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HYDRAULIC REMOTELY ADJUSTABLE PULMONARY ARTERY BANDING

Davide Dal Pozzo

Massachusetts Institute of Technology
Cambridge, MA, USA

Damien Eggenspieler

Massachusetts Institute of Technology
Cambridge, MA, USA

Alexander Slocum, Ph.D.

Massachusetts Institute of Technology
Cambridge, MA, USA

Martin Deterre

Massachusetts Institute of Technology
Cambridge, MA, USA

Maxim Lobovsky

Massachusetts Institute of Technology
Cambridge, MA, USA

Frank Pigula, M.D.

Children's Hospital
Boston, MA, USA

ABSTRACT

Each year approximately 2000 children are born with a form of congenital heart disease that would benefit from mechanical restriction, or banding, of the pulmonary artery. ^[1,2] Installing or changing the setup of the banding requires an open chest surgery and during the first 6 months of the patient's life, physiological parameters evolve rapidly, resulting in need for frequent reoperations. Mortality for those treated patients may be as high as 10 to 20%. ^[3] While many devices have been patented, none of them have been adopted due to size, adjustability, or reliability constraints with regard to implantation in newborns, especially below 6 months of age.

Here we present the conception, design, and scale model testing of a novel pulmonary banding system for infants. This system features a hydraulic mechanical stepper actuator that offers great advantages in both reliability and compactness. As a proof of concept, we built a 5:1 scale working prototype that demonstrated the desired functionality of the device. Further steps involve scaling down the device so first porcine trials can be started.

INTRODUCTION

Newborn congenital heart defects are often characterized by left-to-right shunting and pulmonary over circulation, such as functionally uni-ventricular hearts, ventricular septal defects and complete atrio-ventricular septal defects whereby the pulmonary and the systemic vascular resistances are not balanced. This leads to abnormal oxygen content in blood and excessive airway pressure. Eventually children are subject to paralysis, alkalosis, hypocarbia, hypothermia and death.

Pulmonary Artery (PA) banding is a palliative surgical therapy used to treat the imbalance of vascular resistances by increasing the pulmonary vascular component. Permanent

reconstructive surgery follows PA banding when the patient is deemed ready, typically at the age of 6-12 months by rerouting arteries (e.g. the Norwood operation). Traditional PA banding consists of a challenging surgical operation in which a band of silk, GoreTex or other material is wrapped around the artery, and tightened precisely in order to narrow the internal diameter of the pulmonary artery of newborns (Figure 1). ^[4,5,6] Several re-interventions are required to adjust the setting of the band as the patient grows. Every year, approximately 2,000 patients are subject to PA bandings and the mortality rate for each surgical adjustment is between 10 and 20%. ^[7] Thus, a system to adjust the banding in vivo without the need for open-chest surgery would be extremely valuable.

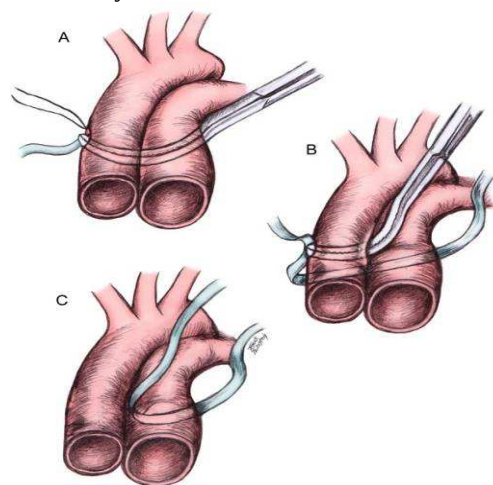


Figure 1: Traditional pulmonary artery banding: (A) encircling the aortopulmonary trunk, (B) encircling the aorta, and (C) completing the pulmonary artery band at the final location. ^[8]

Functional requirements

The targeted practice being neonatal implantation, the primary functional requirement is to have a compact device. This device should be functionally equivalent to the suture bands that are currently used, and avoid frequent, risky re-operation. The overall size of the device, implanted on the PA, must be less than 1 cm³, in order to be fit for infants under 30 days of age.

