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**DRAFT: DESIGN AND FABRICATION OF A SOFT ROBOTIC DIRECT CARDIAC
COMPRESSION DEVICE**

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ABSTRACT

A direct cardiac compression (DCC) device is an active sleeve that is surgically placed around the heart to help the failing heart to pump without contacting blood. Soft robotic techniques enable fabrication of a conformable DCC device containing modular actuators oriented in a biomimetic manner that can restore the natural motion of the heart and provide tunable active assistance. In this paper we describe the fabrication of a DCC device; the optimization of pneumatic actuators, their integration into a matrix with a modulus in the range of cardiac tissue and methods to affix this device to the

heart wall. Pneumatic air muscles (PAMs) were fabricated using a modified McKibben technique and four types of internal bladders; low durometer silicone tubes molded in-house, polyester terephthalate (PET) heat shrink tubing, nylon medical balloons and thermoplastic urethane (TPU) balloons thermally formed in-house. Balloons were bonded to air supply lines, placed inside a braided nylon mesh with a 6.35mm resting diameter and bonded at one end. When pressurized to 145kPa silicone tubes failed and PET, nylon and TPU actuators generated isometric axial forces of 14.28, 19.65 and 19.05N respectively, with axial contractions of 33.11, 28.69 and 37.54%. Circumferential actuators placed around the heart

reduced the cross-sectional area by 33.34% and 50.63% for silicone and TPU actuators respectively. PAMs were integrated into a soft matrix in a biomimetic orientation using three techniques; casting, thermal forming and silicone lamination. Different designs were compared on an *in vitro* cardiac simulator. The optimal design (silicone laminate with TPU actuators) could eject 92ml of saline per cycle when actuated for 200ms at 1Hz. This design also produced the lowest profile device that successfully conformed to the heart *ex vivo* and this design is currently undergoing *in vivo* testing.

INTRODUCTION

Direct cardiac compression (DCC) is a treatment for end-stage heart failure. Unlike other treatment options, DCC does not require contact with the patient's circulating blood. This is advantageous because blood-contacting devices are associated with thromboembolic events, hemolysis, immune reactions and infections [1]. A number of actuation strategies for DCC have been implemented [2–9]. These actuation strategies include inflatable bladders [3–8], ionic polymer metal composites [2] and covalent shape-memory alloy fibers [8] and linear ultrasonic motors [9]. This paper discusses the application of soft robotics and fluidic actuators to direct cardiac compression. To mimic the natural pumping of a heart requires complex motions of multiple loading conditions. These actuators can achieve the speed and force required to actuate the heart in a conformable sleeve with materials whose mechanical properties are close to that of the heart tissue.

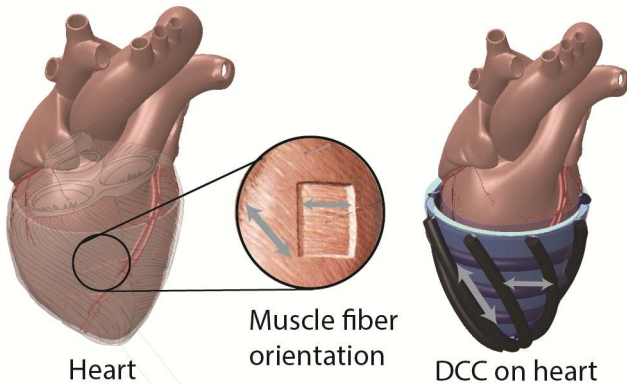


FIGURE 1: THE MUSCLE ORIENTATION IN THE OUTER TWO LAYERS OF THE HEART INSPIRES THE PAM ARCHITECTURE OF THE DCC DEVICE.

The research goal of this paper is to experimentally identify the optimal design parameters, materials and fabrication methods for (i) independent actuators and (ii) an integrating sleeve to apply direct cardiac compression to the heart. We describe the application of soft robotic techniques (casting, thermoforming, heat sealing and selective welding) to fabrication of individual actuators and an integration matrix that can be wrapped around the heart and orients actuators in a

biomimetic manner. We characterize the individual actuators and compare their performance in terms of axial force, circumferential force and shortening ratios. We then compare different fabrication methods for the integration matrix in terms of dynamic volumetric displacement on an *in vitro* cardiac simulator.

We chose to use pneumatic artificial muscles (PAMs) for our DCC device. Broadly, this class of actuators contract when pressurized with fluid. The most widely used PAM is the McKibben PAM [10] that is currently used in robotics, orthotics, and industrial automation [11]. McKibben PAMs have not been used to actuate DCC devices to date, and may provide an atraumatic actuation strategy because they are self-limiting and have load-length curves similar to human muscle [12,13]. These actuators consist of an internal inflatable bladder enclosed in a textile mesh or braid. The mesh contracts axially when the bladder expands it radially, acting in a manner similar to a scissor linkage. In traditional McKibben PAMs the bladder and mesh are crimped together at both ends to allow mechanical coupling to a load, but here we suggest decoupling one end of the braid from the bladder, allowing maximum contraction of the PAM. We investigate four types of internal bladder for PAM construction for this application; silicone elastomer, polyester terephthalate (PET) tubes, nylon balloons and thermoplastic urethane balloons. For consistency we use the same braided mesh for fabrication of each

For an integration matrix we chose three fabrication techniques; casting of the actuators in the desired configuration in a multi-step 3D molding process, thermoforming the matrix into a 3D shape thermoplastic urethane, and a layering process where thin silicone layers and a 3D printed mold were employed to apply pressure during curing for selective “welding” of silicone layers between actuators.

Design Requirements for PAMs

The following section outlines the design requirements for the independent actuators. Our goal was to design actuators that operate at low threshold pressure and generate contractions and forces within the range of cardiac compression devices [14,15]. The force requirements of the actuators can be estimated using a simple model of a DCC device around the bottom chambers of a heart (assumed to be hemispherical and spherical respectively). If the device and the heart are in equilibrium, the tension, T , required to apply the pressure P_{assist} to the heart is

$$T = \frac{P_{assist} \cdot A_x}{2}, \quad 1)$$

where A_x is the projected cross-sectional area of the device. An assistance pressure of 2.7kPa applied using a DCC device has

been shown to significantly increase the ejection fraction of failing hearts in live sheep [15]. Using equation 1, this corresponds to a tension of 10N, assuming a typical transverse heart diameter in adult males (13cm)[16]. This first order estimate suggests that a tension roughly in the range of 10N is suitable for augmenting pumping function in the heart using a DCC device. Required contraction can be estimated using the measure of cardiac function called fractional shortening (FS). FS is a measure of the percent change in the length of a cardiac dimension between diastole (expansion) and systole (contraction). In cases of left ventricular dysfunction, FS is less than or equal to 25% [17]. The design requirements for the actuators are therefore (i) generation of greater than 10N tensile force (ii) contraction of greater than 25% and (iii) ability to be integrated into a matrix or sleeve that surrounds the heart and conforms to the irregular surfaces of the moving heart.

