The CardiAMP Heart Failure Trial:
Efficacy Outcomes from Roll-In Phase

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Disclosures

P.V. Johnston: *Consultant/Advisory Board;Modest; Biocardia, Inc.*
H.J. Duckers: *Employment;Significant; BioCardia, Inc.Ownership Interest; Significant; BioCardia, Inc.*
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P.A. Altman: *Employment;Significant; BioCardia, Inc.Ownership Interest; Significant; BioCardia, Inc.*
C.J. Pepine: *Consultant/Advisory Board; Modest; Biocardia, Inc.*

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CardiAMP-HF Study Rationale

Stem cell therapy shows promise in experimental models of ischemic cardiomyopathy, but results from clinical trials are variable

Potential reasons include:

- Variable potency of autologous cells
- Poor cell retention and survival following delivery
- Sub-optimal dosing

The CardiAMP Heart Failure Trial (CardiAMP-HF) was designed to address these shortcomings through:

- Prospective assessment of cell potency
- Intramyocardial delivery using helical injection catheter to maximize retention
- High cell dose (200M bone marrow mononuclear cells)

Clinical Trial Design

Prospective, randomized, blinded, sham-controlled multi-center clinical trial

250 patients + 10 patient “Roll-In” Cohort (open-label)

Enrollment criteria

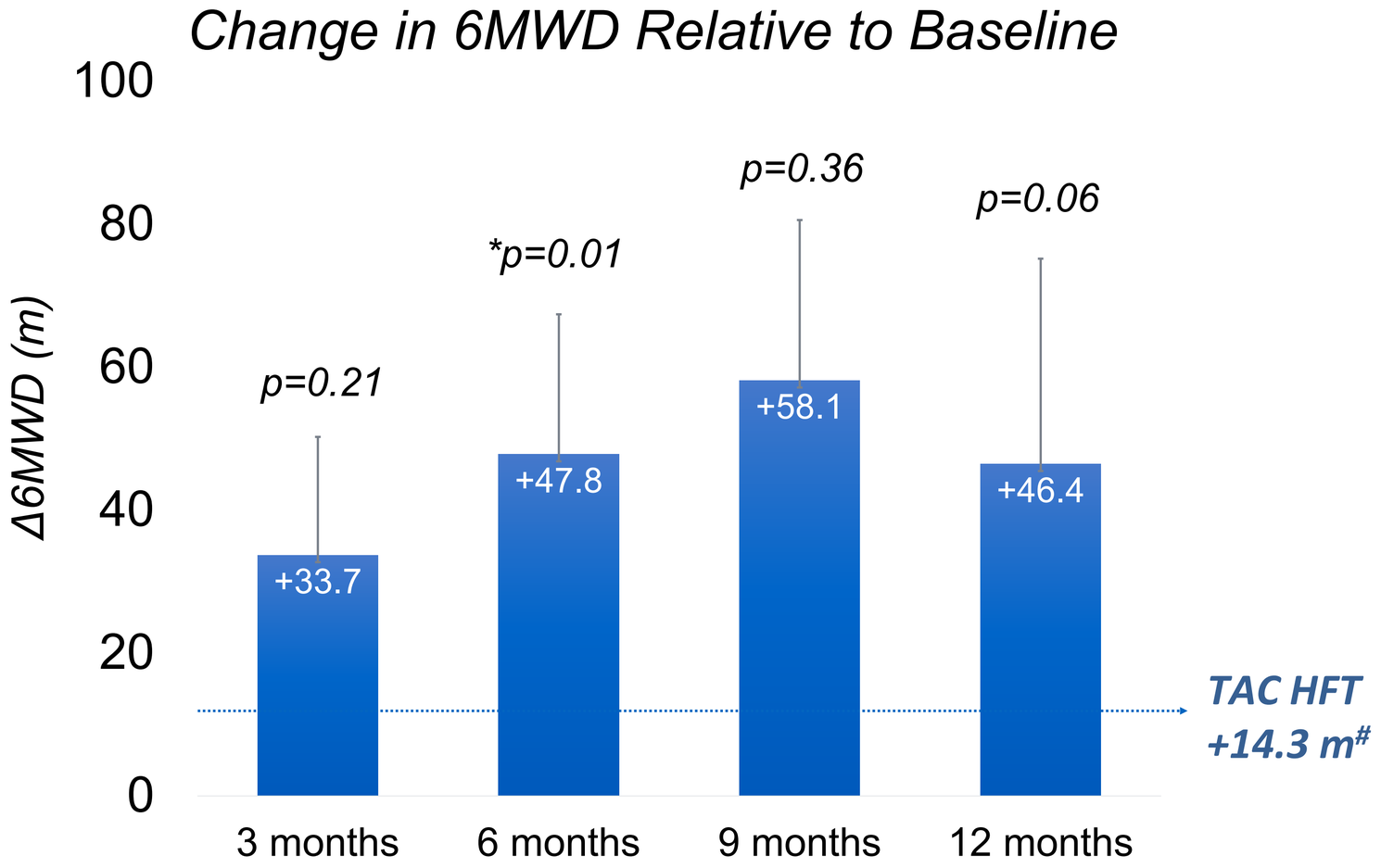
- Ischemic cardiomyopathy with EF 20-40%
- NYHA Class II-III symptomatic CHF
- Optimal medical therapy +/- CRT
- Sufficient cell potency score on screening bone marrow aspiration

