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Hemodialysis Graft Resistance Adjustment Device

Up to eight percent of patients develop steal syndrome after prosthetic dialysis access graft placement, which is characterized by low blood flow to the hand. Steal syndrome results in a cold hand, pain, and in extreme cases, loss of function and tissue damage. A practical and easy way of adjusting the fluidic resistance in a graft to attenuate the risk of steal physiology would greatly benefit both surgeons and patients. This paper describes the design and development of a device that can be attached to a dialysis access graft at the time of surgical implantation to enable providers to externally adjust the resistance of the graft postoperatively. Bench level flow experiments and magnetic setups were used to establish design requirements and test prototypes. The Graft Resistance Adjustment Mechanism (GRAM) can be applied to a standard graft before or after it is implanted and a noncontact magnetic coupling enables actuation through the skin for graft compression. The device features a winch-driven system to provide translational movement for a graft compression unit. We expect such a device to enable noninvasive management of steal syndrome in a manner that does not change the existing graft and support technologies, thus reducing patient complications and reducing costs to hospitals. [DOI: 10.1115/1.4006545]

Keywords: blood, blood vessels, kidney, patient treatment, graft

1 Introduction

Up to eight percent of patients undergoing permanent hemodialysis (HD) access placement develop steal syndrome [1], which is characterized by low blood flow to the hand (ischemia) due to flow through the implanted access graft. Steal syndrome causes a cold hand, pain, and in extreme cases, loss of function and tissue damage.

Maintaining vascular access is a significant challenge in HD, because the portal is vulnerable to infection, stenosis, and thrombosis. Vascular access options for HD include the placement of arteriovenous (AV) fistulas, AV grafts, and double-lumen, cuffed central vein catheters. Catheter use is generally associated with higher rates of infection and can compromise the adequacy of HD. Primary AV fistulas, which are the current gold standard and provide access with the fewest complications when successful, are not always the ideal choice for certain patients, including the elderly or patients with specific vascular anatomies, as a suitable segment of vein and artery must be available in the patient's body. A popular alternative, AV grafts allow usage at any time and they have a large surface area available for cannulation. AV grafts are typically implanted in the forearm or upper arm of the patient. In the forearm, loop grafts between the brachial artery and an antecubital vein and straight grafts between the radial artery and an atecubital vein are most common. In the upper arm, the graft typically bridges between the brachial artery and the axillary vein. Both AV fistulas and AV grafts are vulnerable to thrombosis and stenosis. Due to their relatively large size and high initial flow rates, AV grafts are particularly prone to result in a steal physiology. Therefore an easy way to adjust the fluidic resistance in a graft will greatly help both surgeons and patients [2,3].

For steal syndrome (presence of a steal physiology and specific medical signs and symptoms in the patient), currently utilized treatments involve increasing the fluidic resistance by invasive revision surgeries to replace or band the graft, or rerouting the blood flow such that the graft path is effectively elongated through distal revascularization-interval ligation (DRIL). Various alternative approaches have been proposed in literature and patents, which can be generally placed into the following categories: (1) mechanical (via pressure or electric) methods to change the shape of the graft [4–9], (2) special geometries that can passively adjust the resistance of the graft without external actuation [10], and (3) grafts made of smart materials [11] (e.g. wire tissue, shape memory alloys).

We demonstrate here a simple device that can be attached to the graft at time of surgical implantation that will allow providers to externally adjust the resistance of the graft postoperatively.

2 Design Requirements

In order to develop an appropriate and effective graft adjustment solution that meets clinical needs, input from experienced physicians (in both surgery and nephrology) was obtained. A review of the current literature on graft placement and complications was conducted to supplement the physicians' comments.

Flow rates within blood vessels are generally hard to measure, but vascular physicians use methods such as duplex ultrasound to estimate the flow. Often, grafts that are accompanied by steal physiology have higher flow rates through them, anywhere from 1500 mL/min to over 2000 mL/min. The minimum required for

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dialysis is 300 mL/min through the machine, which translates to about 800 mL/min in the source artery.

