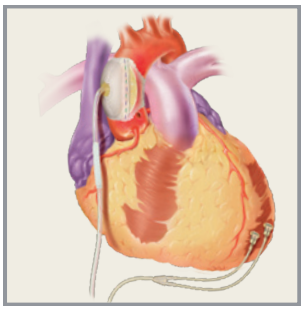
Case Study: C-Pulse® Heart Assist System

Single Patient Experience: 6-month Follow-up

Introduction of C-Pulse



The C-Pulse® Heart Assist System has been evaluated as part of a US feasibility study in patients suffering from moderate to severe heart failure (HF). The C-Pulse is an assist device that is designed to optimize the conditions under which the heart operates. C-Pulse is intended to enhance coronary perfusion and decrease the work imposed on the heart by the arterial system. With chronic use, the C-Pulse therapy is expected to reduce HF symptoms, improve patient's quality of life, and improve functional capacity.

The following report details an individual patient case experience providing specifics on hemodynamics, cardiac remodeling, and patient quality of life through 6-month follow-up.

Medical History

A 45 year-old male with a history of familial dilated cardiomyopathy, Intermacs Profile 6, and previous CRT/ICD implants presented with worsening heart failure. The patient was on maximally tolerated, guideline directed heart failure medication therapy and had a history of smoking, renal insufficiency and intracranial hemorrhage.

C-Pulse Surgical Implant

The patient underwent screening and met all criteria for enrollment in the C-Pulse US feasibility study. The C-Pulse Heart Assist System was implanted through a right parasternal mini-thoracotomy without the use of cardiopulmonary bypass. The total skin-to-skin procedure time was 247 minutes.

The patient spent 24 hours in the ICU followed by 3 days in cardiac stepdown and was discharged on post-op day 4.

Results

The following summarizes the patient's outcomes from baseline to 6-month follow-up:

	Baseline	6 Months
NYHA Class	3	2
MLWHF	54	49
6 MHW (meters)	307	355
EF (%)	27	35
LVESV (ml)	200	177
Septal E/e'	20	12.2
CO (L/min)	3	5.85
HR (min^{-1})	70	62
MR grade	2	1
PAP (mmHg)	52/22	35/13
BNP (pg/ml)	484	113
Diuretic (Lasix)/day	60 mg	40 mg

During this time period the patient had one adverse event, an exit site infection. This was addressed through in hospital antibiotic treatment, surgical debridement, and wound care.

Conclusion

Patients with moderate to severe heart failure who are experiencing worsening heart failure symptoms and poor quality of life while on optimal medical therapy with or without CRT or CRT-D implants continue to be a challenge to treat effectively. This patient was implanted with the C-Pulse Heart Assist System and experienced improvements in cardiac remodeling, hemodynamics, and quality of life at 6-months. A heart rate reduction was observed despite maintained beta-blocker dose possibly indicating improvement in circulatory homeostasis. This is further supported by a reduction in diuretic dose.

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CAUTION: C-Pulse is an Investigational device. The device is limited by Federal (or United States) Law to Investigational use only.

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