Avenns Medical
The Art of Tissue Regeneration

Heart Regeneration ~~becomes~~ is Reality

Avenns® HeartWave

Regenerative Cardiac Shockwave Therapy

- Benefits for clinical users & patients
- Delivered as a complete, ready-to-use system
- No significant prolongation of the surgery
- The significant increase of left ventricular ejection fraction (LVEF) at 12 months after the intervention results in an improvement of the patients' physical capacity, increased quality of life and a prolonged life expectancy
- This improvement of the LVEF has been proven a long-term effect in an up to 4-years follow-up

Avenns® Wave

- Most advanced shockwave tabletop device
- Delivers focused shockwaves to the hibernating myocardium
- Plug & play integration into surgical workflow
- CE marked in accordance with MDR (EU) 2017/745

Avenns® Heart

- Sleek and ergonomic design
- Designed for intraoperative use during coronary artery bypass graft (CABG) surgery
- Simple handling in the sterile field allows for direct treatment of the hibernating myocardium
- CE marked in accordance with MDR (EU) 2017/745

Living with reduced LVEF

Normal: LVEF 50 - 75 %

- No limitation of physical activity

Medium: LVEF 35 - 50 %

- Limitation of physical activity
- Fatigue and shortness of breath during ordinary physical activity

Low: LVEF < 35 %

- Unable to carry out any activity
- Limited in daily routine
- Possibly bed bound

BENEFITS OF SHOCKWAVE TREATMENT

* The improvement of heart performance through our technology enables for a jump in the clinical class of patients and thereby for a relevant improvement of the patients quality of life.

EXAMPLE: A patient with a LVEF of 40%, highly limited in daily activities, improved to an LVEF of ~ 50% and a prolonged life expectancy of **~ 4 years** after surgery and SWT.

Clinical Study: CAST-HF Trial

with Long-Term Follow-Up

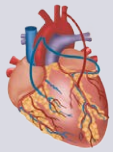
- Randomized, sham-controlled, single-blinded clinical trial
- Population: Patients with LVEF ≤40% undergoing CABG
- Primary Endpoint: Change in LVEF after 360 days (MRI)
- Patients were followed up to 4 years after treatment

Read more
about our clinical trials

n=63 iCMP + indication for CABG

1:1 randomization

- **Sham**
- **Shockwave**

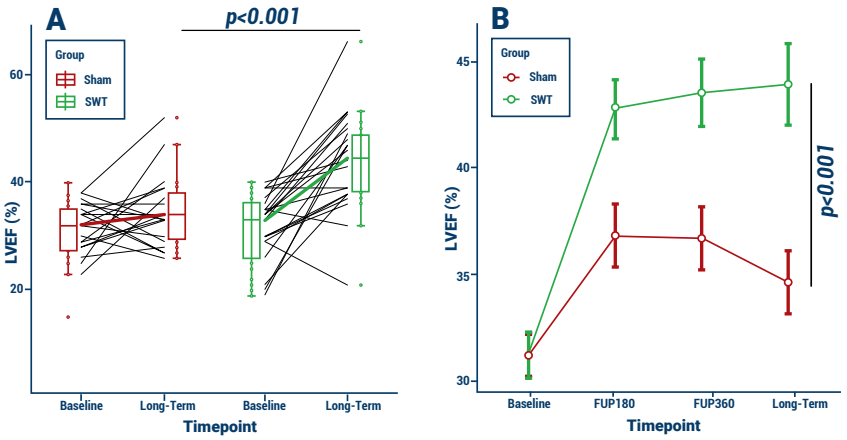


Single intraoperative treatment

Patients

- Elective surgery
- Blinded analysis
- Stable GDMT
- 70% NYHA III and IV
- LVEF ≤40%
- External validation

Long-Term Efficacy



(A) *LVEF improvement for each patient, from baseline to Long-Term follow-up.*
(B) *LVEF improvement from baseline to day 180, day 360 and Long-Term follow-up.*

Safety

- ✓ No device-related adverse events
- ✓ No difference in primary and secondary safety endpoints

Results at 360 Days[1]

- LVEF: +11.3 % (SWT) vs. +6.3 % (Sham) (p = .0146)
- 6-Minute Walk Test: +127.5 m (SWT) vs. +43.6 m (Sham) (p = .028)
- MLHFQ: Greater quality of life improvements in the SWT group

Results at Long-Term Follow-Up[2]

- LVEF: +11.5 % (SWT) vs. +2.8 % (Sham) (p = .0009)
- 6-Minute Walk Test: +62.6 m (SWT) vs. -1.5 m (Sham) (p = .031)
- MLHFQ: Greater quality of life improvements in the SWT group

Direct cardiac shockwave therapy in addition to CABG surgery improves LVEF, physical capacity and quality of life in patients with ischaemic heart failure.