Outcomes

- 1° Endpoint: Change in 6MWD at 12 months
- 2° Endpoints: NYHA HF Class, MLWHFQ, Echocardiography: LVEF, Wall motion

Roll-In Cohort follow-up complete to 12 months

1°Endpoint: Change in 6-Min Walk Distance



Mean +/-SEM; n=10, except at 9 months, when n=9
8/10 patients had improved 6MWD at 12 months

#Wong Po Foo et al, World Congress of Regenerative Medicine 2015

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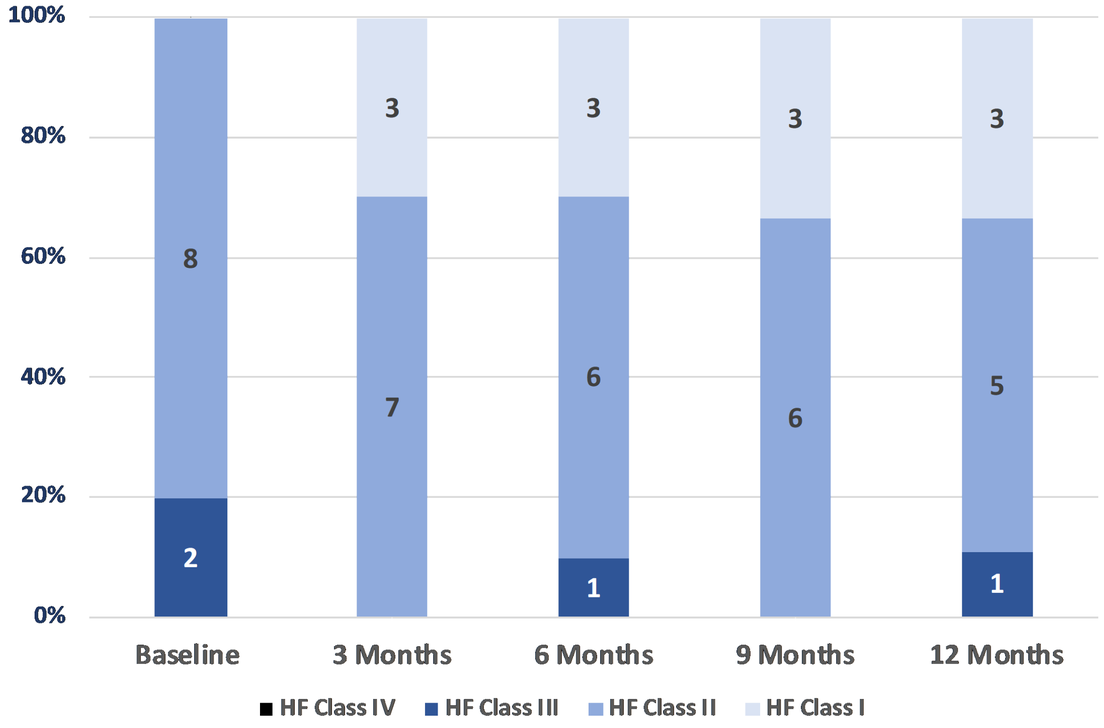
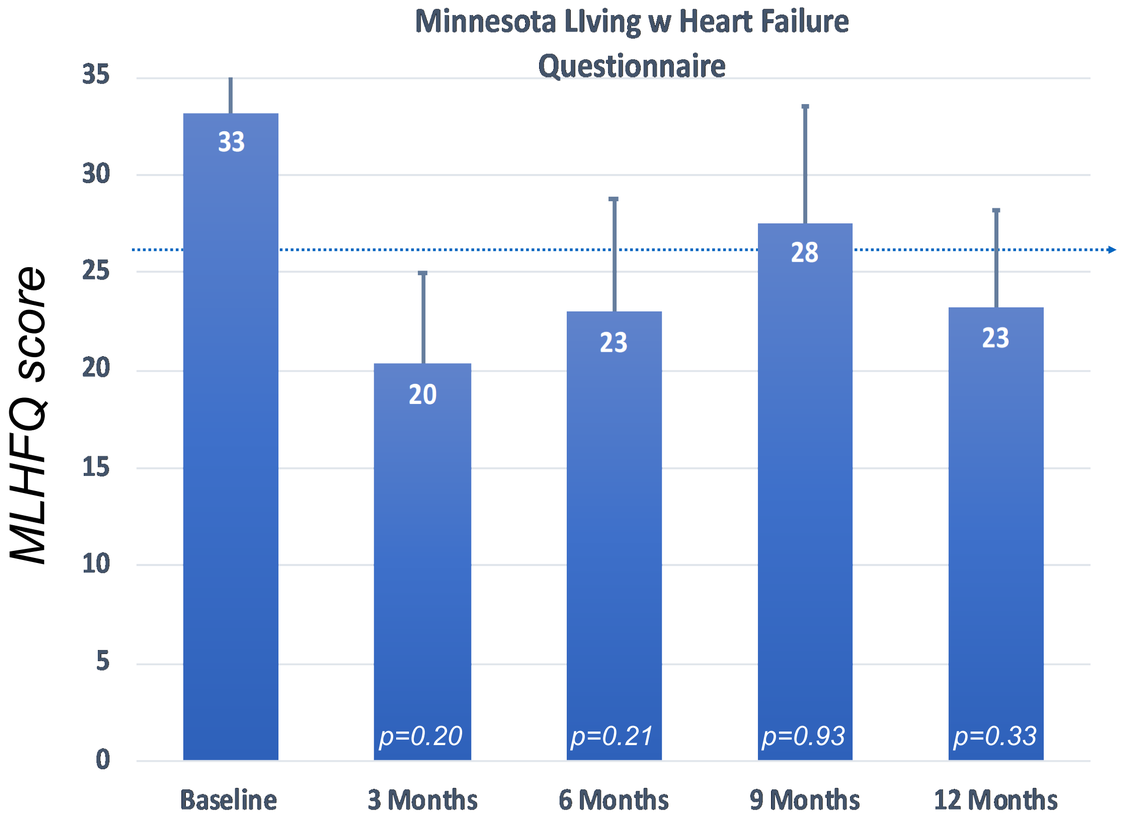
Clinical Assessment of Heart Failure Severity