During graft implantation, an incision about 2.5–3.5 cm long is made at each point where the graft will be sutured to the vessels. A metal tube is inserted to guide the graft into the correct position, and then removed. The graft is then sewn into the appropriate artery and vein on either end. A device that attaches to the graft can be implanted at this time with minimal modification to the procedure. Given that skin and tissue are elastic and how invasive the current procedure already is, the extra implant volume should affect healing time minimally. The incision may need to be enlarged by up to 1 cm (for a device of the dimensions used in this paper) and the overall procedure time will increase slightly, but compared to a second surgery to revise a failing graft, this would be a vast improvement for the patient both physically and financially.

Visits to the operating room and a dialysis center to observe graft implantation surgical procedures further contributed to understanding of the clinical need and the environment in which the device would be used. Based on this work, a list of functional requirements that the final device would have to meet was developed. The device should be:

(1) able to adjust the blood flow rate between 500 mL/min and a maximum of 2000 + ml/min in approximately 100 ml/min steps.
(2) adjustable postoperatively in a minimally invasive way, requiring no additional surgery or other tissue damage to change the resistance.
(3) fit inside a volume of approximately $1.5 \times 3 \times 4$ cm or less.
(4) used in conjunction with currently available grafts (PTFE or Dacron, 6 mm diameter).
(5) enclosed in a box, sealed off from bodily tissue to prevent disturbance of surrounding scar tissue.
(6) capable of allowing thrombectomies to be performed by providers using current techniques.
(7) fully open failure mode to prevent clotting off.
(8) cost-effective.
(9) capable of a two-year lifespan in vivo.

3 Strategy and Concept Development

At a strategic level, we considered the following: (1) which parameter of the graft should be adjusted, and (2) what actuation method should be used to change the flow rate.

The resistance R of a cylindrical graft varies as $R \propto l/r^4$, where l is the length of the cylindrical graft and r is its radius. Resistance adjustment can be further divided into discrete and continuous modes. As the words imply, discrete adjustments would occur in predefined step sizes. In contrast, a continuous mode would offer a much finer level of adjustment. Although both are feasible, the higher resolution offered by the latter provides an attractive level of control–especially in light of the flow rate sensitivity to compression of a graft, which will be discussed later.

Adjustment can also be either active or passive. Active adjustment would involve an external actuation method to change the graft geometry. In passive adjustment, the graft will adjust itself in response to changes in flow rate: as the flow rate increases, the graft resistance will also increase to maintain a constant flow rate. Given the wide range of flow rates the device is required to accommodate and the fact that practitioners should be able to adjust the flow rate during HD or in an outpatient setting, an active control strategy was preferred over a passively adjusting strategy.

A number of different ways of actuating the change in radius of the graft were considered including, but not limited to, electronically, optically, thermally, applying pressure, and using magnets. Magnets were chosen because they do not require an implanted power source and can transfer power noninvasively (i.e. no connection through the skin such as injecting air or fluid to tune the pressure), and are reasonably cost-effective. Therefore, the selected

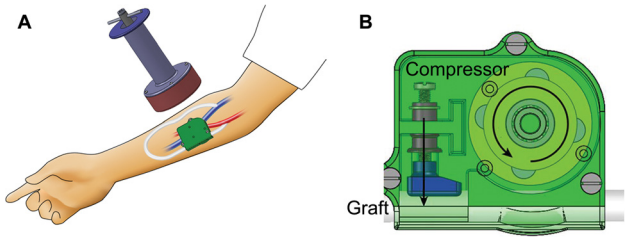

Fig. 1 (*a*) Schematic of the concept to use magnetic force to actuate a device that is implanted inside the body. (*b*) Schematic of the inside structure of the device.

design strategy was to use magnetic forces to actuate a mechanism that would selectively compress the graft to a desired amount. A schematic of this concept is shown in Fig. 1(*a*), where a wand that contains magnets is used outside of the body to control a device that is implanted inside the body (green box). Figure 1(*b*) shows (not in detail) the structure of the device, in which a plate is employed to compress the radius of the graft.

