Title: Dielectric Elastomer Actuator-Based Valveless Pump as Fontan Failure Assist Device: Introduction and Preliminary Study

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Abstract:

Objective

Fontan failure refers to a condition in which the Fontan circulation, a surgical procedure used to treat certain congenital heart defects, becomes insufficient, leading to compromised cardiac function and potential complications. This *in-vitro* study therefore investigates the feasibility of bladeless impedance-driven cavopulmonary assist device *via* dielectric elastomer actuator (DEA) as a means to address Fontan failure.

Methods

A cavopulmonary assist device, constructed using DEA technologies and employing the impedance pump concept, is subjected to *in-vitro* testing within a closed-loop setup. This study aims to assess the device's functionality and performance under controlled conditions, providing valuable insights into its potential application as a cavopulmonary assistive technology.

Results

The DEA-based pump, measuring 50mm in length and 30mm in diameter, is capable of achieving substantial flow rates within a closed-loop setup, reaching up to 1.20 L/min at an activation frequency of 4 Hz. It also provides a broad range of working internal pressures (less than 10 mmHg to more than 20 mmHg). Lastly, the properties of the flow (direction, magnitude, etc.) can be controlled by adjusting the input signal parameters (frequency, amplitude, etc.).

Conclusions

In summary, the results suggests that the valveless impedance-driven pump utilizing DEA technology is promising in the context of cavopulmonary assist devices. Further research and development in this area may lead to innovative and potentially more effective solutions for assisting the right heart, ultimately benefiting patients with heart-related health issues overall, with a particular focus on those experiencing Fontan failure.

Keywords: Fontan failure, cavopulmonary assist device, congenital heart defect, valveless pumping

Abbreviations:

CHD	Congenital heart defect
DEA	Dielectric elastomer actuator
EAP	Electroactive polymer
PET	Polyethylene terephthalate
PMMA	poly(methyl methacrylate)

Introduction:

The Fontan procedure (1,2), introduced over fifty years ago, represents a landmark surgical intervention designed to address the unique challenges of single ventricle congenital heart defects (CHDs). These complex congenital anomalies result in the presence of a single pumping ventricle, necessitating intricate surgical solutions to ensure adequate systemic circulation. The Fontan procedure, a staged surgical approach, redirects venous blood directly to the pulmonary arteries, bypassing the missing ventricle. Although this procedure has undoubtedly improved the prognosis for people with single ventricle anatomy, long-term results are far from ideal, with failure of the Fontan procedure becoming a substantial cause for concern.

Fontan failure refers to the progressive decline in cardiac function and exercise tolerance that affects a substantial proportion of people who have undergone the Fontan procedure. This can lead to various complications, such as arrhythmias (3), thromboembolism (4), liver dysfunction (5), and plastic bronchitis (6), which substantially impact these patients' quality of life and overall survival. Understanding the underlying mechanisms of Fontan failure requires a comprehensive exploration of the complex hemodynamic alterations (7) and physiological adaptations accompanying single ventricle circulation (8). A promising solution is to compensate for the absent right ventricular function by utilizing a cavopulmonary assist device made of soft robotic technology.

Inspired by the innate intelligence of living organisms, soft robotics has made substantial advances in recent decades. By merging traditional robotics with smart soft materials, this field has attracted the attention of researchers and engineers alike. The dielectric elastomer actuator (DEA) (9), often referred to as artificial muscle (10,11), is an example of such a material. Belonging to the electroactive polymers (EAPs) class, DEAs share similarities with natural muscles and exhibit qualities such as softness, lightness, large strains (12), high energy density (13), dynamic responsiveness (14), and even self-sensing capabilities (15). These attributes make them prime candidates for soft robotics applications, particularly for specialized uses in biomedicine (16,17).

Another promising system within the realm of biomedical applications, boasting unique capabilities, is the impedance pump (18). It offers a simple method of generating or amplifying flow without the need for valves or impellers (19,20). The concept can operate on both macro (21) and micro (22) scales and is achieved using a straightforward concept: a flexible tube filled with fluid, compressed off-center from its ends. This action generates waves propagating along the tube, reflecting at its ends, and producing a unidirectional net flow. The characteristics of this flow, including its direction and magnitude, are highly related to compression parameters such as frequency, duty cycle, and position.

