New smaller LVADs will play an important role in the management of Congestive Heart Failure

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Texas Heart Institute
at St. Luke’s Episcopal Hospital
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Implantation of new smaller LVADs will be one of the most commonly performed procedures in cardiovascular medicine.

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In the interest of maintaining academic integrity, I would like to disclose the following conflicts…

- Apaxis - founder, patent holder, board member
- Viacor - co-founder, patent holder
- **SENTREHEART** - co-founder, patent holder, board member
- Acorn Cardiovascular - consultant, stock holder
- Onyx - board member, stock holder
- Houston Medical Robotics - co-founder, stock holder, board member, patent holder
- TVA - founder, stock holder, board member, patent holder
- Medtronic Inc. - consultant, Sub-X atrial fibrillation project
- TeleFLEX medical - royalties
- PluroMed - stock holder, Medical director
- Kips Bay - stock holder, Scientific Advisory Board
The instruments and implants demonstrated in this presentation are under development and are not approved by the FDA for clinical use.
End stage heart failure is the largest unmet clinical need in developed countries.
Interest in mechanical circulatory assist technology has steadily increased over the last 2 decades.
A number of continuous flow blood pumps have been developed and tested over the past decade that are smaller, easier to implant, and mechanically more robust than the pulsatile volume displacement pumps that preceded them.
Thoratec HeartMate I XVE
Thoratec HeartMate II

Advanced Continuous Flow Technology
Thoratec HeartMate II
MicroMed Heart Assist 5

Actual size: 71mm x 30mm, 92 grams
HeartWare HVAD
Do patients benefit from mechanical circulatory assist?
Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device

Mark S. Slaughter, M.D., Joseph G. Rogers, M.D., Carmelo A. Milano, M.D., Stuart D. Russell, M.D., John V. Conte, M.D., David Feldman, M.D., Ph.D., Benjamin Sun, M.D., Antone J. Tatooles, M.D., Reynolds M. Delgado, III, M.D., James W. Long, M.D., Ph.D., Thomas C. Wozniak, M.D., Waqas Ghumman, M.D., David J. Farrar, Ph.D., and O. Howard Frazier, M.D., for the HeartMate II Investigators*
ABSTRACT

BACKGROUND
Patients with advanced heart failure have improved survival rates and quality of life when treated with implanted pulsatile-flow left ventricular assist devices as compared with medical therapy. New continuous-flow devices are smaller and may be more durable than the pulsatile-flow devices.

METHODS
In this randomized trial, we enrolled patients with advanced heart failure who were ineligible for transplantation, in a 2:1 ratio, to undergo implantation of a continuous-flow device (134 patients) or the currently approved pulsatile-flow device (66 patients). The primary composite end point was, at 2 years, survival free from disabling stroke and reoperation to repair or replace the device. Secondary end points included survival, frequency of adverse events, the quality of life, and functional capacity.

RESULTS
Preoperative characteristics were similar in the two treatment groups, with a median age of 64 years (range, 26 to 81), a mean left ventricular ejection fraction of 17%, and nearly 80% of patients receiving intravenous inotropic agents. The primary composite end point was achieved in more patients with continuous-flow devices than with pulsatile-flow devices (62 of 134 [46%] vs. 7 of 66 [11%]; P < 0.001; hazard ratio, 0.38; 95% confidence interval, 0.27 to 0.54; P < 0.001), and patients with continuous-flow devices had superior actuarial survival rates at 2 years (58% vs. 24%, P = 0.008). Adverse events and device replacements were less frequent in patients with the continuous-flow device. The quality of life and functional capacity improved significantly in both groups.

CONCLUSIONS
Treatment with a continuous-flow left ventricular assist device in patients with advanced heart failure significantly improved the probability of survival free from stroke and device failure at 2 years as compared with a pulsatile device. Both devices significantly improved the quality of life and functional capacity. (ClinicalTrials.gov number, NCT00121485.)
Figure 2. Kaplan–Meier Estimates of Survival from the As-Treated Analysis, According to Treatment Group.

The data shown are for the 192 patients who received a left ventricular assist device (LVAD). Of the 59 patients who had a pulsatile-flow LVAD, 20 had the device replaced during the study period, with 18 (31%) receiving a continuous-flow LVAD instead of another pulsatile-flow LVAD. By 2 years, only 2 patients had a pulsatile-flow LVAD, both of whom had replacement devices.
If they work so great, why are LVADs implanted so infrequently and how come taking care of LVAD patients is so expensive and labor intensive?
IABP results at the Texas Heart Institute 1972-1979

(Survivors/No. pts.)

