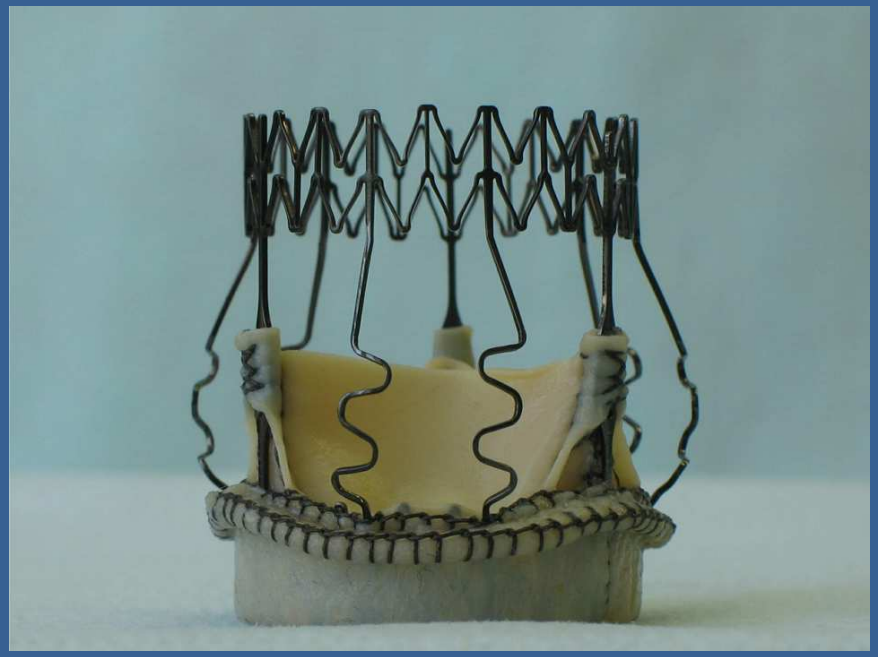
KATHOLIEKE UNIVERSITEIT
LEUVEN



Sorin Perceval

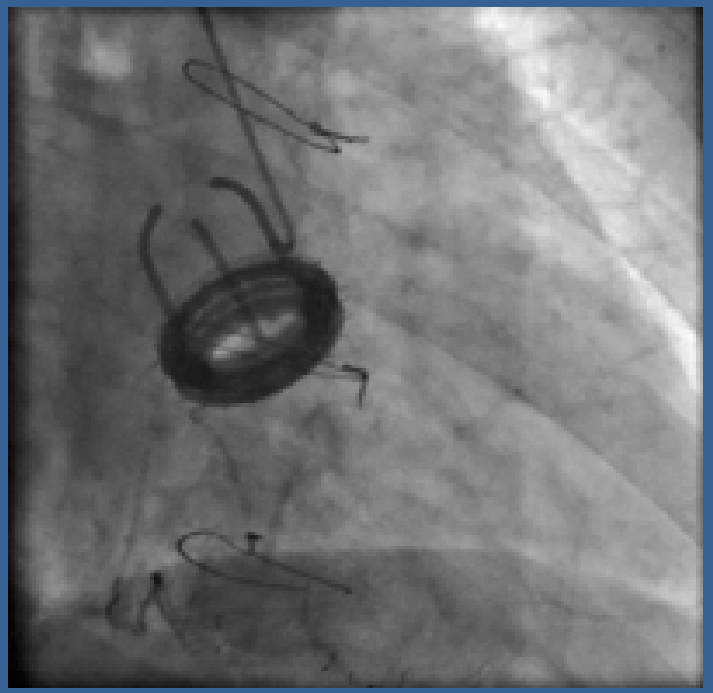
Sutureless aortic valve replacement: results with the Perceval bioprosthesis.

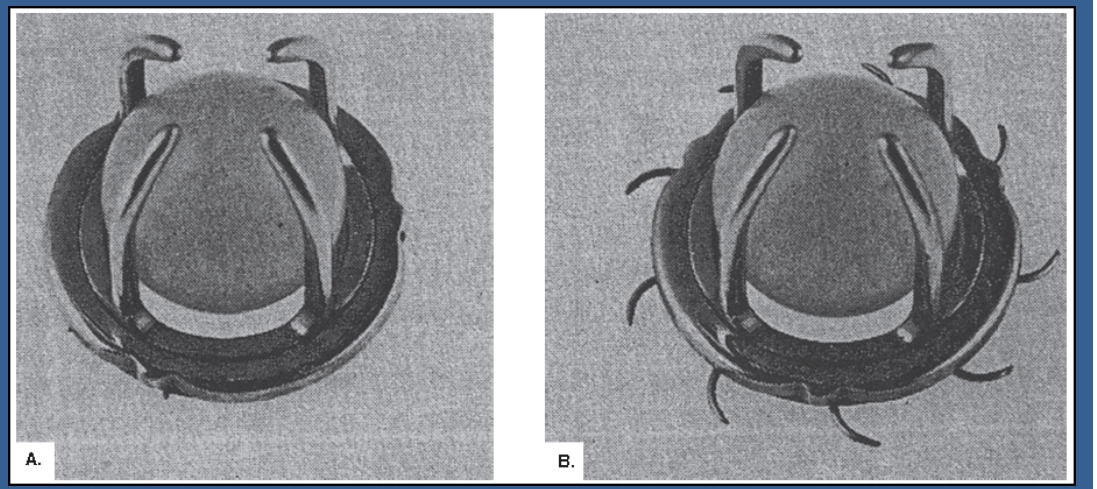
B. Meuris

University Hospitals Leuven
Belgium

Sutureless aortic valves

Magovern-Cromie valve: 1962-1980





Sutureless aortic valves

Magovern-Cromie valve: 1962-1980

- > 7.300 implants
- Reduced operative mortality
- Stopped in 1980
  - Thrombo-embolism
  - Ball/cage design
  - Paravalvular leaks

(*Circulation.* 2008;117:e1-e2.)

