Non-Surgical Removal of Partially Absorbable Bionic Implants

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***Abstract*—Bionic implants offer the potential to augment human performance and to assist the body in recovering functions lost to disease. While some may be permanently implanted, others provide temporary support. The challenge for the second case is how to remove the device from the body once its task is complete without forcing the patient to undergo a second surgical procedure. While some devices may be fabricated entirely from absorbable materials, this may not always be possible. This paper investigates a strategy in which an implant is fabricated from a combination of absorbable and non-absorbable materials with the latter connected by a tether to the skin. At the time of removal, the device is disassembled in situ such that the absorbable components can remain in place while the non-absorbable components can be removed non-surgically by pulling them out of the body by the tether. The concept is demonstrated in the context of an implant that induces bowel growth by applying traction forces over a several-week period. In vivo experiments in swine are used to validate the approach.**

***Index Terms*—Bionic implant, tissue regeneration, bowel lengthening, absorbable implants, non-surgical implant removal.**

I. Introduction

BIONIC implants comprise a new category of robotic systems. Examples include the bioartificial pancreas for restoring insulin production in diabetic patients [1], soft compressive sleeves that envelop the heart to improve circulation in heart failure patients [2], [3], artificial sphincters to restore urinary continence [4] and implants to induce tissue regeneration in tubular organs [5].

While some of these devices are intended for permanent implantation, e.g., heart assist devices, others, such as for tissue regeneration, need only be implanted temporarily. Unless the device can be placed endoluminally, e.g., an artificial urinary sphincter, implantation involves a major surgical procedure. If the device needs to be removed, a second major surgical procedure is also required and this can be more complex than the original implantation owing to the formation of tissue adhesions and scar tissue [6].

One promising alternative to surgical removal is to fabricate the bioni implant entirely from absorbable materials. Absorbable suture, hernia mesh and orthopedic screws are currently in clinical use and many recent advances have been reported in the creation of "transient electronics," e.g., absorbable sensors [7] and batteries [8]. For small temporary implants, completely absorbable designs may be the best approach.

For larger temporary implants, however, relying entirely on absorption has several limitations. First, the byproducts of the absorption process produce an inflammatory response on the surrounding tissue [9]. Consequently, absorption of a larger implant can result in a significant and sustained inflammatory response that may lead to permanent damage to the surrounding tissue.

The contribution of this paper is to propose and demonstrate a new approach for the non-surgical removal of temporary bionic implants. The technique involves designing the device as a combination of absorbable and non-absorbable components which are attached to a tether that runs out of the body through the skin. The tether can be used for communication and power supply or simply as a means of attachment. To remove the device from the body, it is disassembled in situ such that the absorbable components are released and remain in place while the non-absorbable components are pulled out of the body by the tether. The fibrotic capsule that forms around the device and along the entire length of the tether serves as a channel through which the non-absorbable bionic implant components can be safely removed from the body in a non-surgical approach.

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The proposed method is developed here in the context of an implant for inducing the small bowel to grow in length as a treatment for short bowel syndrome. In the next section, the clinical need and implant specifications are defined. We then present the implant design and compare it with a prior design requiring surgical removal. The following section describes in vivo animal evaluation experiments. Finally, conclusions are presented.

II. Implant Design

Short Bowel Syndrome (SBS) is a devastating pediatric condition associated with massive loss or resection of the small intestine due to congenital or acquired disease. Since the remaining bowel length is insufficient for absorption of nutrients and fluids to maintain health and support growth, the child is dependent on parenteral nutrition. Long-term parenteral nutrition can lead to a series of morbidities including bloodstream infections and liver disease [10].

Care of SBS patients includes weaning from parenteral nutrition, promoting enteral autonomy through judicious feeding programs, and allowing the foreshortened small intestine to adapt over time. Adaptation, however, does not necessarily result in independence from parenteral nutrition. About 16,000 children require home parenteral nutrition in the U.S. and about half are SBS patients [11]. With per child annual costs of $250-$300k (neglecting the more expensive first year of treatment) [12], total annual SBS expenditures in the U.S. are $2-2.4 billion.

A technique for increasing bowel length in SBS patients would help these patients attain enteral autonomy and accelerate intestinal adaptation while mitigating the cost, inconvenience, and morbidity associated with prolonged parenteral nutrition dependence.