Analytical and experimental models were created in order to understand the relationship between resistance of the graft and its radius and length as well the force that is required to change the resistance. Water ($\eta = 1$ mPa·s) was used for all modeling and experiments because of its similarity in viscosity to blood ($\eta \sim 3$ mPa·s in HD patients [12]). This work was used to validate the feasibility of this approach and the results were employed to develop more detailed specifications for the final device design.

3.1 Analytical Model of Resistance Change by Compressing the Graft. A graft can be modeled as a cylinder with length L_0, and radius r_0. Assuming ΔL of the total length L_0 has its radius changed by an amount Δr, as is shown in Fig. 2, the graft resistance $R \propto l/r^4$, and $\Delta R = \frac{\Delta L}{(r_0-\Delta r)^4} - \frac{\Delta L}{r_0^4}$. Therefore the absolute value of flow rate change can be expressed as:

$$\left|\frac{\Delta v}{v}\right| = \frac{\Delta R}{R} = \frac{\Delta L}{L}\left(\frac{r_0^4}{(r_0-\Delta r)^4}\right) - 1 \tag{1}$$

Figure 3 shows a contour plot of how the flow rate is expected to change as a function of normalized change in length ($\Delta L/L_0$) and radius ($\Delta r/r_0$). Typically, an implanted graft has a length of 30–40 cm, and the modified length ΔL will be typically 1 cm (constrained by the size of the device), therefore $\Delta L/L_0 \sim 0.03$. Since a flow rate change from 2000 mL/min to 500 mL/min is desired ($|\Delta v/v| \sim 1$), Fig. 3 indicates that the graft would need to have its radius reduced by approximately 60% of its original radius. This analytical result is confirmed by the bench-level experiments in the next section.

3.2 Flow Change Resulting from Graft Compression. To verify the above analytical analysis, a bench-level flow rate experiment was carried out. A clamp was used to compress the graft as shown in Fig. 4(*a*). The compressed graft had a generally uniform inner height, which was measured using a caliper. Figure 4(*b*) shows a highly nonlinear change in flow rate as a function of

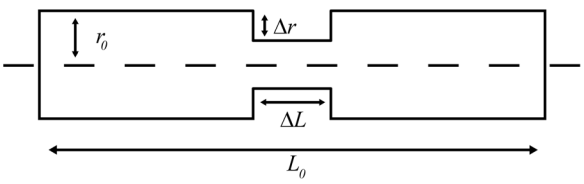

Fig. 2 Schematic cross section of a compressed graft modeled as a cylinder with uniformly decreased radius

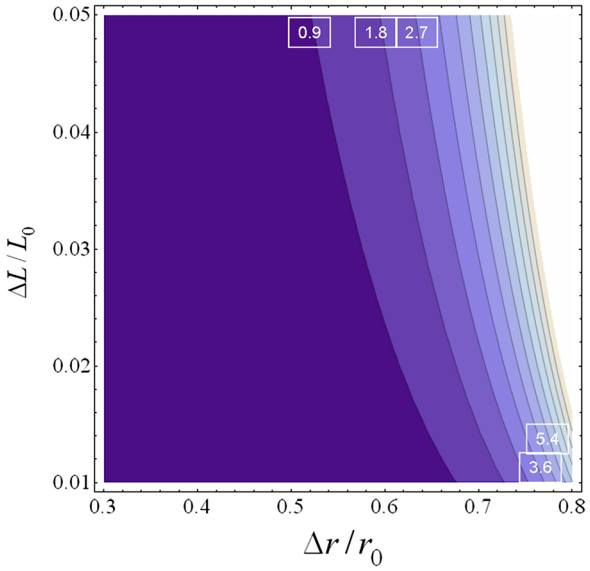

Fig. 3 Contour plot of the flow rate change $|\Delta v/v|$ (value marked on the plot) as a function of $\Delta r/r_0$ and $\Delta L/L_0$, the normalized change in radius and compressed length, respectively, as predicted by the model

the graft compression level. Although the model assumes a concentric decrease in radius whereas physical compression changes the cross-sectional geometry, both demonstrated the need to compress the graft by more than half of the original diameter to obtain a significant flow rate change. Also consistent with the contour plot in Fig. 3, the flow rate becomes very sensitive to further compression beyond a critical point (about 2 mm for an 8 mm-diameter graft).