This study investigates the feasibility of an innovative valveless impedance-driven pumping device based on a fully integrated DEA actuation, emphasizing its application as a cavopulmonary assist device (Fontan failure patients). However, the main target application for such a device is Fontan failure, where the pre-existing passive conduit of the Fontan procedure could be replaced by an active conduit (DEA pump), offering a potential long-term solution to mitigate the complications associated with the Fontan failure (see **Figure 1a**). The pump is made of an active DEA tube interconnected with a passive tube via a poly(methyl methacrylate) (PMMA) decoupling link.

The literature presents few examples of cavopulmonary assist devices, with examples falling into two categories. Firstly, short and medium-term devices utilize percutaneous axial-flow systems to enhance blood flow from the inferior vena cava (23,24) or provide combined superior and inferior vena cava support (25). Secondly, long-term devices differ based on outlet configuration, featuring double-outlet designs positioned between the pulmonary arteries (26,27) or single-outlet concepts implantable anterior to the total cavopulmonary connection (28). Despite the demonstrated merit in these approaches, it is noteworthy that a majority of them necessitate more intricate surgical interventions and modifications to the Fontan procedure. In contrast, our design relies on DEA, eliminating the need for further surgical alterations in Fontan procedures. This key distinction underscores the potential advantage of our device, offering a streamlined solution for circulatory support without imposing additional surgical complexities. Furthermore, traditional pumping configurations relying on valves, AC/DC motors, and intricate components, this design presents several advantages: it operates without valves, thereby minimizing the risk of flow disruption or hemolysis; it displays softness, which reduces the potential for damage due to impacts; its lightweight construction weighs less than 25g in total; It exhibits high energy efficiency, requiring minimal power consumption (258 mW for 5kV activation); and it features a monolithic structure (DEAs capable of enduring over 400 million cycles (14)). Moreover, the inherent pulsatile nature of this system holds substantial implications within the realm of biomedical applications (29).

Materials and Methods:

Ethical statement: None.

Working principle of DEA and DEA pump:

DEAs, typically composed of compliant electrodes sandwiching a dielectric film, function as a capacitive system. When an electric field is introduced, it triggers a mechanical force on the hyperelastic material due to the charges on the electrodes. This force compresses the film, reducing its thickness while expanding its surface area. Consequently, the conversion of an electric field into a mechanical deformation occurs. The extent of voltage application and resulting displacements hinges on the film's thickness.
The concept of the valveless pumping system based on DEAs is presented in **Figure 1b**. This design consists of an active DEA combined with a passive tube linked through a rigid decoupling PMMA link. Here, the tubular DEA ensures the off-center compression (or, in this case, decompression), thus achieving wave generation. Before activation (applying electrical voltage), the tubular DEA is subjected to internal pressure. Once activated, the mechanical properties of the DEA will change (drop), causing it to inflate like a balloon under internal pressure and leading to the required waves generation. On the other hand, the passive tube acts as a soft tube, while the rigid link ensures a decoupling between the two (DEA and passive tube).

Fabrication process

The tubular DEA comprises multiple modules that are assembled in a stacked arrangement and subsequently rolled to create the final device. The manufacturing procedure involves a series of distinct stages, encompassing module creation, stacking, rolling, and establishment of electrical connections. A module is composed of a silicone film (Elastosil film 2030, Wacker, Munich, Germany), compliant electrodes containing carbon powder, and silver lines serving as electrical conduits.

The manufacturing process commences by cutting silicone film sheets and polyethylene terephthalate (PET) masks (ES301130, Goodfellow) to the desired dimensions using a CO2 laser cutter (Trotec, Speedy 360 flexx). After accurately sizing the silicone films, narrow strips of silver ink (CreativeMaterials, 125-19(SP)A/B) are applied through PET masks. This deposition is accomplished using an automatic film applicator coater and a universal applicator (Zehntner ZAA 2300 and ZUA 2000, Proceq Group, Switzerland). Following this, a curing period of 16 hours at 80°C is necessary. Similarly, a layer of carbon ink is subsequently deposited, and it requires a curing time of 4 hours at 80°C. At this juncture, the modules are considered prepared.