Creating growth through precise application of traction force to healthy tissue is a promising approach to tissue regeneration. This method is applied to lengthening bones [13] and to producing skin grafts [14]. Bowel lengthening has also been demonstrated with this approach using a variety of techniques for applying traction forces [15], [16].

In prior work [5], our group has shown how a mechatronic device can be used to lengthen the esophagus by applying traction forces through rings sutured to the outside of the organ (Fig. 1). The device is connected by tether to an external control box. By moving the rings apart by several millimeters per day, the strain applied to the tissue between the rings induces tissue growth. In vivo testing in swine showed that applying traction over 8-9 days resulted in an average lengthening of 77%.

Creating a comparable device that could be temporarily implanted in the abdomen (for 2-4 weeks) to induce bowel lengthening via tissue regeneration is a promising concept, but requires surmounting several challenges. First, the device of Fig. 1 is too large for use in the pediatric abdomen. Second, it would be highly beneficial to avoid a second surgical procedure to remove the device. The first surgical procedure causes adjacent sections of bowel to form fibrotic adhesions to each other. Subsequent bowel procedures are challenging as the adhesions must be dissected carefully to avoid creating tears or perforations in the bowel wall. Consequently, surgical removal of the device risks damaging the regenerated tissue. Avoiding a second surgical procedure has the added benefit of eliminating the risks and cost associated with a second general anesthesia.

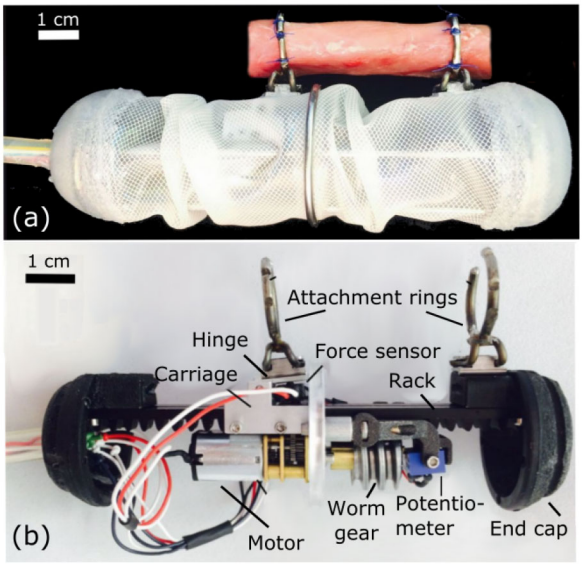

Fig. 1. Bionic implant for inducing lengthening of the esophagus [5]. (a) Implant shown with rings sutured to esophageal segment. (b) Implant shown with waterproof skin removed.

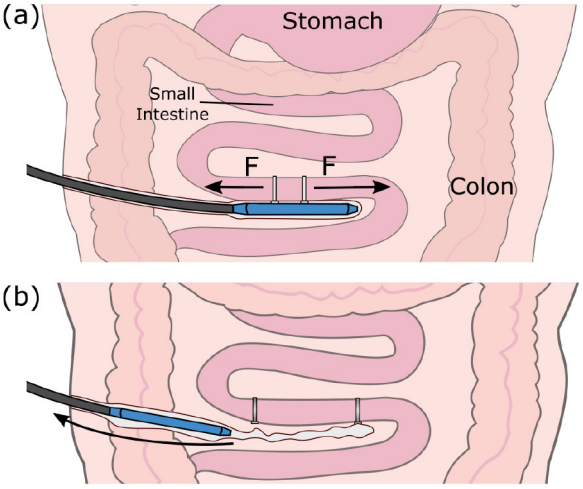

Fig. 2. Implant for inducing bowel growth. (a) Traction forces, F, stimulate bowel to grow longer. (b) Non-surgical removal: After lengthening, absorbable rings are released and structural component is pulled out of body by its tether.

A. Design for Non-Surgical Removal

The concept of a partially absorbable implant that can be removed without a surgical procedure is shown in Fig. 2. At the time of implantation, absorbable rings are sutured externally to a segment of small intestine using absorbable suture ((polydioxanone). Equal and opposite traction forces are generated on the rings via the implant body for inducing growth (Fig. 2(a)). Over a period of weeks, significant lengthening of the segment under tension can be achieved.

