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Approach of soft robotics applied to heart failure: demonstration of the McKibben actuator in a simulation of cardiac movements and investigation into the manufacture of protective components

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Abstract. Numerous diseases are associated with the malfunction of the heart, with heart failure being one of them, affecting many individuals and often proving to be fatal. Among the current solutions and treatments for this issue, ongoing research and trials are investigating the application of soft robotics—an innovative technological approach within the field of robotics involving robots with soft components and gentle touches. These robots can perform delicate operations and interact with humans, thereby assisting the field of medicine with diverse applications. This study aimed to examine and analyze the functionality of this technology through a literature review, coupled with the development of a simple prototype incorporating McKibben muscles—an extensively used actuator within this domain—consolidating a portion of the gathered information. Additionally, this work focused on analyzing and selecting suitable materials for safeguarding soft robotics equipment used in bioengineering, with a specific emphasis on applications related to cardiac issues.

Keywords. *Bioengineering; Soft Robotics; McKibben Muscle; Robotics; Heart Failure.*

Introduction. According to data provided by the World Health Organization (WHO), cardiovascular diseases, particularly heart diseases, stand as the foremost cause of mortality globally. The spectrum of these diseases, inclusive of congenital heart conditions identifiable in early life, manifests diverse trajectories, with some evolving over time without immediate symptomatic manifestation. In the year 2019, Global Burden of Disease estimates disclosed that heart-related issues claimed the lives of 9 million individuals worldwide (1).

Heart failure, characterized by the heart's inability to pump blood efficiently, emerges as a chronic condition entailing debilitating symptoms necessitating specialized medical intervention and, in severe instances, culminating in fatality. A study conducted by Malta et al. (2) revealed that approximately 359,000 deaths in Brazil were attributed to cardiovascular diseases.

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Contemporary treatments for heart failure span pharmaceutical interventions, surgical procedures, utilization of prosthetics/devices, and organ transplants. However, challenges such as limited medical access, financial constraints, and resource scarcity persist, perpetuating the suffering of many individuals. In this context, Ventricular Assist Devices (VADs) are pivotal in supporting cardiac functions. Research suggests that circulatory mechanical assistance devices can permanently or temporarily stabilize heart function, particularly relevant for patients awaiting transplant procedures (3).

Despite the advancements in VAD technology, notable complications arise from using hard materials in their manufacture, termed Hard Robotics. These complications encompass risks such as bleeding, infections, and the necessity for intervention surgeries. Technological evolution has spurred potential solutions to this issue with the emergence of Soft Robotics—a subfield dedicated to constructing robots and devices using flexible materials, in contrast to the rigid materials employed in Hard Robotics (4).

Soft Robotics draws inspiration from nature, mimicking organic movements observed in the animal kingdom. Incorporating soft materials in VADs holds promise in mitigating risks associated with rugged materials, potentially enabling more natural and smooth cardiac support. Soft robotics technology employs flexible components, often imitating movements observed in animals like octopus tentacles. When injected with fluid (pneumatic or hydraulic), these components stiffen, facilitating gentle and natural activities.

The relevance of soft robotics in areas demanding robots with delicate interactions is well-established. The technology's flexibility enables nuanced movements, often achieved through specialized actuators like McKibben muscles—artificial pneumatic muscles designed for flexible linear contraction mechanisms operated by gas or hydraulic pressure. Initially developed for medical applications, these muscles present attributes of flexibility, lightness, and strength (5).

This investigation delves into the prospective application of soft robotics technology as a therapeutic modality for addressing heart failure, particularly emphasizing a minimally invasive approach. The study assesses the viability of employing a glove equipped with McKibben actuators to offer mechanical support to a heart afflicted by heart failure, providing a conceptual demonstration of its operational framework. It is imperative to note that the prototype under discussion remains in its early developmental stage, thereby emphasizing the fundamentally theoretical nature of the discourse.

Furthermore, this study highlights the potential of a soft robotic solution to circumvent the need for direct blood interaction with artificial materials, consequently mitigating diverse complications associated with existing VADs. As a consequence of this consideration, the selection of biomaterials becomes paramount. Biomaterials, categorized into classes such as metals, ceramics, and synthetic and natural polymers, must adhere to stringent criteria encompassing chemical, physical, mechanical, and biological compatibility, thus preventing the initiation of adverse reactions within the organism (6).

Introduction to Soft Robotics Technologies, McKibben Muscles, and Other Pneumatic Artificial Muscles (PAMs). Soft robotics technology constitutes a novel realm within robotics research, crafting robots from flexible mechanisms and materials known as elastomers. Highly elastic and viscous polymers, elastomers can deform and revert to their natural state without compromising integrity. Consequently, soft robotics find extensive use in replicating human, animal, and even plant movements, such as finger bending or the motions of an octopus's tentacles. Using elastomers to construct these models enables them to execute specific tasks with greater freedom and delicacy, significantly enhancing safety for both the application environment and the humans involved in the manufacturing and final use (7).

In the prototype of an octopus with tentacles reproduced through soft robotics technology, actuators are designed to mimic the movement of real tentacles, utilizing shape memory alloy springs to replace longitudinal and transverse muscles. Applying electric current to different sets of springs, the tentacle can bend at various points, shorten, lengthen, and even grasp objects (8).

Compared with a rigidly classified robot, soft robots offer advantages that facilitate specific projects and redefine existing applications. While rigid robots are designed for highly predefined activities with extreme precision, soft robots have the technical potential to achieve infinite degrees of freedom, enabling unique and varied purposes. Another observed aspect is their safe interaction capabilities with humans, owing to their soft composition and gentleness, thereby expanding robotics applications (9).

Due to their unique characteristics, soft robots find diverse applications in sectors such as painting processes, transportation of fragile loads, food handling, packaging, and even medical purposes, such as prosthetics for individuals with movement limitations, whether in a finger or a hand. Movement within the application field is measured and executed through air or fluid chambers within the model, causing the walls to inflate and generate the predetermined action by the manufacturing mold (10).

With the evident growth of the soft robotics sphere, developing and enhancing flexible actuators has proven to be a powerful ally. Among these, Pneumatic Artificial Muscles (PAMs) are adjustable devices that undergo linear contraction resulting from internal pressure. They bring various properties, including flexibility, strength, lightness, bidirectional activation, direct connection, quick maintenance, and safety. Generally, they consist of a mesh composed of an elastomer and a reinforced material so that when air is applied, inflating or expelling from the actuator, this membrane is compressed or expanded. The construction of these actuators ensures that their force is linear but also radial and axial, directly impacting the load capacity and mechanical power they can generate (5). Some examples of these actuators include in Figure 1:

- **McKibben Muscle:** McKibben muscles are currently the most studied in the literature and were the first to be developed, with initial prototypes dating back to 1950. They consist of braided cylindrical muscles, with the tube and the mesh connected on both sides. This design allows them to transfer tension along the fiber while encapsulating gas inside.

- **Pleated PAM (Pleated Pneumatic Artificial Muscle):** This type of actuator has a different construction, where its membrane is self-organizing. This implies axial folds along the actuator's body, similar to a car's air filter, and when the actuator is inflated, the folds open, resulting in low friction. Therefore, these actuators require minimal effort for membrane expansion.
- **Yarlott Muscles:** Developed through an elastic bladder with a spherical shape, stretched at its ends, cords or wires are braided axially from one end to the other. These wires provide additional adjustable resistance to the actuator. As the muscle inflates, it takes on a spherical shape, and when stretched, the fibers beneath the actuator's surface force it into peaks and valleys. The more winding of wires or cables around the actuator, the more energy can be transformed into mechanical power.

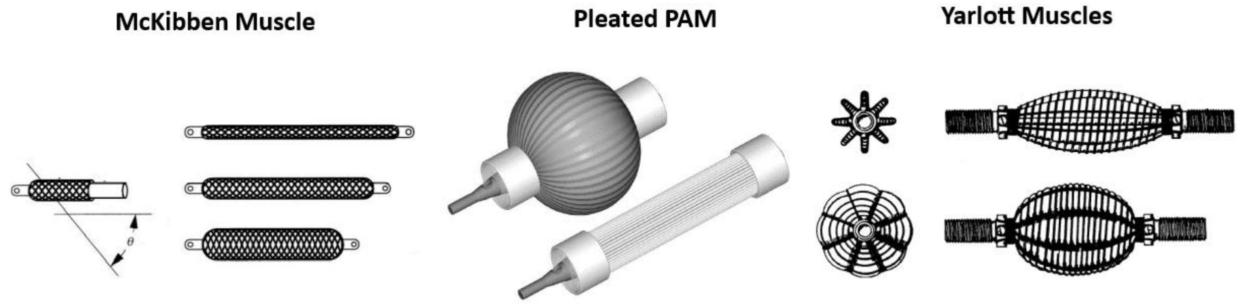


Figure 1. Some examples of these actuators are McKibben Muscle, Pleated PAM, and Yarlott muscles. Source: Daerden, F., & Lefeber, D. (5).