Images in Cardiovascular Medicine

A Perfectly Functioning Magovern-Cromie Sutureless Prosthetic Aortic Valve 42 Years After Implantation

Amnon Y. Zlotnick, MD; Avinoam Shiran, MD; Basil S. Lewis, MD; Dan Aravot, MD

Sutureless aortic valves
2005: 3F Therapeutics ‘Enable’ (ATS)

- Equine pericardium
- 3 centers (Germany, Poland, Switzerland)
- First generation: significant paravalvular leakage
- Second generation: total n = 28
- X-clamp time: 39min
- Good early hemodynamic performance
- 1 early explant for severe paravalvular leakage
- Max follow-up: 18 months

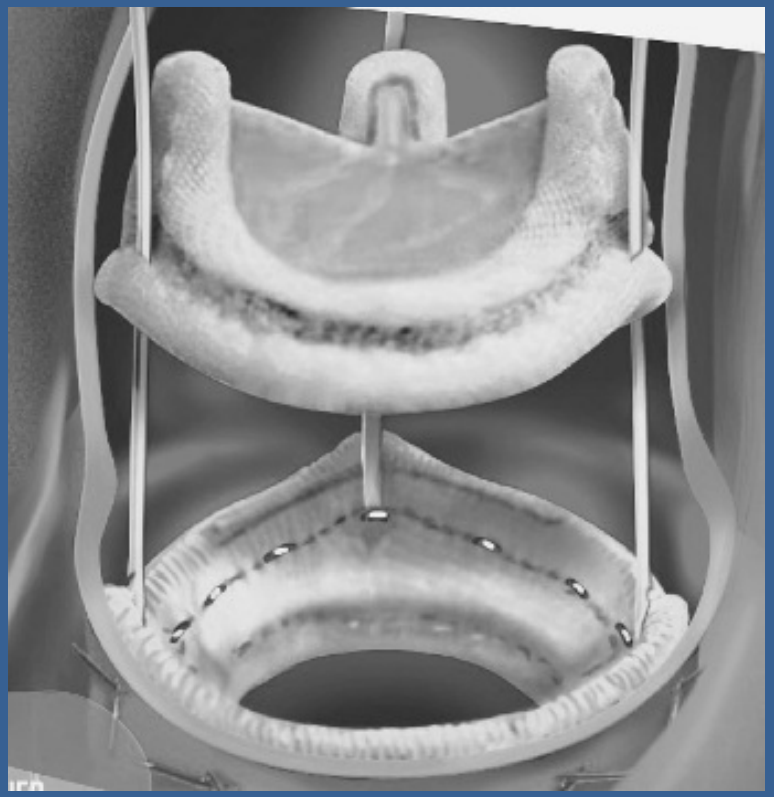
Clinical experience with the second-generation 3f Enable sutureless aortic valve prosthesis

Thierry Aymard, MD,[a] Alexander Kadner, MD,[a] Nazan Walpoth, MD,[b] Volkhart Göber, MD,[a] Lars Englberger, MD,[a] Mario Stalder, MD,[a] Friedrich Eckstein, MD,[a] Claudia Zobrist, MD,[c] and Thierry Carrel, MD[a]

J Thorac Cardiovasc Surg, 2010

Sutureless aortic valves
2006: Trilogy valve (Arbor)

- Bovine pericardium
- 5 centers (Germany, Poland, Russia)
- Total n = 32
- X-clamp times: 70min
- Good early hemodynamic performance
- 1 early explant (endocarditis)
- Max follow-up: 2y