Additionally, laser-engraved markers aid in aligning the modules during the stacking process. Silicone glue (Silbione, LSR4305) is employed for stacking, containing 0.3% carbon powder by mass to enhance charge distribution. After stacking, the assembly is cured for 2 hours at 80°C. Once the layers are fully stacked, the resulting multilayer system undergoes a rolling process. This rolling action utilizes a 30 mm diameter PMMA tube, along with the same silicone glue used for stacking, albeit without carbon powder. The multilayer stack is rolled and then subjected to a 2-hour curing period at 80°C within an oven.

For wiring purposes, high-voltage copper wires are affixed to the ends of the silver lines using conductive silicone (Wacker, ELASTOSIL LR 3162 A/B). To prevent unintended arcing during activation, the conductive silicone is coated with molded silicone (Dow Corning, Sylgard 186). Both types of silicone require a 2-hour curing duration at 80°C each. Further details of the fabrication of the tubular DEA used here is available in (30).

<u>Experimental Setup</u>

The experimental arrangement designed to assess the efficiency of the proposed impedance pump is a closed-loop in vitro system. This setup consists of a Tygon tube interconnected with the tubular DEA-based soft pump, utilizing aluminum components for connection. These aluminum parts facilitate the integration of pressure sensors (PBMN-258 1 2R A21 44621 2000, provided by Baumer, Germany) at both ends of the pump. Additionally, the setup incorporates a laser sensor (LK-G23/LK-G3001P, Keyence, Osaka, Japan) to measure the radial deformation of the active DEA. Furthermore, a flow sensor (ME16PX, Transonic Systems Inc., NY, USA) is installed externally around the Tygon tube to gauge the resulting net flow rate generated by the tubular pump. Notably, this setup does not incorporate any type of valves. The fluid used for the experimental testing is water with a density of 1000 kg/m3 and a viscosity of 1 mPa-s.

Controlling and overseeing the experimental arrangement is achieved through MATLAB / Simulink software, Massachusetts, US. To facilitate this, a versatile data acquisition module (NI cDAQ-9179) from National Instruments (Texas, US) is employed. This module serves the dual purpose of providing the input control voltage and measuring the output current. The module is capable of generating precise voltage levels (with a resolution of 3.5 mV) ranging from -10 V to +10 V. To administer the input signal (up to 20kV), a high-voltage amplifier (Trek

20/20C-HS, manufactured by Advanced Energy, Denver, Colorado, USA) is employed. The same data acquisition module is responsible for real-time measurements of pressure waveforms, radial deformations, and flow rates.

All testing procedures and parameter adjustments (both input and output) are executed and controlled in real-time using a unified MATLAB / Simulink program. The experimental study operates with a time step of 0.004 seconds.

Results and Discussion:

To illustrate the effectiveness of the proposed concept, an innovative scenario is envisioned to support the pumping function of a weakened or failing heart, particularly in individuals with Failing Fontan. This scenario centers on the implementation of a cavopulmonary assist device targeting the right side of the heart, providing a unique approach to enhancing cardiac function and improving the quality of life. Specifically, it focuses on replacing the existing Fontan conduit with the tubular DEA pump (internal pressure of 10 - 20 mmHg), as depicted in **Figure 1a**. Thus, it is a more targeted approach for individuals who have previously undergone or in need of a Fontan procedure. The Fontan procedure is typically performed on patients with CHDs to redirect blood flow directly to the lungs without passing through the heart. In this envisioned scenario, the existing Fontan conduit is replaced with a specialized pump designed to optimize circulatory efficiency (See **Figure 1a**).

The custom-built DEA pump (see **Figure 1b**) is designed, fabricated, and subjected to testing to emulate the operational parameters of a Fontan conduit (characterized by an internal pressure range of 10 - 20 mmHg). As previously indicated, this pump consists of three primary components: a tubular DEA (depicted in black in Figure 2a) measuring 50 mm in length, 30 mm in diameter, and possessing a thickness of 0.12 mm; a passive tube (shown as transparent in **Figure 2a**) with the same dimensions of 50 mm length, 30 mm diameter, and a thickness of 0.1 mm; these two components are interconnected through a PMMA link measuring 10 mm in length, 30 mm in diameter, and 1 mm in thickness (see **Table 1**). The link's small size minimizes additional system length. Each of the three elements plays a vital role in achieving a unidirectional net flow. The active DEA functions as a pressure wave generator, the passive tube acts as a pressure wave damper, and the rigid ring ensures each part adheres to its designated function by decoupling their motions. This guarantees that the passive tube responds exclusively to fluid movement. For instance, in the absence of or insufficient decoupling, the sum of all incident and reflected pressure waves produced by the tubular DEA equals zero, resulting in no flow.

