JOHN DEMARIE  | Heart and Liver Transplant Recipient

“My life is much better knowing I have a future. It truly is a miracle.” — John DeMarie, 59, Lemont, Ill. A congenital heart defect caused John’s heart — and later his liver — to weaken over time. After spending nearly a year in the hospital awaiting his transplant, John is on the road to recovery and enjoying time with his new baby granddaughter.
2011 Highlights

Cleveland Clinic’s Cardiac Transplant Program is a key component of the George M. and Linda H. Kaufman Center for Heart Failure. The clinical activity of the Cardiac Transplant Program remained robust in 2011. A total of 201 patients were formally evaluated for transplantation; 69 candidates were listed and 58 transplants were performed. Of these, three were heart/lung, one heart/kidney and one heart/liver.

The program also continued to achieve excellent outcomes. The Scientific Registry of Transplant Recipients (SRTR) demonstrates that for patients receiving their first transplant between July 1, 2008, and Dec. 31, 2010, 96 percent of adult recipients were alive one year after transplant, compared with the 89.7 percent that would be expected based on the characteristics of these patients. Moreover, the \( P \) value of 0.011 indicates that this difference is statistically significant. For patients receiving their first transplant between Jan. 1, 2006, and June 30, 2008, the three-year survival rate for our program is 82 percent, which is the expected survival based on national experience. These excellent results are testimony to the outstanding multidisciplinary care provided by our transplant program.

Sangjin Lee, MD, joined the Section of Heart Failure and Cardiac Transplantation in the Tomsich Family Department of Cardiovascular Medicine, Sydell and Arnold Miller Family Heart & Vascular Institute, in 2011. His specialty interests include cardiac transplantation, cardiac assist devices and the genetics of heart disease.

Mechanical Circulatory Support

The use of mechanical circulatory support, both for bridge to transplant and for destination therapy, continues to grow. Fifty-six support devices were implanted in 55 patients at the Kaufman Center for Heart Failure. Of these, 25 were implanted as a bridge to transplant and 31 as destination therapy. Access to and expertise with mechanical support devices (Thoratec’s HeartMate II\(^\circledast\), SynCardia’s Total Artificial Heart\(^\circledast\), Berlin Heart and HeartWare\(^\circledast\)) allow us to use the optimal device for each adult and pediatric patient.
Research and Innovations

Our program continues to participate in many clinical research studies. The goals of these trials are to manage acute heart failure, improve long-term survival, minimize postoperative morbidity in the transplant population, and evaluate the safety and effectiveness of mechanical circulatory support as a bridge to transplant and destination therapy.

Principal Investigator — Dr. Nicholas Smedira
The HeartMate II LVAS Pivotal Study Protocol IDE #G010230

Principal Investigator — Dr. Randall Starling
Clinical Trials in Organ Transplantation (CTOT) Protocol CTOT-05: Observational Study of Alloimmunity in Cardiac Transplant Recipients

Principal Investigator — Dr. Edward Soltesz
PROCED II: Prospective, Multi-Center, Randomized Clinical Investigation of Transmedics, Inc.’s Organ Care System (OCS) for Cardiac Use

Principal Investigator — Dr. Nicholas Smedira
Evaluation of the HeartWare® Left Ventricular Assist Device System for the Treatment of Advanced Heart Failure

Principal Investigator — Dr. Randall Starling
Echocardiography Guided Cardiac Resynchronization Therapy Clinical Investigation (EchoCRT)

Principal Investigator — Dr. Wilson Tang
THAOS: Transthyretin-Associated Amyloidosis Outcomes Survey — A Global, Multi-Center, Longitudinal, Observational Survey of Patients with Documented Transthyretin (TTR) Mutations or Wild-Type TTR Amyloidosis

Principal Investigator — Dr. Randall Starling
A Multicenter, Randomized, Double-Blind, Parallel-Group, Active-Controlled Study to Evaluate the Efficacy and Safety of LCZ696 Compared to Enalapril on Morbidity and Mortality in Patients with Chronic Heart Failure and Reduced Ejection Fraction

