New Developments in Cardiac Intervention

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Cardiac Intervention

- Coronary intervention – BVS
- Valvular heart disease – TAVI, Mitraclips
- Ventricular arrhythmias – SICD
- Bradycardia – leadless pacemakers
Cardiac Intervention

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Bioabsorbable Vascular Scaffold System (BVS)
Scaffold design

Locating scaffold marker beads

– To locate the markers, select a view that minimizes overlap with the ribs, spine, diaphragm, branches, etc.

– It may be helpful to use a freeze frame and
Absorb GT1

Bioresorbable vascular scaffold system

- **Bioresorbable Scaffold**
  - Poly (L-lactide) (PLLA)
  - Based on proven MULTI-LINK pattern
  - Naturally resorbed, fully metabolized*

- **Bioresorbable Coating**
  - Poly (D, L-lactide) (PDLLA)
  - Naturally resorbed, fully metabolized

- **Everolimus**
  - Similar dose density and release rate to the XIENCE family of products

- **Enhanced Delivery System**
  - Improved ease of use†
  - Improved push transmission†
  - Broad patient applicability

*Except for platinum markers; †Improved as compared to Absorb BVS. Tests performed by and data on file at Abbott Vascular. All illustrations are artists’ renditions.
Clinical evidence available along the entire continuum of the therapy

- Baseline
- 6 m
- 2 y
- 5 y

Months

- 0
- 1
- 3
- 6
- 9
- 12
- 2
- 3
- 4
- 5

Years

- >98%
- Procedural Success
  - REPARA¹
  - GABI-R²
- Healing comparable to best DES
  - TROFI II³
  - ESTROFA-BVS⁴
- Efficacy & safety comparable to DES
  - ABSORB III⁵
  - ABSORB Japan⁶
  - ABSORB China⁷
  - ABSORB-FIRST⁸
  - GHOST EU⁹
- Low rate of very late events, indicating trend towards excellent LT outcomes
  - ABSORB II¹⁰
  - ASSURE¹¹
- Low event rates maintained very long term
  - ABSORB Extend¹²
- Stable lumen area (OCT), restoration of vasomotor function
  - ABSORB Cohort B¹³

See Appendix for source references.

Cohort B OCT images - courtesy of RJ van Geuns, Erasmus Medical Center, Netherlands
Resorption: Vascular Response in a Porcine Model

**Absorb BVS**
- Polymer is replaced by an increasingly cellular provisional matrix

**Resorption Site**
- 1 month
- 6 months
- 12 months
- 24 months
- 30 months
- 36 months
- 42 months
- 48 months

**XIENCE V**
- Representative photomicrographs of porcine coronary arteries, 2x, Movat’s pentachrome.

Bioresorbable Scaffolds –
A Template for Vessel Healing

Baselines – 6 Months – 2 Years – 5 Years

Smooth muscle cells fill the spaces between the framework of the scaffold’s template

Restored physiologic environment drives structural and functional changes toward a stable neomedia

Cohort B OCT images - courtesy of RJ van Geuns, Erasmus Medical Center, Netherlands
Absorb leaves nothing* behind but a restored vessel, resulting in renewed possibilities for the patient.

Absorb continues to demonstrate proven safety and efficacy comparable to best in class DES at 1 year, now in 6 RCTs.

Proper implantation technique is paramount for good clinical outcomes¹

*Small platinum marker beads remain in the vessel wall.
¹Gori, T., 4 Cities Registry, EuroPCR 2015.
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Pathophysiology and Prevalence of AS

• Pathophysiology
  – Progressive, degenerative disease of the native leaflets
  – Mechanism of stenosis is similar to atherosclerosis¹

• Prevalence
  – 5% of people over 75
  – Most prevalent native valve disease
A Significant Unmet Need

• Over **300,000 severe aortic stenosis patients** worldwide

• More than **30% of all patients** with symptomatic severe aortic stenosis are not referred or are contraindicated for the golden standard surgical valve replacement\(^1\)

• Of the patients treated surgically, many are at **high risk of morbidity / mortality** from the procedure\(^2\)

• **Inoperable and high risk patients** are difficult to treat and have no option for treatment

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Severe Aortic Stenosis Survival Results

Patients who do not have surgical AVR have a shorter life expectancy than patients who undergo surgical AVR.