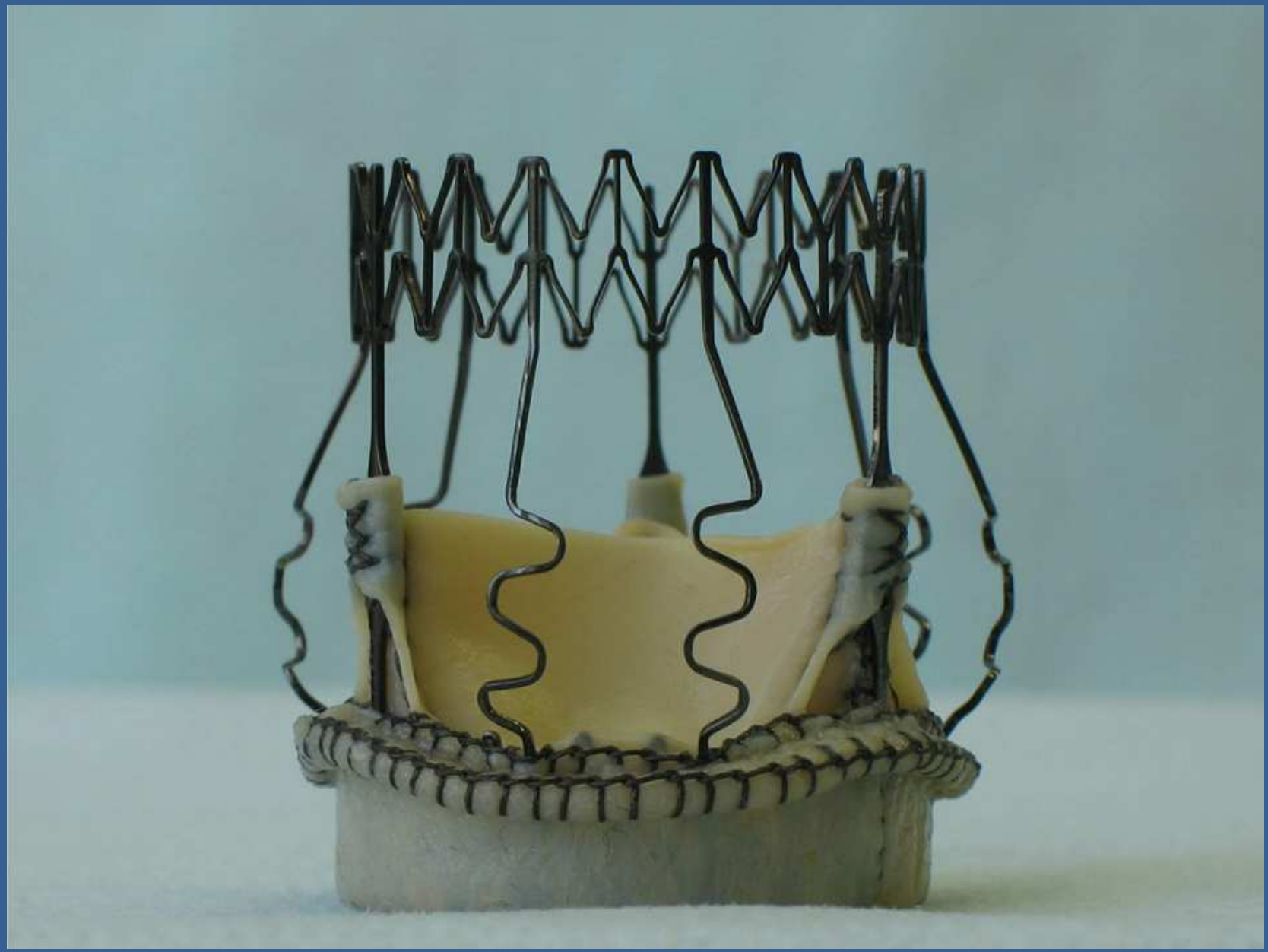
Sutureless aortic valve replacement with the Trilogy Aortic Valve System: Multicenter experience

Ingo Breitenbach, MD,[a] Gerhard Wimmer-Greinecker, MD,[b] Leo A. Bockeria, MD,[c] Jerzy Sadowski, MD,[d] Christoph Schmitz, MD,[e] Boguslaw Kapelak, MD,[d] Krzysztof Bartus, MD,[d] Ravil Muratov, MD,[c] and Wolfgang Harringer, MD[a]

J Thorac Cardiovasc Surg, 2010

Sutureless aortic valves

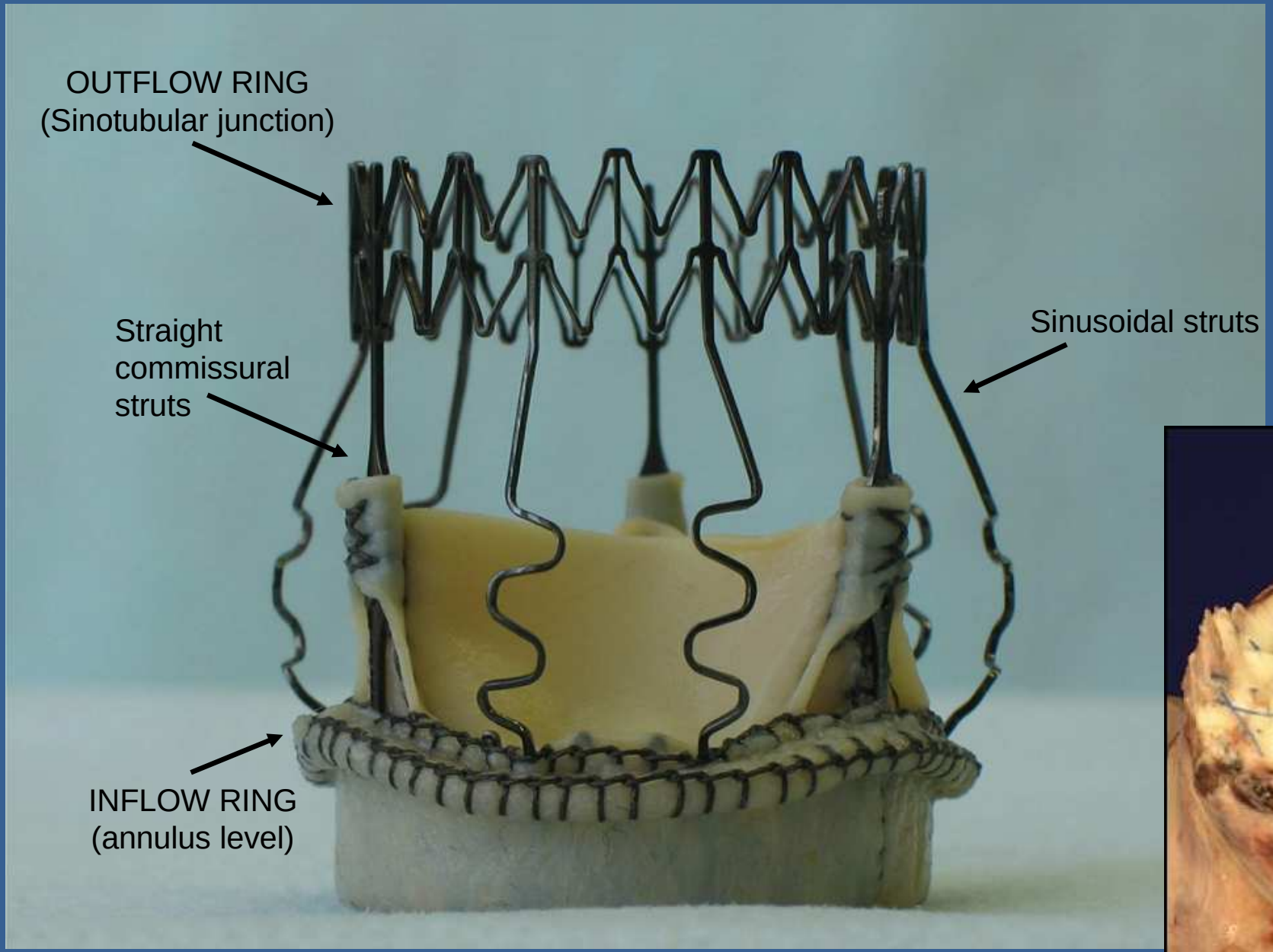
2007: Perceval valve (Sorin)