3.3 Force Required to Adjust the Resistance. In order to determine the compressive force necessary to change the flow rate in the graft, the experiment shown Fig. 5 was performed. Weights were laid on the graft (Fig. 5(*a*)) and the corresponding percentage change in flow was recorded in Fig. 5(*b*). A piece of plastic was placed under the weights to ensure a constant compression length between trials. In order to achieve a resistance change of more than 80% (for example, from 2000 ml/min to 500 ml/min), approximately 1000 g (10N) is needed.

Based on our conversations with physicians, this device would be implanted a maximum of 1 cm beneath the surface of the patient's arm. Thus, when evaluating the force transmission required between the magnets, it was assumed that the magnets in the implanted device and the wand would have a separation of at least that much. Given that the force between magnets decreases quickly with increasing separation distance [13], a bench level

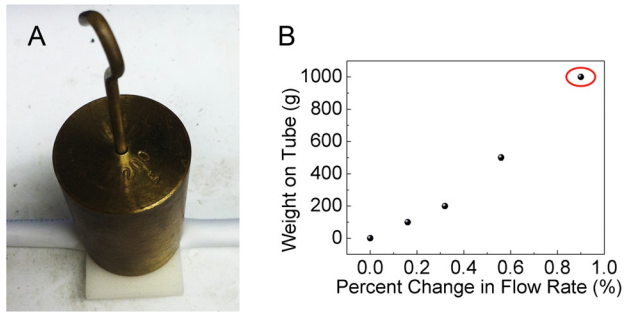

Fig. 5 (*a*) Standard weight compressing the tube used to determine the force requirement for the actuator. (*b*) Plot of the percentage of the resistance change (change in flow) as a function of weight applied to the graft.

experiment was performed to determine the shear force/torque that could be achieved with magnets that would fit within the target volume. The moment arm distance was selected according to the device size constraint that was mentioned previously. A freely-rotating plate containing a smaller magnet (7/8" diameter × 3/4" thick, N42 magnet, K&J) was attached to a shaft using a bearing and an outer casing provided an adjustable separation from a larger magnet (1/2" diameter × 1/2" thick magnets, McMaster-Carr) as shown in Fig. 6(*a*). A weight attached to the plate allowed measurement of the shear force at various distances as plotted in Fig. 6(*b*). At ~1 cm, the two magnets have can generate sufficient shear force to lift up a weight of 100 g (1N).

Based on compression experiments described previously, a ten-fold increase in the applied force is thus necessary to sufficiently decrease flow. This can be obtained using a 4-magnet system combined with a device transmission ratio of at least 3.

4 Concept Selection

Based on the concept of using magnetic shear force to actuate compression of the graft, we designed the four drive mechanisms depicted in Fig. 7. Two elements common to all four designs are: the graft slides lengthwise into a cylindrical cutout in the box, and the magnets are inside the larger turning plate. In Fig. 7(*a*)–7(*c*), the larger turning plate is a gear.