## Treatment

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgical Aortic Valve Replacement (SAVR)</strong></td>
<td>In the absence of serious co-morbid conditions, SAVR is indicated in virtually all symptomatic patients with severe AS¹</td>
</tr>
<tr>
<td><strong>TAVI</strong></td>
<td>High risk or contraindications for SAVR</td>
</tr>
<tr>
<td><strong>Aortic Balloon Valvuloplasty</strong></td>
<td>Bridge to surgery in hemodynamically unstable adult patients with AS who are at high risk for AVR¹&lt;br&gt;For palliation in adult patients with AS in whom AVR cannot be performed because of serious comorbid conditions¹</td>
</tr>
<tr>
<td><strong>Medical Management</strong></td>
<td>Serious comorbid conditions, malignancy, short life expectancy or patient preference¹</td>
</tr>
</tbody>
</table>
### Surgical Aortic Valve Replacement (SAVR)

- General anesthesia
- Heart stopped / patient on heart-lung machine
- Chest open, 7 inch incision
- 2 – 4 hours procedure
- 5 – 10 days hospital stay
- 6 – 8 weeks recovery period

### Transcatheter Aortic Valve Implantation (TAVI)

- Local or general anesthesia
- Heart pumps normally, patient breathes independently
- Catheter through femoral artery, small incision
- 1 – 2 hour procedure
- 3 – 5 day hospital stay
- Approx. 1 week recovery period
TAVI Implantation Approach Options

- Direct Aortic
  - 5% (increasing)

- Transfemoral
  - 70%

- Subclavian
  - 15-20%

- Transapical
  - 5% (decreasing)
# Patient Evaluation Matrix

<table>
<thead>
<tr>
<th>Product</th>
<th>CoreValve® Evolut™</th>
<th>CoreValve®</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size</strong></td>
<td>23 mm</td>
<td>26 mm</td>
</tr>
<tr>
<td>Annulus Diameter</td>
<td>18-20 mm</td>
<td>20-23 mm</td>
</tr>
<tr>
<td>Annulus Perimeter</td>
<td>56.5-62.8 mm</td>
<td>62.8-72.3 mm</td>
</tr>
<tr>
<td>Annulus Area</td>
<td>254.5-314.2 mm²</td>
<td>314.2-415.5 mm²</td>
</tr>
</tbody>
</table>
| Ascending Aorta Diameter | ≤ 34 mm
@ 30 mm from annulus    | ≤ 40 mm
@ 40 mm from annulus    | ≤ 43 mm
@ 40 mm from annulus    | ≤ 43 mm
@ 40 mm from annulus    |
| Sinus of Valsalva Diameter | ≥ 25 mm                    | ≥ 27 mm                     | ≥ 29 mm                     | ≥ 29 mm                     |
| Sinus of Valsalva Height | ≥ 15 mm                    | ≥ 15 mm                     | ≥ 15 mm                     | ≥ 15 mm                     |
Pre-TAVI
TAVI (1)

Severe AS

Balloon aortic valvuloplasty
with rapid RV pacing 180/min
Position of CoreValve at 4-6mm below aortic cusps

Deployment of Core Valve #26
Confirmation of position before full deployment

Core Valve deployed – mild AR
Post-TAVI
Edwards Sapien XT
Transcatheter aortic valve

Cobalt chromium frame with high radial strength for uniform leaflet coaptation
Frame height is designed to minimize risk of
- AV block
- Disruption of MV function
- Interference with coronary ostia
Treats annulus size range of 16 to 27mm
TAVI – Edwards Sapien

Valve deployment

Valve in-situ
TAVI and Paravalvular Leak

• Recent published studies report an incidence of moderate/severe AR after TAVI of approx. 15% to 20%

• Primary factors for post-TAVI PVL:
  – Undersizing of the prosthetic valve relative to native aortic valve
  – Presence of calcification within aortic root, leaflets and annulus
  – Implant depth of prosthetic valve relative to native aortic annulus
Mechanism of PVL after TAVI

Figure 5  Mechanisms of Peri-Prosthetic Aortic Regurgitation After Transcatheter Aortic Valve Implantation

Paravalvular leaks with concomitant peri-prosthetic aortic regurgitation result from under-expansion of the prosthesis stent frame, which might be caused by calcifications of the annulus or the cusps of the native valve (A), valve malposition with too shallow (B) or too deep (C) implantation depth of the prosthesis, and/or annulus-prosthesis-size mismatch (D).
The AR Index

Hemodynamic assessment of AR:
Simultaneous determination of LVEDP (blue line) and DBP (red line) in patient without AR (A) and in a patient with moderate AR (B)

AR Index:
$$\left[ \frac{(DBP - LVEDP)}{SBP} \right] \times 100$$

(A) AR Index = $$\left[ \frac{(65 - 10)}{160} \right] \times 100 = 34.4$$
(B) AR Index = $$\left[ \frac{(40 - 20)}{130} \right] \times 100 = 15.4$$

The AR Index and Outcome

• Optimal AR index cutoff value:
  – Patients with AR index <25 had a significantly increased 1-year mortality risk

Aortic Valve Replacement and Conduction Disorders

Permanent AV Block is a well-know complication of Aortic Valve Replacement

Surgical Aortic Valve Replacement (SAVR): 7.2%\(^1\) (Range: 3.2% - 8.5%)

Transcatheter Aortic Valve Implantation (TAVI): 15%\(^2\) (Range: 0 – 47%)

