

# COUNTER PULSATION BY TRIGGERED ELECTRICAL STIMULATION OF LEG MUSCLES FOR CHRONIC HEART FAILURE TREATMENT

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**Abstract:** A new system for external counter pulsation is presented. The leg muscles are stimulated periodically by textile electrodes which produce diastolic extra-flows into the peripheral vascular system. In an initial clinical experiment advanced peripheral perfusion and reduced systematic vascular resistance could be demonstrated. Therefore the use in chronic heart failure therapy is suggested.

**Keywords:** External counter pulsation, textile electrodes, chronic heart failure therapy, pulse wave trigger

## Introduction

External counter pulsation (ECP) is a non-invasive method for assisting the circulatory system. The main principle of ECP is to initiate a diastolic pulse wave in the arterial system by squeezing the inner leg vessels. Thus a flux expulsion into the peripheral vascular system is induced leading to improved perfusion. In clinical studies positive effects of the ECP treatment to the therapy of refractory angina pectoris and diabetes patients is shown [1, 2]. So far pneumatic leg cuffs are used to induce the additional pulse wave. The leg muscles are compressed by simultaneous abrupt inflation of the cuffs. In consequence of the muscle compression the inner arteries are squeezed. An alternative method of artery compression is the electrical stimulation of specific leg muscles areas by electrodes (producer Cardiola AG, Switzerland). It is crucial to ensure that the aortic valve is closed before the retrograde flow arrives at the heart. Otherwise a reflow into the ventricle would impact the heart. Therefore the impetus to the legs must be triggered to the heart activity. At previous systems the trigger is realized by an R-wave detection algorithm whereat the trigger point is set at a delay time after the occurrence of the R-wave. The delay time is the estimated period between R-wave and the end of the T-wave where the aortic valve closes. However R-wave based triggers usually fail at patients with left bundle branch block or pacemaker spikes in the electrocardiogram.

Here we report about a new system for high-efficient ECP. With it peripheral perfusion can be increased significantly which cause reduced arterial flow resistance and lower cardiac after load. Here the application for chronic heart failure treatment is proposed. The system is designated for mobile use in clinics as well as for home therapy.

## Method

We developed a new ECP system consisting of a pair of tights with integrated electrodes, an electric pulse generator, a control unit, and a pulse wave trigger. Fig. 1 illustrates the set-up.

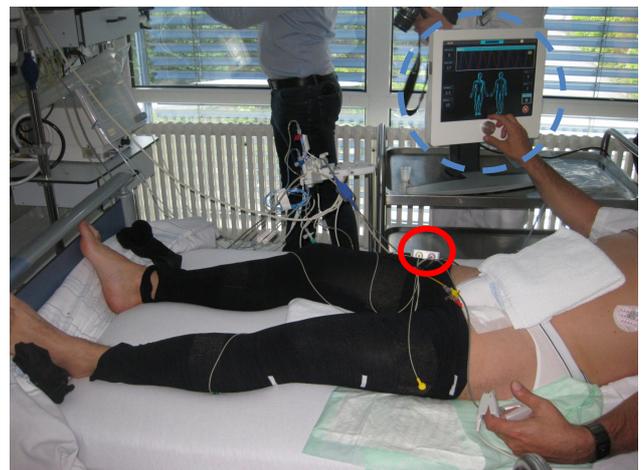


Figure 1: ECP set-up; tights with integrated electrodes, electric pulse generator (red circle), and control unit (blue dashed circle).