In addition to the mentioned examples, there is a wide variety of artificial pneumatic muscles, such as Sleeved Bladder Muscles, Entangled Muscles, Romac, Kukolj Muscles, Embedded Muscles, Morin Muscles, and Baldwin Muscles, among others.

Specifically, the McKibben muscle is one of the most studied and widely used artificial muscles in devices today. This is attributed to the simplicity of its concept and efficiency, coupled with its easy implementation. The construction processes for a McKibben muscle are straightforward, as this actuator comprises an elastic tube surrounded by a mesh for motion control. Both sides of the muscle are sealed, causing it to retain air and create an encapsulation system, completing the contraction movement and remaining pressurized until turned off (11). Also classified as a "soft actuator," the origin of this type of PAM dates back to World War II, authored by Joseph Laws McKibben, a key figure in the research team for the first atomic bombs. Inspired to develop a device capable of restoring some control over hand movements to his daughter affected by polio (infantile paralysis), McKibben created the air muscle using nylon mesh and rubber tubes (12). The original use of this muscle is illustrated in Figure 2. Since then, this device has been extensively studied, particularly in healthcare.

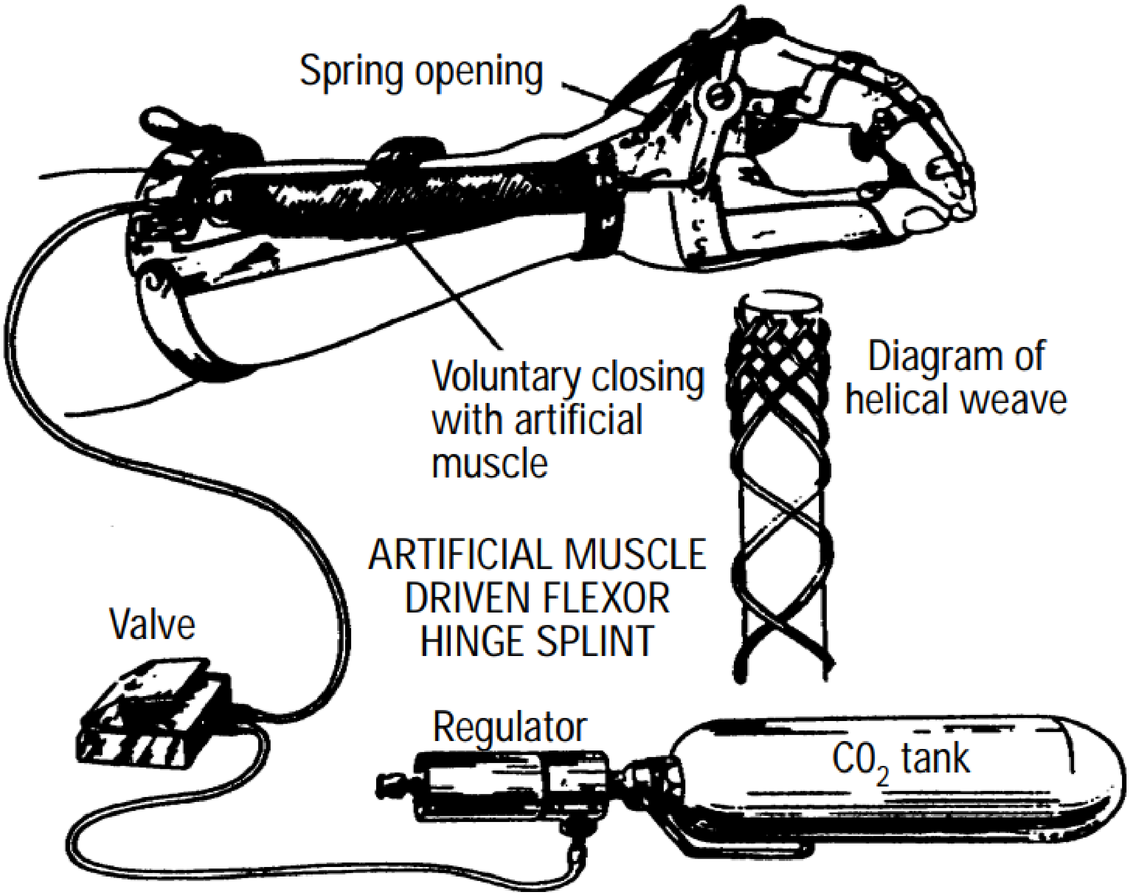


Figure 2. The original use of McKibben's muscle as a prosthesis to aid in the movement of opening and closing the hand. Source: Tondu, B. (11).

Despite its creation with a focus on the medical field, this type of actuator finds broad usage in industries. As proposed by Lopes (13), these devices can be used to create non-conductive manipulators. Various hard-to-reach areas demand specific equipment to perform tasks, and this process becomes even more complex in areas with a high electromagnetic field, where electrical and electronic components, such as electric motors and sensors, lose reliability. The McKibben muscle presents an exciting solution for such applications, requiring a pneumatic system rather than an electronic one.

A third example of using this technology is in developing virtual reality technologies. As Kuusisto et al. (14) proposed, a glove made with McKibben's muscles in conjunction with virtual reality goggles could further enhance this environment, manipulating virtual objects and simulating even the sense of touch. While the tactile sensation would be obtained through separate pressure regulators for each muscle, communication would be carried out through infrared sensors on the glove and an optical tracking system on the goggles.

Although the soft robotics tool is relatively recent, it is evident that it has significant applicability when combined with these actuators, providing various alternatives and new uses within related domains. Many potential benefits are still in the development or testing phases, but their potential is indisputable. Created to transform a part of the robotics industry in general, this technology is gaining more and more ground with its unique characteristics and features, also assisting many people on this journey (7).

Application of Soft Robotics and McKibben Muscles in Medicine. The rapid rise of soft robotics technology has enabled numerous studies on applications within medicine, given its notable precision and interaction sensitivity. The primary field of action for this new technology is developing prosthetics to assist patients experiencing mobility loss. With a focus on this application, Harvard University has developed a glove that uses electromagnetic impulses from the brain to move the five fingers of a patient's hand. The construction of this prosthesis originates from soft robotics, where each actuator is responsible for the movement of one of the fingers. They are attached to the patient's hand using Velcro, as demonstrated in Figure 3 (15).

Figure 3. Electromagnetic pulses power the soft robot glove prototype. Source: Harvard Biodesign Lab (15).

The actuator's contraction and expansion movement is initiated by applying compressed air to its internal pockets. The chamber walls inflate, and they execute the folding motion upon contact with each other. Figure 4 illustrates a model representing the mold's interior (16).

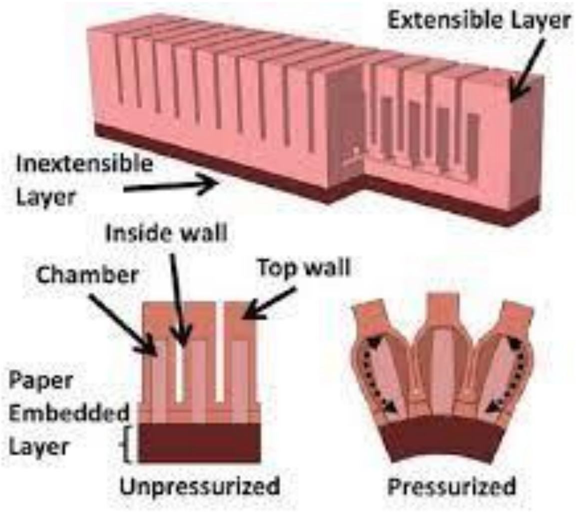


Figure 4. Illustration of a soft robot. Source: Mosadegh (16).

Pneumatic Artificial Muscles (PAMs) are valuable alternatives for human body muscle prosthetics, given their remarkable similarities in construction and operation. They can increasingly replace original muscles with precision and success. These actuators are predominantly employed in systems requiring a high power-to-weight ratio and flexibility, such as walking or running movements (17).

An exemplary application of McKibben muscles in prosthetic development is evident in assisting movements involved in walking, jogging, and running. The flexion of our knees is crucial in these activities, and addressing limitations, Harvard University developed the Soft Exosuit for rehabilitation. The Soft Exosuit consists of a belt attached to the patient's waist with straps encircling the legs, providing support. Actuators are placed at the back of the knees, contracting to flex and allowing the gait, with key sensors positioned at critical locations (hip, ankle, and knee) for performance evaluation. Its construction and mechanics are depicted in Figure 5.