There is wide variability in patient size and morphology. The range of flow regulation can go from 0-75% restriction and the size of the artery ranges from 2 to 6 mm. The required incremental resolution for the device is difficult to determine as in the current operation, the doctor adjusts the band manually with little measurement of the amount of constriction. Physiological signals are ideally used as feedback, but this is difficult with an anesthetized patient; hence it is desirable to easily adjust the band once the patient is awake.

Concerning the surgery itself, the current operation involves opening the chest to access the heart, but does not require incision into the artery. Thus, our solution should minimize damage to the artery by avoiding any cut and using materials that do not adhere to or wear the artery. Another paramount characteristic for our device is that it must be absolutely failsafe. It should fail gracefully (no rapid change, no damage to the local anatomy) as the PA condition is critical to the patient's health.

A final functional requirement is the ability to remotely control the device in order to reduce the frequency of surgery. In fact, our system should need only a single surgery for the initial implantation. Then the device should provide non-invasive adjustment to the flow in the PA over the course of the one-year implantation duration.

Prior Art

There are several patents concerning adjustable pulmonary artery banding systems. However, some of them have been tested but are not commercially available. In particular, we found two interesting approaches.

ABS (Silimed, Brasil): ABS is an extremely compact and adjustable pulmonary artery system (Figure 2).^[10] It is based on the same mechanism and technology used in Silimed's gastric banding product. Sub-cutaneous bladders are used to inject fluid into a hydraulic reservoir. A plastic ring is wrapped around the artery and contains an inflatable balloon mounted on the inner diameter. By adjusting the pressure in the bladder, the balloon size is modified which compresses or loosens the artery. The artery resistance is adjusted and the artery flow is regulated. The primary concern regarding this system is leakage vulnerability. If the system leaks, the pulmonary artery could suddenly become unconstructed, leading to potentially fatal consequences.

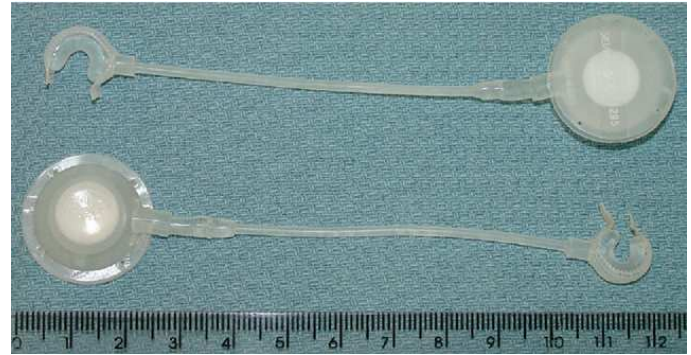


Figure 2: ABS device from Silimed ^[11]

Flowwatch (Endoart, Switzerland) : Flowwatch (Figure 3) implements an electric linear actuator to clamp the artery. Transmission of power and signal employs a wireless system with an external control interface and an internal antenna. The dimensions of this device, however, are too large for the majority of the population that could benefit from PA banding (i.e. newborns).

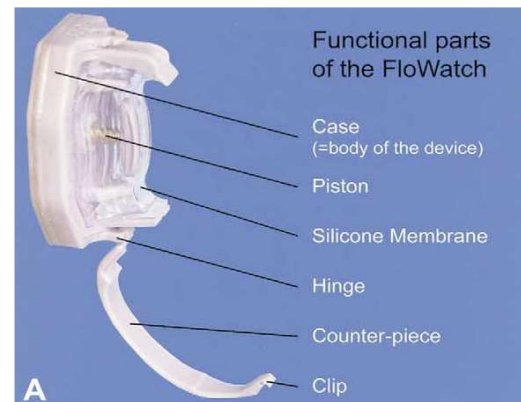


Figure 3: Flowwatch ^[12] (from Endoart SA)

The ABS and Flowwatch each have their own desirable traits and hence niche applications, but for the functional requirements described above, a new approach was deemed necessary.

DESIGN PROCESS

To address this design problem, we divided the system into a set of specific engineering functions: flow reduction mechanism, actuation, transmission of power and control, power source and control system.

Flow reduction mechanism

The first function of our device is the clamping system. We considered three main strategies for this function: a circumferential compression method, an internal obstruction method, and a flattening method as shown in Figures 4, 8, and 11 respectively.

