# CORONARY SINUS NARROWING AND MICROVASCULAR DISFUNCTION

## CHALLENGING CARDIAC FRONTIERS

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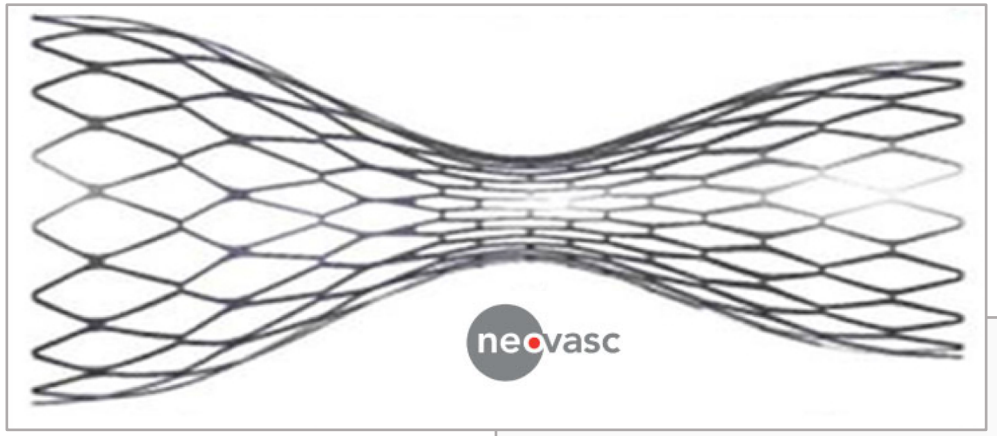
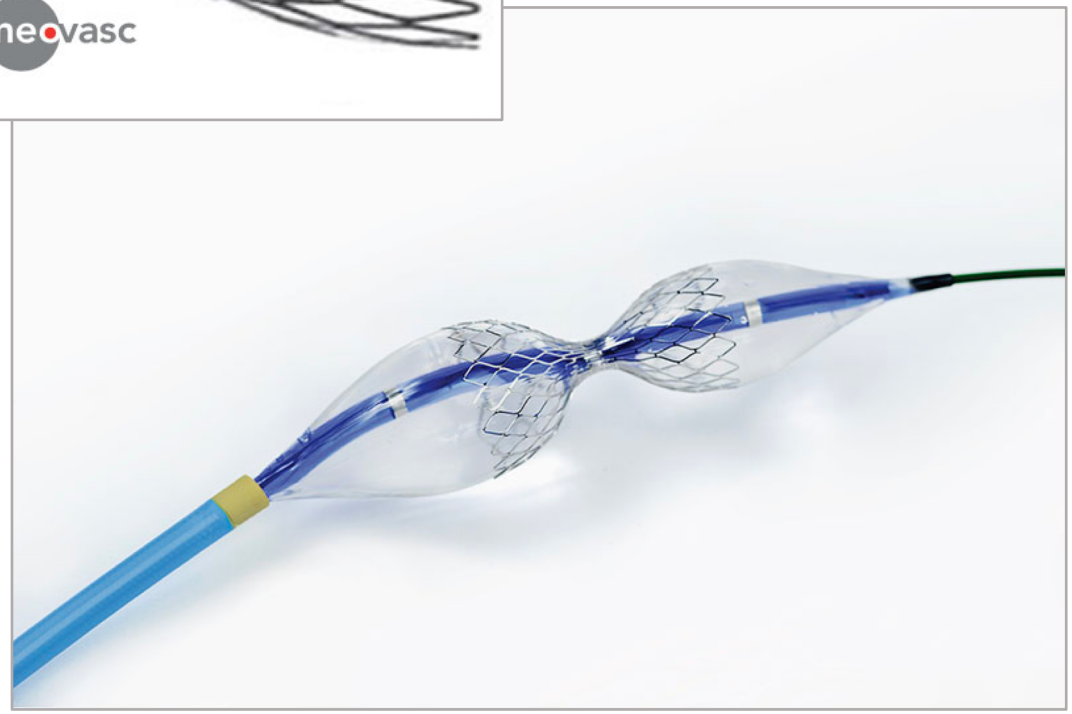
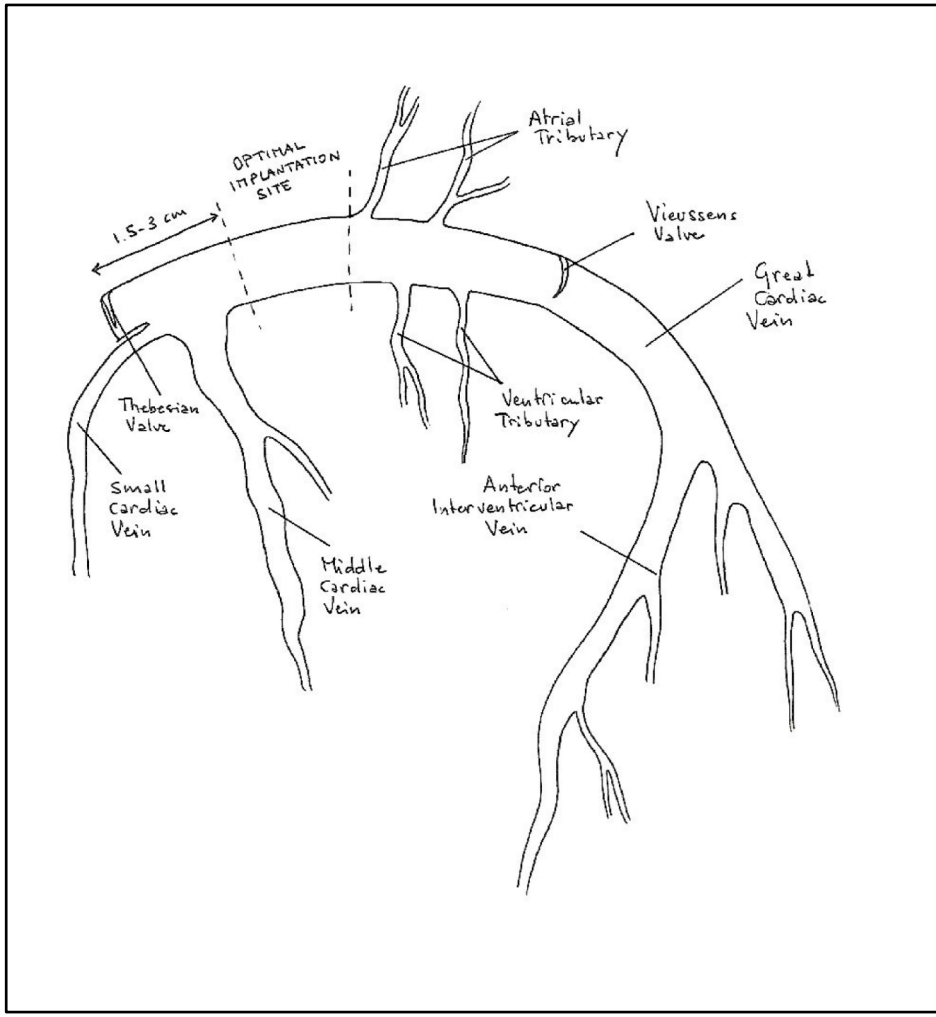
# Coronary Sinus Reducer Device