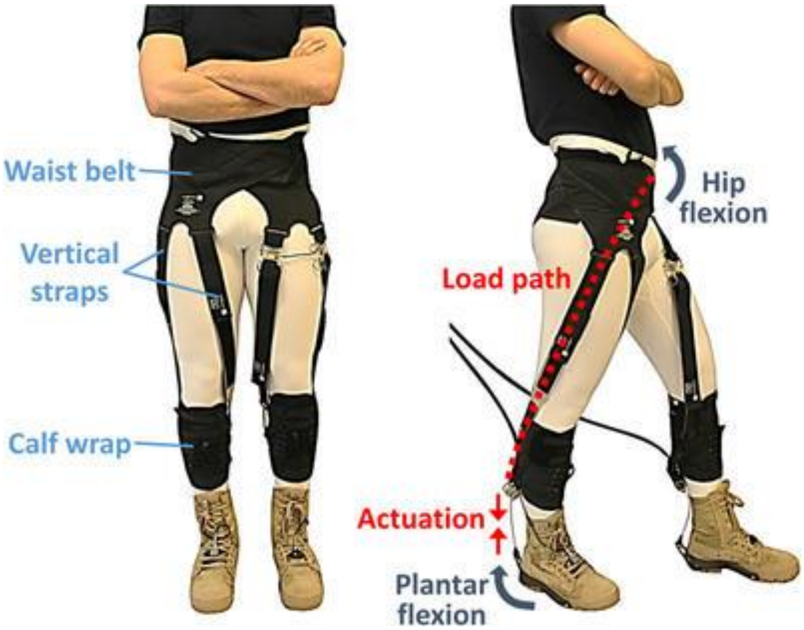


Figure 5. Components of the Soft Exosuit. Source: Harvard Biodesign Lab (15).

In another intriguing example, McKibben's muscles were employed in a human arm to facilitate elbow movement, replacing the biceps muscle. The prosthesis incorporated two actuators, with one end connected to air supply plugs and the other fixed to an artificial forearm with a hand. Upon maximum retraction, the actuators lifted the hand towards the patient's chest and, during expansion, returned the needle to its initial position. This was achieved through a simple control activated by a switch at the patient's foot. Figure 6 provides a general conception of the device (17).

Figure 6. Prosthesis with McKibben actuators. Source: Laksanachaeoren & Wongsiri (17).

However, as noted by McMahon (18), there are substantial differences compared to actual muscles, particularly at the cellular and biological levels, as human forces possess regenerative capabilities. Additionally, the volume of human muscles remains unchanged during contraction, and their natural organization involves units activating depending on the external load. Actual muscles can also vary reaction speed, being slower or faster, depending on the action's speed, a precision challenging to achieve with artificial muscles.

Soft Robotics with McKibben Muscles as a Solution for Heart Failure. Demonstrating considerable potential in the healthcare sector, soft robotics technology became a subject of research for applications in patients affected by heart failure. A joint project by the Harvard School of Engineering and Applied Sciences (19) and Boston Children’s Hospital developed a research project to assist blood pumping through the heart via compressions performed by a soft robotic glove. This glove, mimicking the heart's tissue and natural movement, employs McKibben actuators to execute both compression and twisting movements, providing a more precise simulation of the heart's natural motions. The equipment's functionality was initially demonstrated through an in vitro test, as shown in Figure 7. Subsequently, the equipment was implanted in vivo in a pig with induced heart failure, as depicted in Figure 8.

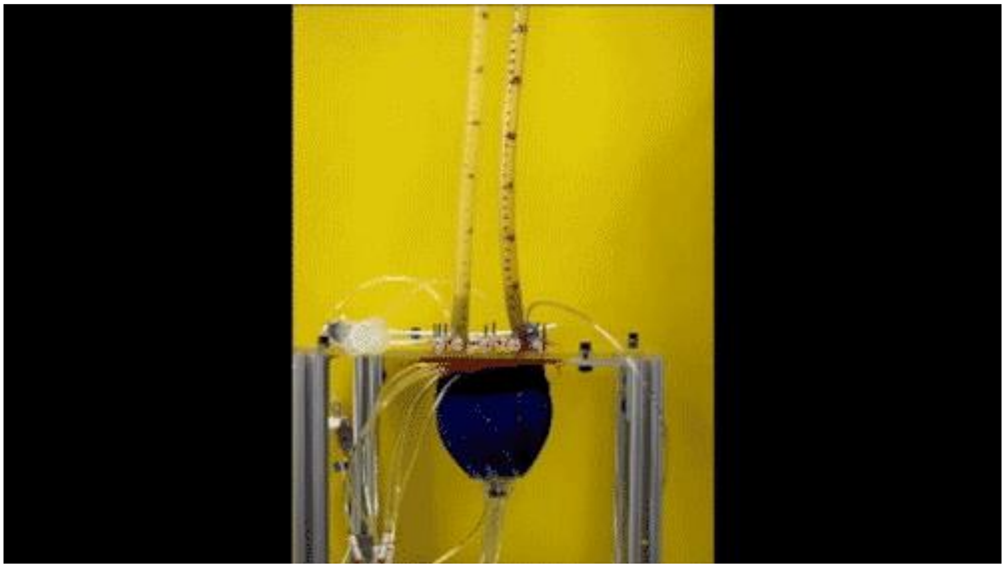


Figure 7. In vitro test of the developed prototype. Source: Harvard School of Engineering and Applied Sciences (19).

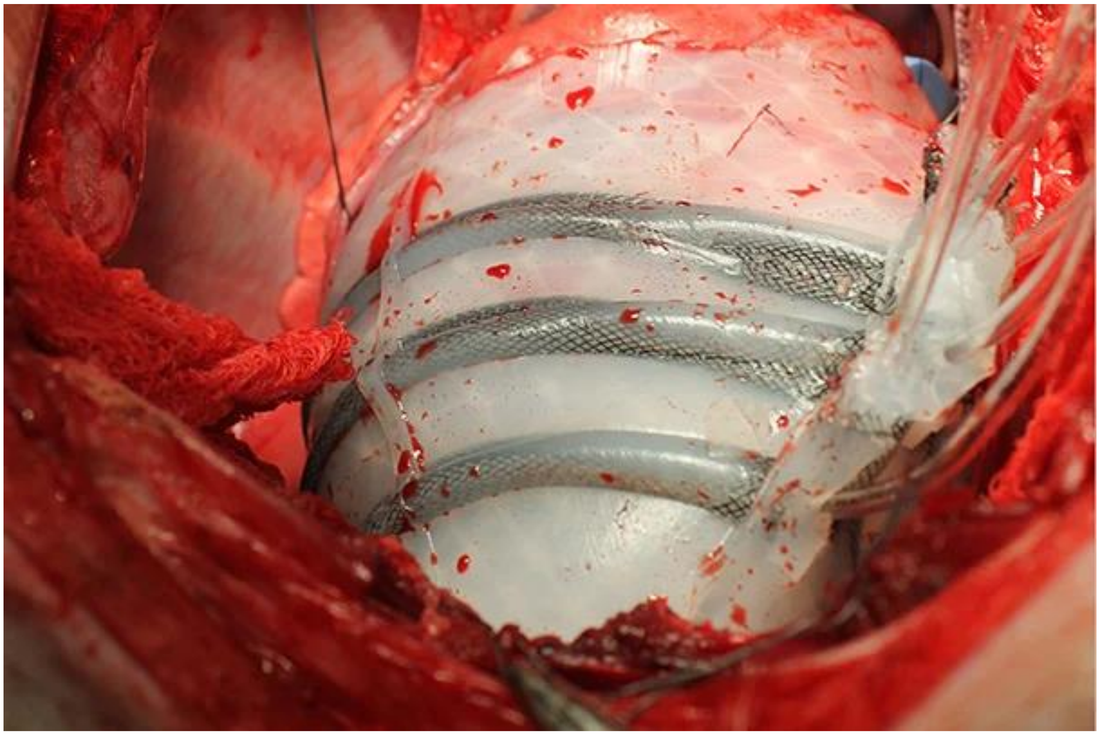


Figure 8. In vivo test of the developed prototype. Source: Harvard School of Engineering and Applied Sciences (19).

According to Roche et al. (20), the intricate movement in the heart is achieved through the functional arrangement of multiple McKibben actuators spatially oriented in a soft matrix, activated synergistically. The heart's muscle layers, arranged in helical and circumferential patterns (21), simultaneously undergo twisting and compressive movements. The native heart architecture inspired the device creation, featuring an utterly flexible glove with two layers of contractile elements inserted into an elastomeric model with mechanical properties similar to cardiac tissue.

Manufacturing techniques were explored to create flexible 3D devices testable in animal models, allowing the integration of custom PAMs into a soft matrix that resembled and conformed to the heart's external surface. This technology provides atraumatic assistance to enhance native muscle function, replicating its movement while providing synchronized mechanical support (20). Moreover, Roche et al. (20) highlight a crucial advantage of using the soft robotic glove for cardiac compression—the implementation of personalized control and instrumentation systems. This allows the inclusion of timing and monitoring schemes to optimize the actuation sequence, which is crucial for synchronizing the device with the native cardiac cycle when used in vivo.

Nevertheless, various approaches have been proposed for constructing a soft robotic glove for cardiac support, which is technically equivalent to developing heart support functionality. Horvath et al. (22) suggested alternative construction methods, including using adhesive tape patches (3M) mounted on a silicone base, medical mesh, silicone combined with cyanoacrylate adhesive, a custom-made strip with various suction elements, and Velcro (one side sutured to the heart and the other to the glove). In one method, Velcro was employed for attachment instead of completely enveloping the heart like a glove, as illustrated in Figure 9. Different fixation methods were debated, each with its unique advantages and disadvantages. In this case, a clear advantage was the ease of installing and uninstalling the equipment during tests. Despite the differing perspectives, the goal is precisely the same—to mechanically assist the heart in performing its function.