The circumferential method acts uniformly along the perimeter of the artery. The artery wall buckles resulting in smaller cross section area for the same perimeter of the artery as shown in Figure 4. The PA banding operations currently in use are based on this buckling approach. In one embodiment, a ribbon band is looped around the artery and a linear screw-type actuator tightens or loosens the band, as illustrated in Figure 5.



Figure 4: Buckling strategy, reducing the circumferential perimeter of the artery

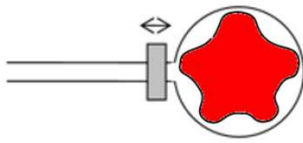


Figure 5: Loop concept

The wedge concept depicted in Figure 6 consists of two rings moving relative to each other along the axis of the artery. This axial motion is converted into a reduction of the diameter of the inner (black) ring due to a wedge-like structure (between black and blue ring).



Figure 6: wedge concept

The last method of inducing a buckling of the artery wall is to inflate a ring around the artery, as shown on Figure 7. This is the concept used for the ABS banding.



Figure 7: inflatable ring concept

This buckling strategy was eliminated as the force required for this was much higher compared to the flattening approach (3 times as much according to our bench level experiment on 1cm diameter flexible silicon hoses). Furthermore, this buckling relies on a mechanical instability and thus it is difficult to predict the cross section area for a given reduction of the outer diameter of the ring.

Another strategy represented in Figure 8 would be to diminish the cross section artery by partially obstructing its lumen (inserting an inflatable element inside the artery). This strategy is very complex especially regarding the risk of clogging and the difficulty to deliver the system without cutting the artery.



Figure 8: Section reduced through the use of an internal inflatable element

The last strategy is the flattening of the artery, shown in Figure 9. Changing the shape of the artery from a circle to an ellipse allows a decrease of cross section area for a given perimeter of the artery.

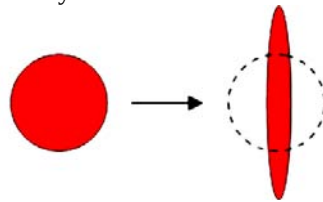


Figure 9: Flattening the artery from one side

Two concepts were studied. For the first one, shown in Figure 10, a piston moves perpendicular to the axis of the artery and deforms it.

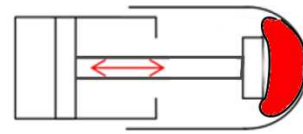


Figure 10: Valve strategy

A second concept involves the pinching of the artery between three poles. Different mechanisms to actuate the poles will result in the pinching of the artery and a diminution of the cross section area due to asymmetric flattening.

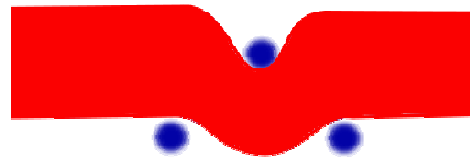


Figure 11: Triangle concept

Overall, this flattening of the artery requires less force and is more repeatable than the two other strategies.

Actuation

We considered three types of actuators: electric, hydraulic and magnetic. The critical parameters are force, required space, control system, and power transmission mechanism.

First, a magnetic actuator is considered: an external permanent magnet or controlled magnetic field is applied to the device which contains another small permanent magnet. The internal magnet made of strong permanent magnetization material (like neodymium) aims to stay aligned with the applied external magnetic field. Hence by changing the external field orientation, a torque can be provided to make the internal magnet rotate. This torque can be used to move a screw or similar device as shown in Figure 12.

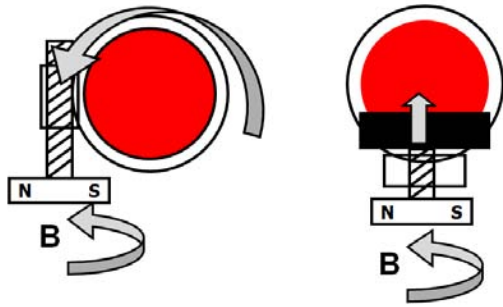


Figure 12: Rotary and linear motion provided by magnetic actuation

Magnetic actuation can provide reasonable force and has the advantage of being driven externally. An example of magnetic actuated medical implant is the PS medical Strata™ valve by Medtronic.^[13] However, the position and orientation of the device have to be known precisely in order to align the external field appropriately, and this can be very challenging as the device is largely free to move with the artery in the body. Its sensitivity to electro-magnetic noise is another weakness of this type of actuation.