## NeoVasc Reducer ®

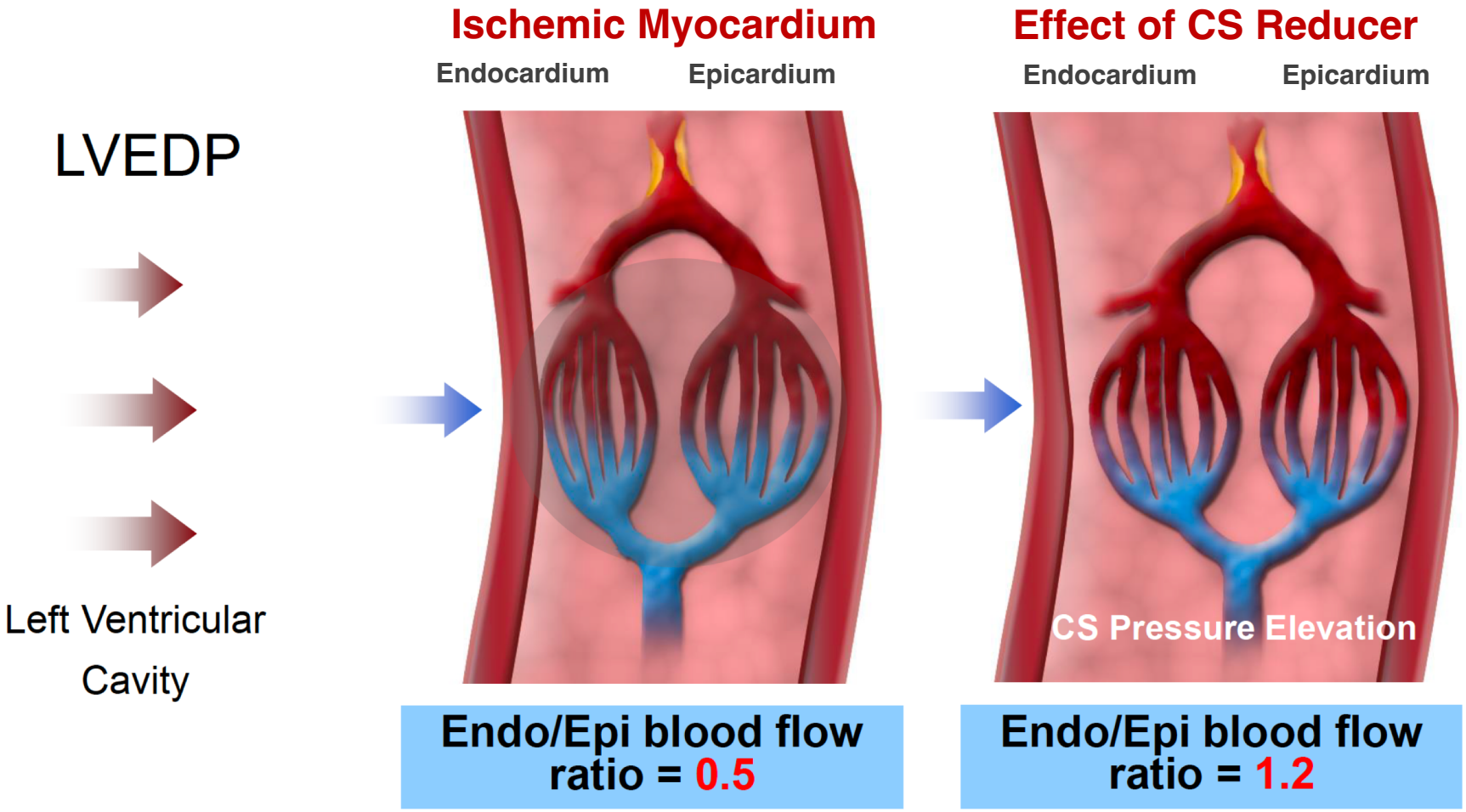




# Mechanism of action - Coronary Sinus Reducer

## Improved coronary flow with decreased ischemia






Ido et al. CS occlusion enhaces collateral flow and reduces subendocardial esquemia
**Am J Physiol Heart 2001**

