- 2 Introduction and Preliminary Study
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31 Abstract:

32 <u>Objective</u>

33 Fontan failure refers to a condition in which the Fontan circulation, a surgical procedure used

34 to treat certain congenital heart defects, becomes insufficient, leading to compromised

35 cardiac function and potential complications. This *in-vitro* study therefore investigates the

- 36 feasibility of bladeless impedance-driven cavopulmonary assist device *via* dielectric elastomer
- 37 actuator (DEA) as a means to address Fontan failure.

38 <u>Methods</u>

39 A cavopulmonary assist device, constructed using DEA technologies and employing the

- 40 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,
- 42 providing valuable insights into its potential application as a cavopulmonary assistive
- 43 technology.

44 <u>Results</u>

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,

50 amplitude, etc.).

51 <u>Conclusions</u>

- 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.
- 57 **Keywords:** Fontan failure, cavopulmonary assist device, congenital heart defect, valveless 58 pumping

59 Abbreviations:

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

The Fontan procedure (1,2), introduced over fifty years ago, represents a landmark surgical 64 65 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 66 67 pumping ventricle, necessitating intricate surgical solutions to ensure adequate systemic circulation. The Fontan procedure, a staged surgical approach, redirects venous blood directly 68 to the pulmonary arteries, bypassing the missing ventricle. Although this procedure has 69 70 undoubtedly improved the prognosis for people with single ventricle anatomy, long-term 71 results are far from ideal, with failure of the Fontan procedure becoming a substantial cause 72 for concern.

- Fontan failure refers to the progressive decline in cardiac function and exercise tolerance that 73 affects a substantial proportion of people who have undergone the Fontan procedure. This 74 75 can lead to various complications, such as arrhythmias (3), thromboembolism (4), liver 76 dysfunction (5), and plastic bronchitis (6), which substantially impact these patients' quality of 77 life and overall survival. Understanding the underlying mechanisms of Fontan failure requires a comprehensive exploration of the complex hemodynamic alterations (7) and physiological 78 adaptations accompanying single ventricle circulation (8). A promising solution is to 79 compensate for the absent right ventricular function by utilizing a cavopulmonary assist device 80 81 made of soft robotic technology.
- Inspired by the innate intelligence of living organisms, soft robotics has made substantial 82 advances in recent decades. By merging traditional robotics with smart soft materials, this 83 field has attracted the attention of researchers and engineers alike. The dielectric elastomer 84 85 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 86 natural muscles and exhibit qualities such as softness, lightness, large strains (12), high energy 87 density (13), dynamic responsiveness (14), and even self-sensing capabilities (15). These 88 attributes make them prime candidates for soft robotics applications, particularly for 89 specialized uses in biomedicine (16,17). 90
- Another promising system within the realm of biomedical applications, boasting unique 91 capabilities, is the impedance pump (18). It offers a simple method of generating or amplifying 92 flow without the need for valves or impellers (19,20). The concept can operate on both macro 93 (21) and micro (22) scales and is achieved using a straightforward concept: a flexible tube 94 filled with fluid, compressed off-center from its ends. This action generates waves propagating 95 along the tube, reflecting at its ends, and producing a unidirectional net flow. The 96 97 characteristics of this flow, including its direction and magnitude, are highly related to 98 compression parameters such as frequency, duty cycle, and position.
- 99 This study investigates the feasibility of an innovative valveless impedance-driven pumping 100 device based on a fully integrated DEA actuation, emphasizing its application as a 101 cavopulmonary assist device (Fontan failure patients). However, the main target application 102 for such a device is Fontan failure, where the pre-existing passive conduit of the Fontan 103 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 107 108 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 109 superior and inferior vena cava support (25). Secondly, long-term devices differ based on 110 outlet configuration, featuring double-outlet designs positioned between the pulmonary 111 arteries (26,27) or single-outlet concepts implantable anterior to the total cavopulmonary 112 113 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 114 Fontan procedure. In contrast, our design relies on DEA, eliminating the need for further 115 surgical alterations in Fontan procedures. This key distinction underscores the potential 116 advantage of our device, offering a streamlined solution for circulatory support without 117 imposing additional surgical complexities. Furthermore, traditional pumping configurations 118 relying on valves, AC/DC motors, and intricate components, this design presents several 119 advantages: it operates without valves, thereby minimizing the risk of flow disruption or 120 hemolysis; it displays softness, which reduces the potential for damage due to impacts; its 121 lightweight construction weighs less than 25g in total; It exhibits high energy efficiency, 122 requiring minimal power consumption (258 mW for 5kV activation); and it features a 123 monolithic structure (DEAs capable of enduring over 400 million cycles (14)). Moreover, the 124 inherent pulsatile nature of this system holds substantial implications within the realm of 125 biomedical applications (29). 126