Second, we considered an electric actuator: electric power can supply number of different actuators. They can be piezo-electric actuators, shape memory alloy actuators, or conventional electro-magnetic motors, all of them providing either a rotary or a linear motion. Conventional piezo-electric actuators can generate very precise but low stroke motion (typically a few percent of strain). It requires high voltage (tens to hundreds of volts) as well as complex mechanisms to amplify the stroke. Some piezo-actuators were also found to produce a rotary or linear motion of an auxiliary part. Those can provide the required stroke while having a small footprint, like the Squiggle™ motor.^[14] But again, need for high voltages and precise controller seems to disqualify this solution.

Conventional electro-magnetic motors fitting our space requirements are not common. They are pushing the size limits of the technology. A few companies specialized in small-scale electric motors provide products with interesting specifications like Faulhaber^[15] and Penny motors,^[16] but none really meet our requirements.

Finally, the hydraulic actuation has been considered: two different hydraulic actuators can be used, bladders and balloons (soft shell) or cylinders (hard shell). In both cases, a fluid inside the actuator is pressurized by an external source and yields a pushing force. Hydraulic cylinders are very robust and have high energy density. Small hydraulic systems are available, for example from Bosch Rexroth Pneumatics^[17] and the Lee company.^[18] However, their size is still too large for our design constraints. Balloons on the other hand clearly have the size advantage. Due to their mechanical simplicity, they can be made very small, and medical applications commonly include balloons that can fit into small conduits like arteries. Common silicone balloons can stretch by several hundred percent. Hence, a large stroke balloon can take a relatively small space. Balloons have also proven to bear pressures of many atmospheres. In our application, this would be more than enough to actuate the system. An example of balloons that meet our force and size requirements can be found in direct coronary atherectomy operations (patents for DCA).^[19,20] On the down side, hydraulic actuators can be subject to leakage (between 1% for intra-aortica balloon pump,^[21] to 1.8% or even 4.4% in adjustable gastric band^[22,23]).

Power source, transmission & control information

Two main strategies can be pursued to provide power and control information to the device. Either the device can operate in a full wireless fashion, or it can stay connected to a remote source by some links such as electrical wires or fluid hoses.

Wireless transmission can be achieved in several ways. A simple way would be to send a conventional RF electromagnetic signal acquired by an internal receiver. This technique has the advantage of being broadly used and easily implemented. Also, it allows signal encryption to avoid parasitic signals that could actuate the device. This could be used for either transmitting power or control information. It can also be coupled to an internal battery. On the down side, the size of such internal receivers is significant. For magnetic actuation, the transmission of power and control is made by the application of a constant magnetic field. This method can be applied easily. Finally, another possible wireless transmission can be heat transfer. However, this possibility is discarded due to potential damage to tissues and the fact that standard transmission systems of this kind are not easily available.

On the other hand, a physical transmission line is simpler and more reliable. For electric actuation, it simply requires a couple of electric wires to lead from the device to a safe location (typically the side of the chest). For hydraulic actuation, small diameter tubes can run through the body from the device to the skin. Physical connections offer the significant benefit of delocalizing components such as fluid reservoirs, self-sealing bladders, pumps or electronic components to a less space critical area of the body or through the skin via a catheter. For those reasons, the frequency of use of such devices is increasing. Moreover, for hydraulic actuation, the control over the fluid can be volume regulation depending of the type of actuator. This can be either achieved by calibrated dispensers or

external controlled pumps. Finally, we can design an actuation mechanism in such a way that only a specific sequence of inputs makes the device move (i.e. digital mechanical coding). It was concluded that electric actuators near the heart would not offer the energy density needed given the space requirements, even by delocalizing the power source and the control board.