# Clinical Evidence

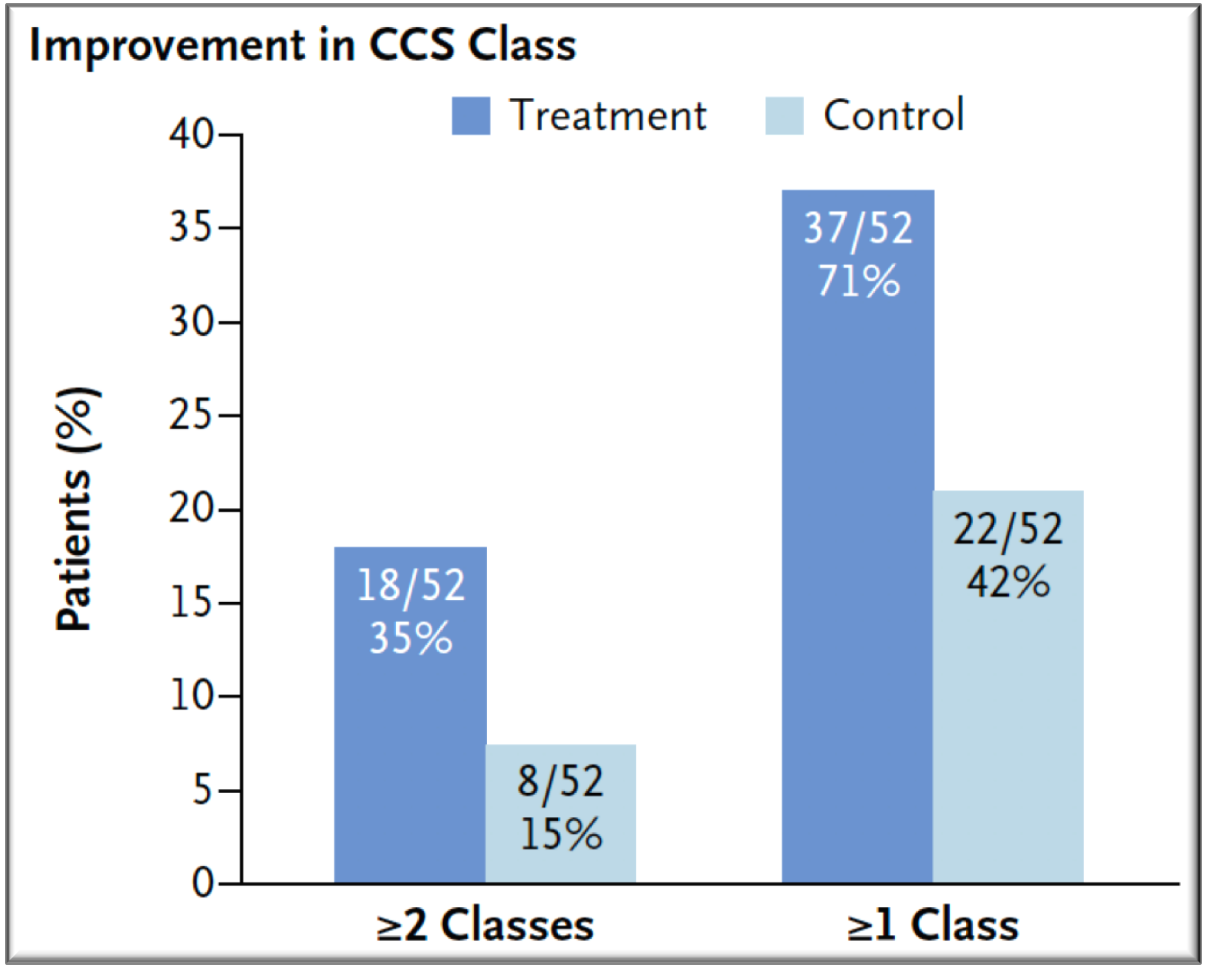
## COSIRA Trial

104 patients

**Angina CCS III or IV**
**Myocardial Ischemia**
**Not suitable for myocardial revascularization**

**CSR vs SHAM**

**Primariy End Point**
**Improvement of at least two CCS angina classes at 6 months**
**35% (Reducer) vs 15% (control)**
**P=0,02**

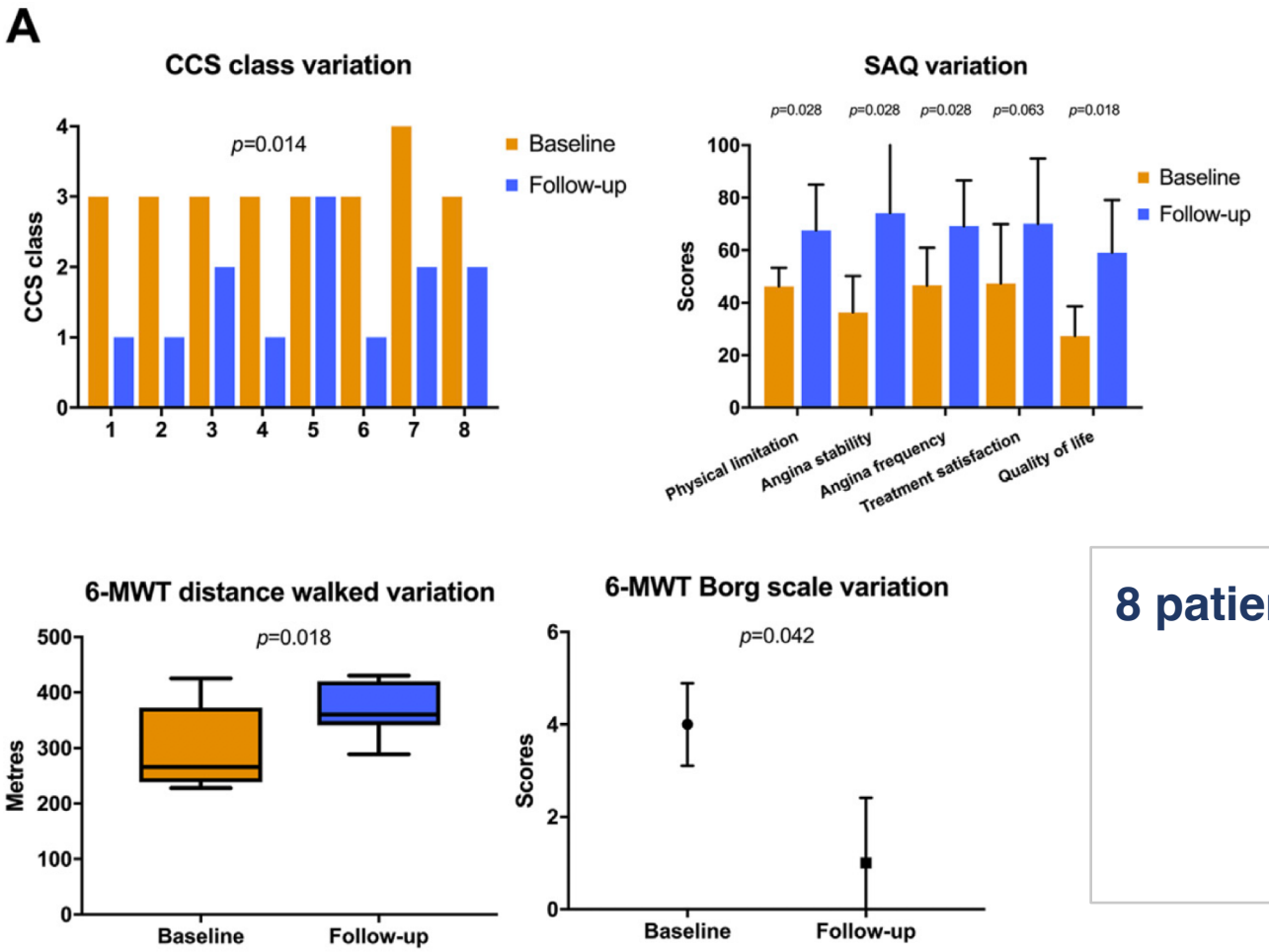





Verheye et al. Efficacy of a device to narrow the coronary sinus in refractary angina
**N Engl J Med 2015**