Figure 7(*a*) is a slider crank design whose motion is locked using a ratchet and pawl setup. The arm is attached to the plate such that the graft will be completely compressed when the top of the shaft is rotated to the lowest point, and completely open at the highest. Figure 7(*b*) uses a worm gear in a nontraditional, back-driven design. Rotating the gear drives the worm, which is threaded and drives a lead screw to compress the graft. Figure 7(*c*) is a helical gear design that operates in similar fashion as the worm gear with the smaller gear being threaded and driving a lead screw. Figure 7(*d*) is the winch-based design which contains two cables

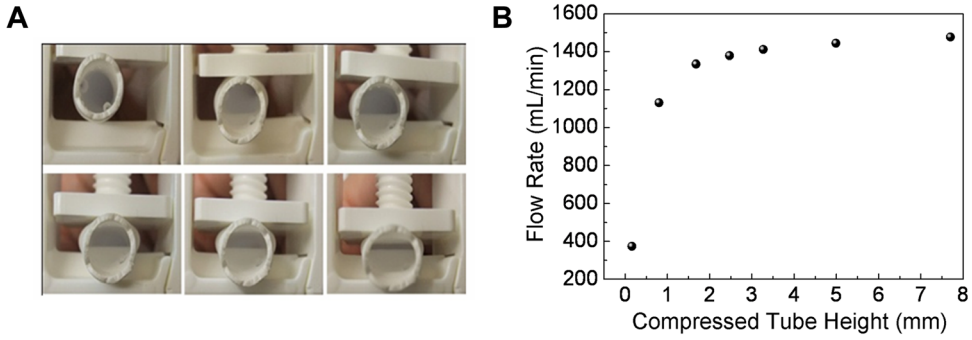

Fig. 4 (*a*) Compressing the graft by varying degrees using a clamp. (*b*) Plot of the flow rate as a function of various amounts of compression.

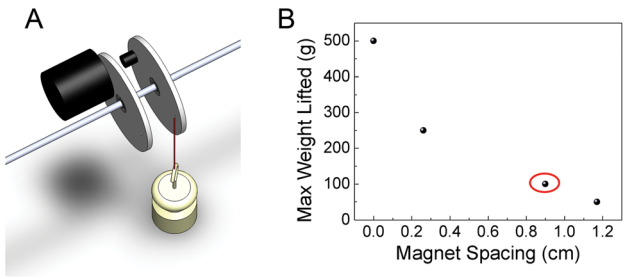

Fig. 6 (*a*) Experimental setup used to measure the shear force between two components of a noncontact magnetic coupling. Magnets attached to two freely-rotating plates were used to lift various weights. (*b*) Plot of the weight lifted by the two magnets at different spacing levels.

strung in opposite directions. The cables turn the threaded small drum, which moves the lead screw.

The slider crank design has the least number of components of the four designs. The compression plate is attached to a shaft at a pivot point by a pin. Another pin connects the shaft to the rotating plate slightly off-center. Since the compression plate is constrained on 4 sides by the casing, when the larger plate is rotated, it must move forward or backward. The primary challenge with the slider crank is having sufficient resolution and sensitivity in adjustment, since it is a discrete solution. The resolution is determined by the ratchet tooth size. Furthermore, due to unidirectional nature of a ratchet, passing the desired position requires the unintuitive action of continuing forward to reset the device. Although the simplicity of the system is attractive, a low transmission ratio prevents it from being a compact solution.

In contrast to the slider crank, advantages of designs utilizing a lead screw are its continuous adjustment range, bi-directional movement, and most importantly, a high transmission ratio so as to achieve sufficient force to compress the graft. A worm gear or a helical gear is mechanically difficult to operate and generally preferred when the smaller gear is driving the bigger one whereas the winch design can be easily driven in either direction and is a relatively simple design.

Table 1 Pugh chart comparing the 4 concepts. The winch design was selected based on this comparison. Each design was rated against each criterion and assigned −1 if it did not meet the criterion, 0 if it did somewhat, and +1 if it fully met the criterion.

Criterion	Slider crank	Worm gear	Helical gear	**Winch**
User friendliness	−1	+1	+1	**+1**
Resolution	0	+1	+1	**+1**
Size	0	+1	+1	**+1**
Cost	+1	0	0	**+1**
Design simplicity	+1	−1	−1	**+1**
Total	+1	+2	+2	**+5**

Table 1 is a Pugh chart comparing the four designs with respect to various criteria. Based on this, the winch design was chosen as the final concept.