CONCEPT SELECTION

After having reviewed all the different design options from the possible combinations of the choice table (Table 1), we opted for a fluidic solution that is externally controlled and powered. The compression mechanism is chosen to be flattening as is it the most reliable, repeatable and least harmful. The actuators chosen are the fluid balloons as they provide significant force for a minimum space. They are linked to fluid lines going to a catheter. The flow in the lines is regulated by an external fluid setup, which for our prototype is composed of syringes operated by the surgeon.

Table 1 : Engineering functions strategies
Flow reduction mechanism

<i>Inside</i>	<i>Flatten</i>	<i>Circumferential</i>	
Partial obstruction	Triangle	Band	
	Valve	Hose clamp	
	Wedge	Loop	
Actuator			
<i>Magnetic</i>	<i>Electric</i>	<i>Hydraulic</i>	
Permanent magnet	Piezo	Balloon	
	SMA	Cylinder	
	Electric motor		
Transmission of power and control			
<i>Wireless</i>	<i>Electric wires</i>	<i>Fluid lines</i>	
RF signal	Subcutaneous receiver	Subcutaneous bladders	
Magnetic field	Through catheter	Through catheter	
Heat			
Power source			
<i>Internal</i>	<i>Wireless</i>	<i>Magnetic</i>	<i>Hydraulic</i>
Battery	RF	External field	Pressurized bladders
Energy harvesting	Induction		Syringes
			External fluid control unit
Control			
<i>Electric</i>		<i>Hydraulic</i>	
Internal controller board		Calibrated dispenser	
External controller board		Flow/pressure controlled pump	
		Valves system	
		Digital actuation	

This design selection is translated into a list of engineering requirements describing all the functions to be accomplished. As concerns the actuator, we opted for a stepping mechanism, having the advantage of full reliability. In case of actuator or control failure, the device does not move and stays securely in place. Also, a stepping mechanism avoids stick/slip phenomena and enables excellent repeatability. Under the simple compression assumption, a target resolution of 0.2 mm step size for the device was estimated as sufficient to provide the doctor enough flexibility.

As we use balloons as actuators, any leakage or excessive pressure due to accidental squeezing or bending of the fluid lines should not affect the stability and reliability of the system. The stepping mechanism should always be stable even if one of the fluid lines becomes unstable. This consideration negates the need for having two fluid lines where one is unlocking the system and the other moves the piston. Two fluid lines must engage in a defined sequence to move the piston. This coding avoids unintended movement of the mechanism.

FINAL DESIGN

Stepping mechanism

Starting from a rest position fully engaged on one side (Figure 13 (i)), the piston (located between two racks) can move either up or down by following the shape of the racks teeth. This is due to the specific spacing between the two racks. Assuming that the operator wants to move down one step: First the piston moves down and the rack is moved left (ii) to engage in the right rack (iii). Then the rack is actuated to move right (iv). The piston is thus moved one step (v). To move up, the operator follows the same procedure but this time the piston has to be pushed up (vi)-(ix).

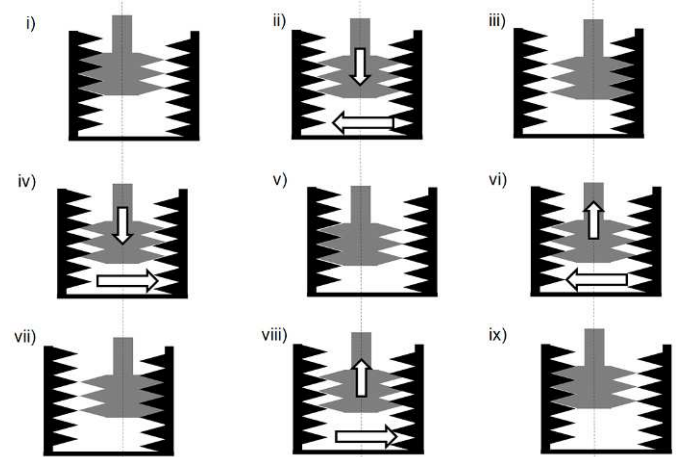


Figure 13: Stepping mechanism with internal piston and double rack part

In our design, the force on the piston and on the rack is exerted by a balloon on one side and a counter-spring on the other. To move one way, the balloon is pressurized, and to move the other way the balloon is deflated and the counter spring pushes back.

