

WaveGraft – A novel endovascular device concept for restoring the natural arterial cushioning effect

Authors: F. Stefanov¹, S. Sayed¹, J. Bouchier-Hayes¹, D. Veerasingam², P. Delassus¹, L. Morris¹

1. Medical and Engineering Technologies Centre, Department of Mechanical and Industrial Engineering, Galway-Mayo Institute of Technology, Ireland
2. Consultant Cardiothoracic Surgeon, Saoilta University Health Care Group, University Hospital Galway, Ireland

Background

The cushioning effect of large, healthy arteries reduces pulsatile afterload to the heart, reduces pulsatility in the microvasculature of target organs, and promotes coronary/cerebral perfusion.(1) With age, large arteries become stiffer, which increases both pulse wave velocity (PWV) and pulse pressure (PP). This results in isolated systolic hypertension(2), causing an uncoupling of the aorta to the left ventricle (LV), which promotes an increase in LV afterload, leading to heart failure.

Objectives

This study aims to replicate, experimentally, arterial stiffness of hypertensive patients, and proposes a novel thoracic endograft for restoring the arterial cushioning function.

Methods – Experimental setup

Two stiff Descending Aorta Silicone Replicas (DASR 1&2), shown in Fig.1 A & B, with 2mm wall thickness, 35mm inner diameter and a length of 150mm, were fabricated by injection molding techniques using Elastosil 4641 silicone-rubber (Wacker). The estimated dynamic replicated aortic distensibility was $1.19 [mmHg^{-1} \times 10^{-3}]$ for the blood pressure: 150/90mmHg, which was in agreement with the range reported in the literature for stiff aortas (3). The two aorta models were mounted in parallel, within a closed flow-loop system with a pulse duplicator (BDC, USA), fluid tank, heater and blood mimicking fluid developed in-house (water and glycerine mixing ratio of 54% to 46%, $1050kg/m^3$ density, at 37°C). Two pressure sensors (RDP electronics, UK) were positioned upstream and downstream of the aorta segments (locations A & B from Fig. 1B), and one ultrasonic flowmeter (Transonic, UK) was used to monitor the inlet cardiac output for each line. The data was acquired at 5,000Hz sampling rate.