Design Requirements for Sleeve

To mimic the natural pumping of a heart requires complex motions of multiple loading conditions. The sleeve should act as an integration matrix for the PAMs, acting as a scaffold to maintain the actuators in the required orientation. It should conform intimately to the curvilinear surface of the heart so that it moves with the heart and the device and it should not restrict the functioning of the device.

FABRICATION OF PNEUMATIC ARTIFICIAL MUSCLES

PAMs with silicone bladders

The fabrication procedure for the PAMs consisted of molding silicone tubing, preparing a mesh, bonding the mesh to the tubing, and then sealing the ends. Elastomeric tubing was molded in house using a low stiffness elastomer (Ecoflex 00-30, Smooth-on, Inc.). To create the tubing, a mold was designed and 3D printed (Fig 3a,b) and the mixed prepolymer was injected into the mold (Fig 3c) and degassed in a vacuum chamber at 10kPa absolute vacuum for 10 minutes. Afterwards, the elastomer was cured for 1 hour in a pressure chamber heated to 60°C. A minimum outer diameter of 8mm and wall thickness of 2mm was chosen because molds for narrower tubing were difficult to fill using gravity alone. Before being molded over the elastomeric tubing, the mesh was locally modified to resist expansion at its ends and to prevent fraying. This was achieved by locally heating the mesh (expandable sleeving, Techflex, Inc.) and increasing the braid angle. The mesh was placed over a steel rod for support and the region of the tube that was not being modified was covered with heat shrink to maintain the orientation of the fibers underneath. The end of the mesh sleeve was held to the rod with a ring of heat shrink tubing to prevent fraying when the ends were heated and compressed. The exposed mesh sleeve was compressed by sliding the two heat shrink protected areas together. When the exposed mesh was compressed, it bulged to a larger diameter, but collapsed back to the diameter of the rod when heated. After the new configuration was achieved, the fibers were allowed to cool to lock the new shape into place. Once the

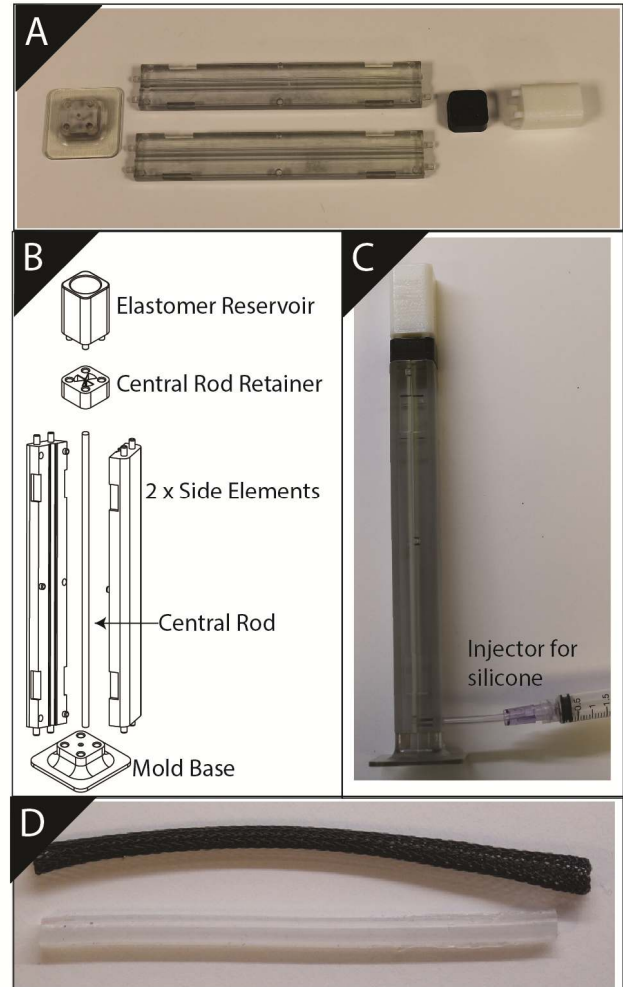


FIGURE 3: FABRICATION OF PAMs WITH SILICONE BLADDERS. A) 3D PRINTED MOLD B) DESCRIPTION OF MOLD PARTS C) ELASTOMER BEING INJECTED INTO THE MOLD C) MOLDED SILICONE TUBE AND BRAIDED MESH WITH LOCALLY MODIFIED ENDS. mesh was prepared, it was bonded to the outer wall of the elastomeric tube with another layer of elastomer. This was done by putting the mesh over the tube (Fig 4d) and dipping both into a reservoir of mixed prepolymer, then blowing with hot air while rotating to evenly spread and cure the elastomer. Finally, an air supply line was inserted into one end of the actuator and silpoxy was placed around the airline to seal it in place. The opposite end was also sealed with Silpoxy silicone adhesive (Smooth-on Inc, USA).

PAMs with TPU bladders

TPU balloons were manufactured using a thermoformer (EZform SY1217, Centroform, USA) and a heat transfer machine (Model QX A1, Printing and heat transfer Machinery Corp, USA). Negative balloon half molds were 3D printed in vero material (Objet Connex 500, USA). Balloons were designed to be 80mm in length (or scaled appropriately depending on location in the DCC device) with an expanded diameter of 16mm, a shoulder of 45° and a neck inner diameter

of 3.2mm. Positive balloon halves were then molded with Dragon Skin F/X Pro (Smooth-on Inc.USA) using these molds.

