Contribution to the Challenge of Cardiac Replacement in Patients Suffering From End-stage Biventricular Failure

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End-stage Cardiac Insufficiency

- Affects 5 millions people in the USA.
- 1/3 of the patients are younger than 65.
- Mortality is 45% per year.
- Heart transplantation is limited by the shortage of donors, justifying the development of total artificial hearts for destination therapy.
Background - I

Pre-existing devices have been developed as:

- Bridge to transplant procedure - Cooley, Jarvik
- Ventricular assist - Frazier
Background - II

Alike cardiac valves existing artificial hearts are confronted with thromboembolism ¹

Clinical experience shows that valvular bioprostheses display a superior haemocompatibility ²

This stimulated our endeavour to use this biological material in the construction of a total artificial heart

² Carpentier A. Nat Med 2007;13(10):1165-8
CARMAT* Bioprosthetic Artificial Heart Characteristics

- Total artificial heart
- Biological material
- Physiological function
- Destination therapy

* CARpentier - MATra
Development

Prototype
Vol.: 1 l.
Weight: 900 g

Animal model
Vol.: 1.25 l.
Weight: 1900 g
Cons.: 70 W

Human model I
Vol.: 1 l.
Weight: 1200 g
Cons.: 30 W

Human model II
Vol.: 0.75 l.
Weight: 850 g
Cons.: 30 W

First human implantation
Dec. 18, 2013

1980 ← CETIM → 1993 → CARMAT → 2014
CARMAT Components

- 2 separate ventricles
- 2 pulsatile pumps
- 4 bioprosthetic valves
- 2 bioprosthetic membranes
- All components motor pumps and electronics are incorporated in a single compliance chamber
- Intrapericardial position
Physiologic movement
Anatomical Constraints - I
Computer Assisted Conception

Animal model

Human model
II - Virtual Fit Study

80% in male, 15% in female
III – Anatomical Compatibility

Pre-implant

Post-implant

1

2

3
Hydraulic test bench serves to develop numeric simulations.
Algorithm of viscoelastic contraction
III - Device Pump Output and Pulsatility

Arterial pressure and finger plethysmographic recordings Patient #1, POD 74

Haemocompatibility - I

I - CE Bioprosthetic valve

II - Flow pattern

CE Bioprosthetic membrane

Carpentier A. Nat Med 2007;13(10):1165-8
No visible intra-device clotting

The Control Agency (ANSM) authorized 4 clinical implantations (Sept. 2013)
LV cavity static surface coated with polytetrafluoroethylene (PTFE).

Pulsatile biomembrane exposed to blood: No visible clot formation.

The biomembrane in contact with blood is covered with a protein layer (Pr) which provides haemocompatibility.

IV - Durability: Fatigue Tests

Motor pumps 250 M cycles* (n=20)
Membrane 250 M cycles* (n=20)
Sensors 240 M cycles* (n=20)

* 90 M Cycles = 2 years
### Clinical Experience \( n=3 \)

Hôpital Européen Georges Pompidou, Paris (Pts #1 & #3)  
Thorax Institute, Nantes (Pt #2)

<table>
<thead>
<tr>
<th></th>
<th>Patient #1</th>
<th>Patient #2</th>
<th>Patient #3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>76</td>
<td>68</td>
<td>73</td>
</tr>
<tr>
<td><strong>LVEF (%)</strong></td>
<td>21</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td><strong>SPAP/DPAP (mmHg)</strong></td>
<td>-</td>
<td>42/19</td>
<td>87/56</td>
</tr>
<tr>
<td><strong>Implant date</strong></td>
<td>18 Dec 13</td>
<td>5 Aug 14</td>
<td>8 Apr 15</td>
</tr>
<tr>
<td><strong>Support duration</strong></td>
<td>74 days</td>
<td>270 days</td>
<td>215 days</td>
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</tbody>
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*Ongoing*

**Cumulative function: 559 days**
Clinical Experience (n=3)
559 days of function

- No haemolysis
- No thromboembolism
- No acquired Willebrand syndrome
- No infection
Wearable System

- Controller/monitor
- Batteries Li-ion
  - 3 kg, 4 hours at 6 L/min
- Future: Hydrogen batteries, 10 hours
Quality of Life

Assessed by the interview of patient #2 addressing the questions of how he feels, is he bothered by the weight of the prosthesis, or its noise? And finally how is his physical condition 8 months after implantation?
Quality of Life

assessed by patient N°2, 8 months after his operation
Merci for your invitation