# TAVI: Factors recognized to influence conduction disturbance

<table>
<thead>
<tr>
<th>Patient History</th>
<th>Patient Anatomy</th>
<th>Procedural Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Septal wall thickness</td>
<td>Onset of AV block during TAVI</td>
</tr>
<tr>
<td>Depressed LVEF</td>
<td>Narrow LVOT</td>
<td>Balloon &amp; prosthesis: Annulus ratio</td>
</tr>
<tr>
<td>Previous AR and MR</td>
<td>Calcification of landing zone</td>
<td>CoreValve</td>
</tr>
<tr>
<td>Previous RBBB</td>
<td></td>
<td>Depth of implantation</td>
</tr>
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Mitraclips

- Percutaneous edge-to-edge mitral valve repair
- Mitraclip Clip Delivery System (CDS) consists of implant catheter and the Mitraclip device
- Permanent implant that attaches to MV leaflets
- Results in double opening of MV allowing greater closure and reduces MR
MitraClip, a new minimally invasive heart valve repair procedure, involves implanting a clip in the heart without opening the chest. This is how it is done:

1. Clip and catheter enter the femoral vein through a 1cm-incision made in the groin.
2. Clip is guided by ultrasound echo and X-ray scans and moved upwards through the catheter to the heart.
3. Clip enters the right atrium and crosses into the left atrium, above the valve.
4. Clip enters the damaged mitral valve, and its two levers clamp the valve shut, reducing backward flow of blood.
5. Catheter detaches from the clip and is withdrawn.

SOURCE: MASSACHUSETTS MEDICAL SOCIETY, ABBOTT LABORATORIES, DAILY MAIL TEXT: AMELIA TENG ST GRAPHICS
Fixing a leaky valve

**BEFORE**
Mitral regurgitation happens when the heart’s mitral valve does not close completely, and blood flows backwards into the heart instead of to the rest of the body.

- Right atrium
- Left atrium
- Blood flows backwards

**AFTER**
With the valve shut, blood can flow to the body.
Deployment of Mitraclip
Severe MR
Post-Deployment of Mitraclip

- View from LA side
- View from LV side
Before & After Mitraclip
Before & After Mitraclip
Mitraclips
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Ventricular arrhythmias (ICD)

VT

VF
Implantable Cardiovertor-Defibrillator (ICD)

Defibrillation
S-ICD (Subcutaneous Implantable Defibrillator)
1. Once the patient has been properly prepped and draped, an incision is made to place the pulse generator at the mid-axillary line between the 5th and 6th intercostal spaces.

2&3. The electrode is positioned through two subcutaneous tunnels from the pocket to the xiphoid incision and from the xiphoid to the superior incision.
S-ICD (Subcutaneous Implantable Defibrillator)

4 & 5. The pulse generator is then connected to the subcutaneous electrode and secured in the pocket.
Benefits of S-ICD

- Avoid complications associated with transvenous leads, e.g. hemothorax, perforation, leads fracture/dislodgement, endocarditis, lead extraction complication etc
- Eliminates potential for vascular injury
- Reduces potential for systemic infection
- Preserves venous access
- Reduces need for fluoroscopy during implant
- Less invasive – protection from sudden cardiac death without touching the heart
Indications for S-ICD

S-ICD System is the preferred device
• No venous access (occluded or congenital)
• High risk of complications for transvenous-ICD (dialysis, pediatric immunocompromised)
• Channelopathies (LQT, Brugada, HCM)
• Previous device infections or lead failures
• H/O endocarditis

S-ICD System should be strongly considered
• Young patients
• Life expectancy > 10 yr
• Primary prevention with ischemic/non-ischemic heart failure
• Prosthetic valves
• Women (preferred generator placement)
• Selected secondary prevention (survivors of out of hospital VF, no evidence of monomorphic VT)

S-ICD System should be avoided
• Systolic HF and LBBB --> CRT
• Symptomatic bradycardia requiring pacing
• Recurrent sustained monomorphic VT for whom ATP is deemed appropriate

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Pacing Therapy

- Senses underlying heart rate
  - Delivers low energy electrical pulses when rate falls below programmed limit
- Low energy pulses capture and depolarize the heart muscle causing it to contract
  - Dual Chamber pacemakers provide A-V synchrony
Leadless pacemakers
St Jude Nanostim Leadless Pacemaker

- Cylindrical, self-contained battery/generator/electrode with a screw-tip
- 4-cm long, 6mm diameter device
- Provides VVIR pacing
- Potential longevity 15 years
- No surgical scar or leads or pocket infection complications
A catheter that contains the leadless pacemaker is passed through a small puncture in the groin and then into the femoral vein.

Using X-ray images as a guide, the doctor guides the catheter to the right atrium of the heart and through the tricuspid valve.

The catheter with the pacemaker is then guided into the right ventricle.

The doctor carefully places the pacemaker and secures it to the wall at the bottom of the right ventricle.

The pacemaker is then tested to ensure it is secured to the wall and programmed correctly.

The catheter is removed and the pacemaker stays within the right ventricle.
Medtronic Micra - Transcatheter Pacing System (TPS)

- VVIR pacemaker
- TPS is delivered to the RV via the femoral vein where it grabs onto endocardial tissue and provides pacing signals through its electrode tip
- Battery life ranges between 7 and 15 years
Deployment of Micra