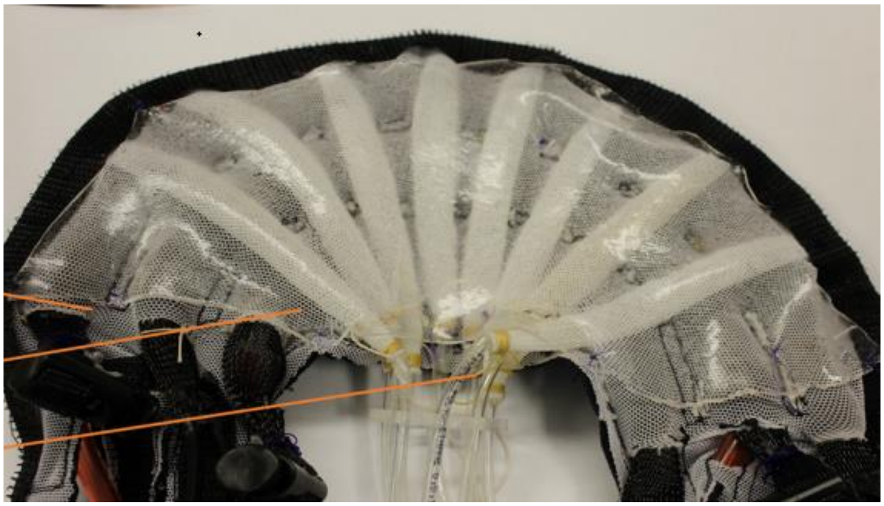


Figure 9. Robotic glove with Velcro. Source: Horvath et al. (22).

Another study, presented by Payne et al. (23), also effectively demonstrated the efficacy of such devices, resembling the one developed by Roche et al. (20) but with some variations. Instead of employing multiple actuators in a glove encompassing the heart, individual McKibben actuators were used wrapped around the heart's ventricles. This approach allows the surgeon to position and orient the actuator precisely in the ventricle, providing better control and enabling the choice of the number of actuators to be coupled, specifying each one's size due to the physical variability among hearts. This also allows actuators to be placed away from critical structures, such as coronary vessels or regions that may compromise valve function. Finally, the total size and weight of the implant can be minimized, potentially allowing better circulation during the diastolic phase. Figure 10 highlights the constructive differences compared to previous models.

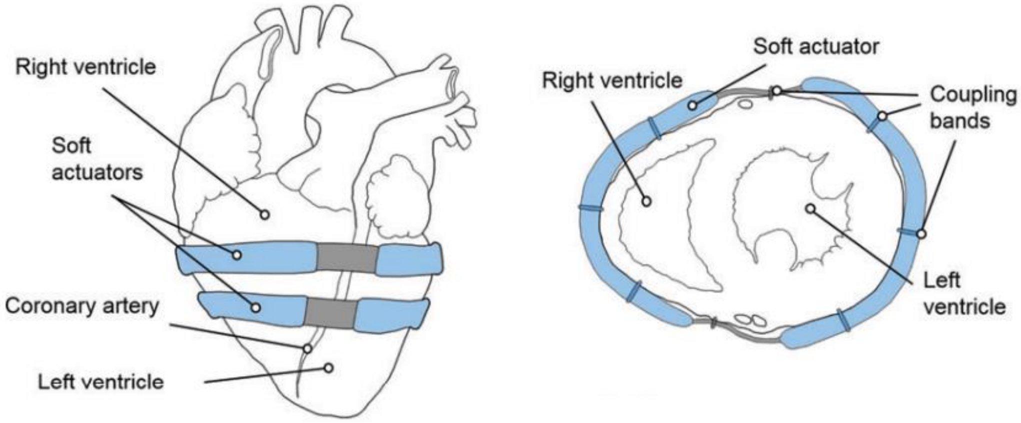


Figure 10. Another model of the robotic glove. Source: Payne et al. (23).

All mentioned projects conducted in vivo tests and demonstrated their efficiency in animal hearts with heart failure. In the examination conducted by Horvath et al. (22), the robotic glove completely restored the pig's heart rate to baseline values and showed the ability to increase diastolic function. The trials performed by Payne et al. (23) showed similar results, emphasizing the need for good mechanical coupling between the actuators and the heart to ensure device invariability. Additionally, the importance of synchronizing McKibben actuators with the affected heart's native heart rate was also emphasized, as highlighted by Roche et al. (20).

As previously presented, these muscles were developed to operate in devices aimed at assisting paralyzed patients, given the similarity between the movements of these artificial muscles and those of the human body. Over time, they have become one of the most widely used Pneumatic Artificial Muscles (PAMs), owing to their versatility and efficiency in various applications. The McKibben muscle is made of a flexible material tube (usually rubber or silicone) powered by a pneumatic system and coated with a mesh of nylon or polyester threads. When air is injected into the box, it inflates, and the mesh extends laterally while contracting longitudinally, generating the contraction movement of a muscle. When the air is released, the muscle returns to its original state (11). As proposed by Roche et al. (20), through the synchronization of several of these artificial muscles in a soft glove, arranged to mimic the arrangement of cardiac muscle fibers, a device is created that, when coupled to a heart, can artificially assist it in performing its natural movements.

Assembly of the Prototype. The prototype consists of McKibben muscles coupled to a flexible device that simulates a heart. The muscles were controlled by a command center, electronically powered by a 12 V/2 A source, and pneumatically by a compressor with a pressure vessel.

For the fabrication of the McKibben muscles, latex tubes, and 6 mm polyethylene nautical meshes were employed, occupying minimal space while providing sufficient contact surface to avoid damaging heart tissues. The box and the mesh were attached to a pneumatic hose using a combination of nylon clamps and cyanoacrylate-based adhesive.

For a 25 cm long and 8 mm diameter actuator, for instance, upon receiving compressed air at 1.5 bar pressure, its diameter expanded from 8 mm to 11.5 mm, while its length reduced from 25 cm to 20 cm. Figure 11 illustrates the length variation after air injection into this actuator, with pressure controlled by the regulator on the air tank.

Figure 11. Demonstration of McKibben muscle activation. On the left, the actuator was activated under a 1.5 bar pressure.

The component's two ends were then connected by a nylon clamp, forming a circumferential muscle so that, in the demonstrated case under 1.5 bar pressure, it compressed, reducing its internal diameter from 60 mm to 45 mm, generating the compression movement in the "heart." This compression is illustrated in Figure 12.

Figure 12. Demonstration of the activation of the circumferential McKibben muscle. On the left, the actuator was activated under a 1.5 bar pressure.

The pneumatic line connecting the compressor to the actuators comprised 4 mm and 6 mm polyurethane pneumatic hoses. The 6 mm air hoses from the pneumatic valve were reduced to 4 mm to occupy less space in the cardiac device. The electro-pneumatic control system of the device was located in a command center, containing both pneumatic control devices and electronic command components. It is presented in Figure 13. The circuit was simplified as it was merely responsible for controlling the activation and deactivation of the artificial muscles. For a prototype closer to actual use, the Arduino would feed and process data from various sensors, adapting operating conditions based on processed information.

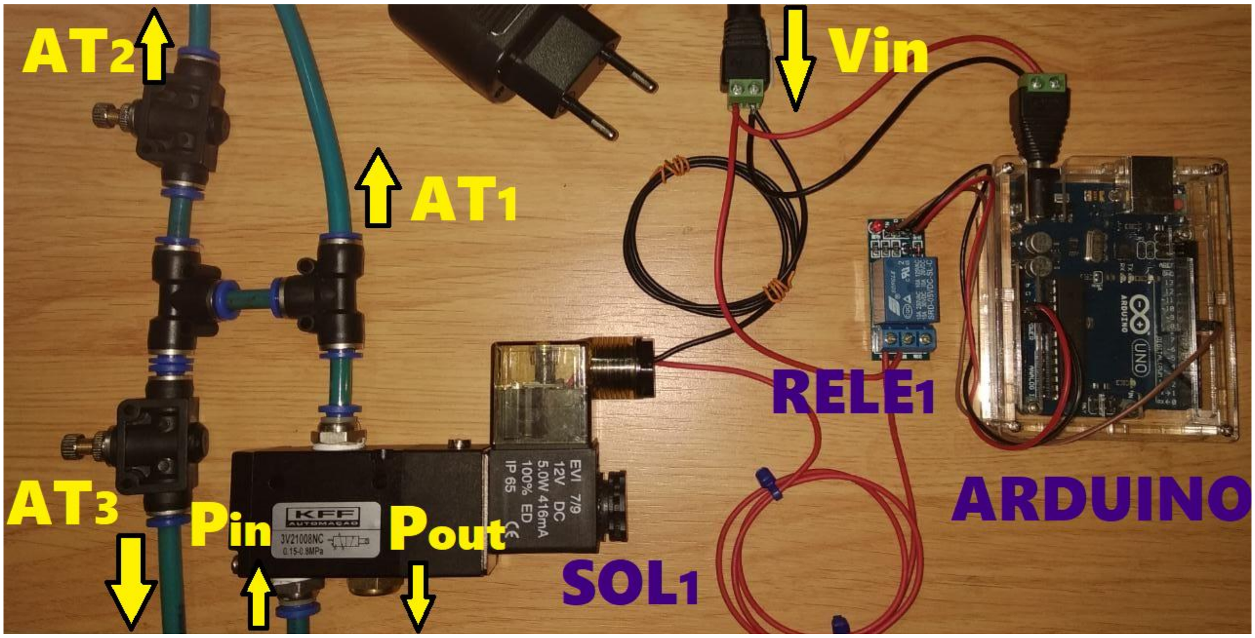


Figure 13. Command center with electro-pneumatic circuit.