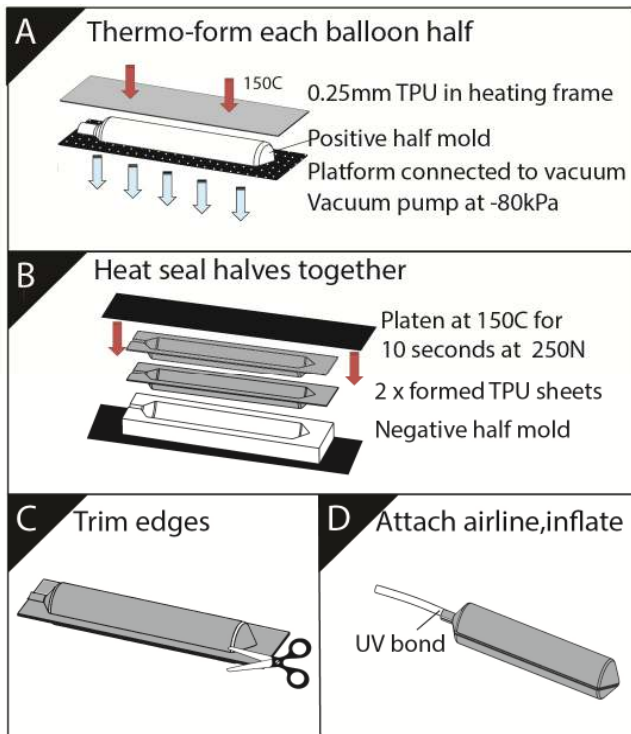


FIGURE 4: FORMING OF TPU BALLOONS. A) THERMOFORMING WAS DONE ON A THERMOFORMER AT 150°C WITH -80KPA VACUUM AND 250N FORCE. B) TWO FORMED BALLOON HALVES WERE SEALED TOGETHER USING A HEAT PRESS. C) EDGES WERE MANUALLY TRIMMED. D) AIRLINE WAS UV BONDED TO BALLOON NECK AND BALLOON WAS INFLATED

Positive molds were placed on the vacuum platform of the heat former and a sheet of 0.25mm TPU (Advanced Polymers Inc.) was placed in the upper heating frame of the and heated for 5 minutes at 150°C, until the sheet sagged in the centre of the heating frame, identifying that it was sufficiently heated for thermal forming (Fig 4a). Once heated the two vacuum pumps connected to the vacuum platform (one for high volume and one for high vacuum) were turned on, and the frame was carefully but quickly lowered onto the platform, causing the heated TPU to be formed around the positive molds. The sheet was allowed to cool under vacuum (15 seconds) and removed from the platform. Multiple balloon halves were fabricated from each sheet. The formed balloon halves were then trimmed so that less than 1cm of TPU remained around the edges of the formed shape. Two formed balloon halves were placed in the negative mold and placed on the base of the heat press (Fig 4b). A sheet of PTFE coated fabric was placed on top of the mold to avoid melting of the TPU onto the heated platen. The two halves were sealed together using a temperature of 150°C and clamping for 10 seconds. This process selectively applies pressure to the edges of the balloons, and avoids the balloon body, causing just the edges of the balloons to seal together. The edges of the balloon were then trimmed (Fig 4c). An airline

(1/8 inch OD pneumatic line, SMC corporation) was bonded to the balloon neck using Loctite 3943 and UV cured for 60 seconds (Fig 4d). Braided mesh was cut to 115mm length, heat formed at each end (one end was closed with application of direct heat to a forming tool and the other cut with a hot knife, then placed over the bladder and bonded with the same UV adhesive at the airline/balloon neck interface.

PAMs with nylon and PET bladders

Nylon medical balloons and PTFE heat shrink were purchased (Vention medical, USA). One end of each was heat sealed with a manual impulse sealer so that the balloon length was 80mm. For the medical balloons airline (1/8 inch OD pneumatic line, SMC corporation, USA) was bonded into the neck using Loctite 3943 UV-curable adhesive. The PTFE heat shrink was shrunk over a mandrel to its smallest diameter then placed around an airline, twisted around the airline to lessen the neck/airline gap and bonded with the same adhesive.

FABRICATION OF INTEGRATION MATRIX

Casting of silicone sleeve

A silicone sleeve was cast to embed oriented actuators in a cup shape using a multi-component reconfigurable 3-D printed mold (Fig 5a). Different cores were printed with channels to accommodate actuators, and liners provided adjustability in terms of size of the cast sleeve. Sleeves with different actuator configurations were cast separately, and could be joined together afterwards. Before casting, airlines were removed from the PAMs and ends were plugged with clay during casting. The flexibility of the elastomer allowed airlines to be re-inserted and bonded after casting. Fig 5b shows the actuator arrangement for circumferentially placed PAMs. Here a liner in the mold is used to keep actuators in place before molding. Fig 5c shows the helical actuator arrangement and an elastic mesh (SurgiPro, bandages.com) was used to keep actuators in place while casting. Once the actuators were aligned in the mold, the mold was assembled degassed in a vacuum chamber at 10kPa absolute vacuum for 10 minutes, then cured in a pressure oven at 350kPa heated to 60°C.

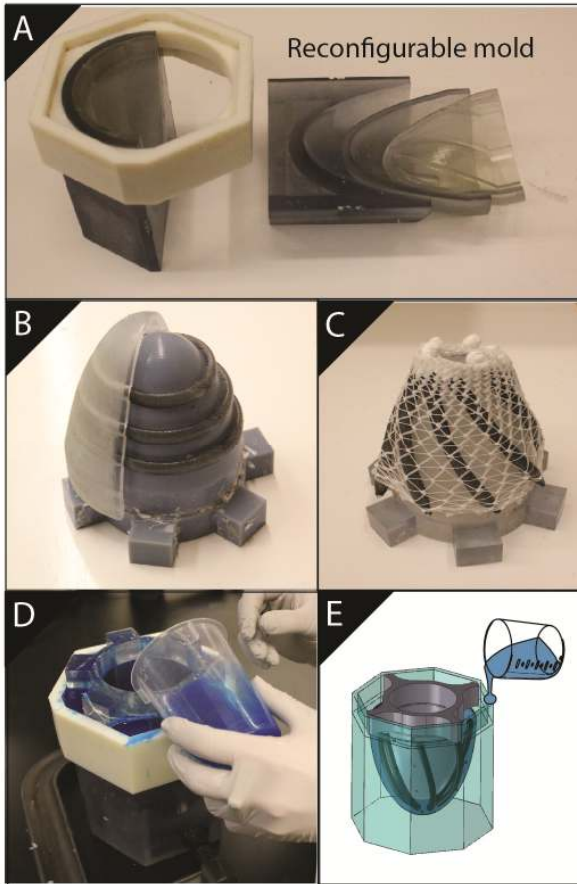


FIGURE 5: CASTING OF SILICONE SLEEVE. A) A RECONFIGURABLE MOLD WAS DESIGNED AND 3D PRINTED TO ALLOW MULTIPLE SLEEVE FORMATIONS WITH ADJUSTABLE SIZE AND ACTUATOR ARCHITECTURE WITH THE SAME MOLD. B,C) CIRCUMFERENTIAL AND HELICAL ACTUATORS PLACED ON CORE (A MESH WAS USED TO KEEP HELICAL ACTUATORS IN PLACE WHILE CASTING). D,E) POURING OF SILICONE ELASTOMER INTO THE MOLD/ACTUATOR ASSEMBLY.

