Role of
Sutureless/Rapid Deployment Valve Replacement

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Current Options for AVR

✓ Surgical aortic valve replacement (Gold standard therapy)
  - Traditional valve replacement
  - Sutureless valve replacement

✓ TAVI
  - Alternative procedure for treating aortic stenosis in high risk patients
  - Expansion of indications from inoperable pts to high risk pts
Expansion of TAVI is justified to low or medium risk patients?
Concept of Sutureless Valve Replacement

✓ George Jerome Magovern (1923 – 2013)
✓ The 20th president of the Society of Thoracic Surgeons
✓ First use of sutureless valve
  - 1962. 4.13
  - Magovern-Cromie sutureless prosthetic aortic valve
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

Circulation 2008;117:e1-e2
Concept of Sutureless Valve Replacement

- Absence or reduction of anchoring suture
  → Shortening the time required for valve replacement
    - Shortening the aortic cross clamp time
    - Shortening the cardiopulmonary bypass time
    - Enhancing minimal invasive surgery
# Current products of Sutureless Valve

## TABLE 1. Design Characteristics

<table>
<thead>
<tr>
<th>Feature</th>
<th>Edwards INTUTY</th>
<th>Sorin Perceval S</th>
<th>Medtronic 3F Enable</th>
</tr>
</thead>
<tbody>
<tr>
<td>CE mark</td>
<td>2012</td>
<td>2011</td>
<td>2012</td>
</tr>
<tr>
<td>Available patient follow-up</td>
<td>3 y</td>
<td>5 y</td>
<td>5 y</td>
</tr>
<tr>
<td>Design platform</td>
<td>Bovine pericardium, trileaflet, balloon expandable, stainless steel cloth-covered frame</td>
<td>Bovine pericardium, trileaflet, self-expandable nitinol frame with additional proximal and distal rings for annulus fixation</td>
<td>Three equal sections of equine pericardial tissue forming tubular structure, self-expandable nitinol frame covered in polyester fabric, equally spaced commissural tabs reinforced with polyester material</td>
</tr>
<tr>
<td>Available sizes</td>
<td>19, 21, 23, 25, 27 mm</td>
<td>21, 23, 25 mm</td>
<td>19, 21, 23, 25, 27, 29 mm</td>
</tr>
<tr>
<td>Rinsing</td>
<td>2 times, 60 s each</td>
<td>Not required</td>
<td>3 times 120 s each</td>
</tr>
<tr>
<td>Sutures</td>
<td>3 actual sutures</td>
<td>None/only guiding sutures</td>
<td>0/1 actual suture</td>
</tr>
<tr>
<td>Collapsible</td>
<td>Crimped</td>
<td>Yes, with collapsing tool</td>
<td>Yes, manual folding</td>
</tr>
</tbody>
</table>

CE, Conformité Européenne.
Advantage of sutureless valve

✓ Compared to traditional AVR
  - Rapid delivery (Reduced CPB and ACC time)
    → Suitable for high risk patients or requiring concomitant operation
  - Enhances MICS procedure

✓ Compared to TAVI
  - Removal of diseased valve
  - Decalcification of the annulus
  - Implantation under direct vision : proper fitting
What is Perceval?

Perceval is pericardial heart valve with a sutureless and collapsible design that simplifies the surgical implantation, reducing operative trauma and post-operative complications and enables faster pt recovery.

1. Santarpino et al. - Ann Thorac Surg 2013; 96(1) 77-81
What is Perceval?

Key Features

Valve features
– bovine pericardium
– eyelets for guiding suture positioning

Self-anchoring frame
– self-expanding, Ni-Ti alloy
– anatomical design to fit Valsalva sinuses
– tapered outflow ring design
– special inflow ring design
– Carbofilm™ coating
What is Perceval?
Valve Design

- Outflow Ring (@ STJ level)
- Sinusoidal Struts (fit Valsalva sinuses)
- Inflow Ring (@ annulus level)
- Straight Commissural Struts
- Double-sheet Valve Design
- Eyelets (for guiding sutures)
What Are the Main Advantages of Perceval? Collapsible

Unique collapsible design

Thanks to dedicated accessories, the valve diameter can be reduced prior to the operation. This increases the visualization and facilitates also more complex procedures.
Current Results

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

Malakh Shrestha, Theodore Fischlein, Bart Meuris, Willem Flameng, Thierry Carrel, Francesco Madonna, Martin Misfeld, Thierry Folliguet, Axel Haverich and Francois Laborde

Excellent clinical results reported:

Conclusions: This European multicentre experience, with the largest cohort of patients with sutureless valves to date, shows excellent clinical and haemodynamic results that remain stable even up to the 5-year follow-up. Even in this elderly patient cohort with 40% octogenarians, both early and late mortality rates were very low. There were no valve migrations, structural valve degeneration or valve thrombosis in the follow-up. The sutureless technique is a promising alternative to biological aortic valve replacement.
Conclusions: The Perceval sutureless valve resulted in low 1-year event rates in intermediate-risk patients undergoing AVR. New York Heart Association class improved in more than three-quarters of patients and remained stable. These data support the safety and efficacy to 1 year of the Perceval sutureless valve in this intermediate-risk population.
Current Results
Sutureless vs Traditional AVR

Better Short-Term Outcome by Using Sutureless Valves: A Propensity-Matched Score Analysis

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Sutureless (n = 82)</th>
<th>Stented (n = 82)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time, min</td>
<td>145 ± 36</td>
<td>173 ± 57</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cross-clamp time, min</td>
<td>47 ± 16</td>
<td>59 ± 23</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>For isolated AVR, min</td>
<td>35 ± 12 (n = 57) 49 ± 16 (n = 62)</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>CPB time, min</td>
<td>71 ± 11</td>
<td>92 ± 33</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ventilation time, h</td>
<td>9.5 ± 4.6</td>
<td>16.6 ± 6.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Intensive care unit, d</td>
<td>2 ± 1.2</td>
<td>2.8 ± 1.3</td>
<td>0.040</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>5 (6.1)</td>
<td>7 (8.5)</td>
<td>0.360</td>
</tr>
<tr>
<td>Reexploration for bleeding</td>
<td>2 (2.4)</td>
<td>5 (6.1)</td>
<td>0.221</td>
</tr>
<tr>
<td>Paroxysmal AF</td>
<td>3/74 (4.1)</td>
<td>12/76 (15.8)</td>
<td>0.015</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>3 (3.7)</td>
<td>11 (13.4)</td>
<td>0.024</td>
</tr>
<tr>
<td>Stroke/TIA</td>
<td>3 (3.7)</td>
<td>6 (7.3)</td>
<td>0.248</td>
</tr>
<tr>
<td>Respiratory insufficiency</td>
<td>2 (2.4)</td>
<td>10 (12.2)</td>
<td>0.016</td>
</tr>
<tr>
<td>Blood transfusion, units</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exitus, 30 d</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital stay, d</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Conclusions: A shorter procedural time in the sutureless group is associated with better clinical outcomes and reduced hospital costs.

Immediate outcome after sutureless versus transcatheter aortic valve replacement

Table 4 Immediate postoperative data on patients who underwent transcatheter (TAVI) and surgical aortic valve replacement with sutureless Perceval S bioprosthesis (SU-AVR)

<table>
<thead>
<tr>
<th>Postoperative outcome</th>
<th>Overall series</th>
<th>25th–75th percentiles of ESI</th>
<th>PS-matched pairs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SU-AVR 379 patients</td>
<td>TAVI 394 patients</td>
<td>SU-AVR 108 patients</td>
</tr>
<tr>
<td>Device success</td>
<td>305 (80.5)</td>
<td>309 (78.4)</td>
<td>0.481</td>
</tr>
<tr>
<td>Paravalvular regurgitation</td>
<td></td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>None</td>
<td>370 (97.6)</td>
<td>163 (41.9)</td>
<td></td>
</tr>
<tr>
<td>MIR</td>
<td>3 (0.8)</td>
<td>17 (4.4)</td>
<td></td>
</tr>
</tbody>
</table>

- Sutureless valves may provide favorable early results vs. TAVI
- Sutureless AVR is associated with a rather low incidence of significant paravalvular regurgitation and excellent immediate postoperative survival.
- Sutureless AVR is a valid alternative to TAVI in intermediate risk patients.

Continuous variables are reported as mean ± standard deviation; dichotomous variables are reported as counts and percentages in parentheses

ESII EuroSCORE II

Heart Vessels 2016;31:427-33
Conclusions: Reproducible short crossclamp and bypass times were achieved in a minimally invasive setting. The valve shows good hemodynamic performance comparable to other sutureless or rapid deployment valves.
Enhances the MICS

Minimally Invasive Implantation of the EDWARDS INTUITITY Rapid Deployment Aortic Valve Via a Right Minithoracotomy

Aristidis Lenos, MD and Anno Diegeler, MD

- 2013.3 – 2013.7, 10pts
- Thoracotomy (7-10cm, 2\textsuperscript{nd} or 3\textsuperscript{rd} ICS)