This center comprised an Arduino UNO, a relay, a 3/2-way pneumatic valve with solenoid, two flow regulators, pneumatic connections, and electronic connections. The Arduino and the pneumatic valve were powered by a dual-input power supply with a 12 V/2 A output, while the relay was activated by a 5 V command output from the Arduino. The primary circuit is illustrated in Figure 14, which was created using the open CADeSIMU software. Pneumatic actuators were used in the circuit for simulation purposes to represent McKibben's muscles.

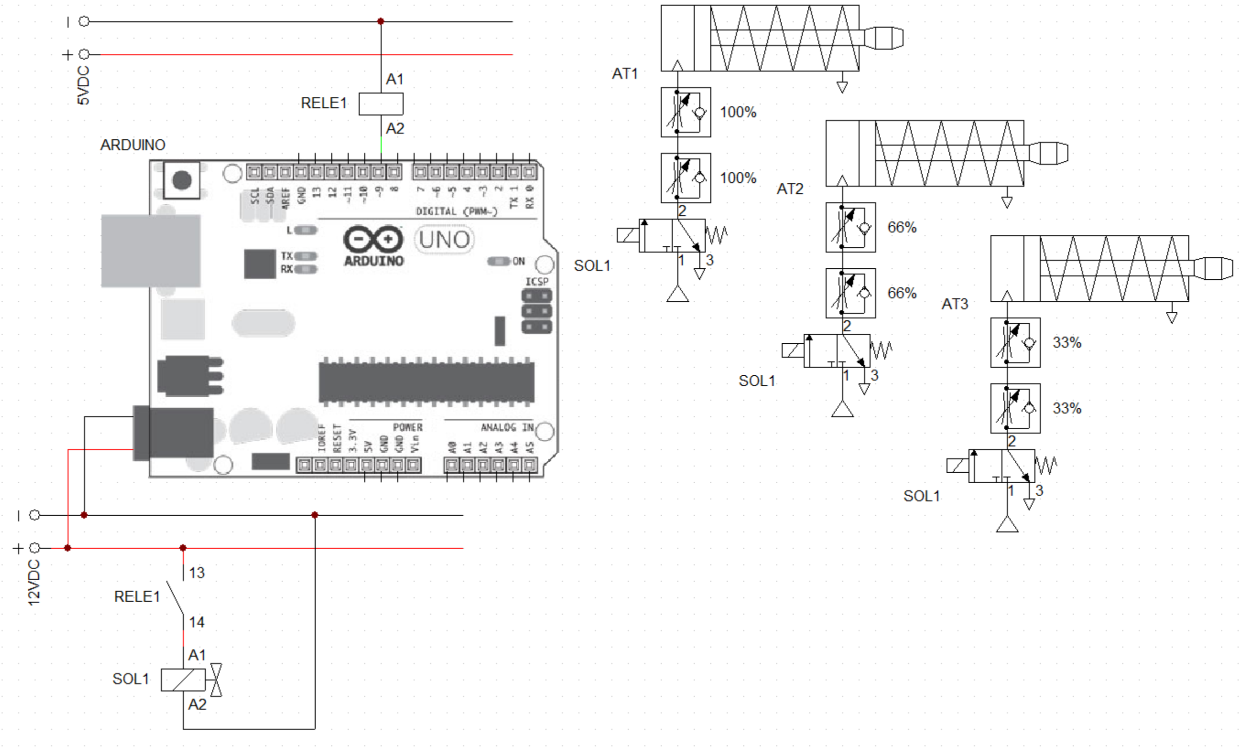


Figure 14. The basic design of the electro-pneumatic circuit.](image link)

To simulate the appearance of a heart, the suction pump from a flexible PVC bidet spray was used, wrapped in a red balloon, as shown in Figure 15. For testing purposes, the pump was filled with a mixture of water and red dye—mimicking blood—and had an acrylic tube attached to its outlet, reproducing the idea of an artery. A tape measure was positioned behind the box to represent a centimeter scale.

Figure 15. The object used for simulating the heart.

Various methods were studied for attaching the actuators to the "heart," based on prototypes from previously mentioned works and solutions presented and looked more deeply by Horvath et al. (22). Different coupling methods were highlighted, along with their advantages and disadvantages. The difficulties of implementing such devices without causing possible harm to the organ were emphasized, and some solutions were presented, compared, and demonstrated with results obtained in different tests. More rustic attachment methods were employed for simulation purposes—since the device would not be inserted into a human—without additional concern for delicacy and perfection.

Two stages were performed to facilitate visualization, understanding, and analysis of the tests: the first involved the compression movement, and the second involved the twisting motion. For an ideal application, both actions must operate simultaneously, as these are the natural movements of an honest heart's pumping, as presented by Roche et al. (20).

Three McKibben actuators were positioned circumferentially around the "heart," where one end was attached to another using nylon clamps to simulate the compression movement. The central actuator remained fixed due to the physics of the suction pump, and the upper one was tied to the lower one with string to prevent them from moving out of position. The lower and upper actuators were 25 cm long, while the central one was 30 cm. Additionally, two flow regulators were used to slow their movements, one on the upper actuator and one on the primary actuator. A pressure of 1.5 bar was used, and the activation sequence was lower, central, and upper. The same sequential pattern is repeated during decompression. Its assembly is illustrated in Figure 16.

Figure 16. Circumferential arrangement of actuators in the compression movement demonstration.

To simulate the twisting movement, five McKibben actuators were positioned transversely around the "heart," all tied together at the top with a string and at the bottom with nylon clamps to prevent them from moving out of position. In this case, all actuators were 12 cm long, and no flow regulators were used. The pressure used was also 1.5 bar. Air injection caused all actuators to be activated simultaneously, and this pattern repeated during decompression. Its assembly is illustrated in Figure 17.

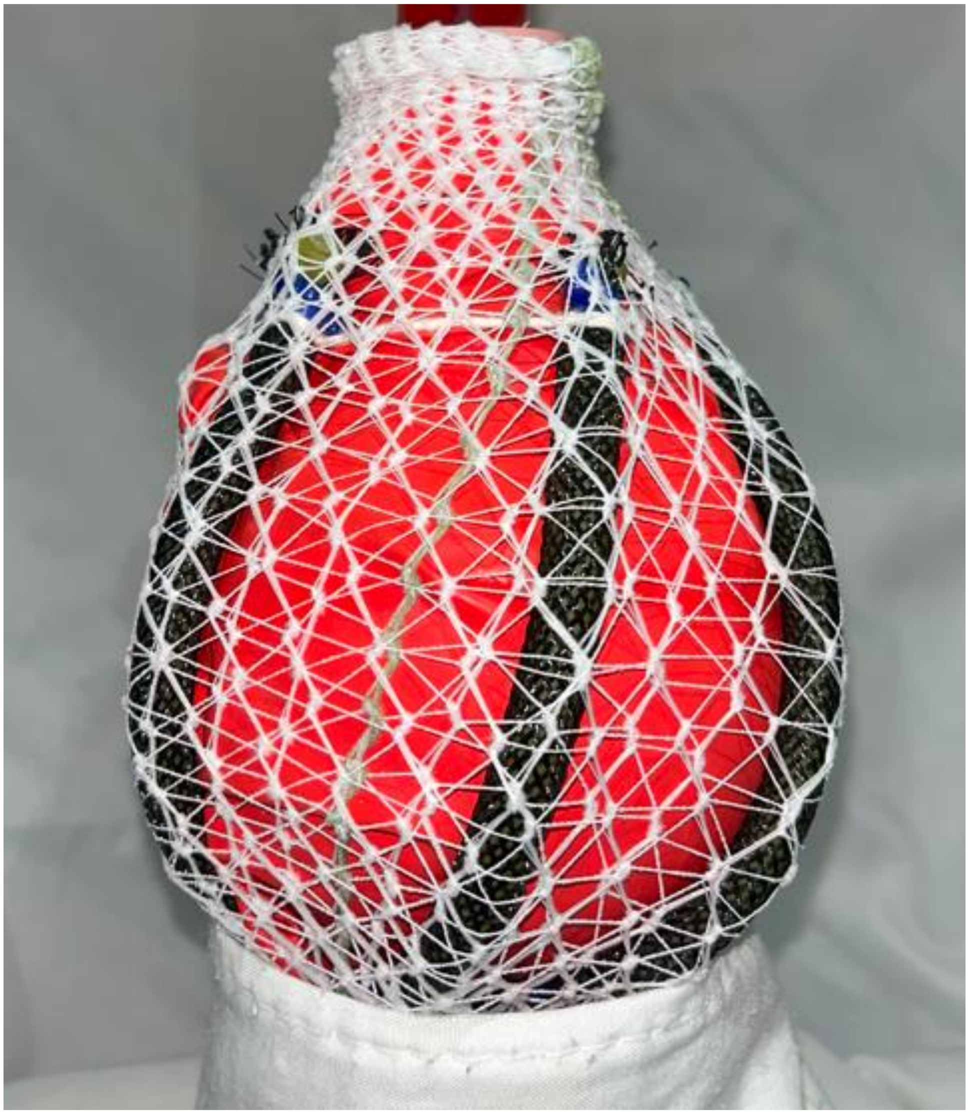
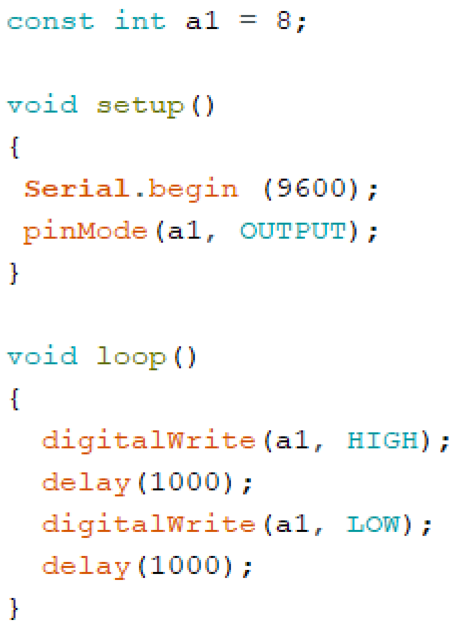