Thermoforming of TPU sleeve

A TPU sleeve was thermoformed using the thermal forming process previously described for the TPU balloon manufacture. Here, a positive core was 3D printed (vero blue, Objet Connex 500). A 0.25mm sheet of TPU (sheet 1) was heated to 150°C and vacuum formed on to the core (Fig 6a,b). The sleeve was selectively masked with laser-cut PTFE adhesive tape (Saint-Gobin, Norton films, USA) in the areas where channels for the actuators were desired (Fig 6c). A second layer of TPU (sheet 2) was then formed onto this assembly so it was thermally fused with sheet 1 everywhere but in the masked areas. This process was repeated for additional channels (Fig 6c). PAMS were then tunneled into these channels.

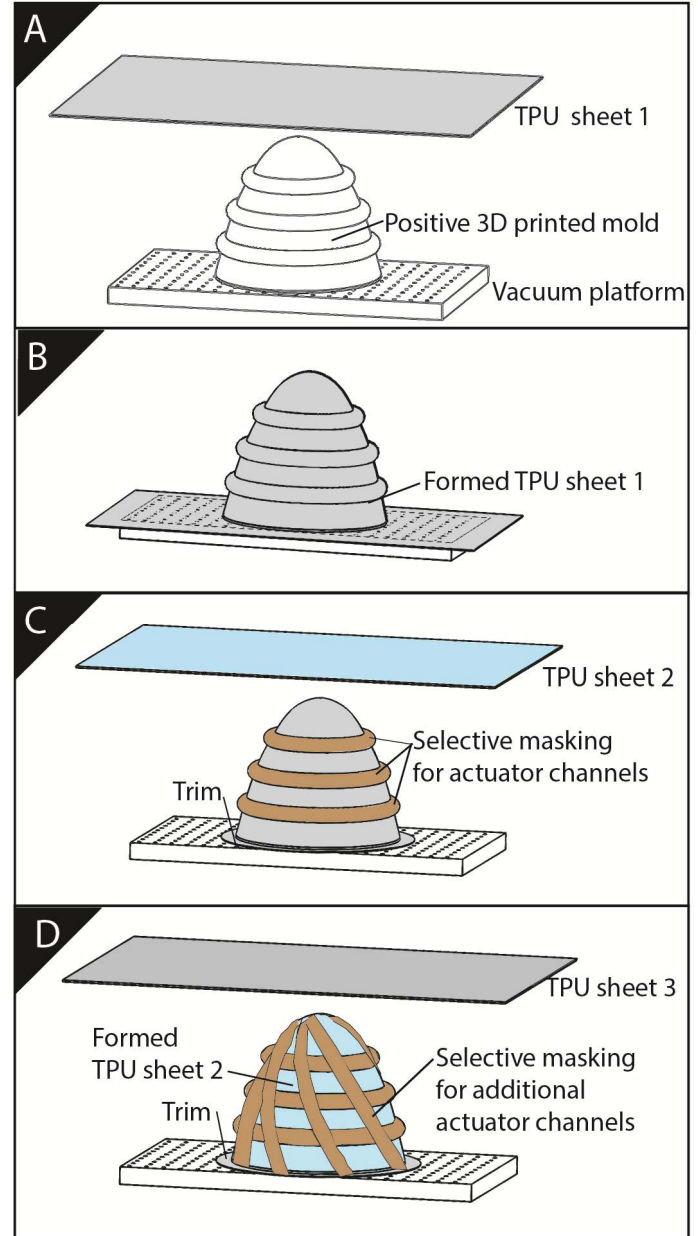


FIGURE 6: THERMOFORMING OF SLEEVE. A) POSITIVE MOLD ON THE VACUUM PLATFORM OF THE THERMOFORMER WITH TPU SHEET HEATED TO 150. B) FORMING OF FIRST TPU LAYER. C) ACTUATOR CHANNELS WERE CREATED BY MASKING SELECTED AREAS OF THE TPU BEFORE THE SECOND LAYER WAS THERMALLY FORMED ON TOP OF THE FIRST. D) ADDITIONAL ACTUATOR CHANNELS WERE MASKED AND A THIRD TPU SHEET WAS FORMED ON TOP.

Layering and selective bonding of silicone laminate sleeve

The final fabrication method for the integration matrix or sleeve was a 2D process involving layering of 250um silicone sheets between actuator layers, and sandwiching them together in a custom designed mold before fully curing so that the layers are selectively bonded in between the PAMs. A flat mold was 3D with the flat pattern of the desired sleeve, and channels

where the actuators are desired (Fig 7a). A 250 μ m layer of silicone (Dragon skin F/X Pro, Smooth-on Inc.) was fabricated using an automatic film applicator (Elcometer, USA) with a modified acrylic platform to enable larger sheet formation. The first layer of silicone (fully cured) was placed on the mold base (Fig 7a), then the first layer of actuators was placed in the corresponding grooves in the mold (Fig 7b). The second layer of silicone was fabricated to a thickness of 200 μ m, allowed to cure, then a 50 μ m layer of uncured prepolymer was coated on top using the automatic film applicator. This was placed, uncured polymer facing down on top of the first layer of actuators (Fig 7c). The second layer of actuators was then arranged on top of this layer and a third layer of silicone with a coating of uncured prepolymer (fabricated as described for layer 2) was placed on top of this assembly. The mold top was placed on this layer and the assembly was clamped and placed in the oven at 60°C. The process allowed selective welding between the silicone layers at the points that were compressed together by the mold in between the actuators. The 2D formation meant that the sleeve was adjustable on the heart, accommodating for different heart sizes and anatomies.