# CSR and Microvascular Dysfunction - First Evidences

## Refractory Angina due to Microvascular Dysfunction




**8 patients without obstructive coronary disease**

**Myocardial ischemia**

**Refractory Angina**

**CSR Compassionate Implant**



Gianinni et al. First experience with the CSR for the anagement of refractory angina in patients wo obstructive CAD
**JACC Cardiovasc Interv 2017**

# CSR AND MICROVASCULAR DISEASE – ONGOING TRIALS

## The Effect of Coronary Sinus Narrowing on Coronary Microvascular Function

### Tel Aviv Medical Center Reducer MVD Prospective Study

| | |
|---|---|
| **Population** | Subjects with refractory angina (CCS class 2-4) and coronary microvascular dysfunction (IMR>25, CFR≤2.5) in the absence of obstructive CAD (FFR≥0.8) |
| **1° Endpoint** | The change in IMR values at 4 months after Reducer implantation, compared with baseline |
| **2° Endpoints** | • Change in CFR<br>• Change in RRR<br>• Change in FFR<br>• Change in angina severity (CCS class)<br>• Change in QOL as assessed by the Seattle Angina Questionnaire (SAQ)<br>• Change in 6MWT |

CRF TCT



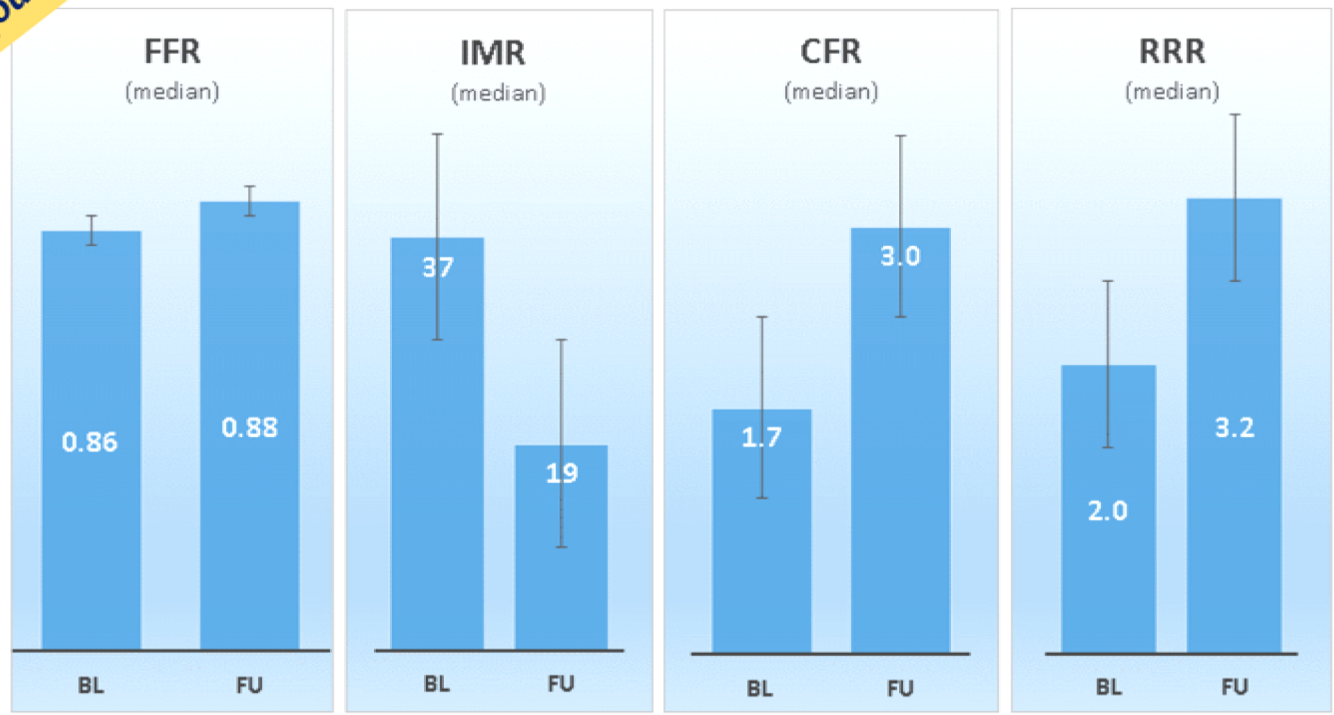
Shmuel Banai et al. Tel Aviv Medical Center, Israel
Data presented at TCT 2023 Meeting

# CSR AND MICROVASCULAR DISEASE – ONGOING TRIALS

## The Effect of Coronary Sinus Narrowing on Coronary Microvascular Function

Preliminary Results
Interim analysis of the first 10 patients (out of 30)

Invasive Coronary Blood Flow Physiology Evaluation

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*Tel Aviv Medical Center single center study*
*N=10*



