DR. STULAK: Hello, my name is John Stulak, and I am a heart surgeon at the Mayo Clinic in Rochester, Minnesota. I have a special interest in the surgical treatment of advanced heart failure, including ventricular assist devices and heart transplantation. The field of mechanical circulatory support has evolved significantly over the past 15 years, and currently, there are two devices-- the HeartMate II and the HeartWare HVAD-- that are FDA approved as a bridge to support the patient in order to receive a heart transplant, and one device-- the HeartMate II-- for destination therapy, where this is the final treatment for the patient, and they live the rest of their life with the device.

We are expecting a second device-- the HeartWare HVAD-- to be FDA approved for destination therapy in the next 12 to 18 months. At Mayo Clinic in Rochester, we utilize both of these devices for patients. And since 2007, we have performed over 200 VAD implants. Ventricular assist device therapy has consistently demonstrated significant improvement in both patient survival and functional status when compared to medical management for advanced heart failure. Refinements in device design and implantation techniques have resulted in improved durability of these devices and improved patient outcomes, compared to the earlier devices.

Significant innovation and further improvement in this technology is currently taking place, and it is expected that several new devices will enter clinical trials within the next two to three years. Future advances in technology are focusing on smaller pumps while still maintaining durability. With smaller pump size, this opens up several new possibilities. First, it may enable surgeons to implant these pumps with smaller incisions, compared to a full open chest. And by avoiding a full sternotomy, it would make a potential future operation less risky. Also, a less invasive approach may allow a patient to recover more quickly from VAD implantation.

Second, with smaller pumps, it may allow the application of this technology to provide assistance for failure of the right ventricular, or RVAD. Currently, there is no long-term implantable RVAD. This would be quite significant, as up to one third of patients still struggle with RV failure after LVAD implantation, and these patients could significantly benefit from future advances in pump technology.

Another major area of advancement is in wireless and remote energy transfer systems. Currently, patients with LVADs have a power cord, which exits the skin, and they must constantly be connected, either to a wall power source or batteries. Complications with the percutaneous drive line can cause patients challenges to their quality of life because of its risk of becoming damaged or infected. If this happens, the entire device may need to be exchanged with a repeat operation. In addition, having to perform daily site care and always needing to carry around a power source is sometimes a strain on quality of life.

There is current research on developing full, implantable systems which may allow discontinuation of this drive line and offer advanced battery technology. We believe that this would be a game changer for VAD therapy and would impart a significantly improved quality of life because there would be no further need for daily dressing changes, patients would gain the ability to swim and shower, and have less limitations on movement and activity. It is expected that clinical evaluation of these new systems will take place in the next three to five years.

Mayo Clinic has one of the largest, most integrated heart programs in the world, with over 300 heart specialists working together to treat more than 120 heart conditions and diseases. We have experience striking growth in our programs for the treatment of advanced heart failure, surpassing 200 VAD implants within just the last five years. We have a very unique mechanical circulatory support and heart transplantation program, and we treat high volumes of complex and rare heart conditions every day. We anticipate an active role in this upcoming innovation in LVAD therapy, as we have been during the past evolution in the development of current devices.

We are currently following over 100 patients on LVAD support, and numerous different professionals collaborate behind the scenes to help find answers for our patients, including surgeons, cardiologists, physician assistants, nurse practitioners, anesthesiologists, and social workers. For more information on LVAD therapy for patients with advanced heart failure, or to schedule an appointment, please call the phone number on your screen or visit our website site at www.mayoclinic.org. Thank you very much.