Furthermore, the selection of the DEA's thickness is contingent upon the operational internal pressure, chosen strategically to optimize the extent of volume variation during activation, thereby facilitating the generation of waves, thus flow rates.

The DEA pump designed and manufactured here underwent testing across a range of 10 frequencies, spanning from 1 to 10 Hz. Each frequency is tested a multiple time. Throughout these experiments, the internal pressure and maximum activation voltage remained constant at 13 mmHg and 4.5 kV, respectively. The outcomes of these tests are graphically depicted in **Figure 3**, revealing the characteristic behavior associated with an impedance pump.

It's worth noting that even though this DEA pump functions through expansion rather than compression and necessitates a decoupling element, it still exhibits behavior typical of an impedance pump. Notably, it displays a resonance behavior, particularly pronounced at 4 Hz (as shown in **Figure 3**), a trait commonly observed in impedance pumps (19). As a result of this behavior, it is reasonable to conclude that the DEA pump indeed functions as an impedance pump. The resonant frequency is precisely identified at 4.0 Hz, and the pump demonstrates the capability to generate a substantial flow rate of 1.20 L/min (as shown in **Figure 2b**) when operating under internal pressure and maximum voltage conditions of 15 mmHg and 5.5 kV, respectively (refer to **Figure 2c-d**). **Figure 4** displays a time series representing the working principle of the DEA pump at the resonant frequency.
Our DEA pump is purposefully designed to seamlessly integrate with the Fontan procedure, introducing no changes except for replacing the traditional passive conduit with our active conduit. When not activated (no applied voltage), our conduit functions as a conventional passive conduit. However, upon activation, the pump amplifies the existing flow in the pulmonary arteries. The DEA tube inflates like a balloon during activation, generating the waves essential for impedance pumping. Most importantly, whether active or not, the DEA pump never obstructs the flow, and in the event of malfunction, it simply functions as a traditional passive Fontan conduit.

By replacing the Fontan conduit with a dedicated pump, medical practitioners could further enhance the oxygenation of blood and alleviate potential complications arising from the modified circulatory system. This innovative approach seeks to address challenges associated with the Fontan procedure and improve the overall cardiac function of patients with congenital heart defects.

<u>Limitations</u>

The tubular DEA Pump exhibits remarkable capabilities in generating substantial flow rates without the need for any valves; however, its limitations are evident. Despite its substantial contributions, it falls short of being a full cardiac replacement, living up to the true meaning of the name only as a heart assist device. Its size, especially the length, reaching up to 110 mm and potentially longer with pre-stretching, poses challenges in terms of implantation. To pave the way for its practical implementation, extensive efforts are required to enhance flow output and minimize its dimensions. Additionally, a comprehensive exploration of its performance within an in-vivo environment is imperative—considering variables such as blood viscosity and lung resistance—to ensure optimal functionality. Despite these challenges, this technology harbors immense potential for the next generation of heart assist devices, characterized by their flexibility, lightweight nature, absence of valves and blades, pulsatile operation, and energy efficiency.

Conclusion:

The developed system demonstrates high capabilities, generating substantial flow rates of up to 1.20 L/min. This device operates effectively across a diverse pressure spectrum, ranging

from less than 10 to more than 20 mmHg. Notably, it showcases the ability to manipulate flow properties such as the magnitude by simply adjusting the input signal and frequency.
In terms of future endeavors, the focus will be on refining the design to enhance performance while simultaneously reducing its overall size. Additionally, the next steps involve conducting thorough tests using a setup that closely mimics anatomical accuracy before advancing to animal trials. As research and technological advancements continue, the proposed pumping device holds the potential to redefine the landscape of cardiac care, offering new avenues of hope and improved health for patients in need.

