

## **Clinical Summary**

The clinical trial with the AbioCor spanned the time period between July 2001 and November 2004. Fourteen patients with end-stage heart failure and no other treatment options were implanted with the AbioCor, a fully implantable replacement heart device. Candidates enrolled in the trial had a one-month survival prognosis of not more than 30%. Candidates were not transplant eligible and could not benefit from destination LVAD support.

An independent patient advocate group consisting of members devoted to end of life patient management was instituted to help patients and their family with the Informed consent process and the challenges and risks associated with living and dying on an experimental device. The trial was initially designed to assess patient survival at two months. The incremental gate for trial continuation in each group of five patients was based on one of five patients surviving to 60 days. Candidates and family members understood the trial criteria and the risks of prolonged recovery, complications of bleeding, stroke, pain, living and dying on the device.

Twelve patients of the fourteen candidates survived surgery, representing an 86% success rate for a radically new procedure. Support duration of the twelve patients ranged from 53 to 512 days. The majority of the patients (71%) survived beyond the 60 day milestone set for one of five patients (20%). The mean duration of support for the supported patients was 5.3 months. The cumulative support time was 64 patient-months substantially greater than initially anticipated.

Many of the patients had renal and hepatic dysfunctions associated with pre-existing debilitating conditions. As with all mechanical support devices, complications included post-operative bleeding requiring re-operation for resolution, and neurologic events. The propensity for bleeding further challenged the need for some level of anticoagulation management desirable to minimize neurologic complications. One anticipated device wearout occurred at 17 months. A device failure occurred at 5 months. Corrective actions have been implemented for this problem. In contrast to other mechanical cardiac support devices, device related infection was non-existent due primarily to its full implantability, eliminating the special attention needed for exit site care and the risks for infection.

Six patients were ambulatory. Four patients have had excursions outside of the hospital, and two of these four patients were discharged to facilities near the hospital as intermediary steps toward final discharge to home. One of these two patients was discharged to home shortly thereafter. The other discharged patient returned to the hospital while home readiness preparation and home care arrangements were being made for discharge to home. Discharge protocol was developed as needed since discharge was not anticipated for patient this initial trial. Three patients were able to go to restaurants, attend shows, sporting events, and religious services, and visit family and friends at their homes. Such activities have been conducted with wearable external components allowing for freedom and mobility. Six patients celebrated their next birthdays on the AbioCor. One patient became a great-grandfather while on the AbioCor.