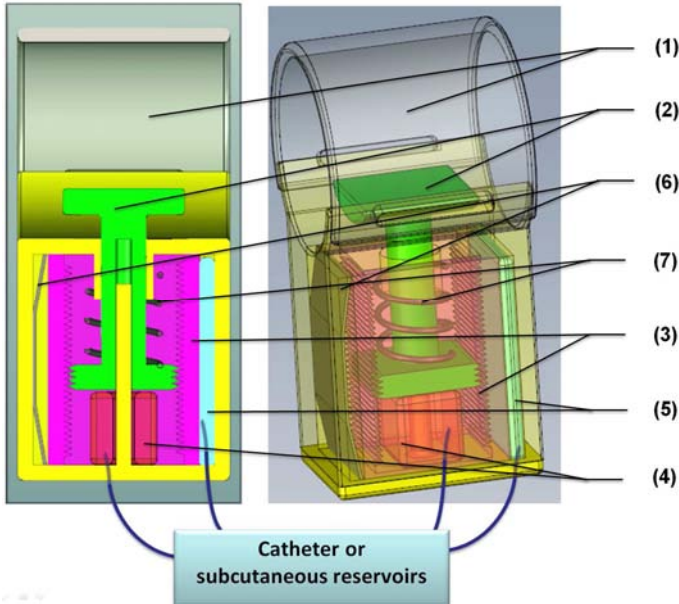


Figure 14: Device details

Our final design is composed of four parts, two balloons and two springs, which can be flexures. Referring to Figure 14, (1) is the cap which goes around the artery. (2) and (3) are the two moving parts. The piston, (2), is constrained to move along the z axis, in translation only. The rack part, (3), is constrained to move only in translation motion along the x axis. The inside distance between the two racks is slightly bigger than the width of the piston minus the depth of the teeth. As a result, even though the teeth are not sharply tipped, the piston engages smoothly in the rack, one step up or one step down.

For artery squeezing, to the “RED” balloon (4) is first inflated. This results in a preload which will put the top part of the teeth in contact with the rack. Then, by inflating/deflating the “SIDE” balloon (5), the rack will move back and forth in the x direction thanks to the return spring (6), resulting in the advance of the piston. Similarly, if the red balloon (4) is deflated, the spring (7) will pull the piston back so that the bottom edges of the teeth are in contact with the rack. Since the counter-spring’s force ranges from 2 to 3 N, the balloon pressure ranges from 2 to 4 bars. When the red balloon is deflated, all the counter-spring’s force is applied to the rack’s teeth. An FEM analysis has been completed and, as a result, the tooth maximum stress due to this force is approximately 4 MPA.

The major advantage of this system is that there is no quick and uncontrolled motion, since the piston cannot go more than a tooth pitch at a time. Similarly, no precise control in pressure or flow is required. A true hydraulic incremental stepper actuator is achieved.

The actuation is based on an incremental sequence of operations; depending on the way the sequence is accomplished, the doctor decides the direction of the adjustment, while depending on the number of cycle the sequence is iterated, the doctor decides the amplitude of the adjustment (Figure 17)