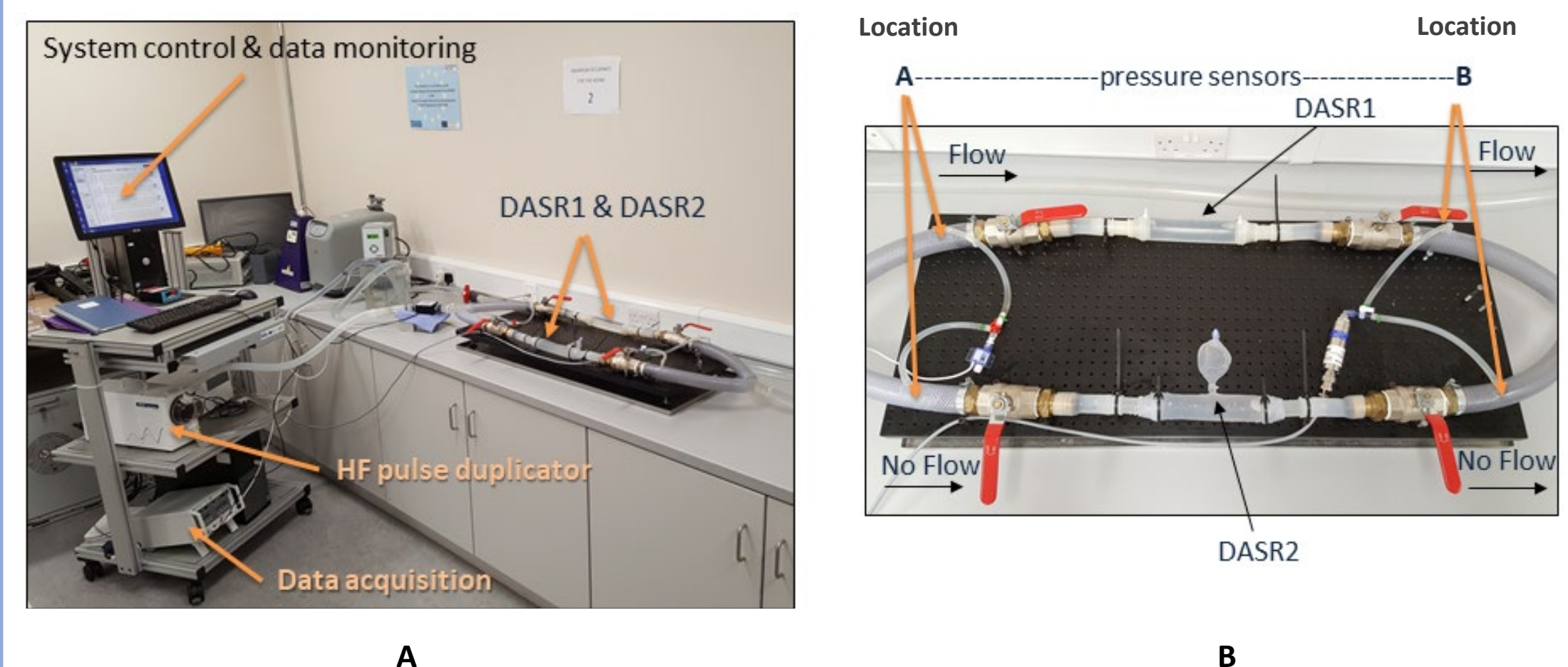


Figure 1. Human haemodynamics parameters simulator and closed flow-loop (A) and two parallel stiff aorta segments replica, one untreated (DASR1) and one treated (DASR2) (B)

The Statys PD software (BDC, USA) used to control the pulse duplicator and acquire data, also allowed live monitoring of the haemodynamic parameters during testing. The parameters ranges used to simulate the hypertensive flow and pressure scenarios, are presented in Table 1.

Table 1. Simulated and estimated haemodynamic parameters

Cardiac Output [L/min]	Systolic blood pressure [mmHg]	Diastolic blood pressure [mmHg]	Pulse Pressure [mmHg]	Heart Rate [bpm]	Pulse wave velocity (calculated) [m/s]
3 - 7	130 - 170	80 - 100	50 - 90	70 - 110	10 - 20

DASR1 line was subjected first to the simulated flow and pressure conditions, while DASR2 was inactive (Figure 1B), to establish the hypertension scenarios baseline, after which DASR2 line was opened and DASR1 was rendered inactive. The pulse wave velocity(PWV) in DASR 1 & 2 was calculated by employing the foot to foot method for the pressure waveforms, which estimated the transit time between the two pressure sensors locations. The distance between the two locations was 700mm. A minimum of 500 pulses were required to achieve stable haemodynamic conditions on each line.

WaveGraft Concept

A novel approach is proposed to safely reverse large artery stiffening in patients diagnosed with hypertension and heart failure. The WaveGraft device concept (Figure 2A), consists of an internal annular cushion primed with a fluid, which communicates to an extravascular passive reservoir. The cushion is housed within a conventional stent-graft device, to achieve secured positioning. An extravascular reservoir is linked to the cushion via a window in the stent-graft and a hole in the aorta. The preferred placement of the WaveGraft device is in the thoracic aorta, as shown in Figure 2B. As the WaveGraft device is a completely passive solution, it has no power-supply, battery, pump, or synchronization system (unlike circulatory support devices like left-ventricular assist devices).

