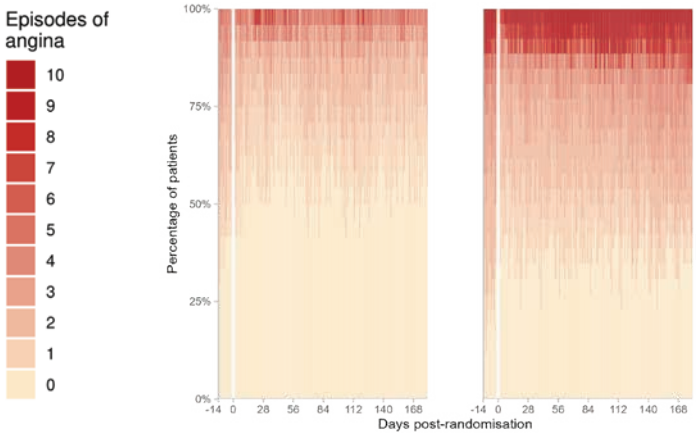
SHOCKWAVE REDUCER

ORBITA-COSMIC RESULTS SHOW THE SHOCKWAVE REDUCER REDUCES ANGINA FREQUENCY AND IMPROVES HEART DISEASE RELATED QUALITY OF LIFE WHILE IMPROVING SUBENDOCARDIAL PERFUSION[1]

ORBITA-COSMIC is a randomized, placebo-controlled trial of the coronary sinus Reducer for the treatment of refractory angina.

PRIMARY OUTCOMES

SYMPTOM OUTCOME



CSR improved angina episodes

OR 1.40
(95% CrI 1.08 to 1.83)

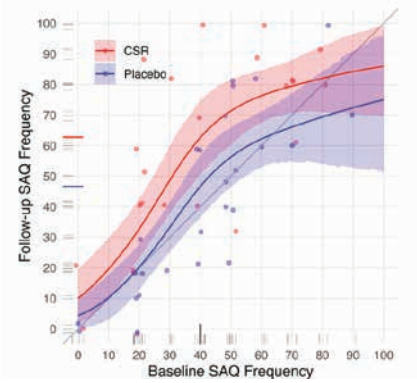
Pr(Benefit)=99.4%

"The symptoms didn't just improve on the angina symptom app, they also improved on the symptom questionnaires and health-related quality of life questionnaires."

— Dr. Rasha Al-Lamee, *Imperial London College, UK*[2]

The Shockwave™ Reducer decreased the number of daily angina episodes compared to placebo at 6 months. This benefit emerged at 10 weeks and persisted to 6 month follow up.

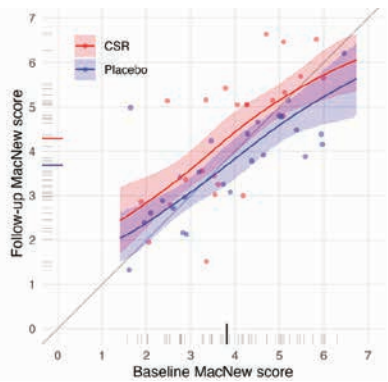
Similar to the daily reported angina frequency, there was evidence of benefit on angina frequency reported using the Seattle Angina Questionnaire and on the MacNew heart disease health related quality of life.



SAQ angina frequency benefit 16.0

(95% CrI 5.1 to 27.3)

Pr(Benefit)=99.7%

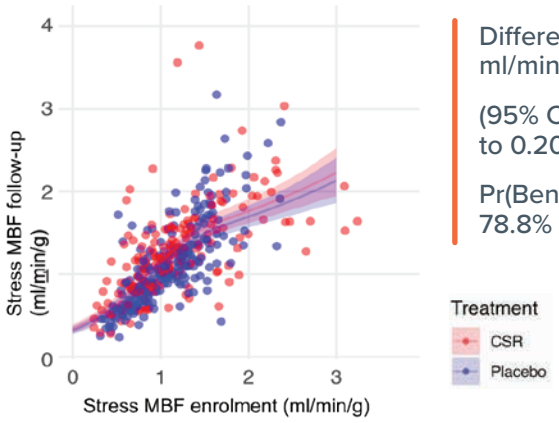


MacNew placebo-controlled increment 0.60

(95% CrI 0.15 to 1.06)

Pr(Benefit)=99.4%

IMAGING OUTCOME



Difference 0.06 ml/min/g

(95% CrI -0.09 to 0.20)

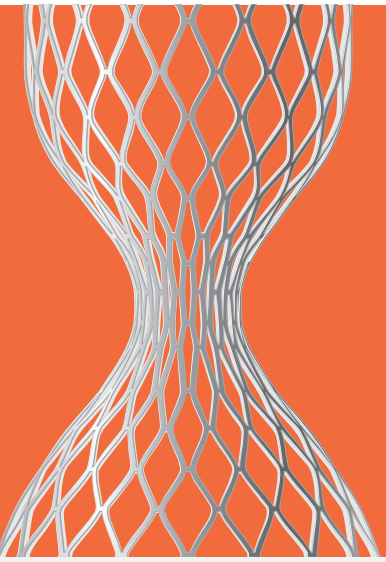
Pr(Benefit)= 78.8%

Endocardial: Epicardial Ratio		
	Difference at follow up for CSR vs placebo	Probability of benefit with CSR vs placebo*
Endo: epi ratio stress MBF Ischaemic segments	0.09 (95% CrI 0.00 to 0.17)	98.2%
Non-ischaemic segments	-0.02 (95% CrI -0.10 to 0.07)	35.1%
Difference	0.10 (95% CrI 0.02 to 0.19)	99.2%

*Difference is Pr(interaction)

While the primary imaging endpoint showed no improvement in transmural myocardial perfusion, it did show improvement in subendocardial perfusion, supporting the theorized mechanism of action of the Reducer.

> *"The device seems to work...there is a transfer of blood from the epicardium to the endocardium and this appears to be part of the mechanism of how the reducer works."*
>
> — Dr. Tommaso Gori, *University Medical Center, Mainz, Germany*[3]



KEY TAKEAWAYS FROM THE ORBITA-COSMIC RESULTS:

- CSR improves angina and heart disease related quality of life compared to placebo.
- Improvement in myocardial blood flow to subendocardium.
- CSR is a third treatment option for refractory angina.

> *"With the results of this placebo-controlled trial, we can tell them that their symptoms are more likely to improve with the reducer."*
>
> — Dr. Rasha Al-Lamee, *Imperial London College, UK*[4]

Late Breaking Clinical Trial presented at ACC 2024 by Michael Foley, MBBS, BSc
Chief investigator: Rasha Al-Lamee MBBS, PhD
Imperial College London

FOOTNOTES
1. Foley et al. The Lancet. 2024 Apr 8; https://doi.org/10.1016/S0140-6736(24)00256-3
2. https://www.statnews.com/2024/04/08/johnson-and-johnson-shockwave-coronary-sinus-reducer-trial/
3. HTTPS://WWW.TCTMD.COM/NEWS/CORONARY-SINUS-REDUCER-EASES-SYMPTOMS-REFRACTORY-ANGINA-ORBITA-COSMIC
4. https://medicalxpress.com/news/2024-04-coronary-sinus-relieves-angina-unclear.html

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