Figure 17. Transversal arrangement of actuators in the twisting movement demonstration.

In both movements, the "heart" and the actuators were externally covered by a layer of elastic tubular netting to ensure positioning and support the system more significantly.

The programming was done in the Arduino IDE using the C++ language with minor modifications. Its function was to control the relay responsible for incessantly opening and closing the pneumatic valve, simulating a heartbeat 30 times per minute. This value is obviously much below the average rhythmic speed of humans but illustrates the operation and can be easily modified. The code is included in Figure 18.



```
const int a1 = 8;

void setup()
{
 Serial.begin (9600);
 pinMode(a1, OUTPUT);
}

void loop()
{
  digitalWrite(a1, HIGH);
  delay(1000);
  digitalWrite(a1, LOW);
  delay(1000);
}
```

Figure 18. Electropneumatic system programming.

For the first test of the actuators, an experimental system was set up using the suction pump from the flexible PVC bidet spray and the acrylic tube with a centimeter scale behind it. The actuators were positioned 50 circumferentially to simulate the compression movement, as described earlier, and received the application of compressed air from the air compressor at 1.5 bar pressure. The bidet suction pump was connected to the tube's inlet, while the tube's outlet was exposed to atmospheric pressure. Water was pressed and displaced from the pump to the box by activating the McKibben actuators. This displacement was measured by the centimeter scale, allowing precise quantification of the height reached by the water, leading to calculating the displaced water volume—a simple and efficient solution for such measurement, demonstrated in Figure 19.

Figure 19. Acrylic tube with a scale behind it, connected to the bidet suction pump.

The same experimental system with the bidet suction pump and the scale behind the acrylic tube was maintained for the second test. This time, the actuators were positioned transversely to simulate the twisting movement, as described earlier. Also, they received the injection of compressed air from the compressor at the same 1.5 bar pressure. Like before, the pump was connected to the tube's inlet, and water was displaced after activating the McKibben actuators. Measurement of the volumetric displacement was also performed for this setup.

The tests aimed to verify the amount of liquid displaced in each movement, encompassing the actuators' performance, resistance, and stability. For the estimation of volumetric displacement, the volume calculation for cylinders was used, represented in the following equation:

$$V = \pi \, . \, r^2 \, . \, h \quad (1)$$

The values required to apply the calculation were the internal radius of the acrylic tube and the height reached by the liquid inside the box after activating the actuators.

Experimental Analysis. The use of these technologies in this field is on the rise and has shown promising results in the literature, indicating significant potential with ample room for improvement. Among the noteworthy outcomes from in vivo experiments, the complete restoration of animals' cardiac rhythm to baseline values and the enhancement of diastolic function were observed. Reiterating a crucial point, avoiding blood contact with artificial materials is a significant advantage in mitigating various secondary complications for patients.

Despite its simplicity, the developed prototype proved highly functional, meeting the expectations for demonstrating the operation of McKibben actuator technology for artificial pumping simulation. The construction posed some challenges, but through iterative attempts, a device was devised that exhibited convincing performance despite the low investment.

An initial challenge worth noting was creating a structure resembling a genuine heart. Most articles examined conducted tests on honest animal hearts, eliminating the need to create an artificial system for actuator integration. An attempt to develop a 3D-printed mold based on nature proved impractical over time, primarily due to the requirement for hollowness and softness to facilitate fluid insertion and compression for pumping. Consequently, the decision to employ a suction pump from a bidet shower for this purpose proved effective, demonstrating comparable dimensions to the heart above, presented in Figure 20.

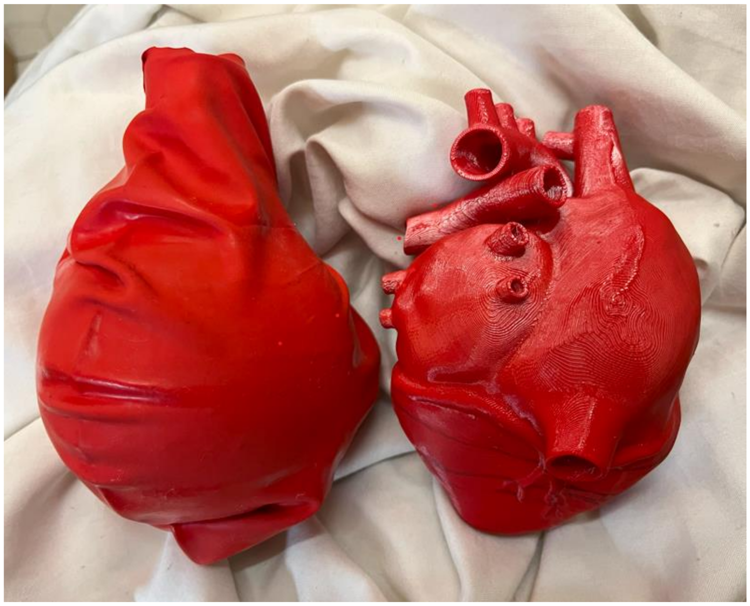


Figure 20. Comparison between the shower suction pump and the full-size 3D printed part.

Another challenge involved securing the actuators onto the "heart," even though precision was not crucial given the simulation nature. Initially, an attempt was made to use fabric and Velcro to envelop the "heart," sewing the actuators onto this fabric to merely "dress" it, akin to a method observed in prior studies. However, this idea proved unfeasible due to the dynamic and uninterrupted nature of the system, posing risks to the structure rapidly and potentially causing actuator detachment. An alternative attempt involved directly gluing the actuators to the suction pump, but the nautical meshes tended to rupture, causing latex tubes to inflate uncontrollably. Ultimately, using strings to tie the actuators together as needed proved to be a viable solution.

A noteworthy decision was the choice of a rhythmic speed of 30 beats per minute for tests, significantly deviating from human averages. This was done to facilitate the visualization of volumetric displacements. While experiments with values closer to human standards were conducted, they proved unreliable due to the rapid fluid movements, compromising measurements. Flow regulators also proved inefficient in simulations with higher rhythms, lacking precise adjustment and potentially hindering complete actuator activation within a cycle. A lower value was deemed suitable for simulation purposes, given the intent was purely to illustrate technology functionality.

As mentioned earlier, a deliberate choice was made to demonstrate torsional and compressional movements separately to enhance external visualization and optimize overall understanding. To measure volumetric displacement in each test, Equation (1) was employed, responding cubic centimeters (cm^3), equivalent to milliliters (ml). The acrylic tube's internal diameter was 1.8 cm, yielding a radius of 0.9 cm. The value of Pi used for calculations was 3.1415926535 (ten decimal places).

The tests were conducted in Guarulhos-SP, near coordinates 23°27'20.8"S, 46°33'24.9"W, with an atmospheric pressure of approximately 1020 hPa or 1 atm.

