed of implantation

- Shorter X-clamp and CPB times
- Shorter procedure overall, isolated and combined cases
- Less transfusion, shorter intubation and ICU stay
- Quicker patient recovery, shorter hospital stay
- Save overall costs

Perceval – Key benefits

- ▣ Speed of implantation
- ▣ Minimal manipulation in aortic root
- ▣ Flexible stent design

Perceval – Minimal invasive surgery




Perceval – Minimal invasive surgery

Article in Press

Aortic Valve Replacement Through Right Anterior Minithoracotomy: Can Sutureless Technology Improve Clinical Outcomes?

Presented at the Poster Session of the Fiftieth Annual Meeting of The Society of Thoracic Surgeons, Orlando, FL, Jan 25–29, 2014.

[Daniyar Gilmanov](#), MD , [Antonio Miceli](#), MD, [Matteo Ferrarini](#), MD, [Pierandrea Farneti](#), MD, [Michele Murzi](#), MD, [Marco Solinas](#), MD, [Mattia Glauber](#), MD

ATS, 2014

Perceval in MICS

- Miceli, JTCVS, 2014
- Santarpino, JHVD, 2013
- Zannis, Curr Opin Cardiol, 2012
- Suri, Innovations, 2010
-

Perceval as bail-out in complex cases

- ▣ In difficult redo cases (Santarpino, JHVD, 2013)
- ▣ In calcified and small aortic roots (Shresta, JHVD, 2013)
- ▣ In degenerated homografts (Folliguet, ATS, 2013)
- ▣ In degenerated Freestyle grafts (Villa, ATS, 2013)
- ▣

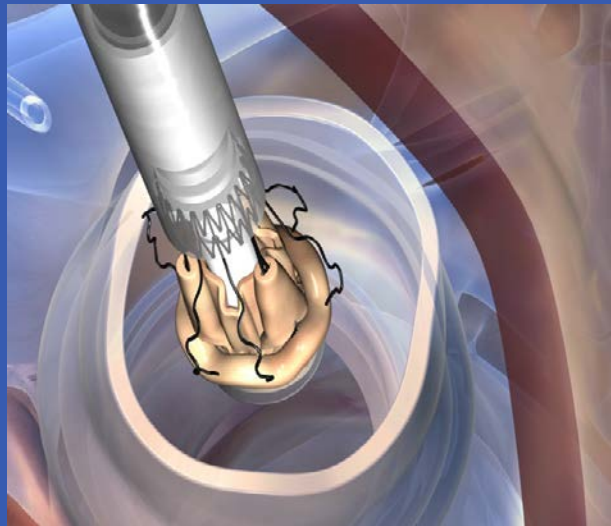
Perceval – Key benefits

- ▣ Speed of implantation
- ▣ Minimal manipulation in aortic root
 - Facilitates minimal invasive surgery
 - Bail-out in complicated cases

Perceval – Key benefits

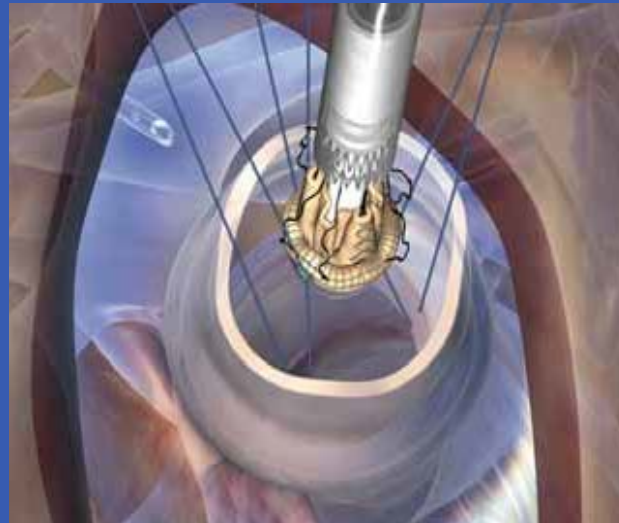
- ▣ Speed of implantation
- ▣ Minimal manipulation in aortic root
- ▣ Flexible stent design