1. **Holfeld J, Nägele F, Pölzl L, Engler C, Graber M, Hirsch J, et al.**
Cardiac shockwave therapy in addition to coronary bypass surgery improves myocardial function in ischaemic heart failure: the CAST-HF trial. Eur Heart J. 2024 Aug 1;45(29):2634–2643. doi:10.1093/eurheartj/ehae341

2. **Holfeld J, Steiner P, Nägele F, Pölzl L, Engler C, Graber M, et al.**
Cardiac Shockwave Therapy Induces Long-term Myocardial Improvement in Ischemic Heart Failure – Results from a Prospective, Randomized Controlled Trial. Swiss Med Wkly. 2025;155:4706. Abstract 006. doi:10.57187/s.4706"

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ESC European Society of Cardiology

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CLINICAL RESEARCH
Ischaemic heart disease

Cardiac shockwave therapy in addition to coronary bypass surgery improves myocardial function in ischaemic heart failure: the CAST-HF trial

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See the editorial comment for this article 'Therapeutic potentials of sound waves in cardiovascular medicine: further important evidence', by H. Shimokawa, https://doi.org10.1093/eurheartj/ehae253.

Abstract

Background and Aims In chronic ischaemic heart failure, revascularisation strategies control symptoms but are less effective in improving left ventricular ejection fraction (LVEF). The aim of this trial is to investigate the safety of cardiac shockwave therapy (SWT) as a novel treatment option and its efficacy in increasing cardiac function by inducing angiogenesis and regeneration in hibernating myocardium.

Methods In this single-blind, parallel-group, sham-controlled trial (cardiac shockwave therapy for ischemic heart failure, CAST-HF; NCT03859466) patients with LVEF ≤40% requiring surgical revascularisation were enrolled. Patients were randomly assigned to undergo direct cardiac SWT or sham treatment in addition to coronary bypass surgery. The primary efficacy endpoint was the improvement in LVEF measured by cardiac magnetic resonance imaging from baseline to 360 days.

Results Overall, 63 patients were randomized, out of which 30 patients of the SWT group and 28 patients of the Sham group attained 1-year follow-up of the primary endpoint. Greater improvement in LVEF was observed in the SWT group (Δ from baseline to 360 days: SWT 11.3%, SD 8.8; Sham 6.3%, SD 7.4, $P = .0146$). Secondary endpoints included the 6-minute walking test, where patients randomized in the SWT group showed a greater Δ from baseline to 360 days (127.5 m, SD 110.6) than patients in the Sham group (43.6 m, SD 172.1) ($P = .028$) and Minnesota Living with Heart Failure Questionnaire score on day 360, which was 11.0 points (SD 19.1) for the SWT group and 17.3 points (SD 15.1) for the Sham group ($P = .15$). Two patients in the treatment group died for non-device-related reasons.