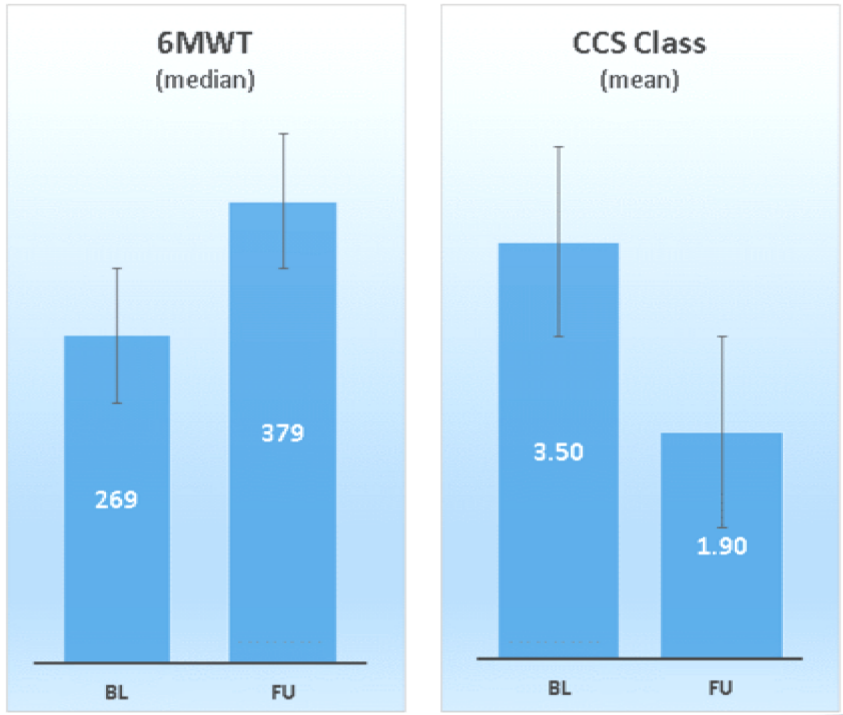
Shmuel Banai et al. Tel Aviv Medical Center, Israel
Data presented at TCT 2023 Meeting

# CSR AND MICROVASCULAR DISEASE – ONGOING TRIALS

## The Effect of CS Narrowing on functional capacity and angina severity in ANOCA patients

Preliminary Results
Interim analysis of the first 10 patients (out of 30)

Functional capacity and QOL




CRF TCT

*Tel Aviv Medical Center single center study*
*N=10*



Shmuel Banai et al. Tel Aviv Medical Center, Israel
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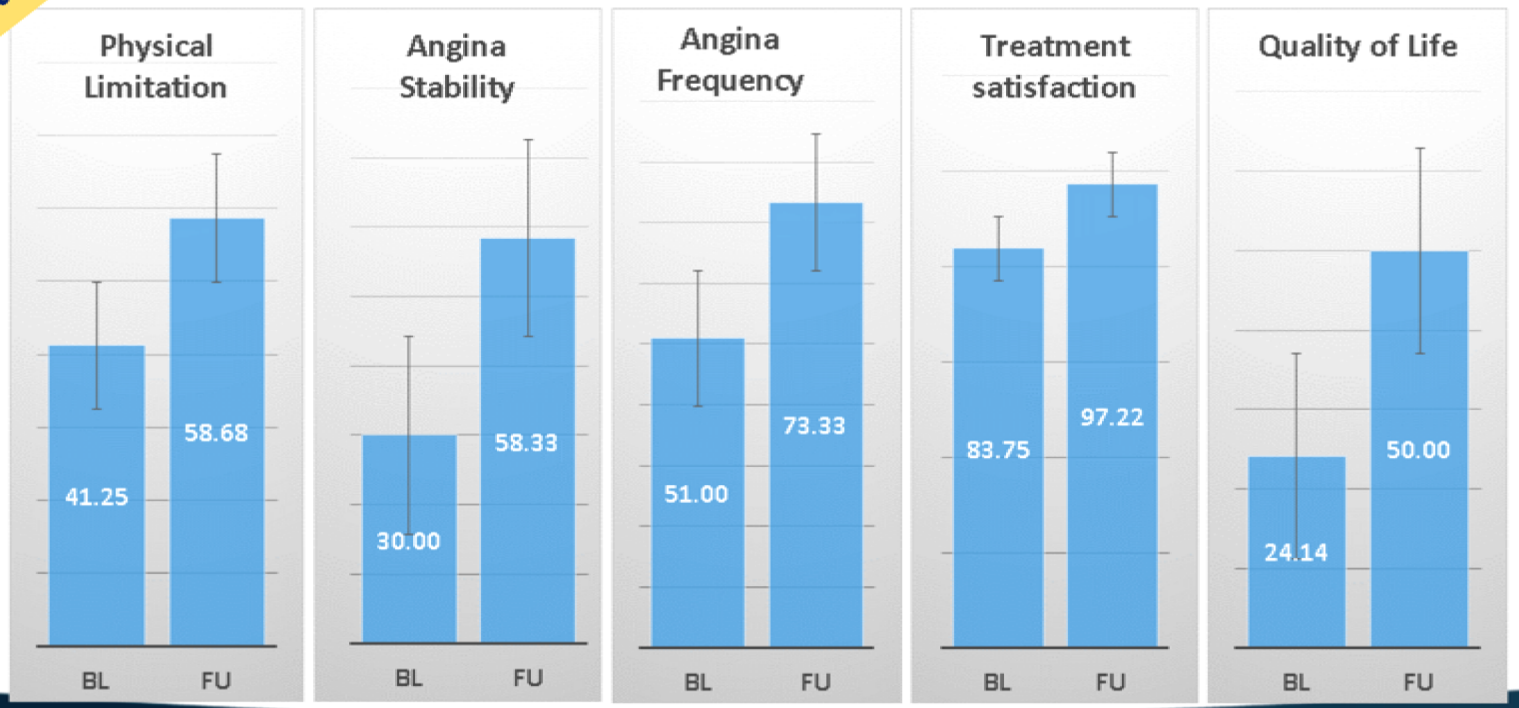
# CSR AND MICROVASCULAR DISEASE – ONGOING TRIALS

Preliminary Results
Interim analysis of the
first 10 patients (out of 30)

## The Effect of CS Narrowing on QOL in ANOCA patients

Seattle Angina Questionnaire

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# CSR AND MICROVASCULAR DISEASE – ONGOING TRIALS

## STUDY DESIGN

- 30 subjects
- Invasive coronary reactivity testing at baseline and 120-days post CS Reducer* implantation
- Primary endpoint
  - Change in invasive CFR or % increase in CBF to Ach at 120-days compared to baseline
- Secondary endpoints
  - Change in CCS angina class
  - Change in Seattle Angina Questionnaire scores