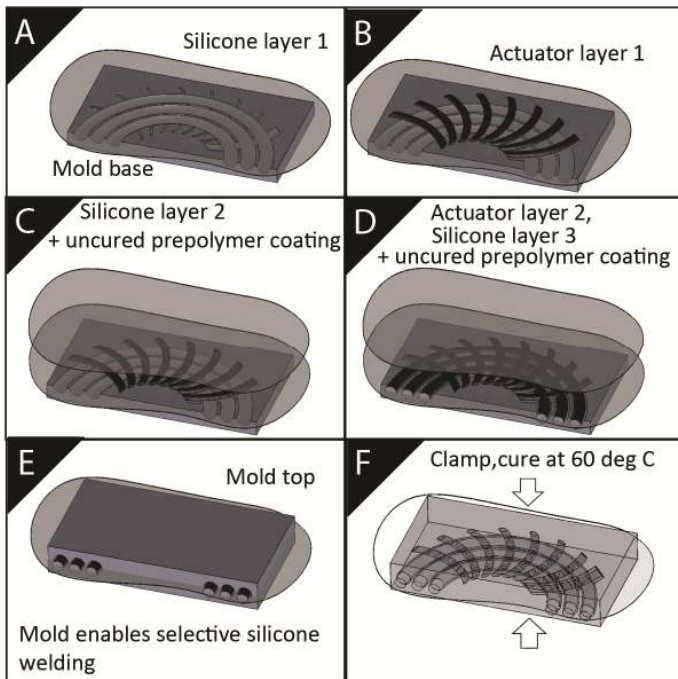


FIGURE 7: SILICONE LAYERING PROCESS. A) LAYER 1 IS PLACED ON MOLD. B) FIRST LAYER OF ACTUATORS ARE PLACED IN CORRESPONDING GROOVES. C) LAYER 2 OF SILICONE (COATED WITH UNCURED PREPOLYMER) IS PLACED ON TOP OF THE ASSEMBLY. D) THIS IS REPEATED FOR THE SECOND LAYER OF ACTUATORS E) THE TOP OF THE MOLD IS POSITIONED AND F) ASSEMBLY IS CLAMPED AND CURED AT 60°C FOR 1 HOUR.

EXPERIMENTAL CHARACTERIZATION

Axial Contraction

Axial contraction of each type of PAM (silicone, PET, Nylon and TPU) was measured by dynamically actuating each at 1Hz for 200ms and 400ms actuation (to represent different clinical scenarios) at a pressure of 80kPa and 145kPa, using a custom designed control box and Labview interface (National instruments). The airline end of the actuators was fixed to a bench using tape, and the actuation was recorded for ten cycles at 60fps. The video was then used to find the point of maximum contraction and this was measured using ImageJ software (NIH) calibrated using a ruler in the video. Percentage contraction was calculated for each set of actuators (n=10).

Circumferential force generation

Force generation was measured using a mechanical tensile tester (Instron 5566, Instron, USA). Custom designed clamshell fixtures with grooves for actuators in diameters corresponding to cross-sections of a 70kg porcine heart were designed and 3D printed (Objet Connex 500). The fixtures were mounted in the upper and lower clamps of the tensile tester and adjusted so that they were just touching (Fig 8). Two connected PAMs were placed around the appropriate sections of the fixtures in turn and connected together (Fig 8). Force was recorded while dynamically actuating each at 1Hz for 200ms actuation (similar to clinical scenario) at a pressure of 80kPa and 145kPa, using a custom designed control box and Labview interface (National instruments). Peak forces were detected and averaged for each PAM (n=10) at each actuation pressure.

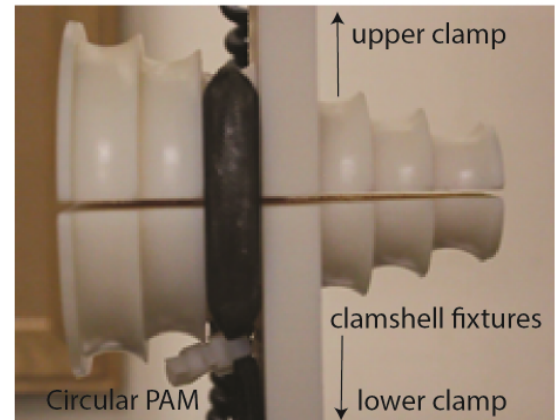


FIGURE 8: FORCE MEASUREMENT SET-UP IN MECHANICAL TENSILE TESTER

Circumferential compression

The diameter of slices of a porcine heart at the apex, middle and base were measured (Fig 9a) to be 5.7cm, 7.4cm and 8.2cm respectively, and molds were 3D printed for discs in each of these diameters (Fig 9b). Discs were molded in ecoflex 00-30 silicone as it has a modulus in the range of that of heart heart muscle [18]. 2 PAMs connected to each other in a circle (as the circumferential PAMs are oriented on the DCC device) were placed around each disc, fixed together at the free end

and then actuated at 1Hz for a 200ms period of actuation at a pressure of 80kPa and 145kPa (Fig 9c). The actuation was video recorded at 60 frames per second. The videos were analyzed for the maximum disc compression. Frames corresponding to zero and maximum compression were exported to Image J (NIH) and a thresholding operation was used to identify the disc (color threshold tool, HSB color space) (Fig 9d). The area of the disc in pixels was calculated using the particles analysis tool for connected areas (circularity 0-1, threshold on pixel size of 5000 pixels). The change in area pixels of the disc on compression was calculated.