<table>
<thead>
<tr>
<th>Year</th>
<th>Survivors</th>
<th>Total</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>'72</td>
<td>0/7</td>
<td>7</td>
<td>0%</td>
</tr>
<tr>
<td>'73</td>
<td>1/13</td>
<td>13</td>
<td>8%</td>
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<td>'74</td>
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<td>39</td>
<td>26%</td>
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<tr>
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<td>'77</td>
<td>67/123</td>
<td>123</td>
<td>54%</td>
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<td>'78</td>
<td>71/127</td>
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<td>56%</td>
</tr>
<tr>
<td>'79</td>
<td>57/107</td>
<td>107</td>
<td>53%</td>
</tr>
</tbody>
</table>
Adoption curves for disruptive technology

- Internet (invented 1991) 26%
- Cell phone (invented 1983) 24%
- Personal Computer (invented 1975) 40%
- Electricity ('Invented' 1873) 98.8%
- Telephone (invented 1876) 93.9%
Heart Transplants and LVADs per year at Texas Heart 1982 - 2009

As of 04/19/2010
Worldwide LVAD Implantation

‘best guess’ as of April 2010

- PVAD 4487
- IVAD 563
- HM I IP 1316
- HM I VE/XVE 4849
- HM II 4141
- Jarvik2000 400
- INCOR 550
- EXCOR 2000
- EXCOR Pediatric 760
- HeartWare 390
- DuraHeart 142
- MicroMed 168

19766
1913

Alfred Rozentals
Perhaps reducing operative morbidity will prove to be the “missing ingredient” that triggers earlier implementation and more frequent utilization of mechanical circulatory assist technology.
Could the avoidance of cardiopulmonary bypass be one of the missing ingredients?
Off-pump LVAD implantation
Reports are starting to show up in the literature extolling the virtues of avoiding CPB in LVAD implantation…


Suction assisted sewing ring attachment
Hybrid approach for hemostatic OP-LVAD insertion
Hybrid approach for hemostatic OP-LVAD insertion
Hybrid approach for hemostatic OP-LVAD insertion
Hybrid approach for hemostatic OP-LVAD insertion
Over-the-wire vacuum assisted LV coring tool
Over-the-wire vacuum assisted LV coring tool and intra-ventricular balloon to facilitate OP-LVAD insertion
Automated over-the-wire LV apical anastomotic device
Automated over-the-wire LV apical anastomotic device
Automated over-the-wire LV apical anastomotic device
Automated over-the-wire LV apical anastomotic device
Is resting the failing heart of value?
“The first principle in the treatment of congestive heart failure is bed rest.”

-Sam Levine M.D.

Clinical Cardiology,

1940
Simplified technique for LVAD removal
### HeartMate II
#### Recovery and Explants at the Texas Heart Institute

<table>
<thead>
<tr>
<th>Pt. Initials</th>
<th>Age</th>
<th>Sex</th>
<th>BSA</th>
<th>Days on LVAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>FxF</td>
<td>30</td>
<td>♂</td>
<td>1.50</td>
<td>313</td>
</tr>
<tr>
<td>ExF</td>
<td>19</td>
<td>♂</td>
<td>1.96</td>
<td>749</td>
</tr>
<tr>
<td>DxP</td>
<td>14</td>
<td>♂</td>
<td>1.86</td>
<td>761</td>
</tr>
<tr>
<td>VxF</td>
<td>21</td>
<td>♂</td>
<td>1.67</td>
<td>737</td>
</tr>
<tr>
<td>DxD</td>
<td>37</td>
<td>♂</td>
<td>2.00</td>
<td>347</td>
</tr>
<tr>
<td>WxU</td>
<td>17</td>
<td>♂</td>
<td>2.15</td>
<td>380</td>
</tr>
<tr>
<td>AxS</td>
<td>33</td>
<td>♂</td>
<td>2.15</td>
<td>382</td>
</tr>
<tr>
<td>MxL</td>
<td>26</td>
<td>♀</td>
<td>2.09</td>
<td>254</td>
</tr>
<tr>
<td>SxG</td>
<td>30</td>
<td>♀</td>
<td>1.53</td>
<td>535</td>
</tr>
<tr>
<td>SxD</td>
<td>38</td>
<td>♂</td>
<td>1.82</td>
<td>94</td>
</tr>
<tr>
<td><strong>AVERAGES/ TOTALS</strong></td>
<td><strong>26.5</strong></td>
<td><strong>8♂ 2♀</strong></td>
<td><strong>1.873</strong></td>
<td><strong>455.2</strong></td>
</tr>
</tbody>
</table>
Is it possible that partially resting the heart early (NYHA class IIIb?) in the development of heart failure will reliably prevent progression to class IV or even result in regression?
Circulite Synergy Micro Pocket Pump
Circulite Synergy Micro Pocket Pump
The Texas Heart Institute
MINVASC really really small VAD
The Texas Heart Institute MinVasc VAD
The Texas Heart Institute MINVASC VAD
The Texas Heart Institute MinVasc VAD
The Texas Heart Institute MINVASC VAD
The Texas Heart Institute MinVasc VAD
Lt. Thomas E. Selfridge