*Limited to investigational use in the United States





David Tryon et al. Mayo Clinic, Rochester, MN
Data presented at TCT 2023 Meeting

# CSR AND MICROVASCULAR DISEASE – ONGOING TRIALS

## CLINICAL AND PROCEDURAL CHARACTERISTICS

- 32 eligible patients
- 2 patients excluded due to unsuitable coronary sinus (CS) anatomy
- Successful CS Reducer* implantation in 30 patients
- No CS Reducer* MACE, device migration, or CS occlusion
- 2 wire-related CS perforations managed conservatively

*Limited to investigational use in the United States

| Baseline Demographics | |
|---|---|
| **Age, y; mean ± SD** | 54.2 ± 10.7 |
| **Sex, n (%)** | |
| Female | 19 (65.5%) |
| Male | 10 (34.5%) |
| **BMI, kg/m², mean ± SD** | 30.8 ± 7.0 |
| **Blood pressure (mmHg), mean ± SD** | |
| Systolic | 123 ± 18.1 |
| Diastolic | 76 ± 10.7 |
| **Cardiovascular Medications, n (%)** | |
| Beta Blockers | 8 (27.6%) |
| Long-Acting Nitrates | 15 (51.7%) |
| Calcium Channel Blockers | 23 (79.3%) |
| Ranolazine | 8 (27.6%) |
| Statins | 17 (58.6%) |
| ACE inhibitors | 7 (24.1%) |
| L Arginine | 14 (48.3%) |
| **Medical History, n (%)** | |
| Hypertension | 14 (48.3%) |
| Diabetes Mellitus | 7 (24.1%) |
| Hyperlipidemia | 16 (55.2%) |
| **Smoking History, n (%)** | |
| Never | 21 (72.4%) |
| Former | 8 (27.6%) |
| Current | 0 (0%) |





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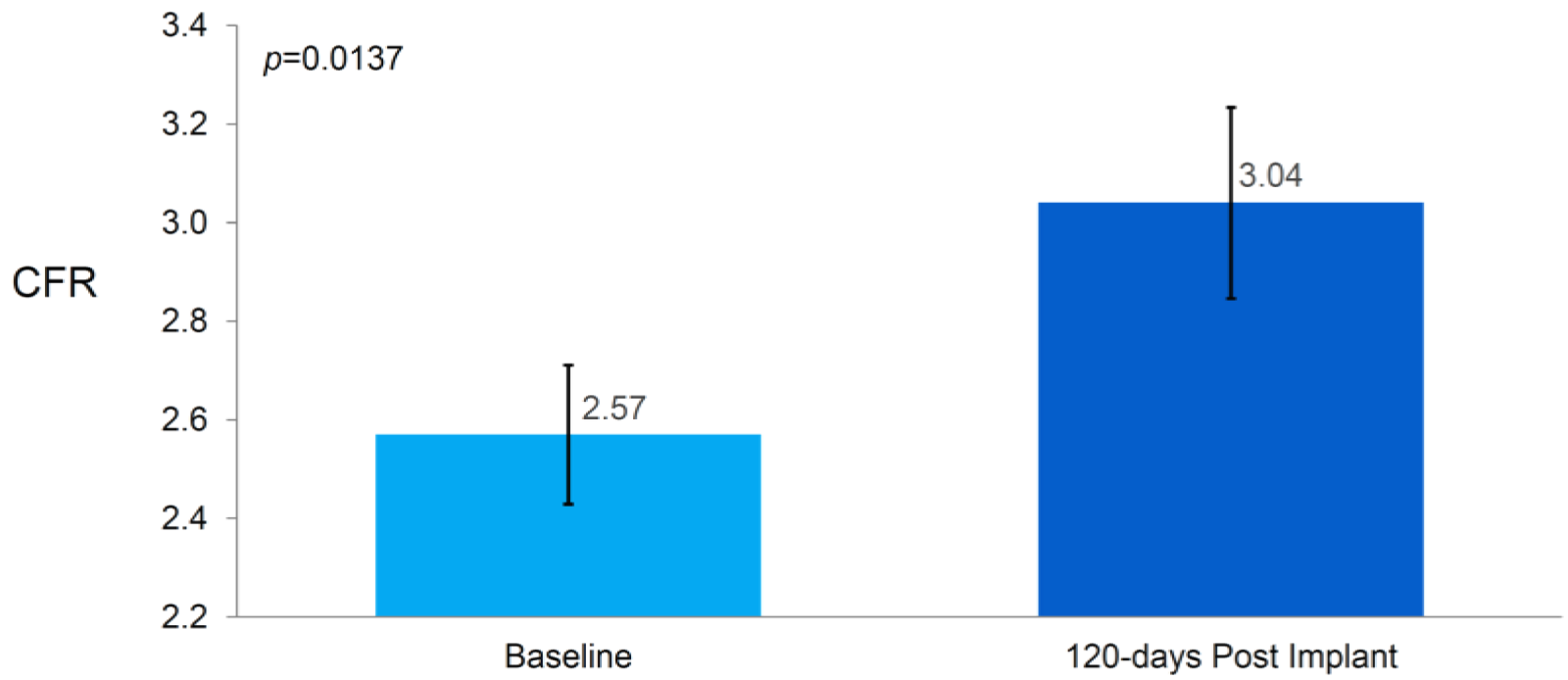
# CSR AND MICROVASCULAR DISEASE – ONGOING TRIALS