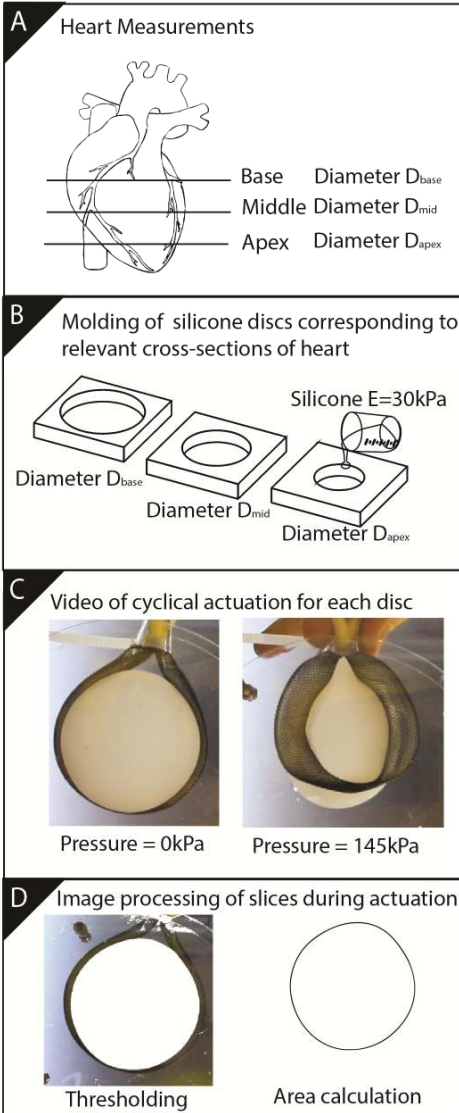


FIGURE 9: TEST METHOD FOR COMPRESSION TEST. A) DIAMETER OF A PORCINE HEART WAS MEASURED AT SLICES CORRESPONDING TO POSITION OF PAMS IN DCC DEVICE B) MOLDS WERE 3-D PRINTED AND DISCS WERE CAST AT EACH DIAMETER IN SILICONE. C) 2 PAMS IN A RING CONFIGURATION WERE PLACED AROUND THE DISC AND ACTUATED WHILE BEING RECORDED. D) AREA OF UNCOMPRESSED AND COMPRESSED DISC WAS MEASURED IN IMAGE J USING THRESHOLDING.

Comparison of sleeves on cardiac simulator

To compare the sleeves (cast silicone, TPU and a silicone laminate) each was integrated with silicone PAMs and tested on a cardiac simulator [18]. The simulator set-up was instrumented to allow intraventricular pressure monitoring (Surgivet, Smith Medical) and flow recording from the outflow tract (Transonics flow probe). Each of the sleeves was placed on the simulator (Fig 10), fixed in place with wire or a band at the top of the sleeve, and actuated at 1Hz for 200ms actuation (similar to clinical scenario) at a pressure of 80kPa (silicone actuators) and 145kPa (TPU actuators). The ventricle was filled with saline solution and dyed for visualization of output from the device. In addition to comparing designs for volumetric output. Two comparisons were carried out - PAM layers (circumferential vs twisting) were evaluated independently for the cast silicone and TPU sleeve designs in terms of pressure and flow rate (Figure 10, silicone actuators used for all designs)

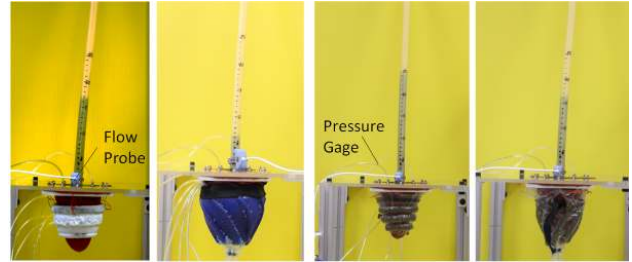


FIGURE 10: TEST-RIG SET-UP FOR PERFORMANCE TESTING OF CAST SILICONE VS TPU SLEEVE DESIGN (FOR CIRCUMFERENTIAL AND TWISTING DESIGNS).

The cast silicone sleeve (with silicone actuators) was compared to the silicone laminate sleeve (with silicone or TPU actuators). The silicone laminate sleeve could be turned “inside out” so that twisting actuators were on the inside. Circumferential actuators were on the outside. This test set-up is shown in Figure 11.

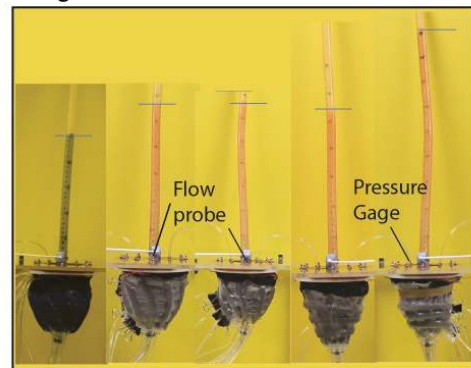


FIGURE 11: TEST-RIG SET-UP FOR PERFORMANCE OF INTEGRATED SLEEVE WITH ACTUATORS FOR DIFFERENT DESIGNS (CAST SILICONE AND SILICONE LAMINATE ARE SHOWN HERE WITH SILICONE OR TPU ACTUATORS). THE SILICONE LAMINATE COULD BE RECONFIGURED SO THAT EITHER THE CIRCUMFERENTIAL OR TWISTING LAYER WAS ON THE OUTSIDE.

RESULTS

Axial contraction

For an inflation pressure of 80kPa, TPU actuators contracted most (34.9%) at 400ms. Contraction of all actuators, with the exception of silicone was higher at 400ms, indicating that they weren't completely inflated at 200ms.

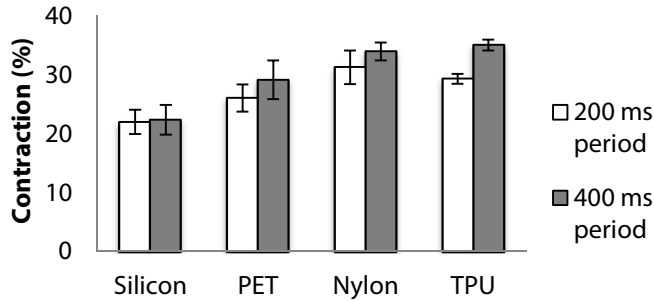


FIGURE 11: PERCENTAGE CONTRACTION AT 80KPA

At 145kPa the silicone PAMs failed. As expected, contraction was higher than PAMs actuated at 80kPa.