Principal Investigator — Dr. Eileen Hsich
Immune Activation and Myocardial Recovery in Peripartum Cardiomyopathy

Principal Investigator — Dr. Wilson Tang
Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy Study (LAPTOP-HF)

Principal Investigator — Dr. David Taylor
A Phase IIa, 3-Strata Dose-Defining Study Evaluating the Hemodynamic Effects, Safety and Tolerability of CXL-1020 in Patients with Systolic Heart Failure
Principal Investigator — Dr. Nicholas Smedira

SynCardia Freedom™ Driver System Study

Principal Investigator — Dr. Maria Mountis

MEDAMACS Pilot Study: Medical Arm for Mechanically Assisted Circulatory Support

Principal Investigator — Dr. Randall Starling

Prevention of Cardiac Allograft Vasculopathy Using Rituximab (Rituxan) Therapy in Cardiac Transplantation

Principal Investigator — Dr. Gonzalo Gonzalez-Stawinski

LVAD Therapy: Exploring the Effect of Intramyocardial Injection of Mesenchymal Precursor Cells on Myocardial Function

Principal Investigator — Dr. Nicholas Smedira

A Prospective, Randomized, Controlled, Unblinded, Multi-Center Clinical Trial to Evaluate the HeartWare® Ventricular Assist System (VAS) for Destination Therapy of Advanced Heart Failure

Principal Investigator — Dr. Eiran Gorodeski

Monitoring Adults with Heart Failure at Home Using an Under the Mattress Contact-Less Sensor: A Pilot Study

Principal Investigator — Dr. Eiran Gorodeski

INcrease Of vagal tonE in chronic Heart Failure (INOVATE-HF) — A Randomized Study to Establish the Safety and Efficacy of CardioFit™ for the Treatment of Subjects with Heart Failure and Left Ventricular Dysfunction

Principal Investigator — Dr. Randall Starling

A Facilitated Access Program to Provide Everolimus (RAD) for Maintenance for Patients Completing Therapy in RAD Trials in Solid Organ Transplantation

Principal Investigator — Dr. Randall Starling

A 24-Month, Multi-Center, Randomized, Open-Label Non-Inferiority Study of Efficacy and Safety Comparing Two Exposures of Concentration-Controlled Certican with Reduced Neoral Versus 3.0 g MMF with Standard Dose Neoral in De Novo Heart Transplantation Recipients
Survival analysis: For patients receiving their first transplant of this type between July 1, 2008, and Dec. 31, 2010, for the one-month and one-year models, and between Jan. 1, 2006, and June 30, 2008, for the three-year model. Single-organ transplants only; re-transplants excluded.

(Source: Scientific Registry of Transplant Recipients [SRTR], January 2012)

### Adult survival

<table>
<thead>
<tr>
<th>Patient survival (percent)</th>
<th>1 Month</th>
<th>1 Year</th>
<th>3 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>99.2</td>
<td>96.3</td>
<td>82.4</td>
<td></td>
</tr>
</tbody>
</table>

### Pediatric survival

<table>
<thead>
<tr>
<th>Patient survival (percent)</th>
<th>1 Month</th>
<th>1 Year</th>
<th>3 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>100.0</td>
<td>90.9</td>
<td>66.7</td>
<td></td>
</tr>
</tbody>
</table>

### Heart transplant volume in 2011

<table>
<thead>
<tr>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart only</td>
</tr>
<tr>
<td>Heart/lung</td>
</tr>
<tr>
<td>Heart/kidney</td>
</tr>
<tr>
<td>Heart/liver</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

### Heart transplant mortality in 2011

<table>
<thead>
<tr>
<th>Hospital deaths only (within 30 days post-transplant)</th>
<th>1</th>
</tr>
</thead>
</table>
Days on waiting list and post-transplant length of stay (LOS) for heart transplant recipients in 2011

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Median</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days waiting</td>
<td>257.3</td>
<td>124.5</td>
<td>58</td>
</tr>
<tr>
<td>Post-transplant LOS</td>
<td>20.4</td>
<td>16.0</td>
<td>55(^a)</td>
</tr>
</tbody>
</table>