127 Materials and Methods:

- 128 <u>Ethical statement:</u> None.
- 129 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 136 design consists of an active DEA combined with a passive tube linked through a rigid 137 decoupling PMMA link. Here, the tubular DEA ensures the off-center compression (or, in this 138 case, decompression), thus achieving wave generation. Before activation (applying electrical 139 140 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 141 pressure and leading to the required waves generation. On the other hand, the passive tube 142 acts as a soft tube, while the rigid link ensures a decoupling between the two (DEA and passive 143 tube). 144

- 145
- 146 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

152 as electrical conduits.

The manufacturing process commences by cutting silicone film sheets and polyethylene 153 terephthalate (PET) masks (ES301130, Goodfellow) to the desired dimensions using a CO2 154 laser cutter (Trotec, Speedy 360 flexx). After accurately sizing the silicone films, narrow strips 155 of silver ink (CreativeMaterials, 125-19(SP)A/B) are applied through PET masks. This 156 157 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 158 curing period of 16 hours at 80°C is necessary. Similarly, a layer of carbon ink is subsequently 159 deposited, and it requires a curing time of 4 hours at 80°C. At this juncture, the modules are 160 considered prepared. 161

162 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).
- 174
- 175 Experimental Setup

The experimental arrangement designed to assess the efficiency of the proposed impedance 176 pump is a closed-loop in vitro system. This setup consists of a Tygon tube interconnected with 177 the tubular DEA-based soft pump, utilizing aluminum components for connection. These 178 aluminum parts facilitate the integration of pressure sensors (PBMN-258 1 2R A21 44621 179 2000, provided by Baumer, Germany) at both ends of the pump. Additionally, the setup 180 incorporates a laser sensor (LK-G23/LK-G3001P, Keyence, Osaka, Japan) to measure the radial 181 deformation of the active DEA. Furthermore, a flow sensor (ME16PX, Transonic Systems Inc., 182 NY, USA) is installed externally around the Tygon tube to gauge the resulting net flow rate 183 184 generated by the tubular pump. Notably, this setup does not incorporate any type of valves. 185 The fluid used for the experimental testing is water with a density of 1000 kg/m3 and a 186 viscosity of 1 mPa-s.

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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.

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204 **Results and Discussion:**

To illustrate the effectiveness of the proposed concept, an innovative scenario is envisioned 205 to support the pumping function of a weakened or failing heart, particularly in individuals with 206 207 Failing Fontan. This scenario centers on the implementation of a cavopulmonary assist device 208 targeting the right side of the heart, providing a unique approach to enhancing cardiac 209 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 210 in Figure 1a. Thus, it is a more targeted approach for individuals who have previously 211 undergone or in need of a Fontan procedure. The Fontan procedure is typically performed on 212 213 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 214 pump designed to optimize circulatory efficiency (See Figure 1a). 215