5 Winch Design Details

The device has several important modules (labeled in Fig. 8): 8(*a*) a rotary to linear motion converter, 8(*b*) the casing, 8(*c*) the compression plate & lead screw, and 8(*d*) the magnets. A fifth module, the wand 8(*e*), is also required for operation of the device. A concept illustration of how the device will be used is shown in Fig. 8*a*. The prototype device measures approximately 5.4 cm × 4.6

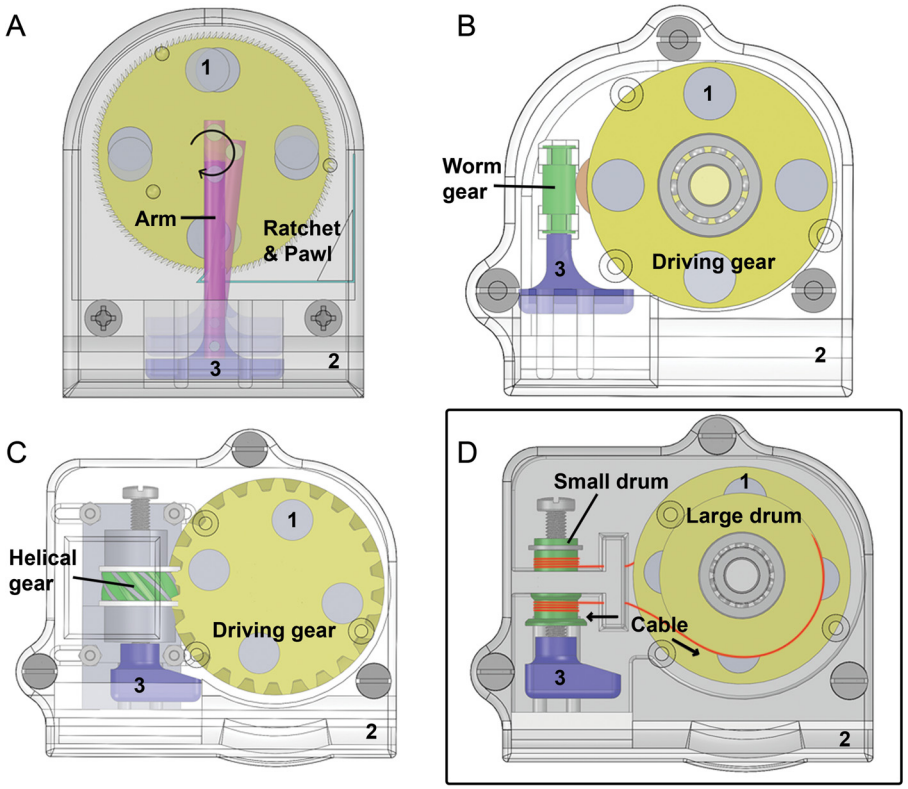

Fig. 7 The four concepts for the drive mechanism for transmitting motion from the magnets in the wand to compression of the graft: (*a*) slider crank, (*b*) worm gear, (*c*) helical gear, and (*d*) winch designs. Components common to all designs are labeled with numbers: magnets (1), slot for graft insertion (2), plate that compresses the graft (3). The winch design (circled) was ultimately selected for its simplicity and functionality.

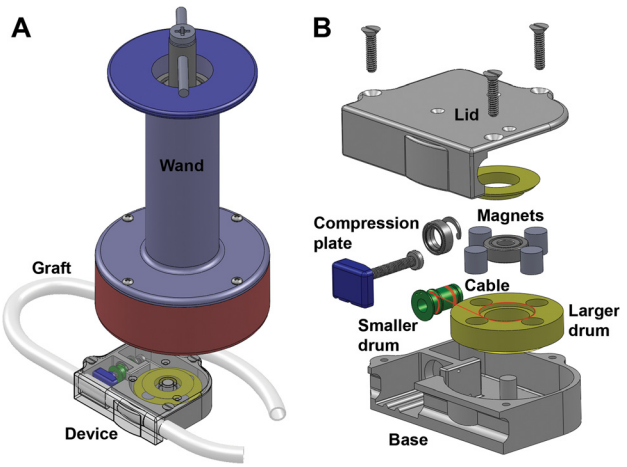

Fig. 8 (*a*) Isometric view of device as it is intended to be used. The device and graft will be implanted while the wand controls the device externally. (*b*) Exploded view of the device to show the various components.

