Mitral valve repair: personal experience with the biodegradable ring

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JTCVS 1983;86:323-337
Cardiac valve surgery- The « French correction »
First attempts to deal with this problem

In 1986: Duran et al. “A new absorbable ring in the tricuspid position: an experimental study”
Complete biodegradation of the bovine fibrine ring in 2 months after implantation

In 1990: Chachques et al. “Absorbable rings for paediatric valvuloplasty: preliminary study”
Absorbable poly-dioxanone ring similar to that of Carpentier covered with synthetic material in order to facilitate its fixation onto the native annulus and prevent embolisation of its fragments
Important fibrous reaction after 12 months

Use of 2-0 PDS. 6 months after its insertion the suture material was completely absorbed by inducing a fibrous tissue and the tricuspid orifice returned to its original dimension

In 1994: Miyamura et al. “Total circular annuloplasty with absorbable suture for the repair of left AV valve regurgitation in AV septal defect”
Use of 4-0 polydioxanone or 4-0 polyglactin suture. 77% of the children preserved good valvular function without residual significant lesions in long term.
Bio-degradable ring

**Between 1994 and 2002: phase of development**

- It comprises of a poly-1,4-dioxanone polymers
- It is a partial ring by design with suture material extensions at each extremity (2-0 polyvinyl)
- This non degradable component is in continuity all over the entire portion of the ring
- Its specific molecular weight provides structural memory to protect it from subsequent deformity
- Implantation of the ring within the native annulus-contrary to the traditional rings that are inserted on the native annulus-prevents it from being in contact with blood

**Biodegradable Polymers: Hydrolysis**

- Hydrolysis: Breakdown of a molecule in presence of water
- Hydrolysis of the ester bond results in formation of an alcohol and an acid
- Inflammation and induction of fibrous tissue
- The final degradation product of poly-dioxanone is: (2-Hydroxyethoxy) acetic acid
Implantation technique

In mitral position

In tricuspid position

Anterior trigone
Anterior commissure
Posterior trigone
Posterior commissure

Antero-septal commissure
Coronary sinus
Postero-septal commissure

Antero-septal commissure
Postero-septal commissure

Measurement of the ring size according to the anterior leaflet surface

Implantation steps 1

Implantation steps 2

Before implantation

Implantation steps 3

Implantation steps 4
Two important points raised with this new concept of biodegradable ring

• Is the fibrous tissue induced by the ring capable of allowing for the natural growth of the valve orifice in children, hence preventing the occurrence of valve stenosis with time?

• Is the fibrous tissue capable of resisting against the tensile stretch of the dilated annulus?
Experimental trial on 16 juvenile pigs (30 - 43 kg)

J Heart Valve Dis 2006;15:783-90

- Implantation of the smallest size (16) into the tricuspid annulus

- All animals were followed-up by TTE to evaluate the TV function

- Animals were sacrificed at 1, 3, 6, 9 and 12 months (> 200 kg) following implantation

- Macroscopic and histological analysis were performed on 3 sections per ring implantation site

- Parameters collected from these animals were compared to those obtained from the control-group animals which underwent CPB without ring implantation

At 1 month

Inflammatory tissue around the ring with proliferating fibroblastic cells and collagen
At 3 months

Signs of superficial erosion and limited material fragmentation, less inflammation and myolysis

At 6 months

Marked signs of implant degradation, few residual debris, dense fibrous tissue
At 9 months

Signs of complete implant degradation, dense fibrous scar tissue

At 12 months

The thickness of the neo-formed annular fibrous tissue reached that of the degraded ring
Results of the animal trial

- The ring was gradually replaced by fibrous tissue with complete degradation by hydrolysis within 6 months.
- The thickness of the dense fibrous tissue reached that of the initial ring at 12 months.
- No tricuspid valve stenosis on echocardiographic controls.
- Macroscopic measurement of the valve orifice area confirmed that the generated fibrous tissue allows for physiological growth of the native annulus.

