FIX-HF-5C2 STUDY

IMPULSE DYNAMICS
Hope is Here

STUDY QUICK LINKS

OBJECTIVES | CONCLUSIONS | TRIAL TYPE | POPULATION | TRIAL METHOD | ENDPOINTS | ENDPOINT RESULTS | NOTES | LEARN MORE

OBJECTIVES

Test the performance, safety and clinical effects of a 2-lead *CCM*® device vs a 3-lead *CCM*® device

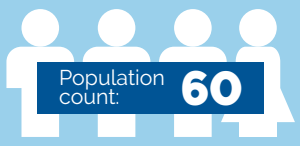
CONCLUSIONS

"The 2-lead system effectively delivers comparable amount of ***CCM***® pulses as the 3-lead system, is equally safe and improves peak VO_2 and NYHA functional class. Device-related adverse effects are less with the 2-lead system."

VO_2 ▲
NYHA ▲
ADVERSE EFFECTS ▼

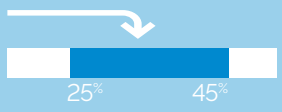
TRIAL TYPE

A **prospective, multicenter, single-arm study**



INCLUSION CRITERIA

- ☑ **NYHA III** or **IVa**
- ☑ **ICD** if indicated
- ☑ **GDMT**
- ☑ **LVEF**



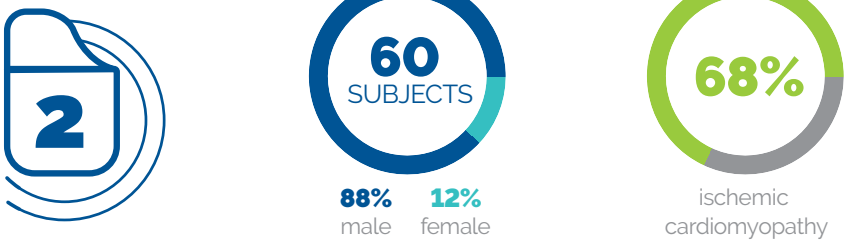
- ☑ **BASELINE PEAK** VO_2 9-20 mL/kg/min

EXCLUSION CRITERIA

- ☑ ~~CRT~~
- Recent (<30 days) intrope
- Recent (<30 days) hospitalization (HF or otherwise)
- Mechanical tricuspid valve
- Scheduled for or had recent CABG, PCI or MI

POPULATION

2-LEAD **COHORT PROFILE**



66
mean age

34%
mean LVEF

The control group for this study consisted of the control group in the previous FIX-HF-5C study that analyzed the 3-lead Optimizer® system. Baseline peak VO_2 and LVEF did not differ significantly between the two groups.

KEY DIFFERENCES BETWEEN THE 2-LEAD AND 3-LEAD GROUPS

- 2-Lead subjects tended to be **older** (66.3 ± 8.9 vs 62.8 ± 11.4) ↑
- Had a lower prevalence of diabetes (30% vs. 48.8%) ↓
- And had a lower LV end-diastolic dimension (57.7 ± 6.8 vs. 60.2 ± 7.0) ↓

ENDPOINTS

PRIMARY EFFICACY

Estimated difference in the change of peak VO_2 relative to control subjects

PRIMARY SAFETY

Comparison of device-related adverse events between FIX-HF-5C2 and FIX-HF-5C subjects

TRIAL METHOD

Screening & Baseline demographic data collected → **Implantation of 2-lead Optimizer®** → **Bayesian repeated measures model** used to estimate group differences between 2-lead group and control group → **Observational assessment at 12 and 24 weeks**

CCM

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ENDPOINT RESULTS

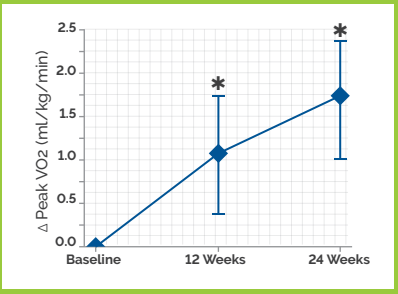
PRIMARY EFFICACY

The **change of peak VO_2 from baseline to 24 weeks was 1.72 (95% Bayesian credible interval [BCI]:1.02,2.42) ml/kg/min greater in the 2-lead device group** versus the control group

PRIMARY SAFTEY

Decreased Optimizer®-related adverse events (0% vs 8%, p=0.03) in the 2-lead device group as compared to 3-lead patients in FIX-HF-5C

NYHA improved by at least 1 functional class in 83.1% of subjects treated with the 2-lead Optimizer® system at 24 weeks compared to only 42.7% in the control group



NOTES

The **main limitation of the present study is that it was a nonrandomized, unblinded study that used a historical control group** from the prior FIX-HF-5C study. **The two studies are reasonably contemporaneous**, having been completed less than 2 years of each other. The **only significant difference in background medical therapy was a slightly greater use of valsartan/sacubitril in the current study (15% vs 4%)** due to its introduction into clinical practice towards the completion of enrollment into the FIX-HF-5C study.

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REFERENCES

https://impulse-dynamics.com/wp-content/uploads/2020/04/CIRCHEARTFAILURE.119.006512.pdf

Indications for Use: The Optimizer® Smart System , which delivers ***CCM®*** therapy, is indicated to improve 6 minute hall walk, quality of life, and functional status of NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy, who are in normal sinus rhythm, are not indicated for CRT, and have a left ventricular ejection fraction ranging from 25% to 45%.

CCM