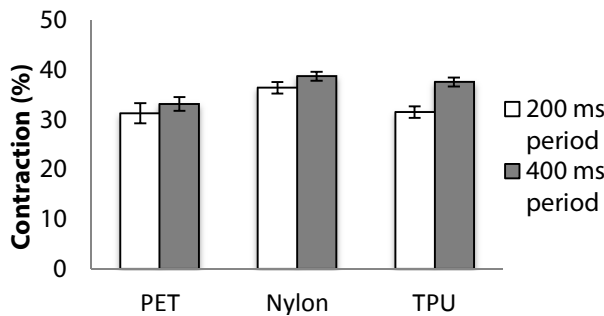


FIGURE 12: PERCENTAGE CONTRACTION AT 80KPA

Circumferential force generation

The force measured on the circumferential test set up was highest for silicone PAMs at 80kPa, but was higher for each PAM at 145kPa (the silicone PAM failed at this pressure). Nylon and TPU PAMs generated the highest force at approximately 19N each,

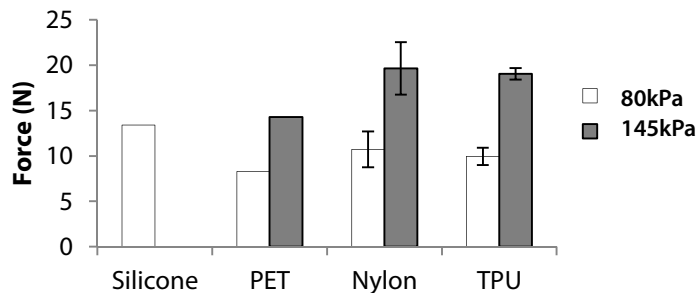


FIGURE 13: FORCE GENERATED BY CIRCUMFERENTIAL ACTUATORS AT 80KPA AND 145KPA.

Circumferential compression

The percentage area reduction resulting from circumferential compression is shown below in terms of cross sectional area. TPU PAMs pressurized to 145kPa result in the highest compression for each disc size, and therefore the highest volume of blood displacement from the heart at each section.

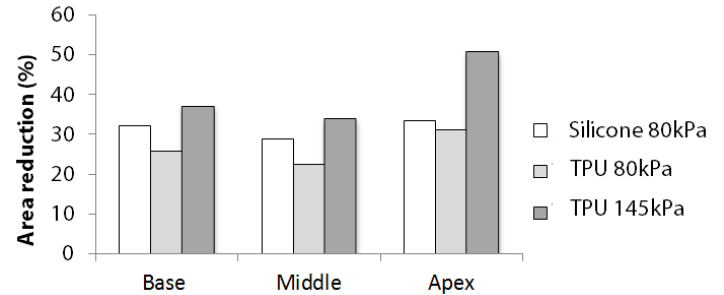


FIGURE 14: PERCENTAGE AREA REDUCTION OF A SILICONE

Performance of sleeves on cardiac simulator

Preliminary data compared the cast silicone design to the TPU design. When we actuated the circumferential PAM layer alone it generated a pressure of 5mmHg (Fig 16) in the ventricle for the cast silicone sleeve compared to a 10mmHg pressure increase in the ventricle for the TPU sleeve (Fig 17). The second peak in Figures 16-18 is likely due to elastic recoil of the simulator.

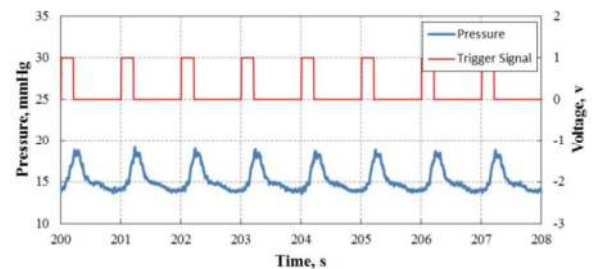


FIGURE 15: INTERVENTRICULAR PRESSURE FOR CAST SILICONE SLEEVE

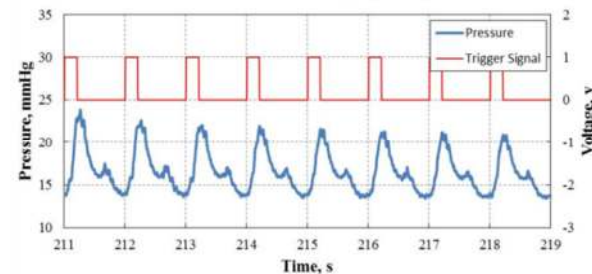


FIGURE 7: INTERVENTRICULAR PRESSURE FOR TPU SLEEVE

We also compared cast silicone and TPU sleeves when actuating PAM configurations independently. The flow rate

from the TPU sleeve was better than the silicone sleeve for both circumferential and twisting actuators (Fig 18).

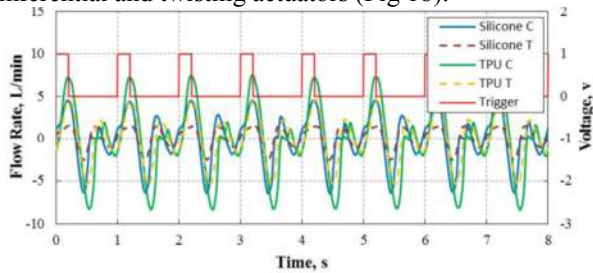


FIGURE 8: FLOW RATE FOR SILICONE AND TPU SLEEVES, WHERE C IS CIRCUMFERENTIAL AND T IS TWISTING PAM LAYERS.

Similarly, in terms of pressure the TPU sleeve had superior pressure increases for cycle than the cast silicone for both circumferential and twisting PAM layers (Fig 19).

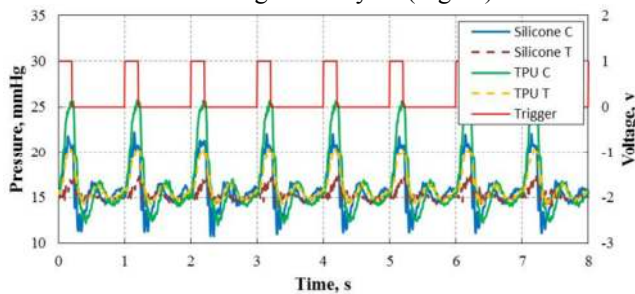


FIGURE 9: FLOW RATE FOR SILICONE AND TPU SLEEVES, WHERE C IS CIRCUMFERENTIAL AND T IS TWISTING PAM LAYERS.

We compared sleeve designs on the cardiac simulator test set up. First we compared the TPU sleeve to the cast silicone sleeve, using silicone actuators, and actuating layers independently. The TPU sleeve gave a superior volume displacement for both circumferential (46 vs 28ml) and twisting (26 vs 16ml) actuation modes (Figure 20).