Is the fibrous tissue capable of resisting against the tensile stretch of the dilated annulus?
### Material & Method
March 2003 - April 2008

<table>
<thead>
<tr>
<th>Group</th>
<th>Mitral Patients n=283</th>
<th>Mean age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>156 (55 %)</td>
<td>49.1 years (+/- 19.0)</td>
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<tr>
<td></td>
<td></td>
<td>Oldest: 85 y</td>
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<tr>
<td>Pediatric</td>
<td>127 (45 %)</td>
<td>9.5 years (+/- 4.6)</td>
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<tr>
<td></td>
<td></td>
<td>Youngest: 5 m</td>
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In both groups, the repair was evaluated in surgery by trans-esophageal echocardiography and by trans-thoracic echocardiography after discharge.

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### Etiology of Mitral Pathologies

#### Adult Population
- Rheumatic: 39%
- Degenerative: 44%
- Ischemic: 6%
- Congenital: 4%
- Other: 9%

#### Pediatric Population
- Rheumatic: 35%
- Degenerative: 9%
- Congenital: 47%
- Other: 9%
Results

• Adults (n=156): Mortality: 2.5%. Mean follow-up: 820 ± 517 days (55-1817).
  • Techniques: valvuloplasty + annuloplasty: 151; annuloplasty = 5.
  • Intraoperative TEE: Competent valve: (54%); Trivial insufficiency: (45%); Mild incompetence: (1 %).
  • Mean mitral gradient: 3.5 ± 3 mmHg.
  • Reoperations: MVR: 7 patients (4.4 %), with rheumatic disease 1 to 55 months after.
  • Patients in NYHA class 1: 92.1 % .

Results

• Pediatric (n=127): Mortality: 0.7 %. Mean follow-up: 710 ± 483 days (16-1816)
  • Concomitant procedures: 46 patients
  • Intraoperative TEE: Competent valve: (80 %); trivial insufficiency: (14%); mild incompetence: (6%).
  • Mean mitral gradient: 2.7 ± 2.5 mmHg.
  • Reoperations: Six patients (4.7 %) between 12 and 50 months;
    –new repair: 1; MV Replacement: 5
    –No reoperations for cong. pure mitral insufficiency
  • Patients in NYHA class 1: 93%
Degenerative mitral valve disease
102 pts 2005-2007

Transmitral gradients:

3±1.2 mmHg in Bio. Group
5.2±1.8 mmHg in CE group

At 2-3 postoperatively years

2.3±0.4 mmHg Bio group
5.2±2.2 mmHg CE group

Variation 15 ± 3% of the AP diameter between systole and diastole at one year


Mitral Valve Repair for Rheumatic Valve Disease in Children: Midterm Results and Impact of the Use of a Biodegradable Mitral Ring

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Mean Mitral Valve Gradient

Unchanged mean gradient during the 1st year: Biodegradable 65%; Rigid 20%

Left ventricular shortening fraction

P <0.001
Advantages of biodegradable ring

1. Preserve the potential of growth of the mitral annulus (paediatric population)

2. No synthetic material (less risk of endocarditis)
   Pektok E, Sierra J, Cikirikcioglu M, Muller H, Myers P, Kalangos A.

3. No need for anticoagulation during the first post-operative 3 months
Advantages of biodegradable ring

- Easier implantation technique (reduction in the duration of aortic cross clamp and ECC)
  - low LVEF

- Make easy the implantation of the ring in minimally invasive and robotic surgery.
  
  Panos A, Myers P, Kalangos A. Thoracoscopic and robotic tricuspid valve annuloplasty with a biodegradable ring: initial experience J Heart Valv Dis, 2009 (in press)

Conclusion

Annulus remodeling by inducing fibrous tissue which:

- Preserves growth potential of the annulus in children and
- Maintains the three-dimensional dynamic geometry of the mitral and tricuspid valves

Undoubtedly contributes to the evolving annuloplasty technology