A Fully Magnetically Levitated Circulatory Pump For Advanced Heart Failure **MOMENTUM 3 Trial**

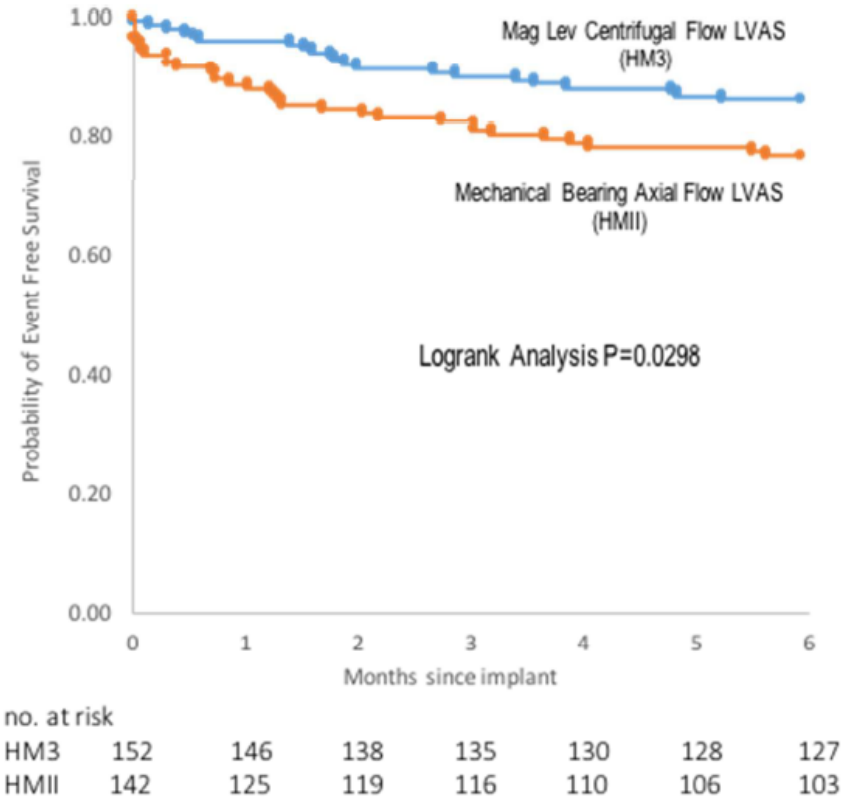
The Trial:

- Prospective, randomized surgical trial
- Indications for use and inclusion mirror current clinical practice
- Adaptive design to adjust sample size
- Well defined patient population for inclusion
- Clinically relevant composite endpoint
- Sets new standard for future trials of new/improved left ventricular assist systems

The Study LVAS:

- Centrifugal flow vs axial flow VAD
  inherent pulsatility
  after-load sensitive I
  less LV unloading in diastole
- No “pocket” required for implantation
  resides in pericardial/thoracic space
- Large gaps with reduced shear stress
- Fully magnetically suspended
  improved durability
- Flow modulation → “artificial pulse”
- Engineering modifications have potential to reduce adverse events including hemolysis, thrombosis, GI bleeding and stroke

MOMENTUM 3 Trial Results



- Minimized/eliminated pump thrombosis
- No difference in mortality or stroke
- ~ 6% “other neurologic events”
- GI bleeding 15% both groups
- Driveline infection 15%
- > 60% INTERMACS 3 and 4
- Was any pulse pressure generated with the flow modulation?

MOMENTUM 3 Trial Summary

- Successfully met pre-specified primary composite endpoint
- Clear reduction in need for pump replacement
- No significant difference in stroke or GI bleeding compared to HeartMate II
- Added benefit of “artificial pulse” to be determined
- Potential benefit of reduced blood trauma and effect on blood elements/proteins needs further study
- Has established new paradigm for LVAS trials and eliminated the need for separate BTT and DT trials
- Impact on expanding the field most likely will depend on outcomes of long term support/24 month study group