The tights are composed of elastic yarn and additive conducting filaments in the electrode segments. According to the automatic manufacturing process there are nearly no limitations on size and position of the electrodes. Thereby the large scale stimulation of the thigh and calf muscles is enabled. The four electrodes are wired to the pulse generator. Per stimulation process a series of single bipolar pulses is transmitted. The pulse duration is 360 $\mu$ s. The pulse repetition rate is 80Hz. The pulse current is stabilized for balancing alterations of the resistance between the electrodes and the skin. The pulse amplitude can be adjusted by the control unit within a physiologically non-hazardous range. The control unit communicates wirelessly with the pulse generator via Bluetooth. The trigger point is set from the rising part of the pulse wave curve captured by an optical transmission plethysmograph at the

ear. Due to the pulse wave delay at the ear with respect to the heart contraction the rising part of the pulse curve nearly coincide with the closure of the aortic valve. Due to the transit time of the counter pulse in the range of 90ms a ventricular reflow can be precluded. Compared to the electrocardiogram trigger the pulse wave trigger enables the application of the ECP treatment also on arrhythmia patients. Additionally the pulse wave signal is much less affected to moving artifacts than the electrocardiogram.

For the first time the effectiveness of that ECP system was clinically tested at one volunteer. The heart beat volume and systemic vascular resistance was surveyed by a catheter in the femoral aorta. The peripheral perfusion was measured by monitoring the plethysmogram at ear and finger.

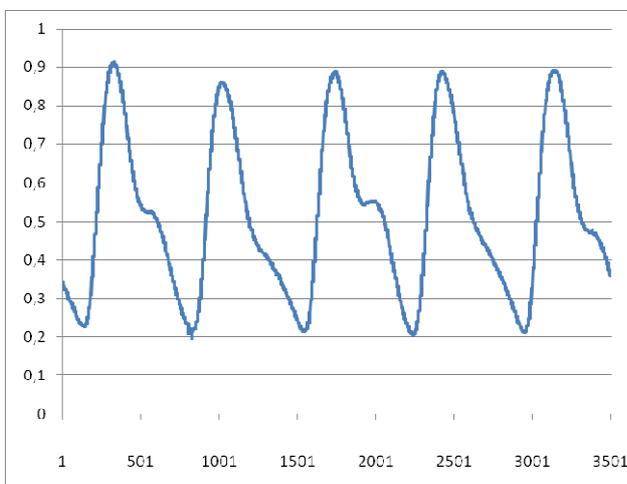


Figure 2: Finger plethysmogram; ECP was applied at the first, third, and fifth pulse.

## Results

The ECP treatment cause significant changes of the hemodynamic situation at the volunteer. Fig. 2 shows the finger plethysmogram over a period of five heartbeats. Here at the first, third and fifth beat the thigh and calf muscles were stimulated on both sides. The counter pulses produce additional humps in the diastolic part of the three curves. At the second and fourth beat no stimulation was applied and therefore no additional hump occurs. Fig. 3 shows a screen shot of the control unit display. The red curve indicates the ear plethysmogram. The blue bars show the trigger points. Here the stimulation is applied with every heartbeat. Again the ECP treatment produces a flow enhancement. The average perfusion gain derived from the plethysmogram curve integration is 17% and 28% respectively. The systemic vascular resistance decreases by 38%.

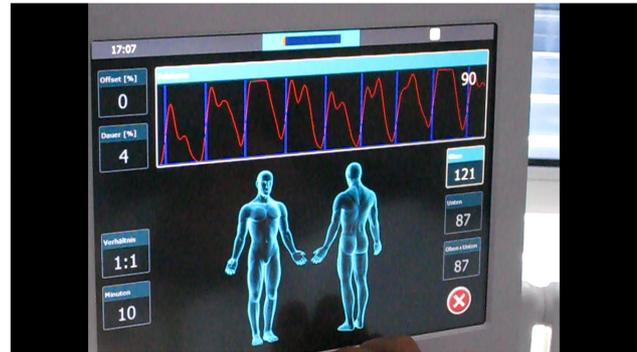


Figure 3: Ear plethysmogram with diastolic ECP peaks.

## Discussion

The effectiveness of the new ECP system was demonstrated at one volunteer with respect to peripheral perfusion and systemic vascular resistance (proof of concept). The system is easy to use and therefore suitable for home therapy. The pulse wave trigger provides reliable stimulation without misfiring and moving artifacts. Prospectively the implementation in chronic heart failure therapy must be investigated in clinical studies.

## Acknowledgement

We would like to thank AiF GmbH for the financial support of this work.

## Literature

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