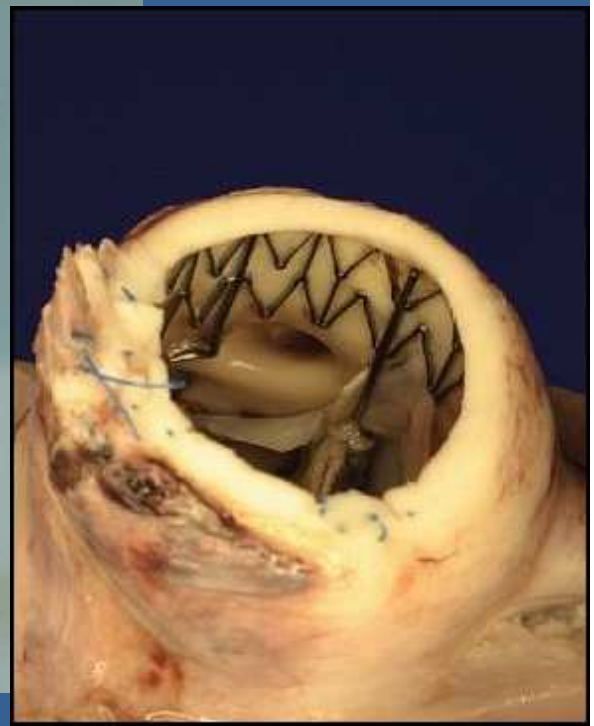


Sutureless aortic valves
2007: Perceval valve (Sorin)

- Bovine pericardium
  - Glutaraldehyde-fixed
  - Detoxified (HA)
    - ≈ Sorin Freedom valve
  - No rinsing
  - Nitinol, self-expanding frame

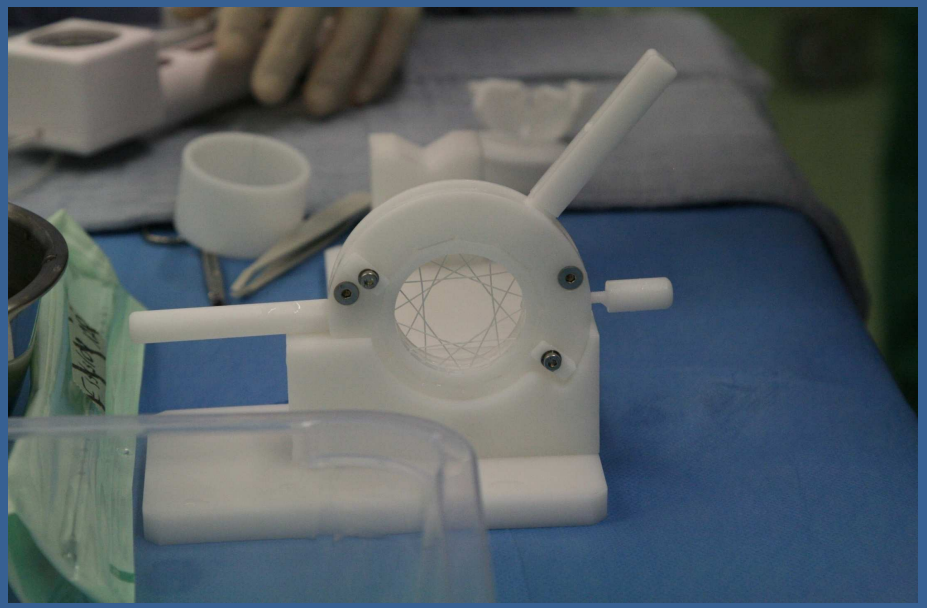
Sutureless aortic valves
2007: Perceval valve (Sorin)