Acknowledgement: This work has benefited from the financial support of the Werner Siemens foundation.

Funding statement: This work has benefited from the financial support of the Werner Siemens foundation.

Conflict of interest statement: None.

Author contribution statement:

Figure:

Central image: Novel DEA-based pump as a substitute for the Fontan conduit and *in-vitro* achieved flow rate.

Figure 1: a) Illustration depicting the utilization of the DEA pump as a substitute for the Fontan conduit. b) Schematics outlining the working principle of the impedance pump in a closed-loop setup.

Figure 2: Experimental results at the resonant frequency (4 Hz) and under conditions of low internal pressure (15 mmHg), specifically for cavopulmonary assist device applications. a) Description of the experimental setup b) reported mean filtered flow rate data generated from 5 experimental tests, c) the applied voltage signal, and d) the measured pressure variation throughout the activation process.

Figure 3: Statistical experimental results for the DEA-based pump across frequencies ranging from 1 to 10 Hz and a maximum applied voltage, and an internal pressure of 4.5 kV, and 13 mmHg, respectively.

Figure 4: The working behavior of the DEA pump observed at the resonant frequency of 4 Hz and an internal pressure of 15 mmHg. a) A time-lapse representation of particles movement within the fluid during the activation process, b) DEA pump at 5.5 kV, c) DEA pump at 0 kV, and d) the applied voltage signal.

Tables:

Table 1: Geometric specifications of the DEA pump are provided for: DEA tube, passive tube, and PMMA link.

Scenario	Input (kV)	Working Pressure (mmHg)	DEA Length (mm)	DEA Diameter (mm)	DEA Thickness (mm)
DEA tube	0 - 5,5	10 -20	50	30	0.12
Passive tube	-	-	50	30	0.1
PMMA link	-	-	10	30	1

Data availability statement

Data are available from the corresponding author upon reasonable request.