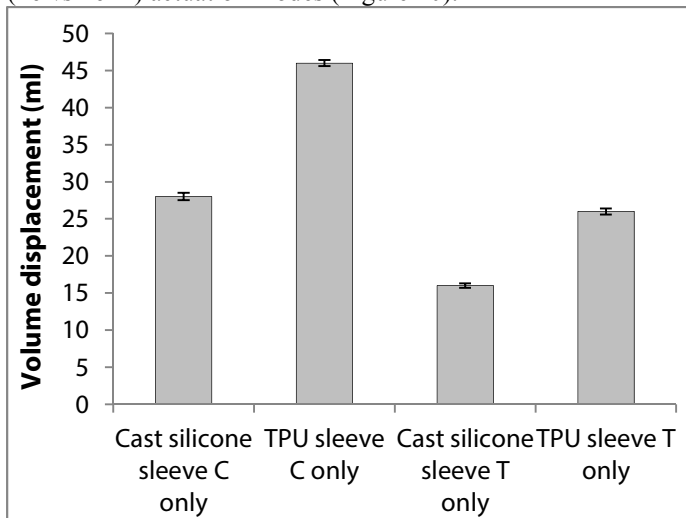


FIGURE 20: VOLUME OUTPUT FROM A CARDIAC SIMULATOR FOR DIFFERENT SLEEVE/ACTUATOR COMBINATIONS AND CONFIGURATIONS

We also compared different actuator/sleeve combinations (cast silicone and silicone laminate with silicone and TPU actuators). All actuators were active in this comparison. Using the same actuators, the silicone laminate showed superior volume displacement to the cast silicone (60ml vs 50ml). The silicone laminate sleeve allowed the sleeve to be reversed so that the helically oriented PAMs were on the inside, and produced volume displacements of 56ml with silicone actuators and 92ml with TPU actuators (Fig 21).

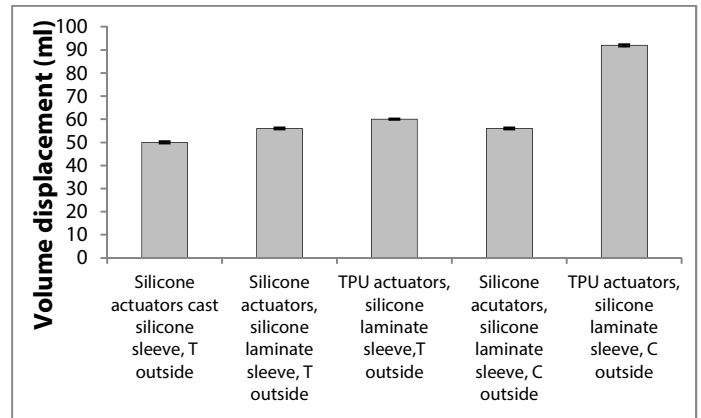


FIGURE 21: VOLUME OUTPUT FROM A CARDIAC SIMULATOR FOR DIFFERENT SLEEVE/ACTUATOR COMBINATIONS AND CONFIGURATIONS

Finally, each sleeve was placed on an ex vivo 70kg porcine heart in the ARCH facility in Boston Children's hospital. The chest was opened using a sternotomy and each device was placed on the heart and assessed by collaborating surgeons for conformability to the external surface of the heart while being actuated (Fig 21c). We observed qualitatively that the thin silicone sleeve (Fig 21c) had the most intimate contact with the heart wall.

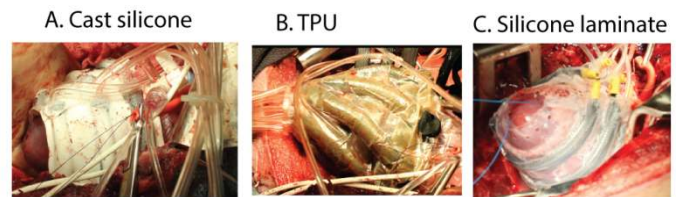


FIGURE 22: EACH HEART SLEEVE DESIGN ON AN EX VIVO PORCINE HEART. A) CAST SILICONE B) TPU C) SILICONE LAMINATE.

CONCLUSION

We demonstrate four different fabrications for modified McKibben PAMs using different internal bladder materials. These PAMs have the ability to deliver suitable forces (up to 19N circumferential compression) and contractions (up to 37%) for direct cardiac compression. The actuators developed here also have threshold pressures significantly lower than traditional McKibben PAMs [10] which enables successful

operation in a pressure range similar to existing direct cardiac compression devices. The PAM manufactured with a TPU internal bladder was capable of the highest force generation, and has been selected as the actuator for ongoing DCC device development.

We also demonstrate three fabrication methods for conformal sleeves for actuator integration. We use a silicone casting method, a thermal forming method and a selective silicone bonding technique. These methods take advantage of the advancements in soft robotic manufacturing techniques, and can successfully produce conformable actuated structures that can interact safely and intimately with complex soft tissue structures such as the heart.

The silicone laminate sleeve manufactured by the selective bonding technique combined with TPU actuators showed superior performance giving a volumetric output of 92ml per cycle (an adult heart typically outputs 70ml per cycle). If a DCC device can increase the output of a failing heart by this amount, it could restore healthy functioning. In the ex vivo setting, the TPU also conformed to the heart more than the other two sleeve designs. This design will be used for future in vivo testing with the device.

Previous devices in this space used simple inflatable bladders to invert the normal curvature of the heart [1-9]. These devices did not move with the heart or have potential to assist diastolic function. As illustrated here, the benefits of using soft robotic techniques for direct cardiac compression are that (i) a sleeve that fully conforms to the anatomy of the heart can be fabricated. (ii) multiple actuators can be embedded or oriented in a sleeve to achieve complex three-dimensional motion that can mimic the architecture and motion of heart muscle (iii) precise timing of individual actuators relative to the native heartbeat and to other actuators can be finetuned to optimize cardiac output and (iv) as the actuators can extend with vacuum, the device has potential to augment diastolic function as well as systolic function.

In summary, we have fabricated, characterized and optimized actuators and a conformable sleeve for the specific application of a cardiac assist device, which is undergoing in vivo testing. In a broader sense we have developed fabrication methods that have a vast range of application in the soft and medical robotics field. The techniques described here could be applied to a vast range of medical applications including external devices for compression therapy for lymphedema, or as implantable artificial urethral sphincters

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