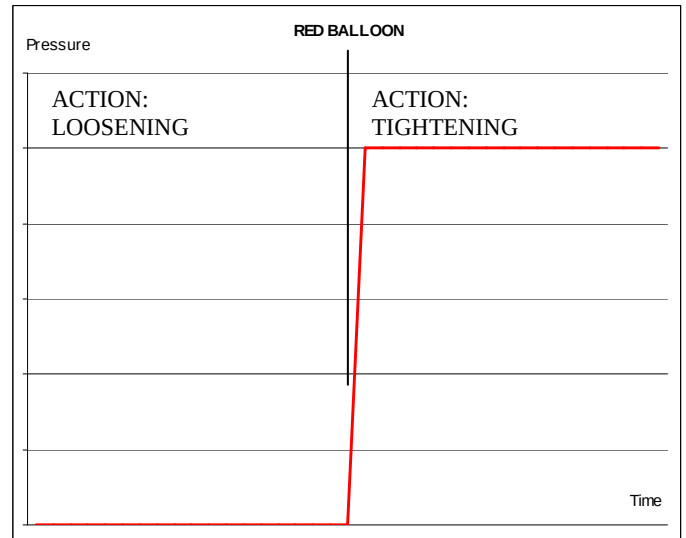
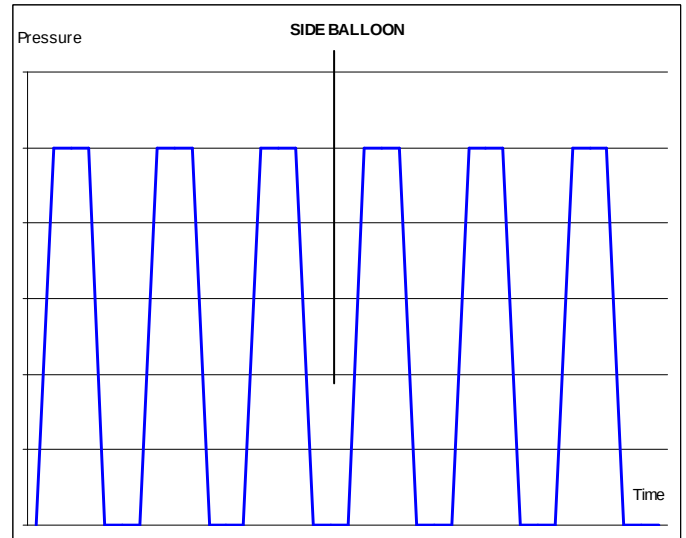


Figure 15: Pressure versus time charts. The Side Balloon (chart above) moves the rack sideward back and forth, while managing the pressure of the Red Balloon the doctor can decide the direction of the movement.

Further than the core system, there are other features of the device that should be considered further. First, a flexural clip simplifies the implantation and avoids any artery cutting: this small and thin part - as shown in Figure 14 (1) - could be easily wrapped around the artery. Second, body movements and shocks do not influence or change the position of the clamp: the leaf spring (6), which engages the piston’s tooth with the racks, has a force that is an order of magnitude bigger than the maximum dynamical force generated by shocks (the maximum acceleration acting on the device being 3g).

No pressure control is required; instead checking the volume displacements in the syringe that engage the red balloon could be enough as feedback for the system, hence assuring that a step has been accomplished.

Manufacturability

One of the most challenging aspects of the design is the small size of the device, and the demands placed on fabrication. Though there are processes that can easily produce the features and precision that we require, the number of parts and the difficulty of assembly increase as the size goes down. Although we do not have a complete design taking into account fabrication processes, overall, we have a plan for how to fabricate the device. The teeth can be made with wire EDM in an MRI compatible metal (specific stainless steel or titanium). The housing and part of the piston that contact the artery can be micro injection molded polypropylene. Polypropylene is well characterized for micro injection molding,^[24] and also FDA approved for implantation. Finally, the balloons can be molded out of elastic silicone. FDA approved silicones up to 1400% elongation are available.^[25]

Effective drop of pressure/ change of flow

The idea of our constricting device is to have a decrease the flux of blood going to the lung. As a result, to measure the accuracy of our system on this performance criterion, we have designed an experimental protocol. The idea here is to reproduce the cardiovascular system. A pump is substituted to the heart and a back pressure valve to the vascular system. An inflatable balloon filled with water is used to mimic the behavior of the artery. Then, we need install the sensors: a flow meter and two pressure gages. A schematic of this test setup is shown in Figure 16.

This experiment will allow us to have a calibration giving the flux and pressure drop as a function of the linear motion of the piston. More than that, the top part of the piston has not been tune yet. Though, we believe that tuning the shape of this part will allow for increase in performance (finer control at the end of the stroke, less damage, ...)