p for change in NYHA Class:	*p=0.015	*p=0.037	p=0.194	p=0.183

Mean +/-SEM; n=10 for NYHA HF Class at 3 & 6 mos, n=9 at 9 & 12 mos

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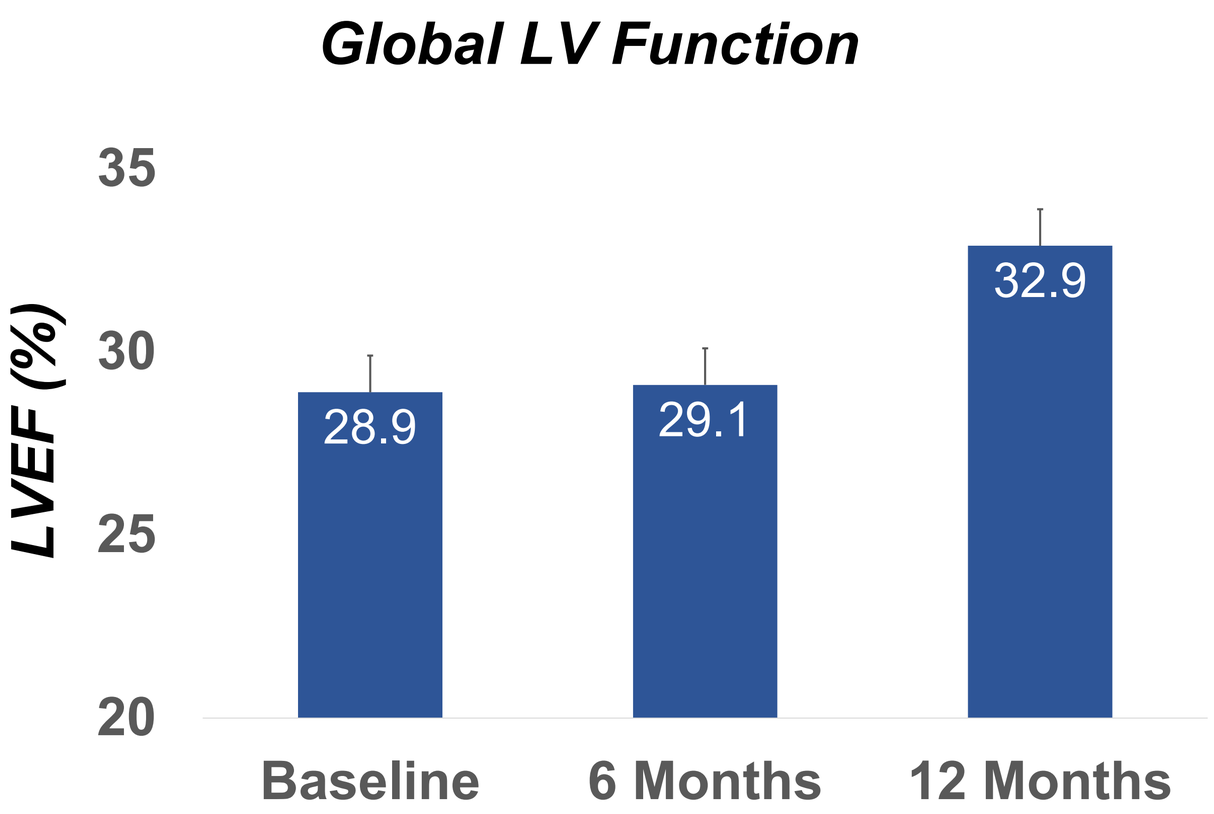
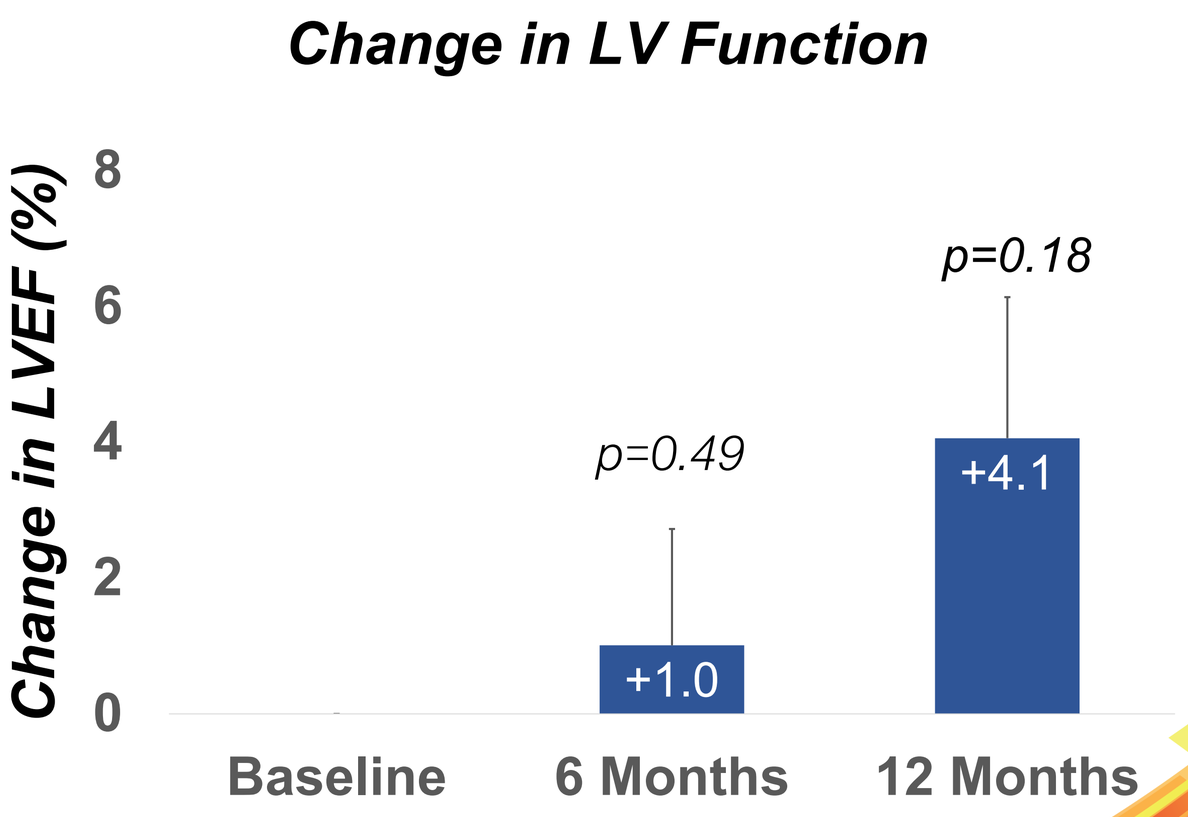
LV Function Assessment at 12 months