Perceval – Unique collapsed profile



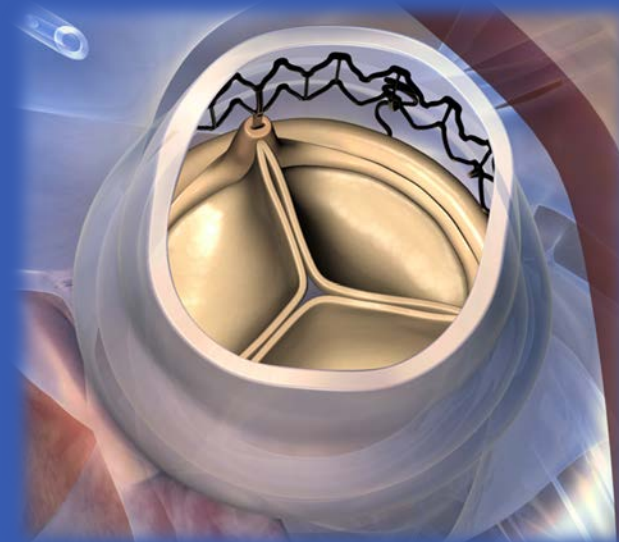
Enhanced visualization

- Dedicated instruments
- Unique collapsed profile



Precise positioning

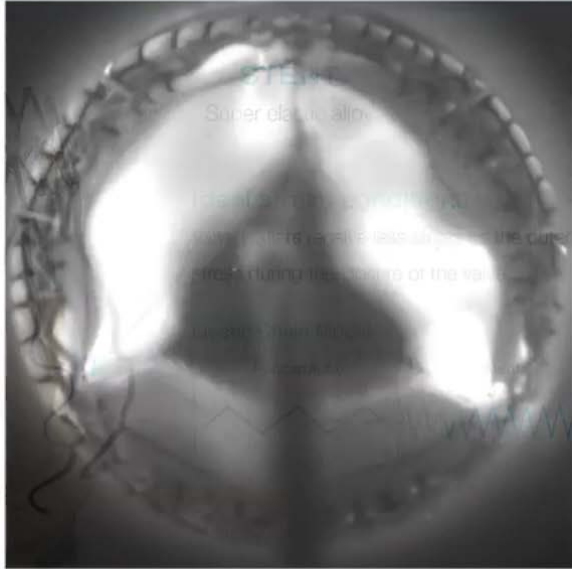
- Temporary guiding sutures



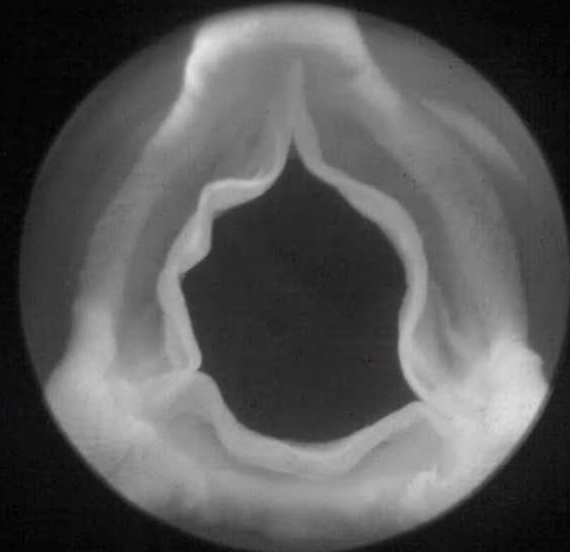
Speed of implantation

- No need of knotting

Perceval – Stent elasticity



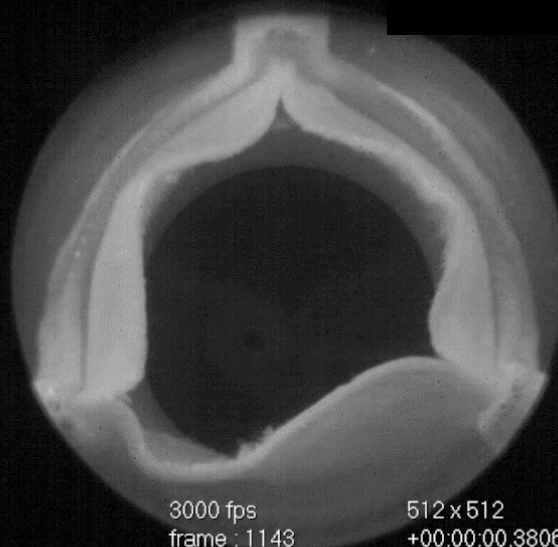
1 Woche



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3000 fps
frame : 1143

512 x 512
+00:00:00.380667sec

Perceval - Conclusion



- ✓ Safe surgical procedure
 - ✓ >800 valves in prospective clinical study, FU up to 5y
 - ✓ Commercial use worldwide
- ✓ Significantly reduced X-clamp times
 - ✓ Can be implanted in 20min
 - ✓ Possible benefit in combined procedures, in elderly and high-risk patients
- ✓ Significantly reduced manipulation in aortic root
 - ✓ No stitches, no knots
 - ✓ Advantage in diseased aortic root (plaques, calcific aggregates,...)
- ✓ Opens possibility towards minimally invasive placement
- ✓ Good hemodynamic performance
 - ✓ Even in small aortic root

Thank you

Bart Meuris, MD, PhD
University Hospitals Leuven
Belgium