<table>
<thead>
<tr>
<th>TABLE 2. Basic Postoperative Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Survival</td>
</tr>
<tr>
<td>Success of valve placement</td>
</tr>
<tr>
<td>Max gradient, mean ± SD</td>
</tr>
<tr>
<td>Mean gradient, mean ± SD</td>
</tr>
<tr>
<td>RCC transfusion</td>
</tr>
<tr>
<td>Length of intensive care unit time, mean</td>
</tr>
</tbody>
</table>
Current weakness of sutureless valve

• Migration
• Paravalvular leakage
• Pacemaker implantation
• Long term durability – need more f/u
Migration – Reported only for 3f Enable

1 case

Delayed dislocation of a sutureless aortic bioprosthesis: the first case
Giovanni Concistrè, Antonio Miceli, Francesca Chiaramonti and Mattia Glauber

3 case

Early single-center experience in sutureless aortic valve implantation in 120 patients
Harald C. Eichstaedt, MD,1 Jerry Easo, MD,2 Tobias Hürke, MD,3 and Otto E. Dapunt, MD, PhD

3f Enable valve
17 cases of migration reported at Nov, 2014
Valve discontinued at May, 2015
Paravalvular Leakage

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

Malakh Shresthaa, Theodore Fischleinb, Bart Meurisc, Willem Flamengc, Thierry Carrelc, Francesco Madonnae, Martin Misfeldf, Thierry Folliguette, Axel Haverichg and Francois Labordeh

<table>
<thead>
<tr>
<th>Event</th>
<th>Early events (≤30 days)</th>
<th>Late events (&gt;30 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Paravalvular leak</td>
<td>10</td>
<td>1.4</td>
</tr>
<tr>
<td>Minor</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Major</td>
<td>10</td>
<td>1.4</td>
</tr>
<tr>
<td>Secondary paravalvular leak</td>
<td>1</td>
<td>0.1</td>
</tr>
</tbody>
</table>

Early PVL rate : 1.4%

TAVI – PVL (moderate to severe) 11.8% - 30 days, 10.5% - 1 year

(JACC Cardiovasc Interv 2012;8:858-65)
Pacemaker Implantation

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


<table>
<thead>
<tr>
<th>Early events (≤30 days)</th>
<th>Late events (&gt;30 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>AV block III in patients without preoperative cardiac rhythm abnormalities</td>
<td>44</td>
</tr>
</tbody>
</table>

PM Implantation rate in sutureless valve: 6 %
8.1% (J Thorac Cardiovasc Surg 2016 in press)

TAVI – Edward SAPIEN <5%, CoreValve up to 30%

(JACC Cardiovasc Interv 2012;8:858-65)
88yr/ F (138.7cm, 51kg)

- Dyspnea on exercise (Onset : 1.5 YA, Aggravation : 1MA)

severe AS, 1VD (RCA 80% stenosis)

Past medical Hx : asthma (20YA), dyslipidemia

Social Hx : smoking/alcohol (---)

Family Hx : none
• Bilateral pleural effusion
• Cardiomegaly (C/T ratio : 0.6)
Echocardiography

1. Small LV and increased LV wall thickness; EF 67%

2. Severe degenerative AS (tricuspid, annulus 20mm, S. valsealva 33mm)

3. Trivial TR with moderate resting pulmonary HTN (PASP = 58mmHg)

LV mass index 119.14 g/m²
Operation

- Sutureless AoV replacement with Sorin Perceval S medium-sized bioprosthesis

CPB time : 150min

ACC time : 77min
POD#8

AV peak velocity 3.9m/s
AVA : 1.47m²
AV mean PG 35mmHg
(R/O mild SAM)
Postoperative course

- POD#1 extubation
- POD#3 Tf to general ward
- POD#15 chest tube removal (d/t prolonged pleural effusion)
- POD#22 Tf to Internal medicine d/t pneumonia
EDWARDS INTUITY Elite Valve System

Rapid Deployment Valve
Rapid Deployment Valve: Intuity ELITE

Intuity valve system (8300AB)

Intuity valve Delivery system (8300DB)

Intuity valve Inflation Device
EDWARDS INTUITY Elite Valve System

EDWARDS INTUITY Elite Valve System combines:

- Proven Pericardial valve technology (Perimount Magna Ease valve)
- Innovation in transcatheter heart valve (Sapien valve)

Rapid Deployment System with 3 guiding sutures & Balloon expandable system.
Case Description:
- 75 Y/O Male, 112 kg
- Symptomatic Aortic Stenosis with DOE
- NYHA III Symptoms
- Dilated LV
- Normal Coronaries
- Endocarditis in 2006
- Hypertension
- Existing AAA (4.2 X 3.4)
45% reductions in cross-clamp times demonstrated in isolated AVR procedures in the prospective, multi-center TRITON trial when compared to data published by McClure et al in 20101,*

