2019 PCR innovators day

Energy Transfer from Systole to Diastole, a Novel Device for Heart Failure with Preserved Ejection Fraction

corassist cardiovascular

CorAssist Cardiovascular Ltd

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Potential Conflicts of Interest

Speaker's name : Yair Feld

☑ I have the following potential conflicts of interest to declare:

Stock shareholder: CorAssist Cardiovascular LTD, Paragate Medical LTD

Heart Failure with preserved Ejection Fraction (HFpEF)

- 5-years mortality rate approaching 60%
- Costly morbidity: 6-month hospitalization rate of 50%
- Debilitating symptoms

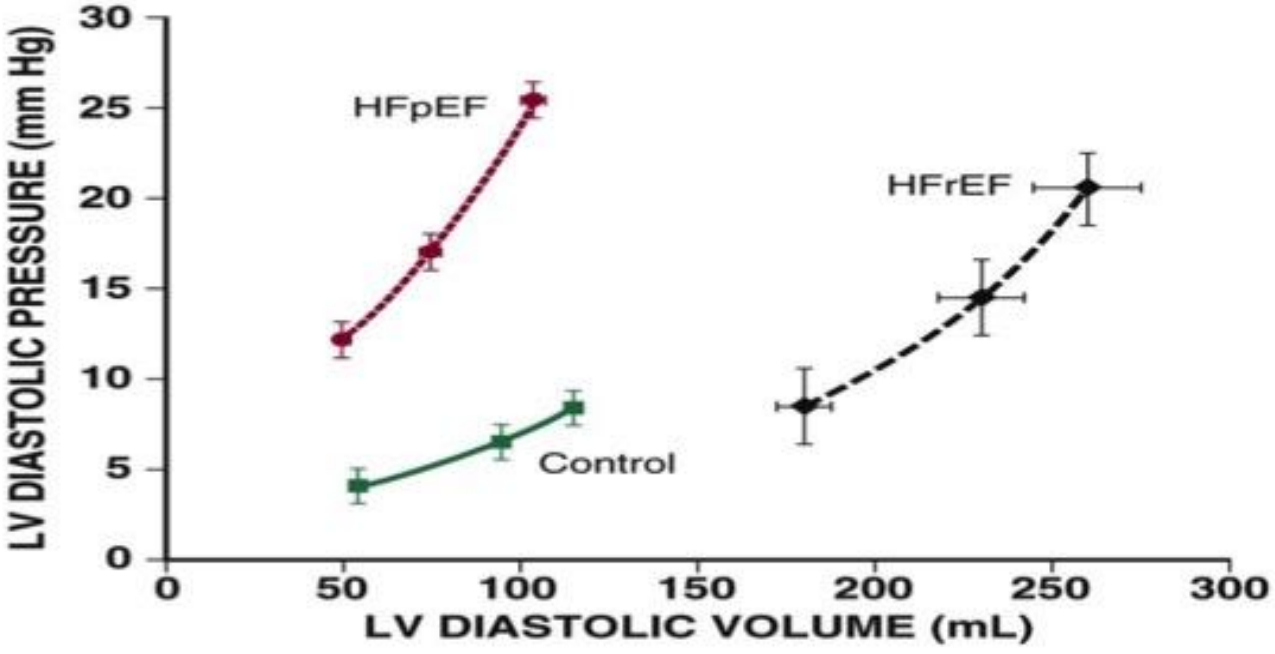
(Braunwald's heart disease a textbook of cardiovascular medicine - 10th edition)

The Market

- > 5.7 (2) million chronic heart failure patients currently in the USA, out of which 45%-54% (3) are HFpEF patients
- CorAssist is targeting HFpEF patients in NYHA stages III-IV (22%); in USA only ~ 630,000 patients (2) (4)