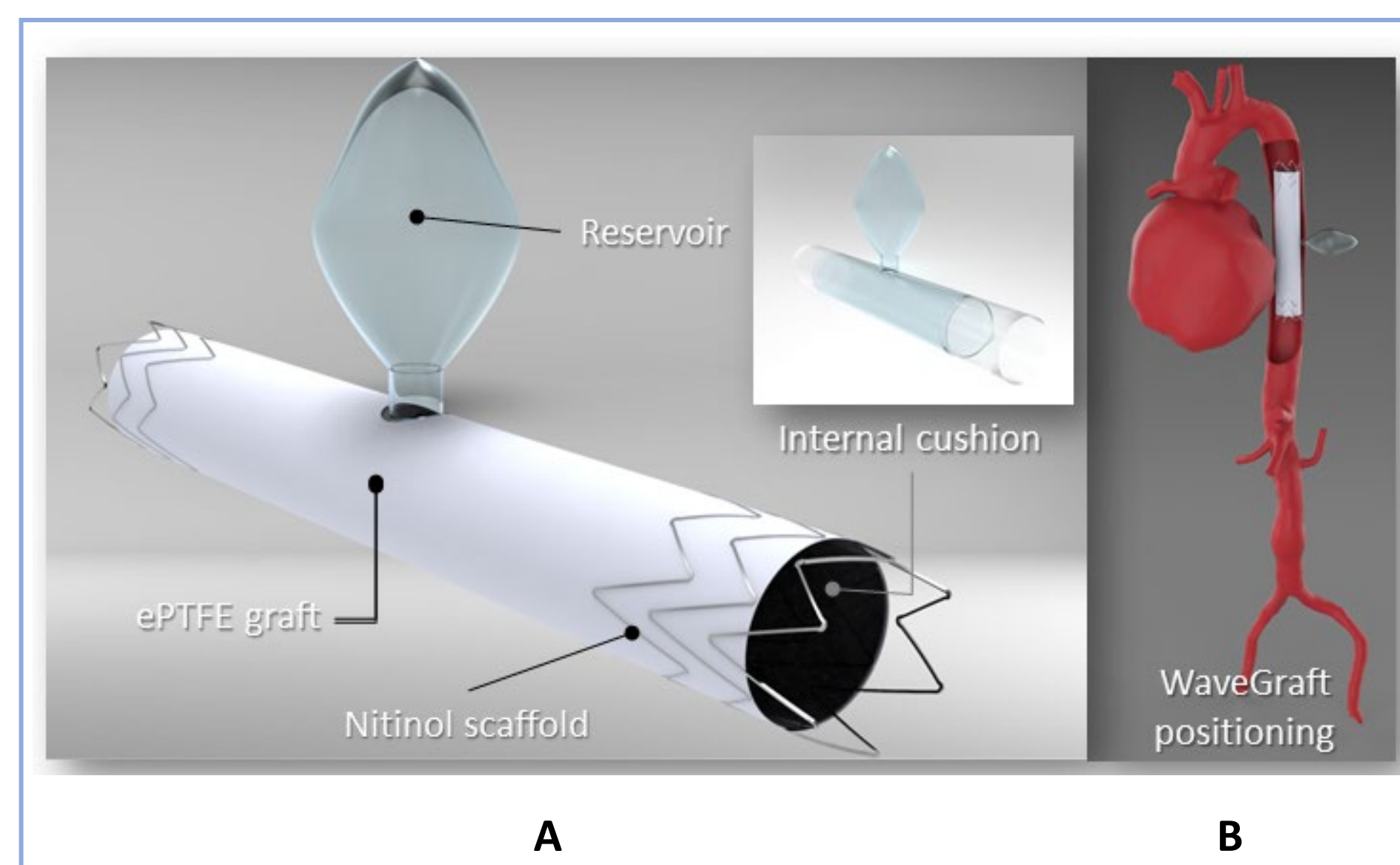


Figure 2. WaveGraft device concept 3D representation with uncovered internal cushion view (A) and designated positioning within the aorta artery (B)

Mechanism of action

During the cardiac cycle, when the forward and backward pressure waves in the arterial system hit the WaveGraft, the cushion is compressed and fluid is forced into the passive extravascular reservoir, as shown in Figure 3 (A - C). The pressure waves pass and fluid moves from the reservoir back into the cushion. Repeated cushioning delays dampens the pressure wave thus restoring aorta compliance. As the fluid returns to the cushion the diastolic pressure increases leading to an increased flow in the diastolic phase of the cycle.