If the implant was to be taken out surgically, removal of the rings would be the most challenging part since it would involve

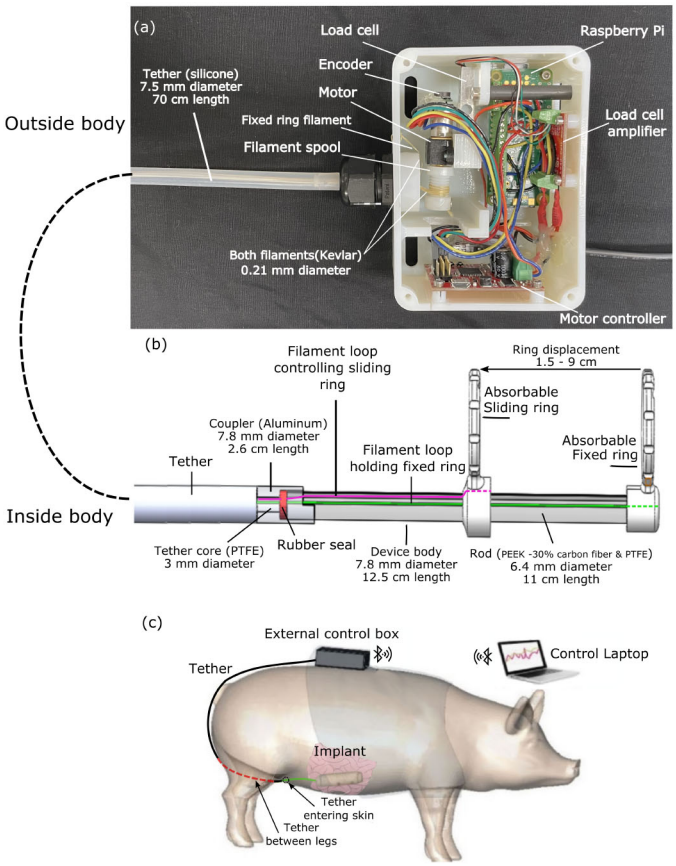

Fig. 3. Partially absorbable implant. (a) External control box connected to implant by tether. (b) Implant body and rings. (c) In vivo testing. Tether runs from incision in skin up and around pig to control box located in pocket of vest worn by pig. Displacement commands and sensor data are communicated wirelessly using a laptop computer.

removing the adhesions to surrounding bowel and cutting the sutures without damaging the bowel tissue. Instead, the rings are fabricated from an absorbable material and attached to the bowel using absorbable suture. At the time of removal, the rings are released from the implant body and the body itself is pulled out by the tether (Fig. 2(b)). The absorbable rings remain in the abdomen sutured to the small intestine and both will be resorbed over time.

There are two main challenges to implementing this design concept. The first is the creation of a compact implant body that enables release of the rings while also providing all of the functionality incorporated in the design of Fig. 1. The second is the design of the absorbable rings. Both are described below.

B. Implant Design

To enable tether-based removal, the diameter of the implant body must be reduced to approximately the diameter of its cable (Fig. 2(b)). This was accomplished by moving the motor and sensors (position and force) from the implant body to the control box as shown in Fig. 3. Component dimensions and material choices are given in the figure.

The distal ring fits on the end of the rod such that its orientation about the axis of the rod is fixed (Fig. 3(a)). To ensure that the distal ring remains on the rod during implantation, a filament loop passes through a channel in the ring, through the center of the rod and out through the tether.

The moving ring slides along the rod with its orientation constrained by a slot in the rod. A filament loop passing through the ring, along the rod and out of the body through the tether is used to control ring displacement. To prevent the passage of bodily fluids and air through the tether, the two filament loops pass through a rubber seal located at the distal end of the tether.

The proximal end of the tether couples detachably to the control box and the filament loop for the distal ring attaches to the control box interior (Fig. 3(b)). The filament loop controlling displacement of the proximal ring winds around a motor-mounted spool in the control box. To release filament tension in an emergency situation, the control box can be opened and the filament either released or cut from the spool. Alternately, the tether can be cut adjacent to the control box. In either case, this would immediately release the proximal ring to slide back toward the distal ring and so relieve the tension from the bowel. Since ring motor-controlled displacements would only be made under operator supervision, the risk of an undetected over-tensioning of the bowel is low.

To remove the implant from the body, the external portion of the tether is wiped with disinfectant and then cut through, exposing the cut ends of the sterile filament loops inside. Then, by pulling one end of each loop, the filaments are pulled free of each ring and out of the tether. At this point, any sutures used to constrain the tether where it enters the body are removed and the tether and implant body are slowly pulled out of the patient. The rings, sutured to the bowel, are free to slide along and off of the implant body.