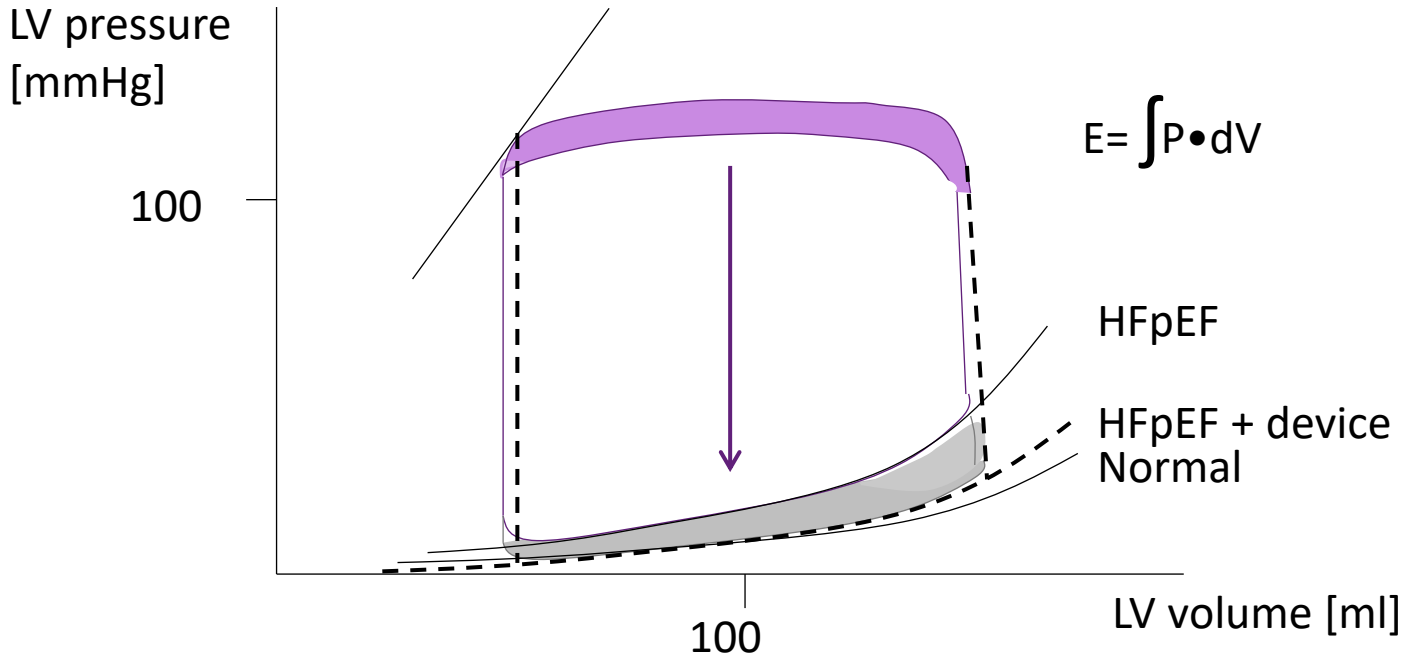
(1) European Journal of Heart Failure (2011) 13,18-28
(2) Heart Disease and Stroke Statistic – 2011 chapter 9
(3) Owen& Redfield MM, trends in prevalence and outcome of HFPEF; New England J Med. 2006;355:251-259
(4) Higher NYHA classes and increased mortality and hospitalization in patients with heart failure and preserved left ventricular function, American Heart Journal, 2009: 151 (444-450)

Heart Failure Pressure Volume Relationship



(From Zile MR, Baicu CF, Gaasch WH: Diastolic heart failure—abnormalities in active relaxation and passive stiffness of the left ventricle. N Engl J Med 350:1953, 2004; and Aurigemma GP, Zile MR, Gaasch WH: Contractile behavior in the left ventricle in diastolic heart failure: With emphasis on regional systolic function. Circulation 113:296, 2006.)

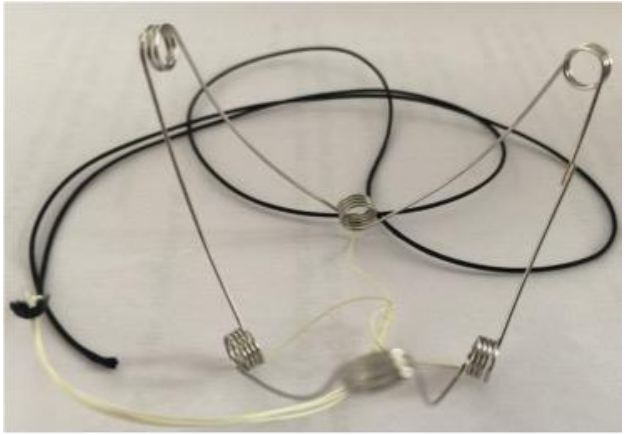
CorAssist Concept - Illustration



Feld et al. Energy transfer from systole to diastole: A novel device-based approach for the treatment of diastolic heart failure. Acute Cardiac Care, December 2011; 13(3–4): 232–242

The CORolla® TAA Intra-Ventricular Device

- Trans Apical Approach (TAVI like procedure)
- Cone like, adjusted to LV shape
- Attached to the LV apex with a fixation suture string
- Outward expansion radial force
- Improved diastolic dynamic and filling performance
- Energy transfer from Systole to Diastole



The CORolla® Stores potential energy during contraction and releases it during diastole
Pressure↓ Relaxation↑

Safety-Pre Clinical

Implantation	Purpose	No. of animals	Follow-Up period
Acute & Chronic (R&D)	R&D and Extreme/challenging conditions	27	Up to 6 months
Chronic (Preliminary)	Preliminary safety Functionality Extreme/challenging conditions	6	Up to 6 months
Chronic	Long term safety Long term functionality	25	1,3,6 and up to 13.5 months
Chronic Final configuration	Long term safety Long term functionality	18+2 (control)	1,3,6,12, 18 and up to 24 months
Total		76+2	