## MEAN CFR BEFORE AND AFTER CS REDUCER* IMPLANTATION, ALL PATIENTS (N=30)

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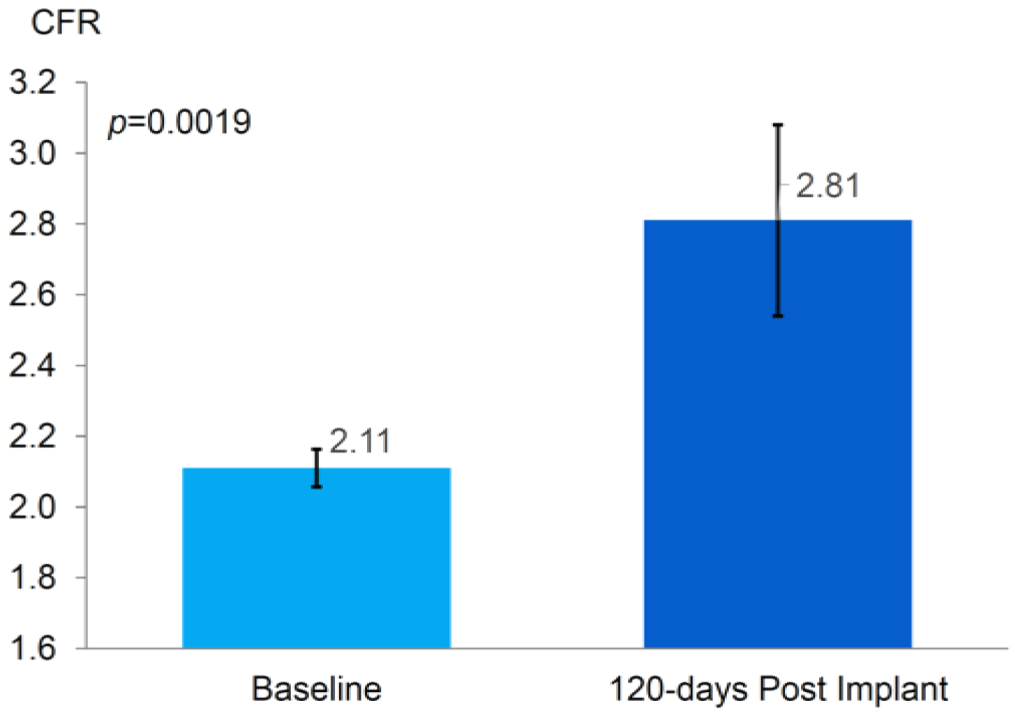
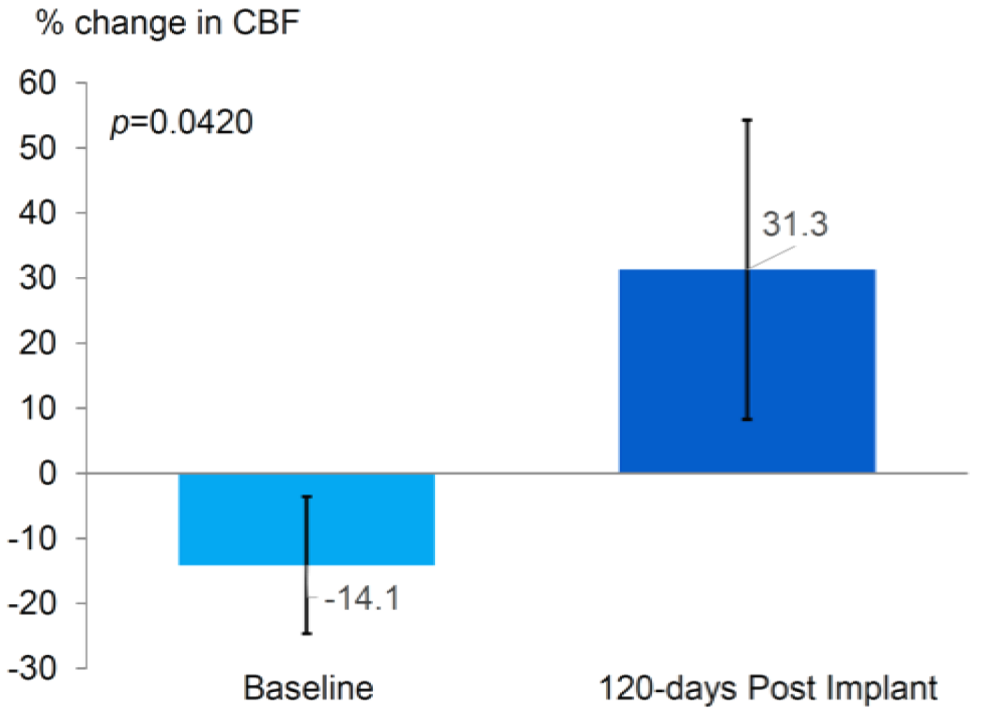
# CSR AND MICROVASCULAR DISEASE – ONGOING TRIALS

## CORONARY MICROVASCULAR FUNCTION FOLLOWING CS REDUCER* IMPLANTATION

### Endothelium Independent Function (n=19)




### Endothelium Dependent Function (n=11)

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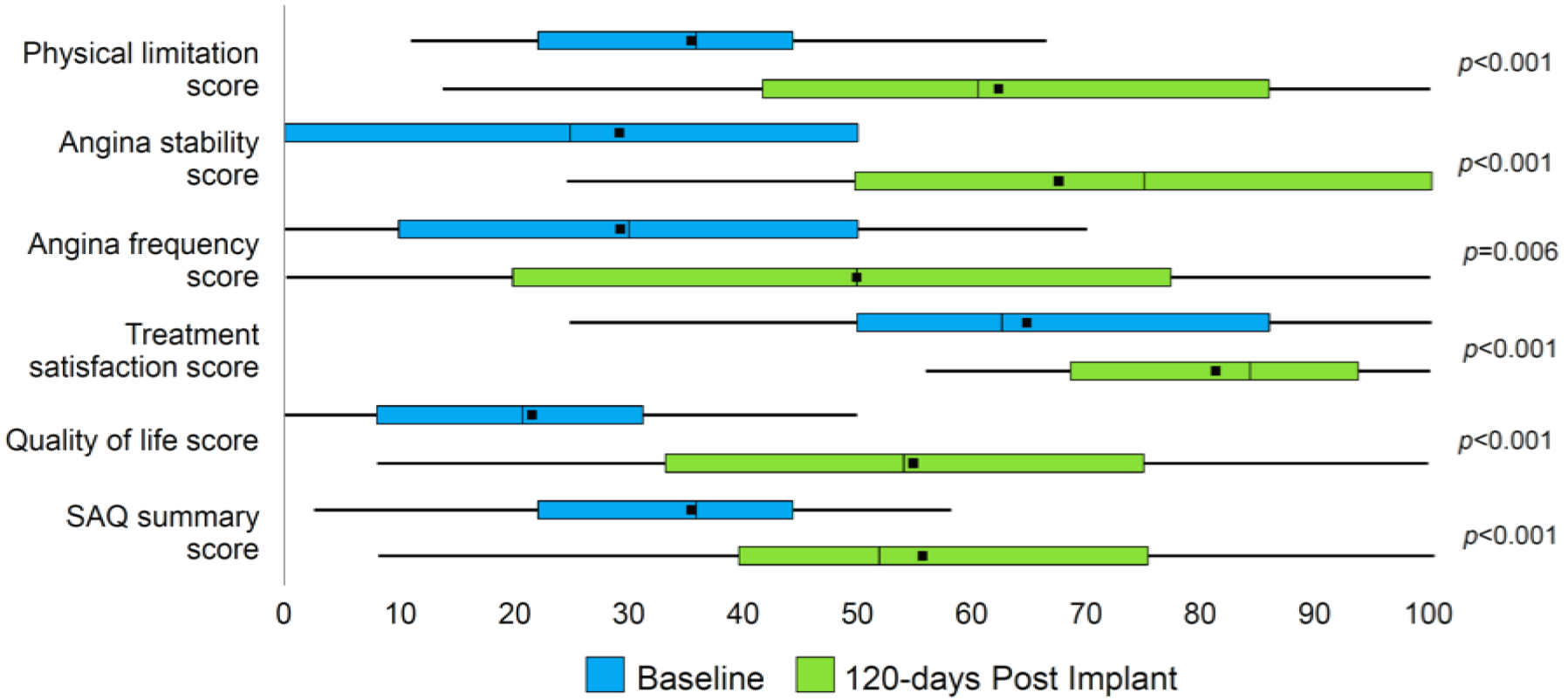
# CSR AND MICROVASCULAR DISEASE – ONGOING TRIALS