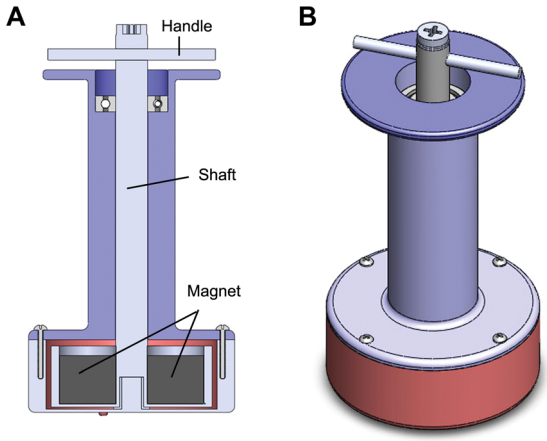

Fig. 9 Section (*a*) and isometric (*b*) views of the wand

cm × 1.5 cm, but the design has potential for being reduced in size in the future.

5.1 Rotary to Linear Motion Converter. The translation of rotary motion to linear is the most critical module in this device. It is crucial for maintaining a small footprint in the final product. In this winch design, the conversion is accomplished using two cables (Coats ® Ultra DEE bonded polyester thread) loaded in opposite directions on the same pair of drums. The cable ends are secured directly to the drums (on one side of the small drum, it is tied to a retaining ring that is attached after tensioning). When a drum is rotated, both of the cables will be under tension; one will wraparound the small drum, and the other will wraparound the larger drum. The smaller drum is held in place by a ball bearing (3/8" OD, 1/4" ID, stainless steel ball bearing, McMaster-Carr) and threaded on the inside. It engages a lead screw that is constrained from rotating, so that drum rotation results in linear movement of the screw and the attached to the plunger that compresses the graft. The two drums have a transmission ratio of 0.4:1 and the screw has a pitch of 0.5 mm.

5.2 Casing. A casing around the device is required to prevent scar tissue formation on the moving parts, which could prevent the device from functioning properly. To facilitate loading of the graft even after it has been sutured in, the casing has a slot through which a flattened graft will fit. The casing also features constraints for the moving parts – a shaft through the center of the large drum, a hole for insertion of a bearing (1/2" OD, 3/16" ID, glass-delrin ball bearing, McMaster-Carr) and the small drum, tracks for the compression plate that constrain the lead screw, and guides for the cables. The casing is split into two pieces–a lid and a box–for assembly purposes. In the prototype, the pieces are held together by screws.

5.3 Compression Plate and Lead Screw. The compression plate is the only moving part to contact the graft. As mentioned previously, it is constrained from rotation by two tracks on the inside of the casing and the lid. The plate is attached to the lead screw by threading and glue. The thickness of the plate is such that it will not fall through the graft insertion slot while the plate passes it.

5.4 Magnets. Four small magnets are embedded in the larger drum. They are arranged in alternating polarity (N-S-N-S) to increase their effectiveness because both attractive and repulsive forces contribute to the motion. The magnets are a major limiting factor for the final thickness of the device.

5.5 Wand. A wand was designed to be able to easily rotate the drum from outside the device. As shown in Fig. 9, it consists of a shaft supported by a ball bearing (1-1/8" OD, 1/2" ID, glass-delrin ball bearing, McMaster-Carr) in the lid. A bushing (3/8" OD, 5/16" ID, Rulon J flanged plastic bushing, McMaster-Carr) prevents the rotating magnet plate from sliding against the base of the wand. Magnets are embedded in the plate which is constrained by the shaft. The magnets in the wand are also arranged in alternating polarity to increase efficiency of shear force application.