Results and conclusions:

- No procedure-related or device-related deaths
- Animal recuperation was quick
- No significant weight reduction
- LV pressures showed no signs of restriction

FIM Study Design - CORolla® Stand alone

Safety & Feasibility, 3 + 7 Patients, Treatment only

Safety endpoints:

- Mortality and SAEAs throughout 6 months post implantation **(Primary)**
- HF death and re-hospitalization (including IV diuretic) at 6, 12, 24 and 36 months
- Procedure and device-related events through 30 days post implantation
- MACNE at 6 months

Feasibility endpoint:

- Incidence of in-hospital implantation procedure success

Efficacy endpoints:

QoL, NYHA, 6MWT, ECHO Dyastolic dysfunction markers- Echo & TDI, LAVi, Capillary wedge pressure

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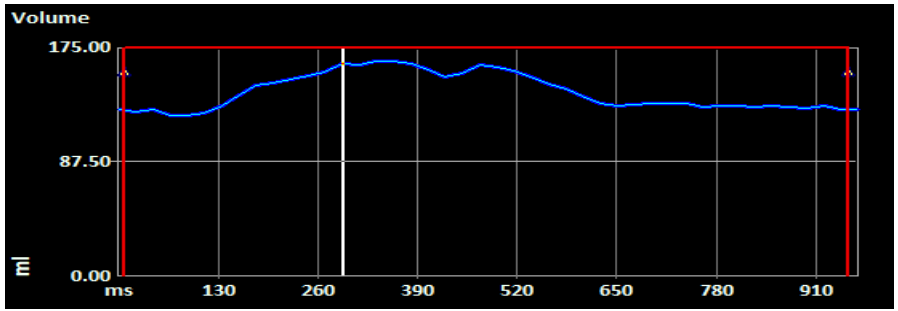
12 Months Echocardiography Follow-Up
SA CORolla Patient

Parameter	Baseline	3 months	6 months	12 months
LV Mass Index	142 gr/m^2	100 gr/m^2	123 gr/m^2	122 gr/m^2
LA Volume Index	58 ml/m^2	44 ml/m^2	40 ml/m^2	43ml/m^2
LV End Diastolic Volume Index	84 ml/m^2	53 ml/m^2	49 ml/m^2	49 ml/m^2
EF%	48 %	48 %	56 %	45 %
Septal E/E' ratio	36	NA	24	11
Lateral E/E' ratio	18	NA	15	10
Mitral Regurgitation	Yes - 2	Yes - 1	Yes - 1	Yes - 1
Aortic Regurgitation	Yes -1	No	No	No
Tricuspid Regurgitation	Yes - 2	Yes -1	Yes -1	Yes -1

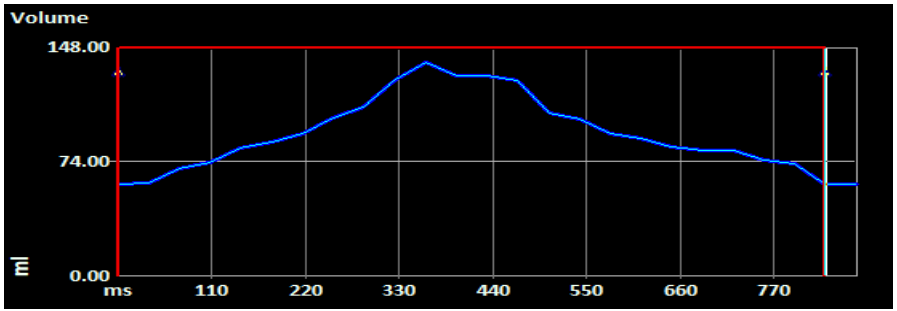
Left Atrial Function 6 month follow-up

Pre Implantation atrial volumes



Vmax = 167ml
Vmin = 124ml
LA EF = 25 %
LA strain = + 11%

6 months post implantation atrial volumes



Vmax = 140ml
Vmin = 60ml
LA EF = 57 %
LA strain = + 15%

Six Months Follow-Up CORolla Patient

Parameter	Baseline	1 month	6 month
NYHA class	III	II	I
MLHFQ (points)	60	---	18
6 min walk test (m)	240	---	420
BNP (pg/ml)	274.6	622.6	217.36

The Essentials to Remember

- HFpEF - major unmet clinical need
- Mechanical device
- Energy transfer from systole to diastole
- First stand-alone implantation demonstrate long term improvement in both Echocardiography diastolic indices and Heart failure symptoms
- Device potentially effect mechanical properties by improving compliance
- Potential therapeutic effect by improving coronary perfusion pressure

The Team

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