\(^a\) 2 patients not discharged as of Feb. 6, 2012, and 1 died during initial hospitalization

Median time to transplant for patients on waiting list\(^a\)

Heart

<table>
<thead>
<tr>
<th></th>
<th>Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleveland Clinic</td>
<td>4.7</td>
</tr>
<tr>
<td>United States (overall)</td>
<td>5.3</td>
</tr>
</tbody>
</table>

Heart/lung

<table>
<thead>
<tr>
<th></th>
<th>Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleveland Clinic</td>
<td>4.7</td>
</tr>
<tr>
<td>United States (overall)</td>
<td>&gt;72</td>
</tr>
</tbody>
</table>

\(^a\) For patients registered on waiting list between July 1, 2005, and Dec. 31, 2010. Source for U.S. data is Scientific Registry of Transplant Recipients (SRTR).

UNOS status of patients transplanted in 2011

<table>
<thead>
<tr>
<th>Status</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>39</td>
<td>67.2</td>
</tr>
<tr>
<td>1B</td>
<td>14</td>
<td>24.1</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>8.6</td>
</tr>
</tbody>
</table>
### Primary diagnoses for cardiac patients transplanted in 2011

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiomyopathy</td>
<td>31</td>
<td>53.5</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>16</td>
<td>27.6</td>
</tr>
<tr>
<td>Other</td>
<td>11</td>
<td>19.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>58</td>
<td></td>
</tr>
</tbody>
</table>

### Number of transplants, 2007-2011

- **Heart Only**
- **Heart/Kidney**
- **Heart/Liver**
- **Heart/Lung**

<table>
<thead>
<tr>
<th>Year</th>
<th>Heart Only</th>
<th>Heart/Kidney</th>
<th>Heart/Liver</th>
<th>Heart/Lung</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>60</td>
<td>1</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>2008</td>
<td>60</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>54</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>47</td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>2011</td>
<td>53</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>274a</strong></td>
<td><strong>2</strong></td>
<td><strong>4</strong></td>
<td><strong>14</strong></td>
</tr>
</tbody>
</table>

*a* Includes re-transplants

### Number of transplants, 1984-2011

<table>
<thead>
<tr>
<th>Total</th>
<th>Heart Only</th>
<th>Heart/Kidney</th>
<th>Heart/Liver</th>
<th>Heart/Lung</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,579</td>
<td>1,541</td>
<td>5</td>
<td>5</td>
<td>28</td>
</tr>
</tbody>
</table>
Selected Publications


Leadership

Randall Starling, MD, MPH
Program and Medical Director, Heart Transplant Program; Vice Chairman, Department of Cardiovascular Medicine; Section Head, Heart Failure and Cardiac Transplant Medicine; Medical Director, Kaufman Center for Heart Failure

Nicholas Smedira, MD
Program and Surgical Director, Heart Transplant Program and Kaufman Center for Heart Failure; Polly and W. Neil Rossborough Chair in Cardiac Transplantation

Phone number

216.444.8351

Fast facts

Initiated: 1984
First adult heart transplant: Aug. 15, 1984
UNOS approval: March 21, 1988
CMS/Medicare approval: June 13, 1988
As of Dec. 31, 2011, 1,579 heart transplants have been performed at Cleveland Clinic
Cleveland Clinic has developed and tested temporary and permanent artificial heart devices
In 2005, Cleveland Clinic was the first in America to implant the CardioWest Total Artificial Heart after its approval by the FDA; the Total Artificial Heart can provide a bridge to transplantation for patients at risk of imminent death from nonreversible biventricular failure
Staff

Eugene Blackstone, MD
Corinne Bott-Silverman, MD
Gerard J. Boyle, MD
Eiran Gorodeski, MD, MPH
Mazen A. Hanna, MD
Robert Hobbs, MD
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Karen James, MD
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Christine Moravec, PhD
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Gustavo Rincon, MD
Rene Rodriguez, MD
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