The motor (1000:1 micro metal gear motor, Pololu Corp.) is mounted on a load cell (Micro load cell 780g, Phidgets Inc., Canada) for measurement of filament tension. An encoder on the motor (magnetic encoder 12 CPR resolution, Pololu Corp.) is used to compute ring displacement. The control box also contains the load cell amplifier ((HX711, Sparkfun Electronics, CO, USA), motor controller (Roboclaw 2x7A motor controller, Basicmicro Motion Control, CA, USA) and a microprocessor with integrated Bluetooth (Raspberry pi Zero 2017, Raspberry Pi Foundation, U.K.). The microprocessor communicates via Bluetooth with a laptop computer to transmit force and displacement data and receive ring displacement commands.

For concept evaluation, we designed the implant components for in vivo testing in 20kg swine. Experiments with ex vivo swine bowel tissue indicated an average small bowel diameter of 2cm and a maximum safe ring traction force of 2.8N at 55% tissue strain. Cadaveric swine studies indicated a maximum safe implant body length of 13cm. Based on our prior esophageal studies, tubular tethers of about 6mm diameter could be safely tunneled out through the skin [5].

Using these requirements, the implant body length was selected to be 12.5cm with minimum and maximum ring displacements of 1.5cm and 9cm, respectively. Given that those children who could benefit the most from the proposed therapy often have less than 10cm of small bowel [17], this range of

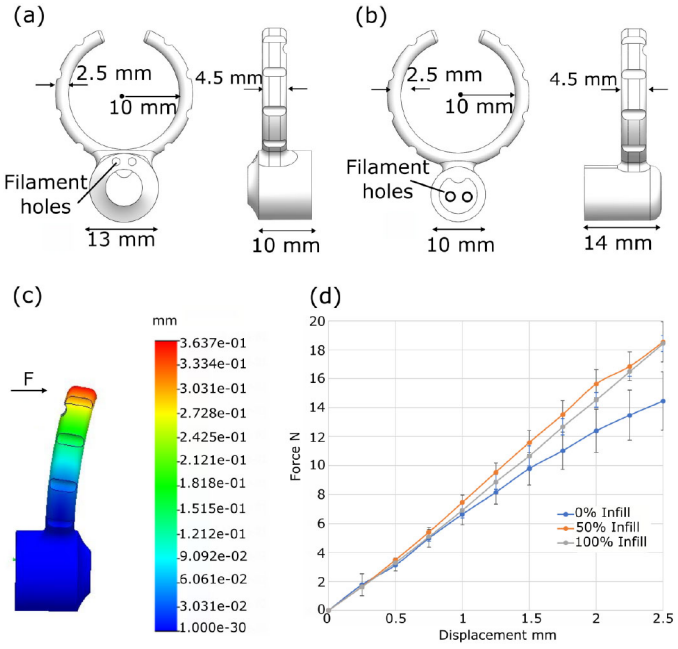

Fig. 4. Absorbable ring design. (a) Sliding ring. (b) Distal ring. (c) FEM predicted ring deflection under 3N load. (d) Experimental force versus ring deflection for infill percentages of 0, 50 and 100% under loading configuration of (c).

travel could produce a clinically meaningful increase in bowel length.

Requirements for the rod comprising the implant body are that it be biocompatible, flexurally stiff and low friction, the latter to facilitate sliding of the ring. To select the rod material, we chose a rod diameter of 6.4mm (1/4") to approximate the diameter of the tether (6mm) from our prior esophageal implant [5]. Assuming a load of 3N applied in the worst case at the outer edge of the rings (See loading in Fig. 4(c)) at an offset distance of 27mm, we solved for the value of elastic modulus that would limit deflection between the rings due to rod flexure and compression to 0.5mm. The resulting elastic modulus was 5.9GPa.

Using this as a minimum acceptable value, the rod material (McMaster-Carr) was selected to be polyetheretherketone (PEEK) with 30% carbon fiber and polytetrafluoroethylene (PTFE). This material is biocompatible, possesses an elastic modulus of 7.5GPa and the PTFE filler ensures a slippery surface. A stock rod diameter of 6.4mm (1/4") was used in the prototypes. Testing indicated that the implant body could be pulled out of the rings by applying a force of less than 0.5N.