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The custom-built DEA pump (see Figure 1b) is designed, fabricated, and subjected to testing 217 to emulate the operational parameters of a Fontan conduit (characterized by an internal 218 pressure range of 10 - 20 mmHg). As previously indicated, this pump consists of three primary 219 components: a tubular DEA (depicted in black in Figure 2a) measuring 50 mm in length, 30 220 221 mm in diameter, and possessing a thickness of 0.12 mm; a passive tube (shown as transparent 222 in Figure 2a) with the same dimensions of 50 mm length, 30 mm diameter, and a thickness of 223 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 224 minimizes additional system length. Each of the three elements plays a vital role in achieving 225 a unidirectional net flow. The active DEA functions as a pressure wave generator, the passive 226 tube acts as a pressure wave damper, and the rigid ring ensures each part adheres to its 227 designated function by decoupling their motions. This guarantees that the passive tube 228 responds exclusively to fluid movement. For instance, in the absence of or insufficient 229 decoupling, the sum of all incident and reflected pressure waves produced by the tubular DEA 230 231 equals zero, resulting in no flow.

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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.

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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

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240 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.
- 242

It's worth noting that even though this DEA pump functions through expansion rather than 243 compression and necessitates a decoupling element, it still exhibits behavior typical of an 244 245 impedance pump. Notably, it displays a resonance behavior, particularly pronounced at 4 Hz 246 (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 247 pump. The resonant frequency is precisely identified at 4.0 Hz, and the pump demonstrates 248 the capability to generate a substantial flow rate of 1.20 L/min (as shown in Figure 2b) when 249 250 operating under internal pressure and maximum voltage conditions of 15 mmHg and 5.5 kV, 251 respectively (refer to Figure 2c-d). Figure 4 displays a time series representing the working 252 principle of the DEA pump at the resonant frequency. Our DEA pump is purposefully designed to seamlessly integrate with the Fontan procedure, 253

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.

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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.

- 267
- 268 <u>Limitations</u>

The tubular DEA Pump exhibits remarkable capabilities in generating substantial flow rates 269 without the need for any valves; however, its limitations are evident. Despite its substantial 270 contributions, it falls short of being a full cardiac replacement, living up to the true meaning 271 of the name only as a heart assist device. Its size, especially the length, reaching up to 110 mm 272 and potentially longer with pre-stretching, poses challenges in terms of implantation. To pave 273 the way for its practical implementation, extensive efforts are required to enhance flow 274 output and minimize its dimensions. Additionally, a comprehensive exploration of its 275 performance within an in-vivo environment is imperative-considering variables such as 276 277 blood viscosity and lung resistance—to ensure optimal functionality. Despite these challenges, 278 this technology harbors immense potential for the next generation of heart assist devices, 279 characterized by their flexibility, lightweight nature, absence of valves and blades, pulsatile 280 operation, and energy efficiency.

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282 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

- 287 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
- 290 animal trials. As research and technological advancements continue, the proposed pumping
- 291 device holds the potential to redefine the landscape of cardiac care, offering new avenues of
- 292 hope and improved health for patients in need.
- 293
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- 297 foundation.
- 298 Conflict of interest statement: None.
- 299 Author contribution statement:
- 300 Figure:
- 301 <u>Central image:</u> Novel DEA-based pump as a substitute for the Fontan conduit and *in-vitro* achieved flow rate.
- 302 <u>Figure 1:</u> a) Illustration depicting the utilization of the DEA pump as a substitute for the Fontan conduit. b)
 303 Schematics outlining the working principle of the impedance pump in a closed-loop setup.
- 304 Figure 2: Experimental results at the resonant frequency (4 Hz) and under conditions of low internal pressure (15
- 305 mmHg), specifically for cavopulmonary assist device applications. a) Description of the experimental setup b)
- 306 reported mean filtered flow rate data generated from 5 experimental tests, c) the applied voltage signal, and d)
- 307 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.
- 310 <u>Figure 4:</u> 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.
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- 315 Tables:
- 316 <u>Table 1:</u> 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

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318 Data availability statement

- 319 Data are available from the corresponding author upon reasonable request.
- 320

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