In Figure 21, the test for compression movement is depicted, showing the actuators depressurized on the left and pressurized on the right. This movement proved the most intense, causing the liquid to rise approximately 9.4 cm. Applying Equation (1) revealed a volumetric displacement of approximately 23.92 cm^3 (23.92 ml) per cycle for this test.

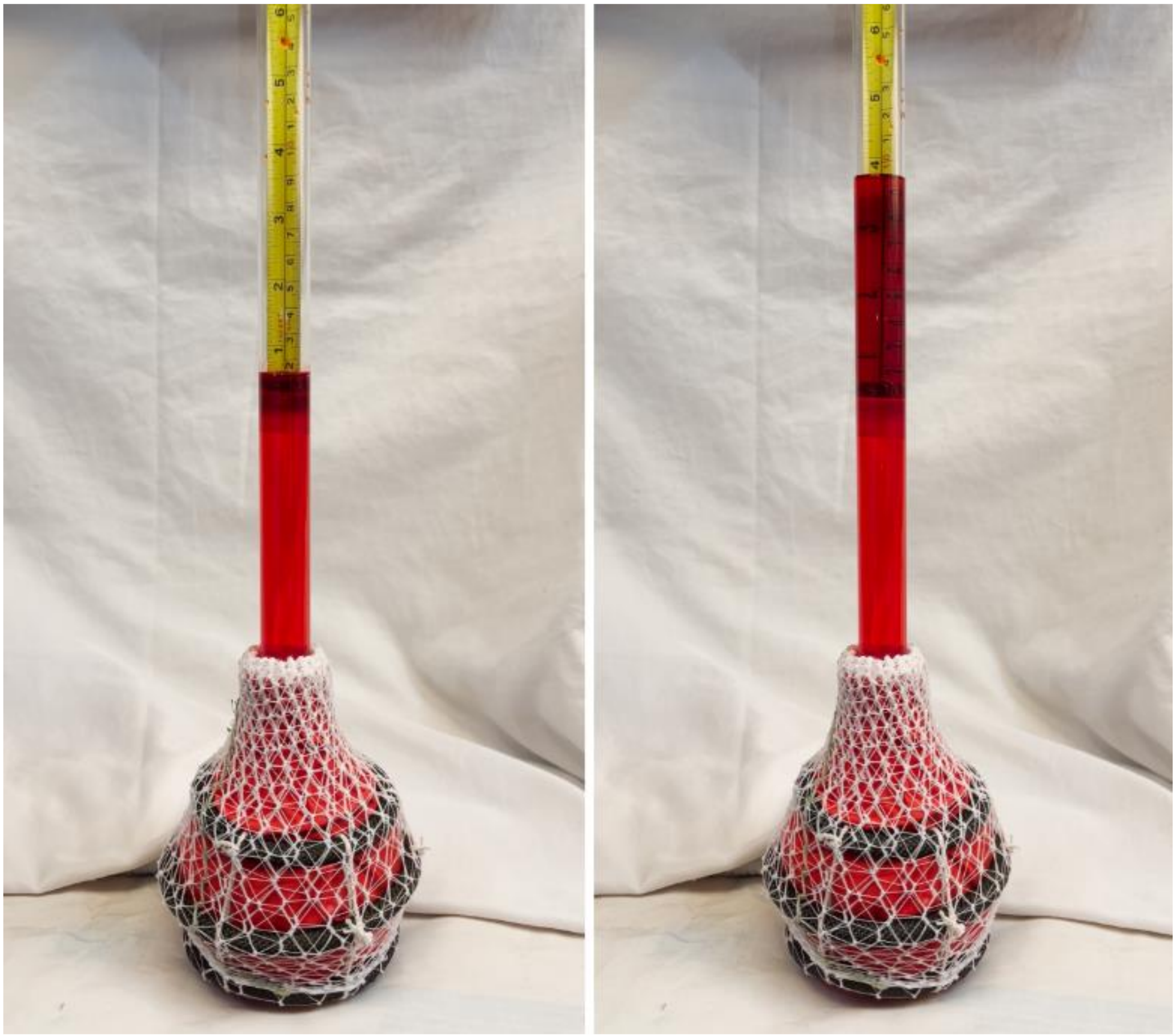


Figure 21. Compression Movement Test.

Figure 22 illustrates the test for torsional movement, with actuators depressurized on the left and pressurized on the right. This movement proved less intense, causing the liquid to rise approximately 3.2 cm. Applying Equation (1) revealed a volumetric displacement of roughly 8.14 cm³ (8.14 ml) per cycle for this test.

Figure 22. Torsional Movement Test.

As mentioned earlier, it is crucial to emphasize that for an ideal application, these actuators should overlap to apply both movements simultaneously and synchronized, simulating the movements of cardiac muscles. For experimental purposes, pressure variation ranging from 1 to 4 bars was used for both tests. These limits were established based on the minimum operating pressure of the pneumatic valve and the maximum pressure supported by the McKibben muscles. Qualitatively, increased force exerted by the muscles was observed with increasing pressure. However, the water displacement remained unchanged, attributed to two factors:

- The manufactured muscle has its contraction limited by the internal latex tube as it fills the entire interior space of the mesh. Once the inner hole is filled, the mesh's contraction ceases. A muscle with a more significant contraction could be constructed with the latex tube detached from one of the mesh ends, as illustrated in Figure 23.

- The minimum pressure used was sufficient to compress the suction pump to the maximum contraction point of the artificial muscle.

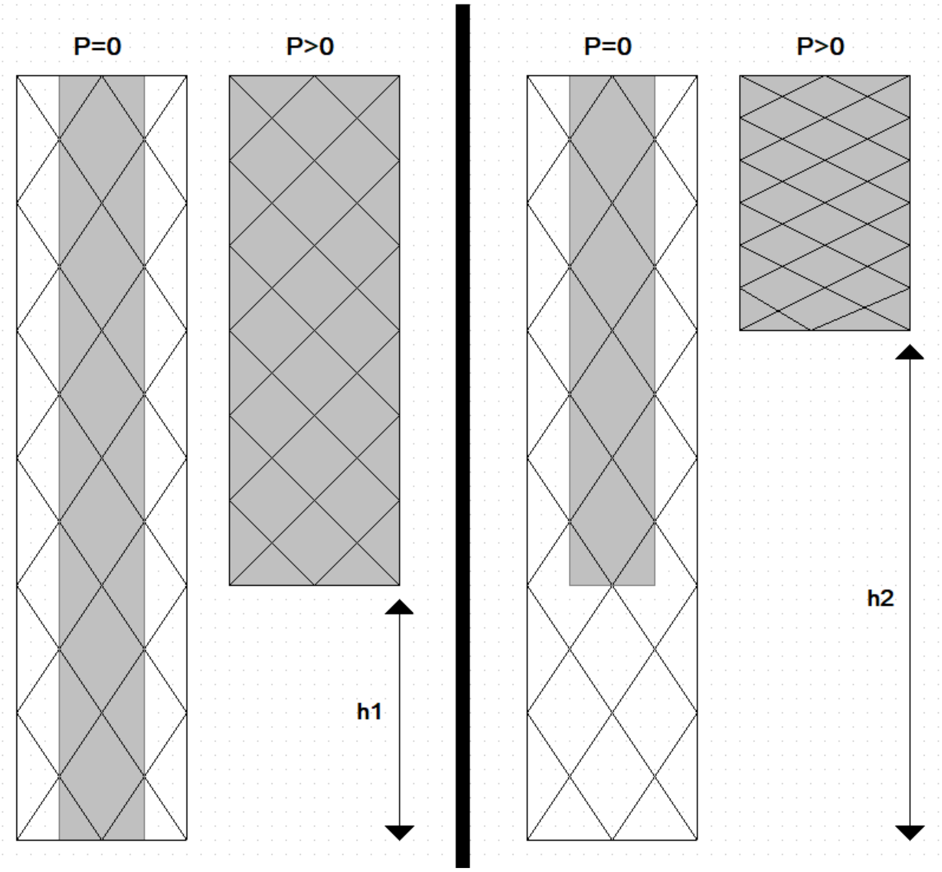


Figure 23. Illustration of McKibben Muscle Compression Limitation.

It is essential to highlight that the volumetric displacements obtained in these tests cannot be directly correlated with the average volumetric displacement of the human circulatory system. The former is an open and static system, while the latter is a closed and dynamic system. A comprehensive study involving various factors, such as fluid viscosity and density, tube characteristics, vascular resistance, and human body characteristics, is required for a comparative calculation between the two systems. Thus, the obtained data from testing currently serves a purely quantitative function without referencing the circulatory system. However, these values facilitate the comparison of tests, whether between different movement types or pressures.

Computational Analysis of Silicone Material for Cardiac Assist Device Protection. When subjected to force, a body can undergo deformation in two ways: elastically or plastically. Elastic deformation is reversible, meaning the body returns to its original shape when the force ceases to act on it. On the other hand, plastic deformation is irreversible, causing the body to remain deformed even after the power concludes.

Due to the flexible nature of Soft Robotics, its components must operate within the elastic deformation region. One method to assess the deformation limits is a tensile test, which "involves the application of gradually increasing uniaxial tensile load to a specific specimen until rupture."