Mean +/-SEM; n=10; Transthoracic echocardiograms assessed by blinded readers in Echo Core Lab (Yale School of Medicine)

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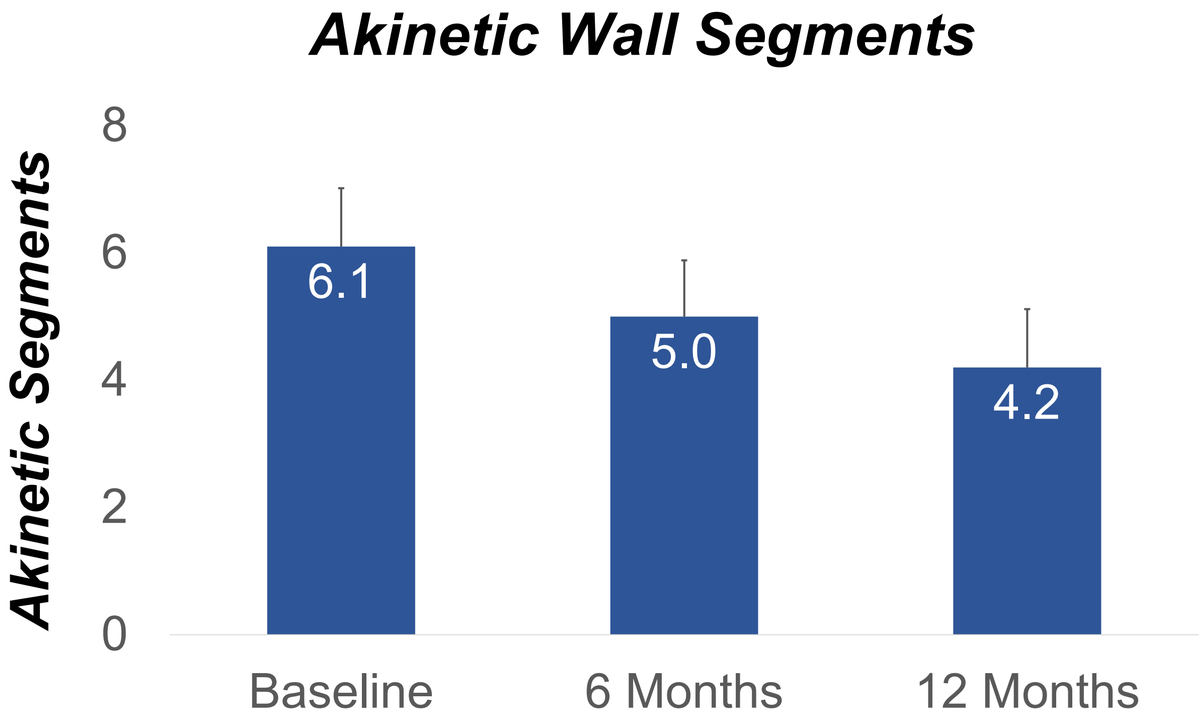
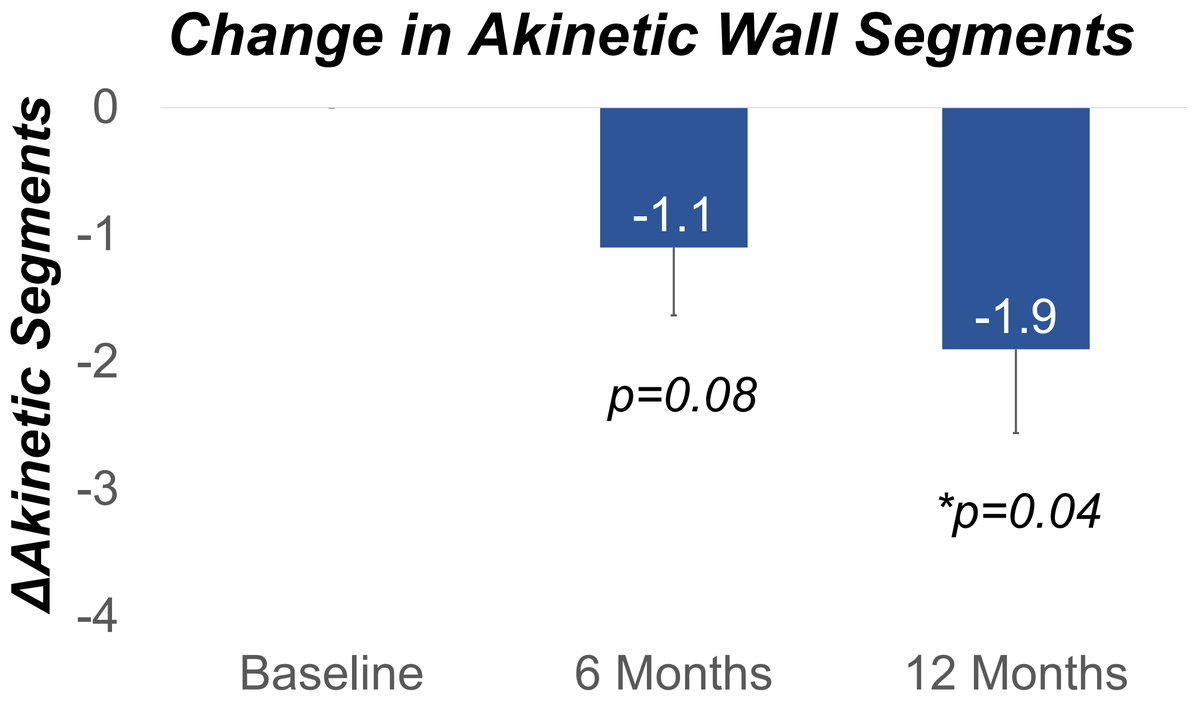
Decrease in Akinetic Wall Segments