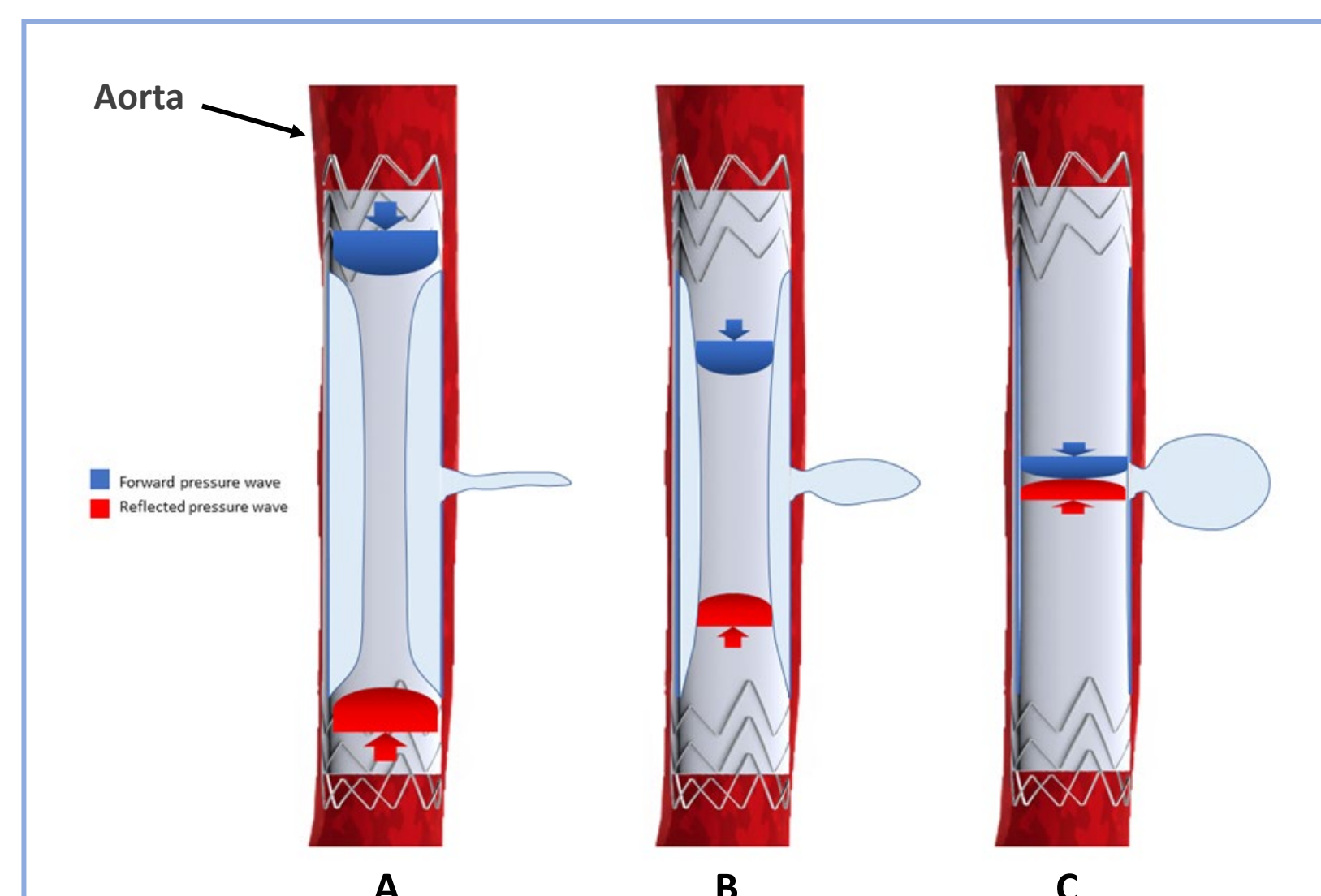


Figure 3. WaveGraft cushion positioned within the aorta (red vessel) longitudinal section view. Forward (blue) and backward (red) pressure waves entering and compressing the cushion A, B & C

Results

The comparative analysis of the recorded pressure and flow waveforms from DASR 1 & 2, showed a waveform modulation effect (Figure 4), which was quantified as follows:

- 9% reduction in maximum peak systolic pressure
- 10% increase in minimum diastolic pressure
- 35% reduction in pulse pressure
- 150% increase in diastolic flow perfusion (black arrow pointing down Figure 4C)
- 60% reduction in pulse wave velocity.

Figure 4 shows examples of the WaveGraft effect on the pressure and flowrate waveforms.