Subsequently, the data obtained from simulating forces acting on the material were analyzed. Following this procedure, the obtained data were compared with the results of tensile and compression tests, aiming to determine the suitability of the proposed silicone for the intended objectives. Figure 24 presents the Heart-integrated glove model.

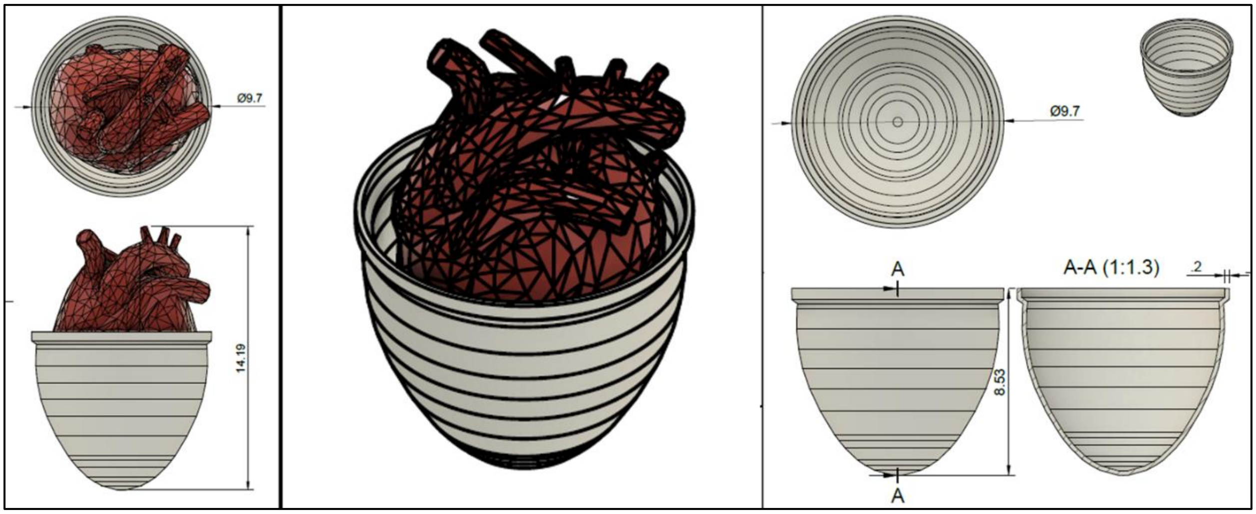


Figure 23. Heart-integrated glove model.

The prepared model underwent computational tensile tests to determine whether silicone is a material capable of withstanding the forces induced by the expansion and contraction of the myocardium without undergoing plastic deformation. A uniform pressure of 0.15 MPa was considered inside the protective cover, exerting tensile stresses. The mesh of the model comprises a total of 12,106 nodes and 5,999 elements (Figure 24). The computational model considered the following material characteristics presented in Table 1.

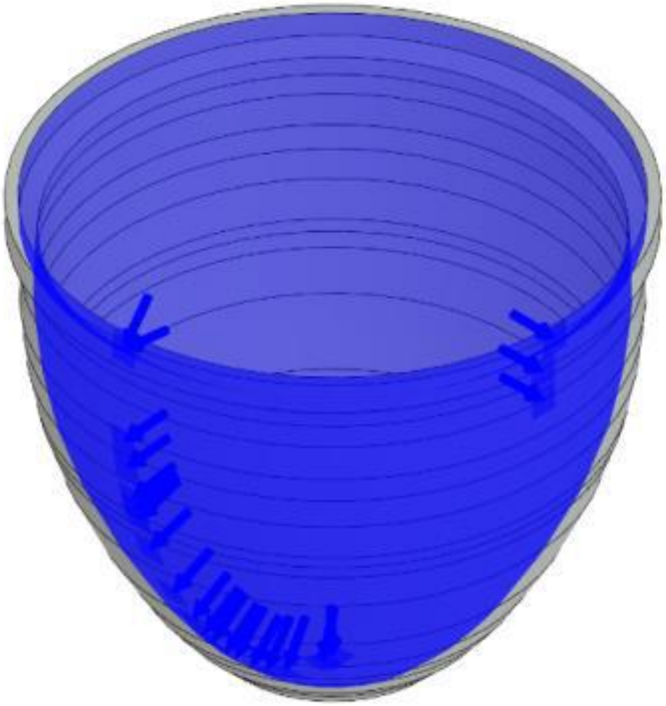


Figure 24. Representation of the pressure acting inside the protective cover

Table 1. The computational model considered the following material characteristics.

Density	1.25E-06 kg / mm^3
Poisson's ratio	0.49
Yield Resistance	10.34 MPa
Maximum Tensile Strength	10.34 MPa
Safety Factor	1.75-15 MPA
Von Mises	0.06-592 MPa

Due to its inverted cone geometry, the device experiences varying stresses at different points. Tensions across the device range from 0.06 MPa to 5.92 MPa, signifying that some issues experience minimal stress while others reach the maximum pressure. As the entire focus is below the silicone's Maximum Tensile Strength of 10.34 MPa, the device operates solely in the elastic deformation regime. The ratio of these stresses yields a minimum safety factor of 1.75, meaning that the tensile stress on the device could be approximately 75% higher without undergoing plastic deformation. Thus, the cover will maintain its elastic properties, ensuring an extended lifespan.

Furthermore, under pressure's influence, the protective cover's deformation ranged from 0.03 mm to 3.05 mm. Considering the material's flexibility, its operation in the elastic regime, and the fact that this deformation is equivalent to only 3% of its width, this deformation does not pose an obstacle to the ultimate goal of the protective cover. Another aspect of using silicone as the cover material is its low weight, approximately 54 grams, which would not impose additional strain on the heart and the device.

In contrast to the flexible materials used in Soft Robotics, the rigid materials employed to construct VADs would exhibit higher stress and deformation values. In extreme cases, this could lead to device breakage, causing a range of problems for the patient, such as fractures, infections, and bleeding, necessitating highly invasive and complex open-heart surgeries.

The results demonstrate that silicone can withstand the stresses arising from cardiovascular movements and is a suitable material for manufacturing protective covers. With its relatively simple design and easily accessible material, coupled with the possibility of 3D printing, the protection can be highly personalized for each patient and their specific needs, facilitating its mass implementation.

Conclusion and Future Perspectives. Based on the outcomes of this research, it can be concluded that the designs and prototypes examined prove highly relevant to medicine and ventricular assistance studies, mainly due to their technology that avoids direct blood contact. These devices repurpose heart tissues, significantly reducing the risk of coagulation—a common occurrence in other treatments due to blood-polymer connection. Furthermore, the significance of addressing solutions for cardiac disease treatment is evident, given that cardiovascular diseases remain a leading cause of mortality worldwide, including in Brazil.

In addition, the successful demonstration of the McKibben muscle functionality in simulating cardiac compression and torsion movements using a simplified prototype is noteworthy. With simple, cost-effective materials, the concept of a device applicable to soft robotics has been introduced. With further research, this device could emerge as a viable alternative to cardiac assistive devices.

It is essential to highlight that developing a complete device applicable to an honest heart requires more financial investments and a more extensive team. Given its multidisciplinary nature, involving various professionals would be beneficial to optimize the apparatus for its final application, considering its crucial role in sustaining an individual's life. Monitoring systems, control mechanisms, alerts, and cutting-edge components would be indispensable for its construction, ensuring safety and reliability for users.

Improvements for this prototype were discussed, focusing on making it more adaptable, controllable, and precise. Various materials and components would need to be employed to create an envelope for the device, making it more akin to a soft robot with high adaptive capabilities. Additionally, implementing control and monitoring systems would be essential to achieve these enhancements.

Among the materials considered for the envelope are elastomers known for their flexibility and adaptive capacity, such as silicones used in prosthetics, medical-grade silicones, or hydrophilic silicone rubber. Chemical and physical modification of the silicone rubber surface, as proposed by Hron (24), enhances its hydrophilic properties, increasing biocompatibility. Another potential material is platinum-cured Ecoflex silicone, commonly used in mask and prosthesis production, offering skin safety, although its biocompatibility with internal tissues over prolonged periods remains unproven. The biocompatibility of the material, coupled with the adaptability characteristic of such polymers extensively used in soft robotics, provides an envelope capable of physically protecting the organ's biological tissue and transmitting artificial muscle movements more effectively and uniformly.

Regarding sensing and control of the device, a precise pressure transducer small enough to be implanted in the pneumatic system would be crucial. This component would monitor whether the actuators receive the optimal pneumatic pressure and detect any variations due to leaks, interrupting the pneumatic system's supply. An example of a sensor suitable for adaptation and testing is the Honeywell TruStability RSC. The TruStability is a small, precise piezoresistive sensor with a measurement range of 1.6 bar to 10 bar, a power supply of 2.7~6 VDC, and approximate dimensions of 10 x 12.5 x 6 mm, capable of providing data at a frequency of up to 2000 times per second.

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