- *Mean +/-SEM; n=10; Transthoracic Echocardiograms assessed by blinded readers in Echo Core Lab (Yale School of Medicine)*
- *Pre-specified 2º Endpoint: Recruitment of myocardial segments*

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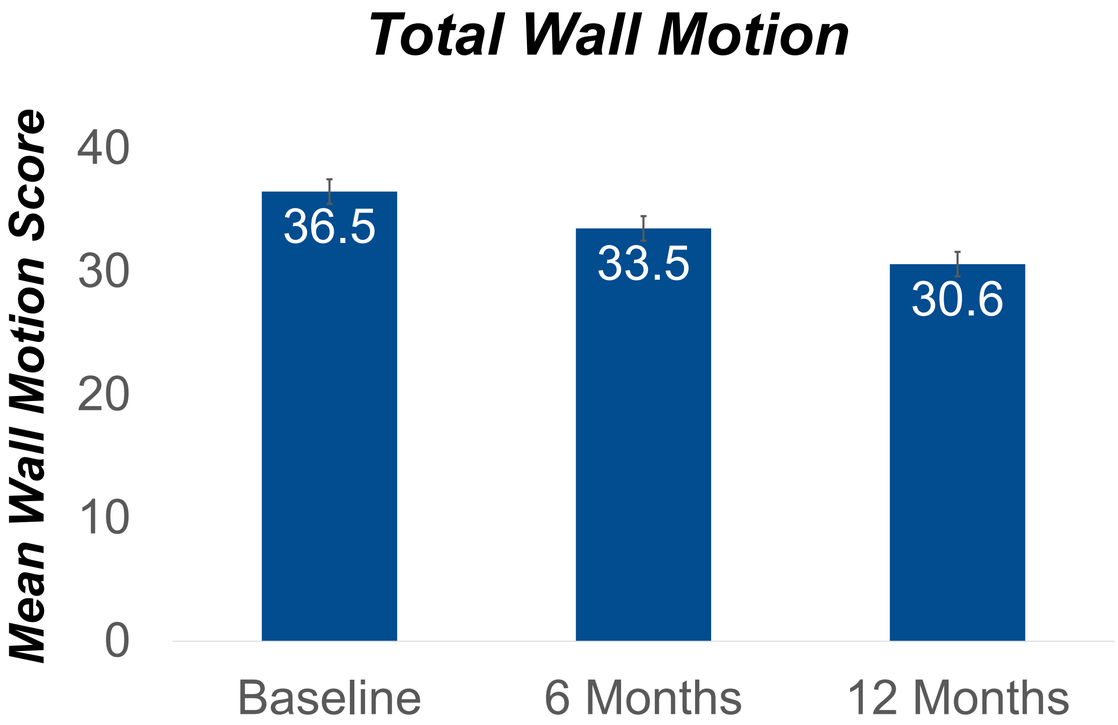
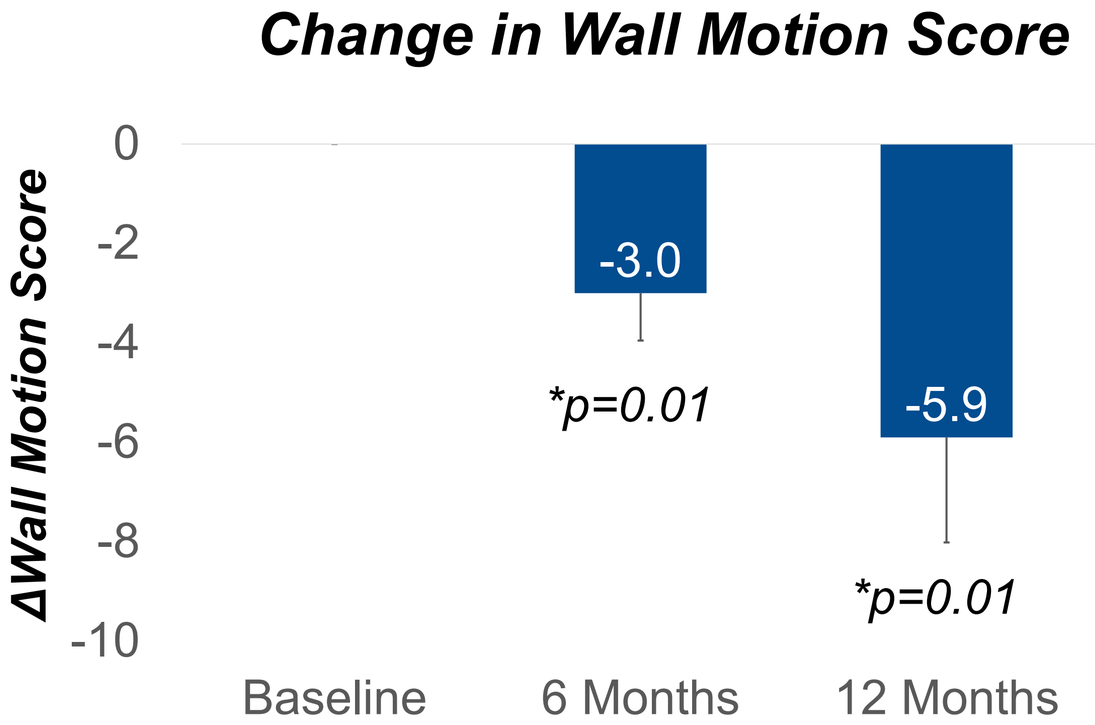
Improvement in Wall Motion Score





- *Mean +/-SEM; n=10; Transthoracic Echocardiograms assessed by blinded readers in Echo Core Lab (Yale School of Medicine)*
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Summary

12-month Results from CardiAMP-HF Roll-In Phase Show:

- Improved 6MWD at 6 mos (p=0.01); borderline at 12 mos (p=0.06)
- Trends for improved NYHA HF Class and MLWHFQ Score
- Recruitment of akinetic wall segments and improved wall motion at 12 mos
- Low MACE (0 treatment related, 1 f/u MACE event, All patients alive at 12 month f/u)

Limitations

- Open label (all patients received cells)
- Small size (n=10)

CardiAMP-HF Randomized Study is actively enrolling

- 250 patients to be enrolled at 40 centers in US
- 3:2 Autologous BMMNCs : Sham

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THANK YOU!

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