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Fig 1

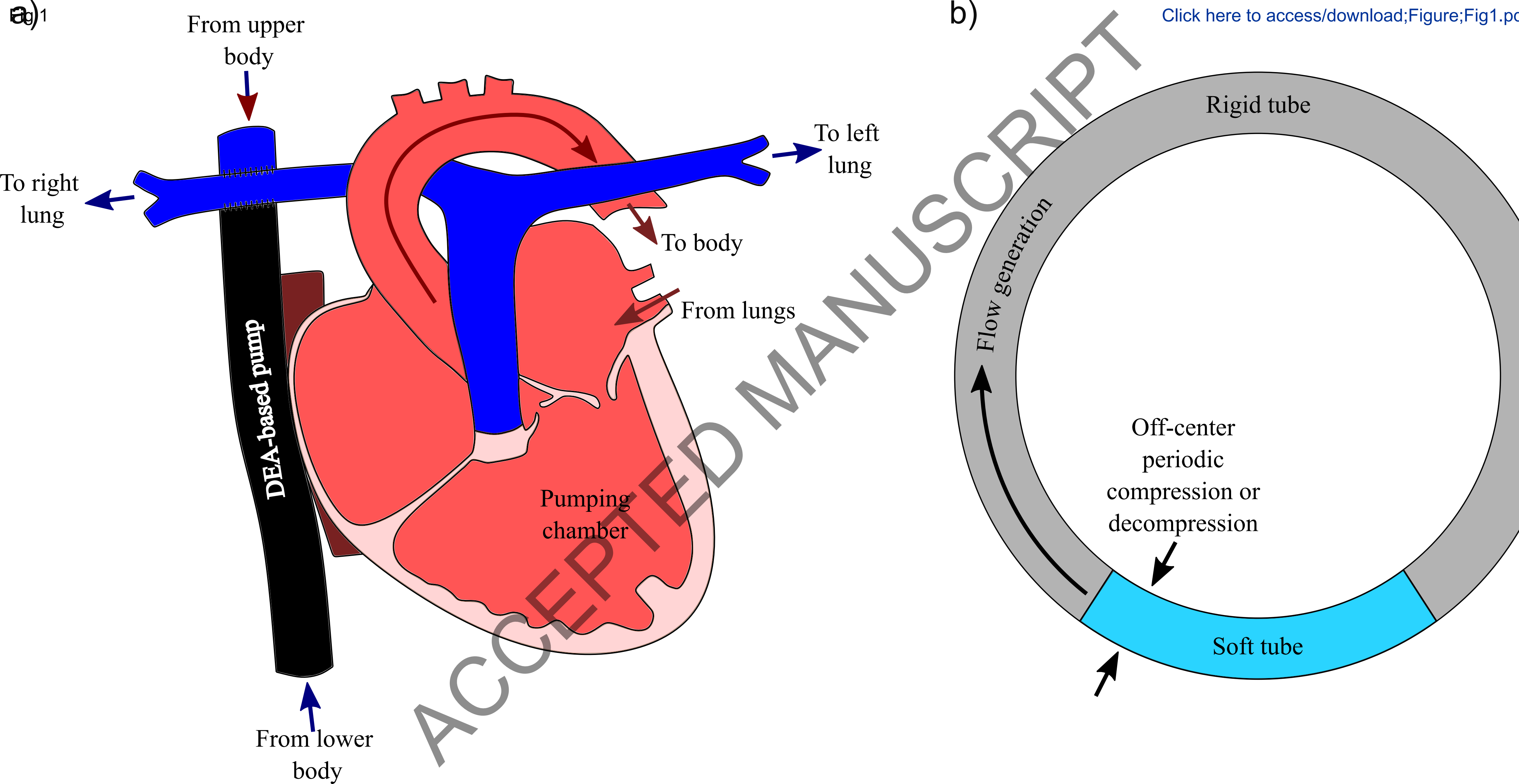

a)
From upper body
To right lung
To left lung
To body
From lungs
DEA-based pump
Pumping chamber
From lower body
b)
Rigid tube
Flow generation
Off-center periodic compression or decompression
Soft tube