The 70cm long tether is comprised of a 7.5mm diameter biocompatible silicone tube (Silicone VP5054-33-10, Translucent 50 Duro, 6mmx8mm, Vanguard Product Corporation, Danbury, CT, USA.) enclosing a PTFE multi-lumen tube. Each of the four filaments passes through its own lumen ensuring minimum friction inside the tether. A biocompatible aluminum coupler (7.8mm diameter) is used to attach the rod to the tether.

To minimize filament stretch under load, the filament was selected to be 0.21mm diameter polyaramid polyparaphenylene terephthalamide (Kevlar fiber, The Thread Exchange) fiber, which has a high elastic modulus and is biocompatible. To assess filament stretch, a 70mm long loop, to match the tether length, was subjected to a 6N load and observed to elongate by less than 1mm. This is over twice the maximum anticipated loading to allow for friction in the tether.

The resulting implant has a maximum body diameter of 7.8mm (from the tether-to-rod coupler), a length of 12.5mm and a tether diameter of 7.5mm. As a point of comparison, the implant of Fig. 1 is 30mm in diameter and 13cm long with a cable diameter of 6mm.

Since the position and force sensors for the rings are now located in the control box, care was taken with respect to sensor calibration. To account for shape-dependent friction in the tether, calibration was performed with tether curvature matching the shape used during in vivo testing (Fig. 3(c)).

Note that during in vivo testing, the control box must be connected to the tether after the tether is passed from the abdomen out of the body through a small puncture in the animal's flank. When it is first connected, there is slack in the filament loop connecting the sliding ring to the motor spool. It was determined that all of the slack could be removed by commanding the motor to perform a 5mm ring displacement.

Once the slack was removed, motor displacement corresponded to ring displacement and force sensor values converged to constant values for constant ring forces. Since ring motion is unidirectional, this initial displacement could be performed during the implantation procedure to create a small initial tension in the bowel segment that would ensure accurate position and force measurements for the duration of traction. Furthermore, we were able to verify that specified commanded displacements corresponded to actual ring displacements using a sterile ruler.

Note that tightening of the distal ring filament loop is not necessary. Bowel tension keeps the distal ring seated on the end of the device body. The filament loop running through the distal ring acts as a failsafe. It needs to be just tight enough so that the ring remains on the implant during the surgical procedure and prior to the application of traction.

C. Ring Design

Many different biodegradable polymers are available and their selection depends on the desired mechanical properties and absorption rate. For this application, the optimal polymer would maintain its mechanical stiffness and strength for a period of 2-4 weeks and then absorb as quickly as possible.

For the demonstration purposes of this paper, no attempt was made to optimize the choice of polymer. Polylactic acid (PLA) was selected since its mechanical strength lasts 3 months [18], which exceeds our experimental requirements, and PLA ring designs can be easily fabricated using Fused Deposition Modeling (FDM) 3D printing. The median half-life for absorption of PLA is 30 weeks, a period that can be adjusted by varying its molecular composition [19].

Given that the titanium rings used in our previous implant (Fig. 1) were 2.5mm in diameter, an initial PLA ring design was created with an elliptical cross section as shown in Fig. 4. While the sutures attaching the bowel to the ring will

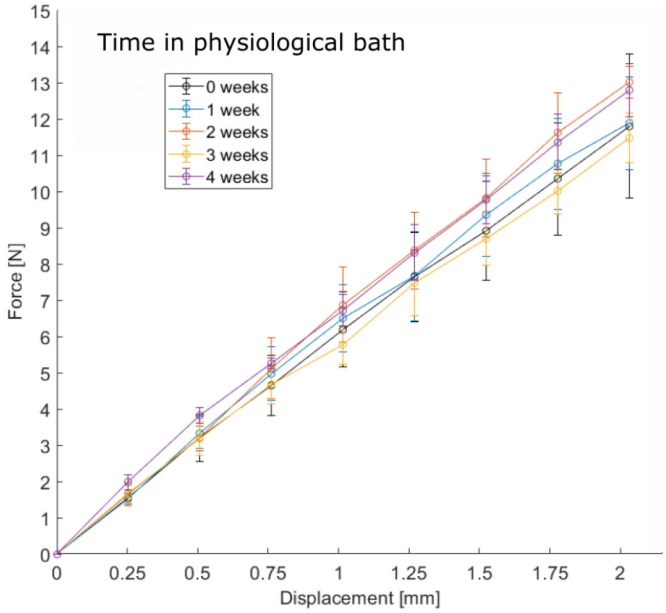

Fig. 5. Ring force versus displacement as a function of time soaking in physiological bath at 37°. Mean and standard deviation bars are plotted.

distribute the load over the entire ring, a worst-case scenario was assumed in which the load was applied to the open ends of the rings (Fig. 4(a)). Ring thickness was maintained at 2.5mm, but, to compensate for the smaller modulus of PLA (2.7GPa [18]), ring height was adjusted using FEM analysis to obtain a maximum ring deflection of 0.36mm for a load of 3N (Fig. 4(a)).

