Dear ladies and gentlemen,

The year 2015 has passed by and the field of mechanical circulatory support continues to go from strength to strength. Continuous-flow left ventricular assist devices (LVAD) are still expanding rapidly worldwide in the treatment of refractory end-stage heart failure with ever improved outcomes, which was reported in the INTERMACS annual report:


As a result, the overall recognition as well as the reputation of mechanical circulatory support (MCS) within the cardiological and cardiac surgical community has also improved further. Moreover, the significance of the whole MCS field has gained both depth and width. This is exemplified by the following scientific, surgical, medical and technical developments, which were achieved in the field of MCS within the year 2015.

1) In 2015, minimally-invasive HVAD (Heartware Inc., Framingham, MA, USA) implantations are increasingly accepted as a standard-of-care for treatment worldwide. More than 50% of the HVAD implantations were being performed minimally-invasively in Germany. In USA, 18% of the HVAD implantations are performed minimally-invasively, too, even though this remains “off-label-use”.
Importantly, the “lateral-thoracotomy-study” to investigate the minimally-invasive LVAD-implantation technique and to achieve “on-label-use” for implantations of the HVAD through a thoracotomy approach was started.


2) The year 2015 has also seen the first implantation in man of another next generation VAD pump: the Heartmate 3 (St. Jude Medical Inc., Pleasanton, California).


This miniaturized, magnetically-levitated centrifugal-flow pump enhances hemocompatibility by minimizing hemodynamic shear forces and a sophisticated blood–biomaterial interface. These features are intended to lower adverse event rates and improve minimally invasive surgical implantation through a compact size. Moreover, the 6 months follow-up of the Heartmate 3 CE mark trial was successfully accomplished and its data have led to the official CE mark approval. These data were published in December in JACC.


This trial was a prospective, non-randomized study with 50 patients enrolled at ten hospitals in six countries. Enrollment included both bridge-to-transplant and destination therapy patients in NYHA Class IIIb or IV heart failure. From the first implantation at Hannover Medical School in Hannover, Germany until completion of the study, 88% of patients continued on support, 4% received transplants, and 8% died. Thirty-day mortality was 2% and 6-month survival was 92%. This represented the highest six month survival reported in a LVAD CE Mark clinical trial. Thus, support with
the HeartMate 3 significantly reduced mortality risk by 66% compared with the Seattle Heart Failure Model-predicted survival of 78% (\( p = 0.0093 \)). Moreover, New York Heart Association classification, 6-min walk test, and quality-of-life scores showed progressive and sustained improvement. Key adverse events included reoperation for bleeding (14%), driveline infection (10%), gastrointestinal bleeding (8%), and debilitating stroke (modified Rankin Score >3) (8%). There were no pump exchanges, pump malfunctions, pump thrombosis, or hemolysis events.

Thus, HeartMate 3 is a very promising LVAD technology based on the improvements in clinical outcomes demonstrated in this trial. Patient follow-up will continue during the first two years of ongoing support, while enrollment in the HeartMate 3 U.S. IDE trial remains ongoing.

3) A third player in the field of MCS, ReliantHeart Inc., came up within another milestone for their product HeartAssist5: In July 2015, the worldwide first less-invasive HeartAssist5 (ReliantHeart Inc; Houston, USA) took place. [personal communication ReliantHeart Inc.]. With its unique technical features, including direct flow measurement instead of flow estimation, and the potential to perform remote monitoring, etc. the novel HeartAssist5 pump might also play a prominent role within the field of MCS in the near future.

The following articles contributed pivotal knowledge within the MCS field in 2015 and are cited according to the order of the journals they were published in:

**Circulation:**
**European Heart Journal:**

**Journal of Heart and Lung Transplantation:**
- Grady KL, Naftel DC, Myers S, et al. Change in health-related quality of life from before to after destination therapy mechanical circulatory support is similar for older and younger patients: analyses from INTERMACS. J Heart Lung Transplant. 2015 Feb;34(2):213-21.
- Potapov EV, Krabatsch T, Buz S, Falk V, Kempfert J. Cerebral protection system applied during washout of thrombus occluding inflow cannula of HeartWare HVAD left ventricular assist device. J Heart Lung Transplant. 2015 Dec;34(12):1640-1.
Journal of Cardiac Surgery:

Journal of the American College of Cardiology:


**Annals of Thoracic Surgery:**


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