Fig 2

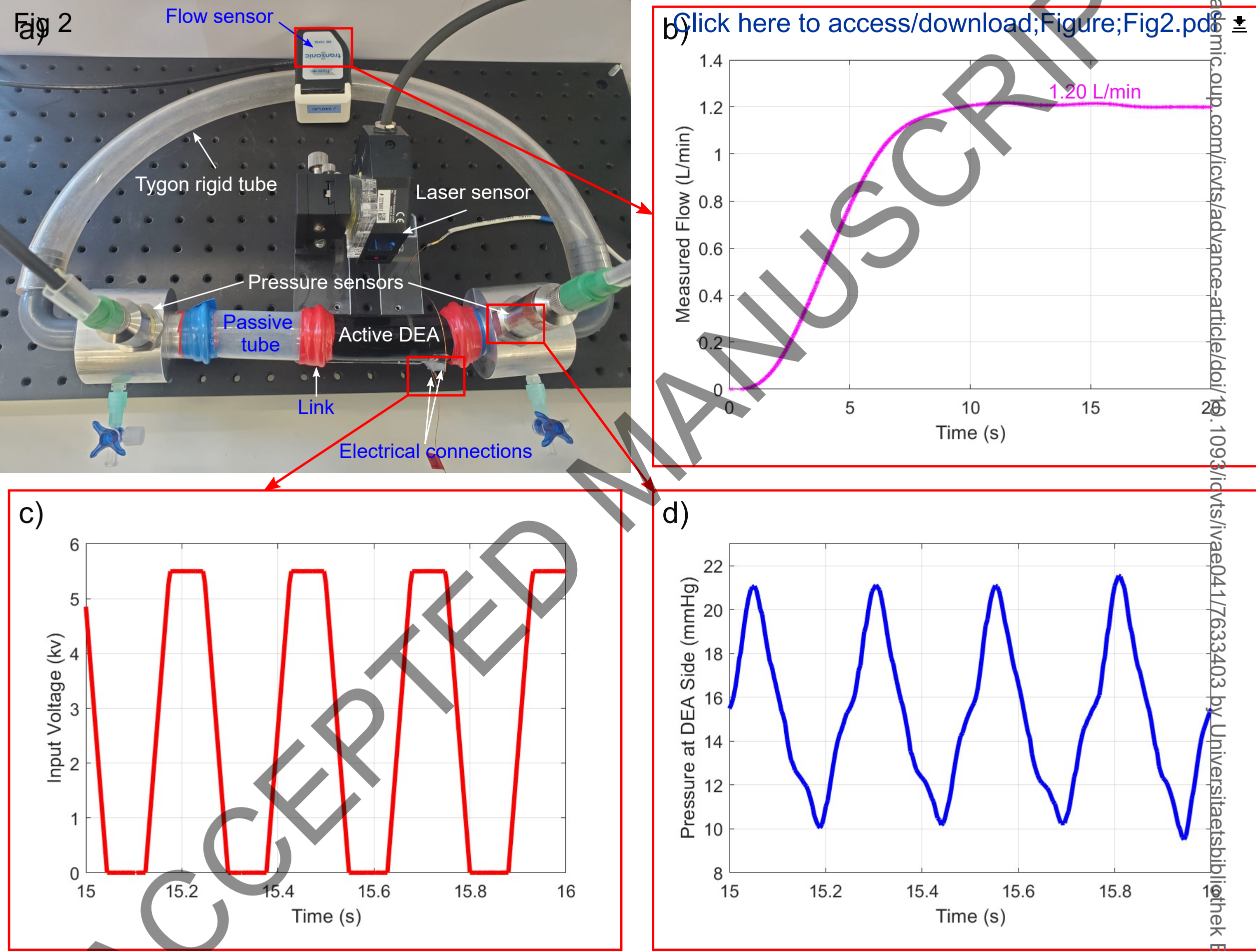

a)
Flow sensor
Tygon rigid tube
Laser sensor
Pressure sensors
Passive tube
Active DEA
Link
Electrical connections
b)
Measured Flow (L/min)
1.20 L/min
Time (s)
c)
Input Voltage (kv)
Time (s)
d)
Pressure at DEA Side (mmHg)
Time (s)