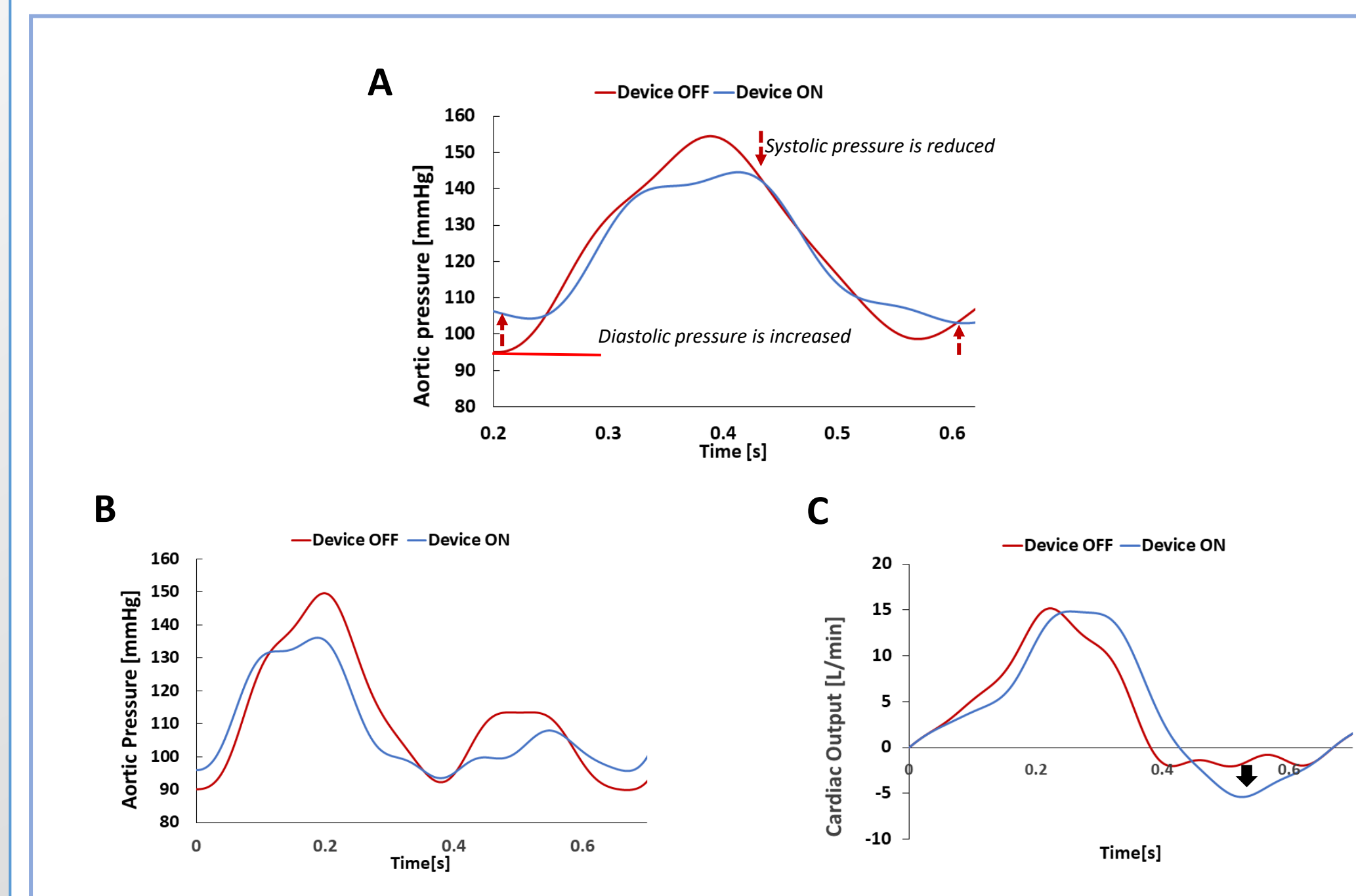


Figure 4. Inlet pressure flow waveforms examples showing the WaveGraft cushioning effect at 90bpm and 4L/min cardiac output (A & B – pressure waveforms, C – flowrate waveforms corresponding to the B pressure waves). Red curves - Baseline waveforms recorded in DASR1; Blue curves - resulted waveforms from DASR2. Black arrow (C) shows increased diastolic phase flow.

Conclusions

This work successfully replicated key features of aortic hemodynamics that are linked to the increase in arterial stiffness in hypertension and heart failure (Intermacs patient levels 5 – 7) (4).

The WaveGraft concept showed great potential in altering blood pressure, flowrates and PWV, which may become an important clinical tool in the management of isolated systolic hypertension, heart failure, chronic kidney disease and other chronic conditions.

Ongoing research is addressing the WaveGraft device mechanism of action in hypotensive patients (Intermacs level 4). Our initial findings suggest that end-organ perfusion could be increased for such patients. This encourages the team to believe that the WaveGraft device may potentially offer a minimally invasive long-term solution to advanced heart failure patients (3).

PCT application was filed in 2020.

References

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