*Reference
EDWARDS INTUITY Elite Valve System
Clinical Data

**Procedure Times**

**CADENCE-MIS**
- 41.3 min XCT MIS RDAVR, p<0.0001 vs. FS AVR

**Bochum**
- 26 min XCT MIS RDAVR, 9 min implantation time

**Leipzig**
- 39 min XCT MIS RDAVR; 42 min XCT in all pts

**Smaller Incision**

**CADENCE-MIS**
- Proven time benefit in MIS, comparable outcomes

**Bochum**
- 100% MIS AVR, very short XCT, excellent outcomes

**Leipzig**
- 72% MIS AVR, short XCT, excellent outcomes

**Hemodynamics**

**TRITON 3-Yr**
- 8.7 mm Hg @ 3 years, n=287

**CADENCE-MIS**
- Statistically better gradients than conventional valves

**Leipzig**
- 8.8 mm Hg @ discharge, n=69

**Bochum**
- 1.7% (1) early PVLs (>1+) and pacemaker; 0% late

**PVLs / Pacemaker**

**TRITON 3-Yr**
- 0.7% early PVLs (>2+); 1.2% late PVLs

**CADENCE-MIS**
- 0% early PVLs (>2+); 4.3% (2) pacemaker
## Side-by-Side Comparison
### INTUITY Elite & Perceval S

<table>
<thead>
<tr>
<th></th>
<th>EDWARDS INTUITY Elite Valve</th>
<th>Perceval S Valve</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tissue</strong></td>
<td>Bovine Pericardium</td>
<td>Bovine Pericardium</td>
</tr>
<tr>
<td><strong>Anti-Calcification Treatment</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Valve Sizes</strong></td>
<td>19, 21, 23, 25, 27 mm</td>
<td>S, M, L, XL (19-27 mm)</td>
</tr>
<tr>
<td><strong>Frame Material</strong></td>
<td>Stainless Steel</td>
<td>Nitinol</td>
</tr>
<tr>
<td><strong>Frame Location</strong></td>
<td>Sub-annular</td>
<td>Supra-annular</td>
</tr>
<tr>
<td><strong>Rinsing Required</strong></td>
<td>Yes (2-minute)</td>
<td>No</td>
</tr>
<tr>
<td><strong>Valve Collapsed / Crimped</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong># of Guiding Sutures</strong></td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td><strong>Guiding Sutures Tied</strong></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>Proven Durability Data</strong></td>
<td><strong>Up to 20yrs</strong> (Edwards Perimount Valve)</td>
<td><strong>Up to 5yrs</strong></td>
</tr>
<tr>
<td><strong>CE Mark Approval</strong></td>
<td>February 2012</td>
<td>January 2011</td>
</tr>
</tbody>
</table>
Pacemaker Implantation

PACEMAKER IMPLANTATION RATE

EDWARDS INTUITY Valve
Sorin Perceval S Valve

Kocher 2013
Young 2015
Borger 2015
Borger 2013
Haverich 2014
Schlömicher 2014
Mazine 2015
Van Boxtel 2014
Baraki 2013
Biancari 2015
Dalen 2015 (MIS)
Rubino 2014
Folliguet 2012
Shrestha 2015
Shrestha 2014
Dalen 2015 (FS)
Miceli 2014
Gilmanov 2013
Villa (size S)

3.9% EDWARDS INTUITY Valve Weighted Mean Rate
7.9% Sorin Perceval S Valve Weighted Mean Rate
Paravalvular Leaks

1.1% EDWARDS INTUITY Valve Weighted Mean Rate
(Note: Does not include Borger 2013 data or Schlömicher 2014 to avoid double-counting)

1.3% Sorin Perceval S Valve Weighted Mean Rate
(Note: There is likely considerable overlap and double-counting across these studies)

Schlömicher 2014
Young 2015
Borger 2013
Haverich 2014
Borger 2015
Folliguet 2012
Shrestha 2014
Shrestha 2015
Rubino 2014
Dalen 2015 (MIS)
Miceli 2014
Biancari 2015
Dalen 2015 (FS)
Mazine 2015
Gilmanov 2013

Comparison of Paraavalvular Leak Rates:
- **EDWARDS INTUITY Valve**
- **Sorin Perceval S Valve**
Further studies would be required to compare the clinical outcomes between sutureless AVR and TAVI.
Conclusions

The sutureless aortic valve replacement showed good early clinical outcomes and is associated with low incidence of complications compared to TAVI and conventional AoV surgery.

The sutureless AVR would be a valid alternative method in high risk patients. However, further studies would be needed to identify the long term results.