Fig 3

Click here to access/download;Figure;Fig3.pdf

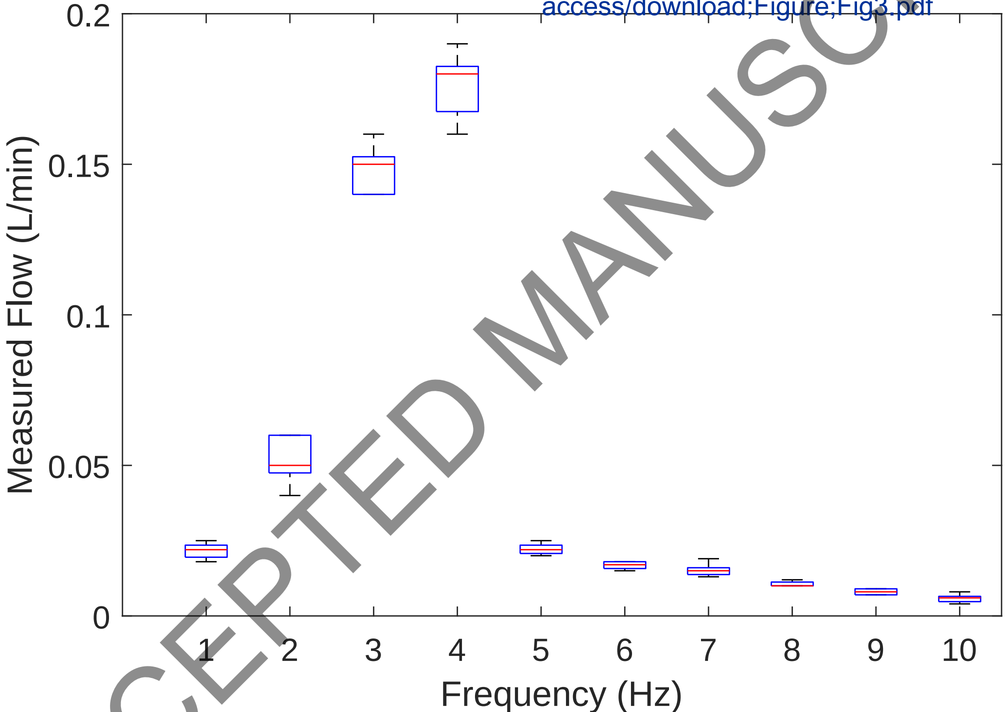
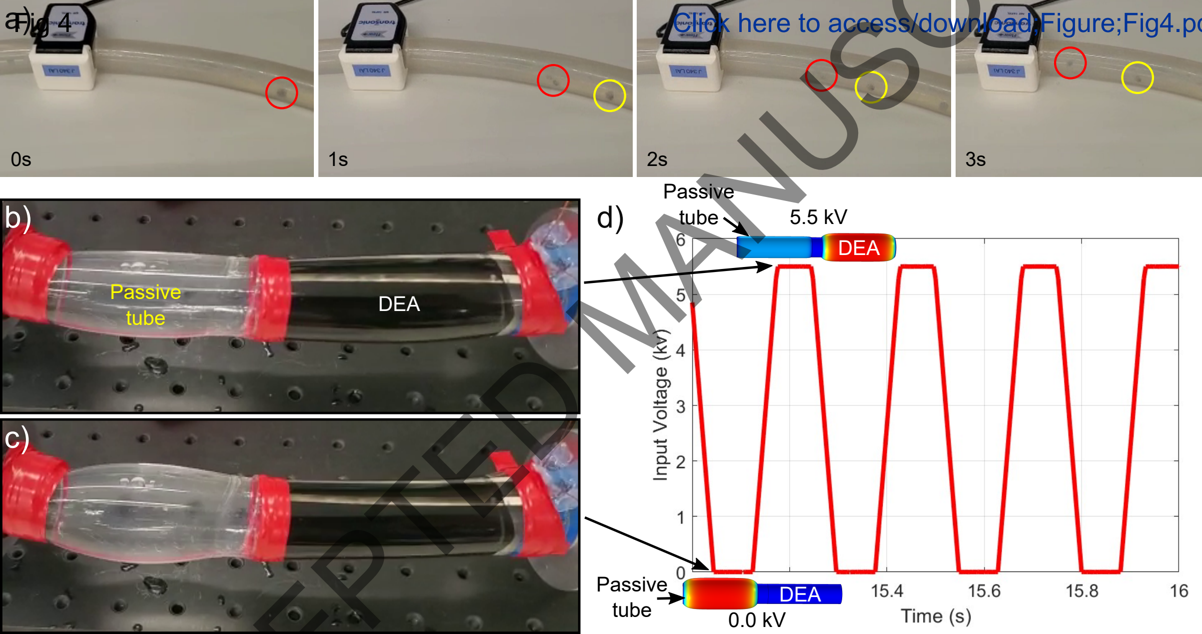


Fig 4


a)
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tube
DEA
c)
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tube
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16
Time (s)

Central image

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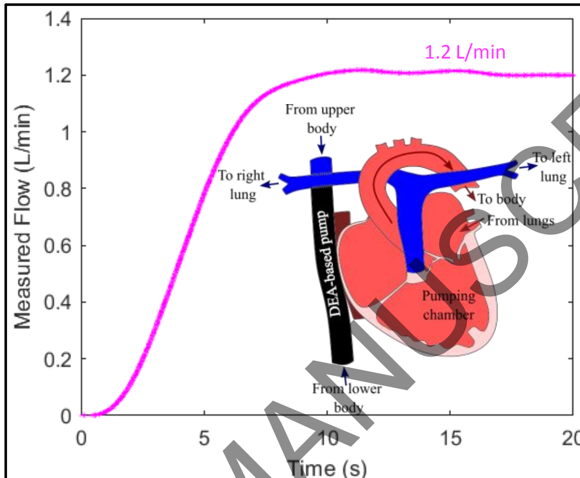
Novel dielectric elastomer actuator pump as a substitute for the Fontan conduit

Summary

This *in-vitro* study explores the viability of a bladeless impedance-driven cavopulmonary assist device utilizing dielectric elastomer actuators (DEA) as a potential solution for Fontan failure. The DEA-based pump undergoes testing within a closed-loop setup, demonstrating its capacity to produce substantial flow rates across various pressure levels.



Legend: Novel DEA-based pump as a substitute for the Fontan conduit and *in-vitro* achieved flow rate.