## SEATTLE ANGINA QUESTIONNAIRE

Seattle Angina Questionnaire results at baseline compared to 120-day follow-up





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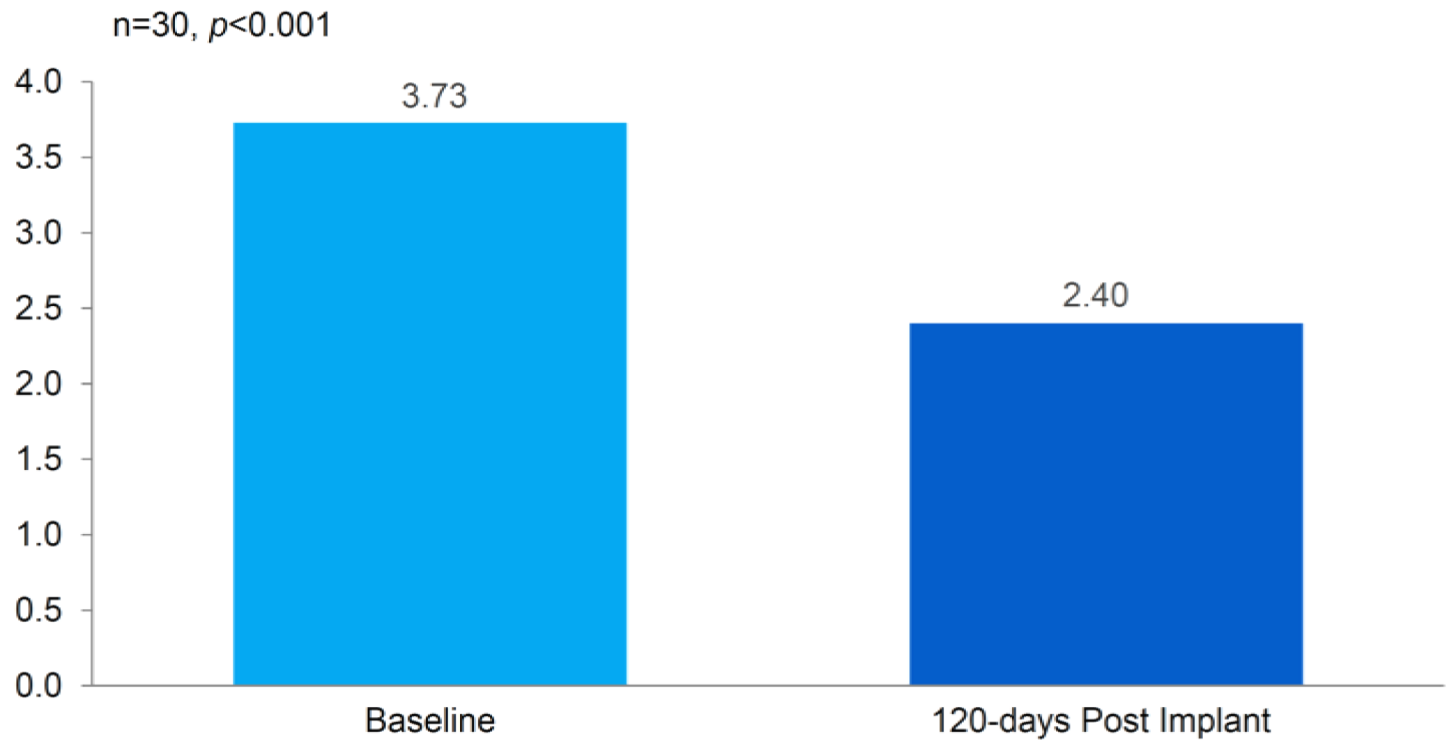
# CSR AND MICROVASCULAR DISEASE – ONGOING TRIALS

## CCS ANGINA CLASS

CCS angina class at baseline and 120-days





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# CONCLUSIONS

CSR implantation in patients with ANOCA and coronary microvascular disease:

- Seems a safe and feasible procedure
- Seems to improve both endothelium dependent and endothelium independent microvascular function
- Seems to improve IMR, CRF and RRR
- Seems to improve symptoms and quality of life
- May emerge as a novel therapy for microvascular angina
- Further evaluation with larger RCT is warranted


THANK
YOU
GRACIAS
ARIGATO
SHUKURIA
JUSPAXAR
BOLZÏN
MERCI
BÏYAN
SHUKRIA
DANKSCHEEN
TASHAKKUR ATU
YAQHANYELAY
SUKSAMA
EKHMET
MEHRBANI
GRAZIE
KOMAPSUMNIDA
MAAKE
GOZAIMASHITA
EFCHARISTO
PALDIES
TINGKI
SPASSIBO
NUHUN
SNACHALHUYA
CHALTU
WABEEJA
MAITEKA
YUSPAGARÀTAM
HUI
GUI
HATUR
UNALCHÉESH
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