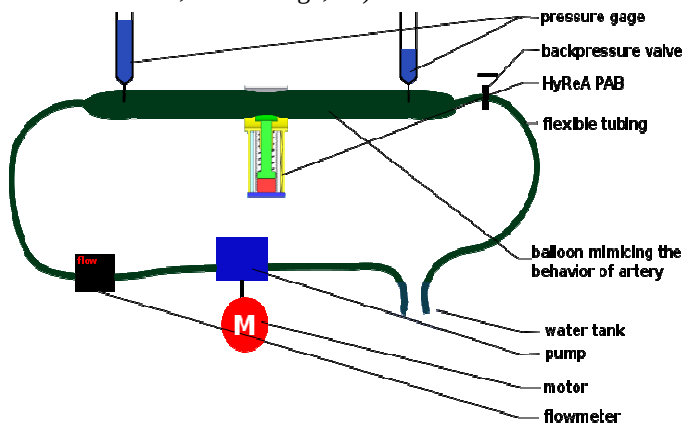


Figure 16: Protocol to map the system (pressure drop and flow reduction for a given position of the piston)

EXPERIMENTAL RESULTS

After having refined the details of each part, the prototyping phase started. To fabricate the prototype quickly, we had to modify the design. First, the model was scaled five times larger (and the teeth 10 times larger), to ease fabrication

requirements and provide better view of the mechanism. Furthermore, custom silicone balloons are expensive and slow to obtain, so we replaced them with small, commercial pneumatic cylinders. Hence, some features have been added to the external housing of the device. The device is operated by hand via syringes filled with water. The custom parts were fabricated with an Invision SR 3-D Printer (3D Systems) which fabricates parts with an acrylic material. This material has a unique advantage for this prototyping purpose because it is slightly transparent so the internal mechanism can be observed during operation. The completed device is show in Figure 17.

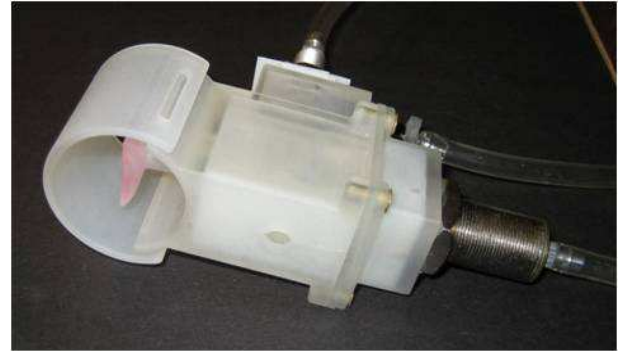


Figure 17: Working prototype actuated with hydraulic cylinders

Initially, there were a few issues that prevented the prototype from operating. First, it was found that the teeth tended to jam together if there was too close of a fit. Adding 50microns of backlash to the 2mm pitch teeth by making one set of teeth smaller remedied this problem.

The second issue we encountered was the rack jamming due to loads causing it to rotate and press against the housing. Two possible methods were used to remedy this: pins through the housing and rack or a closer fit on the top and bottom of the rack. It was found that the latter was sufficient and simpler, so the pins were left out. Note that in the original design, the balloons and springs are designed to push on the rack uniformly to help prevent jamming.

Although several changes were made to the original design for fabrication purposes, the prototype successfully demonstrated the correct operation of the device. Videos of the demonstrations are available at <http://web.mit.edu/~deterre/Public/apab/>. Additionally, it helped to identify a few of the small adjustments in the design necessary for proper operation. Discovering these in a low cost, large-scale prototype will ease further development and prototyping at smaller scales.

Further tuning of the design

The 5:1 scale prototype has helped to fine tune some parts of the design. However, certain parts differ significantly from the final design and this prototype was not useful in testing all aspects of the system. In particular, future prototyping will have to focus on two parts of the design. The first is to quantitatively determine the tolerances and surface finishes that the teeth require to operate. The other major area of future

prototyping work is the balloons. The balloons need to be carefully designed to have sufficient thickness to be tough, but be sufficiently thin to be actuated by a reasonable pressure.

CONCLUSION

In conclusion, we have designed a remotely adjustable pulmonary banding device for neo-natal implantation that achieves our specifications of size and reliability. It utilizes a novel hydraulic stepping mechanism that holds its position in the case of balloon leakage and other known failure. For this reason, this mechanism may have application in other medical devices and even in industrial machinery. A 5:1 scale prototype that successfully demonstrated the concept was built and successfully tested. Further work remains in scaling the design and obtaining balloons for use in testing.

ACKNOWLEDGMENTS

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