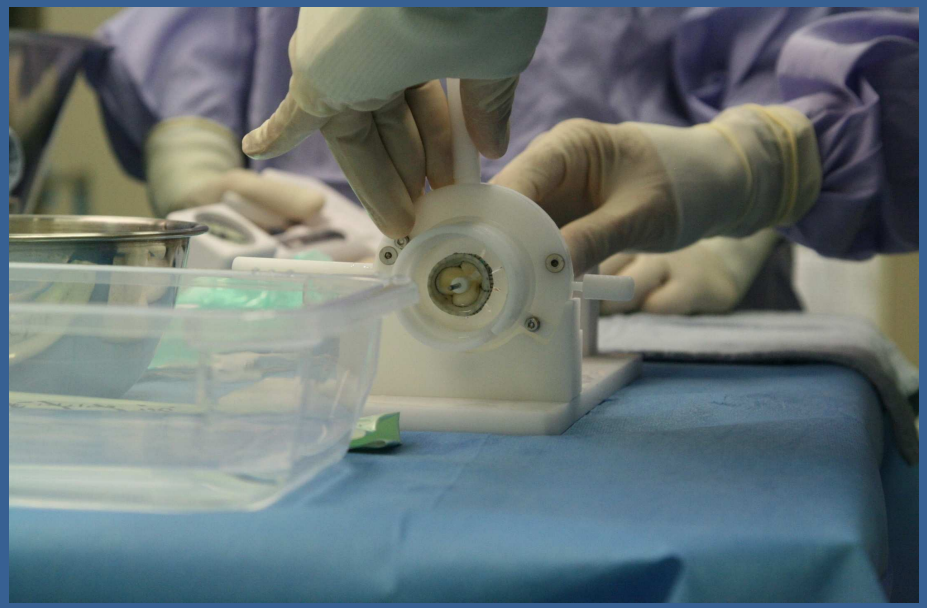


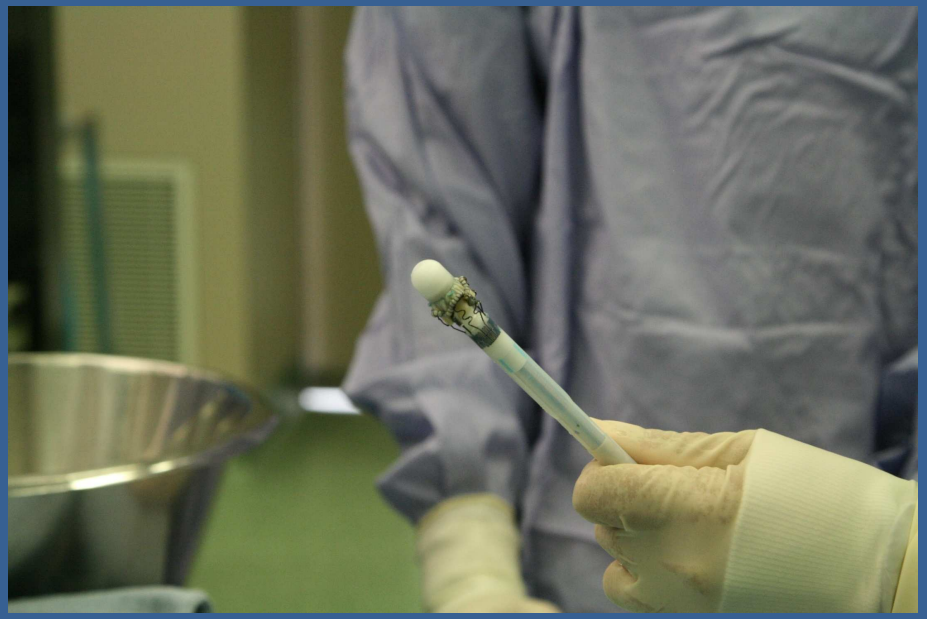


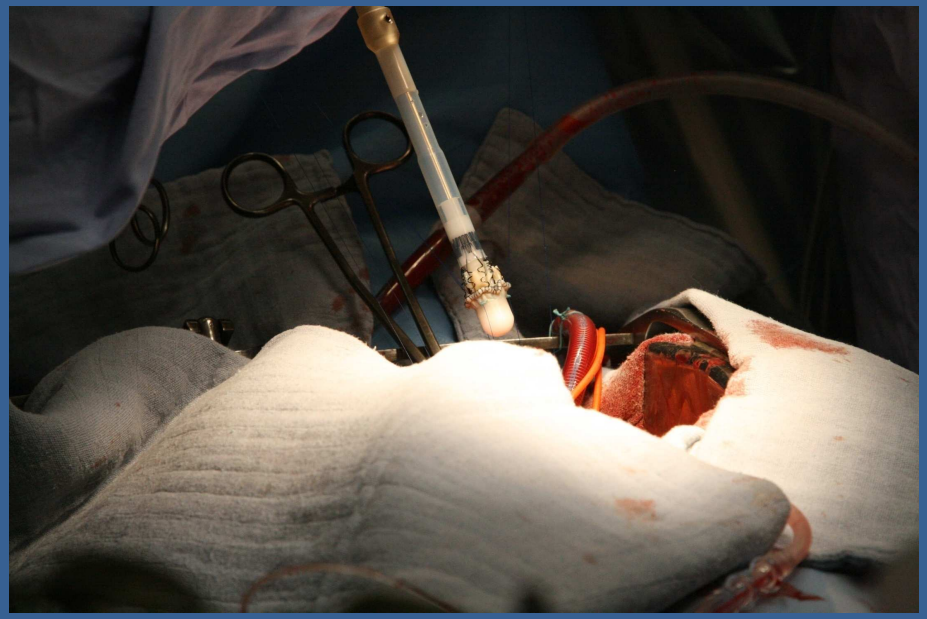
Perceval valve

Valve preparation



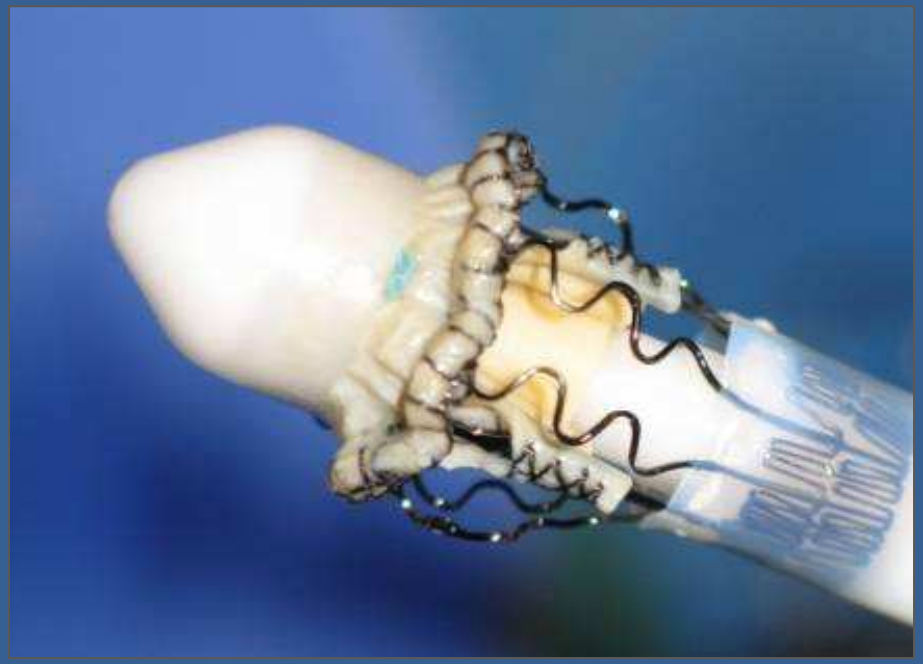


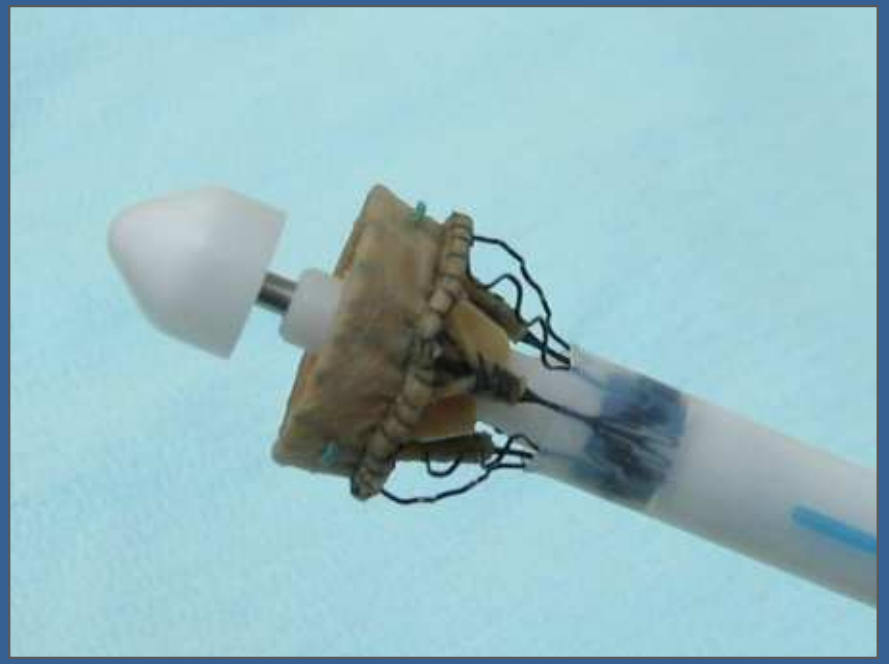




Perceval valve

Valve deployment: 2 steps





Perceval valve
Current trials

FIM 30 patients	PIVOTAL 150 patients	CAVALIER
'First-in-man' trial	150 enrolled	Aim: 240 patients
2007- 2008	2008 - 2009	Current status: 158 enrolled
3 EU centers • Leuven • Hannover • Paris	9 EU centers	17 EU centers
	1y clinical + echo follow-up	5y clinical + echo follow-up
Completed	Completed	Currently ongoing

Perceval valve
Current trials

FIM 30 patients	PIVOTAL 150 patients	CAVALIER
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2007-2008	2008-2009	Status sep/10: 158 enrolled
3 EU center • Leuv • Hann • Paris		17 EU centers
Completed	Completed	Currently ongoing

Size 21 / 23 available

Size 21 / 23 / 25 available

Perceval valve

First trials

Inclusion Criteria

- age ≥ 75 years;
- aortic valve stenosis;
- high surgical risk and candidate for a standard surgical intervention of aortic valve replacement with biological prosthesis;
- NYHA functional class III and IV;
- Small and calcified aortic root / annulus;

Exclusion Criteria

- Aneurismal dilation or dissection of the ascending aorta requiring surgical correction;
- aortic annulus size (after decalcification) **< 19 mm** or **> 23 mm** by direct intra-operative measurement.