6 Device Assembly and Validation

For testing purposes, the device was manufactured by a combination of 3D-printed and commercial parts. The implant modules were assembled piecewise, starting with the lead screw and compression head being threaded through the smaller drum unit. This was followed by pressing the magnets into the larger drum. After the two drum units were secured in the casing by bearings, the cable was manually attached and loaded. Finally, the lid of the casing was secured by screws.

The wand was similarly manufactured, starting with pressing magnets into the magnet plate, and then placing the unit into the wand casing. With large volume manufacturing techniques we estimate that the wand and implanted device would cost approximately $50 and $20 to manufacture, respectively. For both parts, the magnets represent the most expensive component.

The device was tested by evaluating its ability to control the flow of water through a PTFE graft. The graft was connected to a flow source that provided 2000 mL/min through the graft initially. A bifurcation in the flow setup with a smaller diameter tube branching off prior to the graft roughly represented flow through the hand. Anatomically, blood flow through the hand and forearm exits through veins such as the brachial, basilic, or cephalic veins. The pressure in these veins is very small compared to the arteries, so we took it to be negligible and the end of the tube was left open. The assembled device was attached to a 40 cm graft, which is a typical length, and the wand was stationed 1 cm above the device, which is the depth at which the device would be implanted. Assuming that the source flow volume remains constant, any decrease in the flow through the graft is expected to go through the "hand" tube instead. In a patient, this applies as well since a determining factor in how much blood actually makes it to the hand is the fluidic resistance of each component in the system.

Based on the transmission ratio between the drums and the pitch of the lead screw, 3.5 turns of the wand will move the plate from the innermost position (no compression) to the most outer position (maximum compression). The current maximum compression

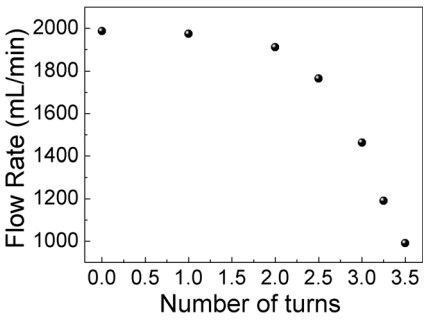

Fig. 10 Flow rate in the graft as the wand is turned

position of the prototype does not fully close a graft of 6 mm diameter but this minimum flow rate can be easily modified by tuning the maximum compression position during assembly.

Figure 10 shows a plot of the flow rate through the graft versus the number of turns of the wand. The data in this figure indicate that a user operating the assembled device is consistently able to reduce the flow rate from 2000 mL/min to 900 mL/min, with a flow profile as seen in the graft compression experiments outlined previously. A smaller pitch lead screw can increase the resolution of the adjustment. Although the graft was not entirely closed in these experiments, a difference of 1100 mL/min is expected to both help avoid thrombosis while being sufficient to decrease the chance of steal syndrome, and thus acts as an inbuilt safety feature.

7 Conclusions and Future Work

In this paper, we have proposed and demonstrated a design for a device that can be attached to a graft at the time of surgical implantation that will allow providers to externally adjust the flow rate through it. Our tests indicated that compression of the graft can provide enough reduction in cross-sectional area to sufficiently reduce the flow rate through the graft for flow rates seen clinically, and that the reduction is extremely sensitive once the compression passes a critical point. The design of a novel actuating mechanism was presented, where a noncontact magnetic coupling was used to noninvasively and precisely move a plate that compresses the tube from outside the skin. We envision this device being suitable for the noninvasive management of steal syndrome and a critical feature is that it works in conjunction with current graft technologies.

The next steps in the development of this device will be to reduce the size, modify the casing to be more ergonomic, attach RFID sensors to report the compression level, and test device sealing schemes. In addition, device testing with blood, and even animal models, will be an important to conduct as well. Apart from assisting patients on hemodialysis, this device has the potential to be useful in other applications in which active control of bodily fluid flow is desirable, such as in treating incontinence.

Acknowledgment

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