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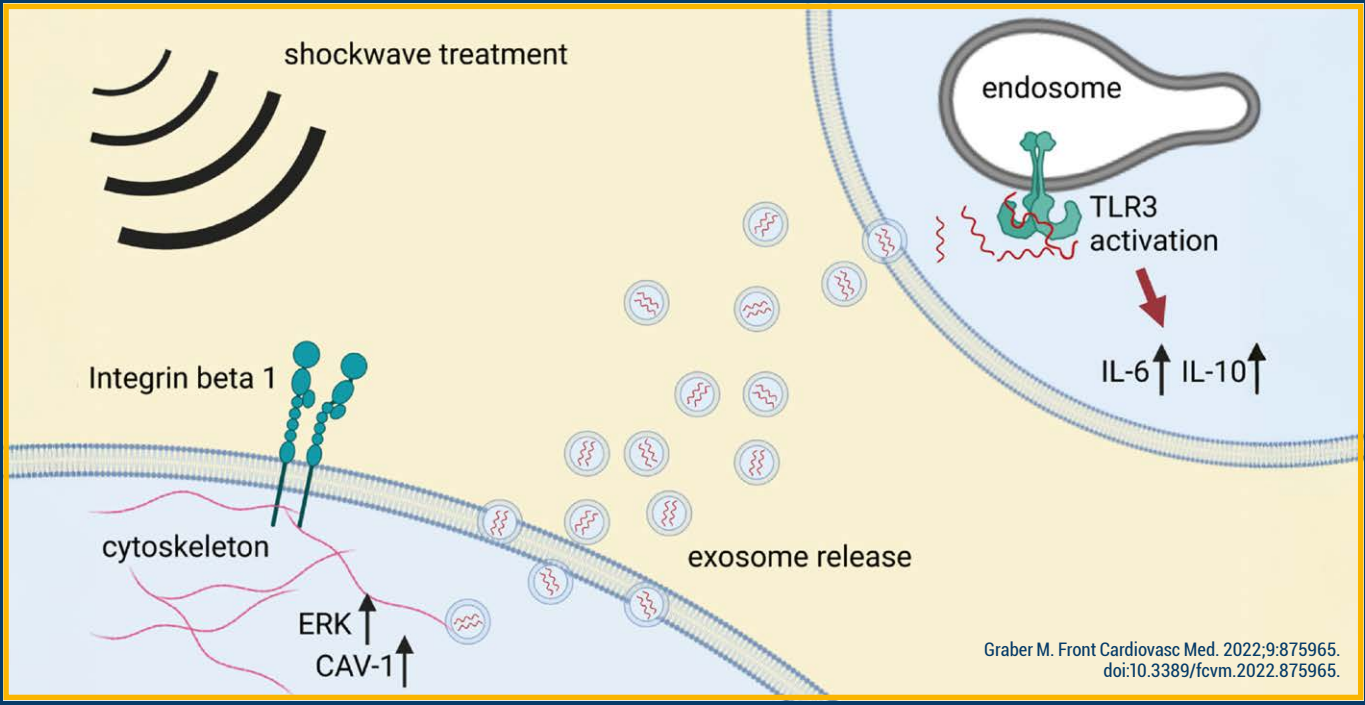
Mode of Action



The illustration shows how shockwave therapy (SWT) triggers regenerative processes through mechanical stimulation. SWT activates β1-integrins on the cell surface, which leads to the upregulation of the ERK signaling pathway. This in turn activates caveolin-1, a key regulator of microvesicle (especially exosome) release. These exosomes carry specific molecular cargo and are released into the extracellular space. When taken up by neighboring cells, they activate the innate immune receptor TLR3. TLR3 signaling initiates an inflammatory response that can lead to epigenetic changes, which are essential for the regenerative effects of SWT.

Effects of SWT

- Immune Modulation (Toll-like receptor 3) [1,2]
- Growth Factor Release (VEGF, PlGF, SDF-1) [3,4,5]
- Angiogeneseis, Vasculogenesis [3,4,6]
- Cell transdifferentiation, Cell recruitment [7,8]
- LVEF improvement [3,5]

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Eur Heart J Open. 2025;5(2):oeaf011. doi:10.1093/ehjopen/oeaf011

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Safety Information

Intended Purpose: The Avenns Heart shockwave applicator is used to treat the hibernating myocardium during bypass surgery to improve left ventricular ejection fraction (LVEF). The Avenns Wave device is used to provide high voltage, is control and trigger unit for electrohydraulic shockwave applicators. The Avenns Wave is intended to be used together with a shockwave applicator approved by the manufacturer and is intended solely to enable its use in accordance with its intended purpose.

Indications for use: The Avenns Heart is indicated for patients with postischaemic heart failure (ICD 10 code: I25.9), during coronary artery bypass grafting (CABG). The Avenns Wave device is an accessory for a medical device and therefore has no independent indications of its own.

Contraindications and exclusions include: Prior significant ventricular arrhythmias (excluding arrhythmias, as a result of myocardial infarction), Presence of ventricular thrombus, Malignant heart tumor, Pregnancy, Lung must not be in the focus of the shockwave

Potential risk associated with the Avenns HeartWave system include: Loss or reduction of the therapeutic regeneration effect, burning grade I, infection, blast trauma, redness and petechiae, damage to the eyes, ventricular fibrillation, death, tissue lesions, tissue irritation, allergic reaction, irritation of the respiratory tract

Precautions: One may only operate this device in accordance with the descriptions in this Instruction for Use use and only use it for the purpose as specified in the intended use. The use of this medical device is restricted exclusively to physicians with specialist training as surgeons. The medical operating room personnel must be trained as surgical assistants or as health care and nursing staff. Users must be instructed and trained in the use of this device by the manufacturer or already trained personnel. Any use by other users is not permitted. Users must check the proper functionality and condition of the product before each use.

Shockwaves do not replace medically recognized standard procedures, which are known to have a good prognosis for healing success. It must be ensured that shockwave treatment is used only as an additional therapeutic procedure that complements the conventional, recognized standard procedures.

Prior to use, please refer to the Instructions for Use for more information on warnings, precautions and residual risk.

This material is intended exclusively for healthcare professionals.