Perceval valve

First trials

Inclusion Criteria

- age ≥ 75 years; → >65 years
- aortic valve stenosis;
- high surgical risk and candidate for a standard surgical intervention of aortic valve replacement with biological prosthesis;
- NYHA functional class III and IV;
- Small and calcified aortic root / annulus;

Exclusion Criteria

- Aneurismal dilation or dissection of the ascending aorta requiring surgical correction;
- aortic annulus size (after decalcification) **< 19 mm** or **> 23 mm** by direct intra-operative measurement. → < 19 or > 25 mm

Perceval valve
Leuven series (n=42)

Mean age:	79,3 ± 3,3 (range 75 – 87)
Mean logistic Euroscore:	12,3 (range 6,2 – 24,9)
Concomitant CABG:	55%
Size 21:	n=6
Size 23:	n=30
Size 25:	n=6

Perceval valve
Leuven series (n=42)

X-clamp times: mean: 19min (range 12 – 35min)

CABG: mean number of distals: 2,1 (range 1 – 4)

→ intermittent X-clamp → total X-clamp: mean 27min

CPB times: range 42 – 64min

Perceval valve
Leuven series (n=42)

- No operative mortality
- Hospital discharge: median day 12 (range 4 – 104)
- Follow-up: mean 23,1 ± 8,4 months (max 36 months, 100%)
- 3 late deaths (valve-unrelated)
- 1 explant (endocarditis)
- 1 postoperative pacemaker

Perceval valve
Leuven series (n=42)

	At discharge (n=42)	6 months (n=31)	12 months (n=25)
Peak pressure gradient	23.2 ± 8.9	21.3 ± 10.7	18.4 ± 7.4
Mean pressure gradient	12.1 ± 5.1	12.4 ± 6.2	10.3 ± 4.3
Effective orifice area	1.5 ± 0.4	1.3 ± 0.5	1.3 ± 0.9
Valvular regurgitation			
•0 - 1	78%	80%	86%
•1 +	22%	17%	13%
•2 +	0%	3% (*)	0%
•3 +	0%	0%	0%
Paravalvular regurgitation			
•0 - 1	87%	83%	92%
•1 +	13%	14%	9%
•2 +	0%	3% (*)	0%
•3 +	0%	0%	0%

Sutureless aortic valves

Perceval valve (Sorin)

Perceval valve
Conclusion

- Safe surgical procedure
  - No significant paravalvular leakage
  - No migration or dislodgement
  - Over 330 valves implanted now, maximum FU > 3y
- Significantly reduced X-clamp times
  - Can be implanted in < 20min
  - Possible benefit in combined procedures, in elderly and high-risk patients
  - Little manipulation in aortic root (calcification, plaque,…)
- Good early hemodynamic performance

Perceval valve Publications

T3. **Sutureless Perceval S Aortic Valve Replacement: Multicentric, Prospective, Pilot Trial**

Malakh Shrestha[1], Thierry Folliguet[2], Paul Herijgers[3], Alain Debie[2], Christoph Bara[1], Marie-Christin Herregods[3], Nawid Khaladj[1], Christian Hagl[1], Willem Flameng*[3], Franscois Laborde[2], Axel Haverich*[1]
[1]Cardiothoracic Surgery, Hannover Medical School, Hannover, Germany; [2]Institut Mutualiste Montsouris, Paris, France; [3]U.Z. Gasthuisberg, Leuven, Belgium

Invited Discussant: George J. Magovern, Sr.

AATS meeting, San Diego, 2008

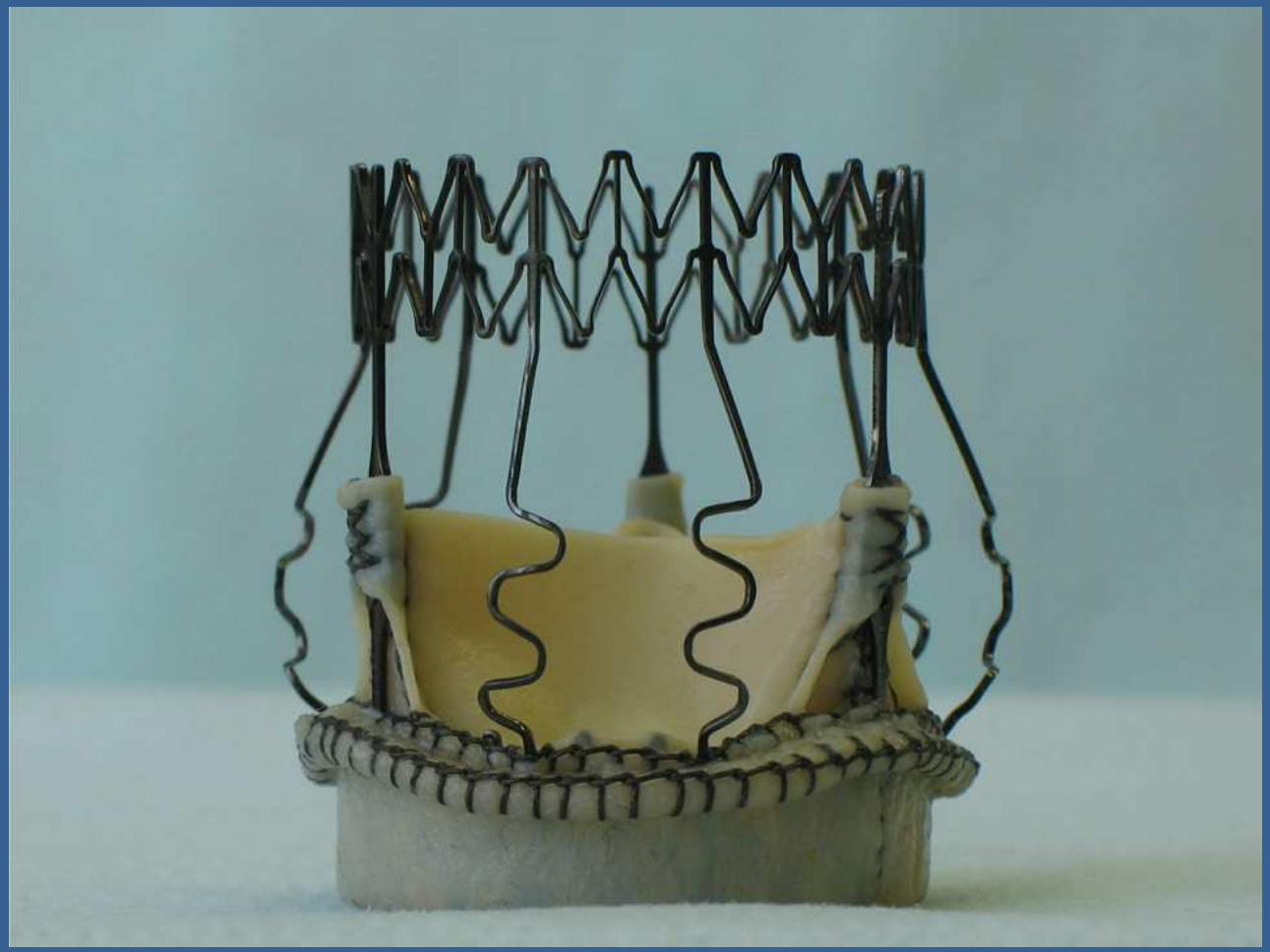
J Heart Valve Dis, 2009

Sutureless Perceval S Aortic Valve Replacement: A Multicenter, Prospective Pilot Trial

Malakh Shrestha, Thierry Folliguet, Bart Meuris, Alain Dibie, Christoph Bara, Marie-Christine Herregods, Nawid Khaladj, Christian Hagl, Willem Flameng, Francois Laborde, Axel Haverich
Division of Cardiac, Thoracic, Transplantation and Vascular Surgery, Hannover Medical School, Hannover, Germany, Cardiac Medico-Surgical Department, Institute Mutualiste Montsouris, Paris, France, Cardiac Surgery, U.Z. Gasthuisberg, Leuven, Belgium

Background and aim of the study: A European, multicenter, prospective, non-randomized, clinical pilot trial was designed to evaluate the feasibility of the Perceval S sutureless aortic valve prosthesis. A clinical and echocardiographic follow up was performed at the time of hospital discharge and subsequently after one, three, six, and 12 months.
Methods: The valve was implanted following sternotomy, extracorporeal circulation (ECC), aortic cross-clamping, cardioplegic arrest, and removal of the native valve. Implantation suturing was not required. Optimal annular sealing was obtained with brief low-pressure balloon dilation. If coronary bypass was indicated, a distal anastomosis was performed first. Between April 2007 and February 2008, 30 patients (mean age: 81 ± 4 years) underwent aortic valve replacement. The prevalence of pure aortic stenosis was 76.7%, and that of mixed lesion 23.3%. The mean logistic EuroSCORE was 13.18%, and the NYHA class was III and IV in 93.3% and 6.7% of patients, respectively. The implanted valve size was 21 and 23 mm in 37% and 63% of patients, respectively, and 14 (46.7%) underwent coronary artery bypass grafting (11 internal mammary artery, nine vein grafts).
Results: The mean aortic cross-clamp and ECC times were 34 ± 15 min and 59 ± 21 min, respectively.
There was one in-hospital death (3.3%), and three deaths occurred within 12 months of follow up (one death was valve-related, and two deaths were independent of the valve implantation). A total of 28 patients was assessed at one month post-implantation, and 23 after 12 months. No migration or dislodgement of the valve had occurred, but there were two mild paravalvular leakages and two mild intra-valvular insufficiencies.
Conclusion: The preliminary results of the trial confirmed the safety and efficacy of the Perceval S sutureless aortic valve. In this high-risk subset of patients, shortening the aortic cross-clamp and ECC times may help to reduce mortality and morbidity.

The Journal of Heart Valve Disease 2009;18:698-702



Thank you