This ring design was then 3D printed using infill percentages of 0, 50 and 100% (n=3). Ring stiffness was evaluated by mounting the ring in a vise on a micrometer stage. As the micrometer stage was advanced, a T-shaped bar attached to a stationary load cell applied loads to the ends of the rings in the same manner as shown in Fig. 4(c). Since smaller infill percentages will absorb faster, it was desired to use the smallest value meeting the design criteria. As shown in Fig. 4(d), rings with a wall thickness of 0.8mm with 0% infill deflected by 0.5mm under a load of 3N which was deemed sufficient for in vivo testing.

To ensure that ring stiffness could be maintained in vivo over a 2-4 week period, sets of rings (n=5) were fabricated and tested under simulated physiological conditions. The rings were immersed in PBS solution (0.1 M, pH=7.4) inside an incubator maintained at 37°C. The solution was agitated daily and, on a weekly basis, the pH of the bath was tested. As needed, the buffer solution was replaced. One set of 5 rings was removed each week over four weeks and subjected to stiffness testing.

Fig. 5 shows that ring stiffness is maintained over the 4-week period. Furthermore, ring deflection under worst-case ring-tip loading remained less than 0.5mm for a load of 3N. Consequently, the ring design was deemed sufficient for in vivo testing as described in the next section. We also found that there was no appreciable absorption during the 4-week period as determined by weighing the rings.

III. In Vivo Experimental Evaluation

Three in vivo experiments were performed in swine. These experiments were approved by Boston Children's Hospital Institutional Animal Care and Use Committee. In the first experiment, the implant developed for esophageal lengthening (Fig. 1, [5]) was used. There were two objectives to this experiment. The first was to demonstrate that bowel lengthening could be achieved using rings to transmit traction forces to a connected section of bowel. The second objective was to evaluate the difficulty involved in surgically removing the implant and rings after traction-induced lengthening. Due to the large size of the implant, a 40kg pig was used for this experiment.

The second and third in vivo experiments used the implant of Fig. 3 and were performed with the objective of demonstrating the concept of non-surgical implant removal. This device is intended for a pediatric population and so was designed to fit in smaller 20kg pigs, which were used in Experiments 2 and 3.

In all experiments, on the first day of traction, a larger initial displacement was performed in order to apply an initial strain of 25-50% to the tissue between the rings. Small daily incremental displacement were subsequently used to maintain strain as the tissue lengthened. All experiments were performed following procedures prescribed by the Institutional Animal Care and Use Committee. The implants were sterilized using ethylene oxide.

A. In Vivo Experiment 1: Implant Requiring Surgical Removal

In this experiment, a 40kg pig was used and the rings were sutured 22mm apart to a section of small bowel located 90cm distal to the ligament of Treitz. The tether was tunneled out through the animal's flank and connected to the control box which was placed in the pocket of a vest worn by the pig.

As shown in Fig. 6(a), suturing the rings to the bowel creates a radial force preventing obstruction. Traction was initiated 48 hours after implantation with an initial displacement of 5.5mm followed by displacements of 2.5mm on the following four days. The animal ate and passed stool in a normal manner. On the eighth day, the animal was sacrificed. During necropsy, bowel adhesions typical of surgical interventions were observed. Using great care, these adhesions were dissected and the implant rings were removed from the bowel segment. As shown in Fig. 6(b), the initial 22mm length had increased by 68% to 37mm over 5 days of traction. Fibrous capsules due to foreign body reaction formed over the implant body and rings isolating them from the surrounding bowel. Remnants of the ring capsules are visible in Fig. 6(b).

While no bowel leaks were created, ring removal was very challenging. The adhesions connecting the lengthened bowel segment to surrounding bowel had to first be carefully separated. Next, the capsules enclosing each ring had to be removed to expose the individual sutures attaching the rings to the bowel. Each suture was then cut and removed.

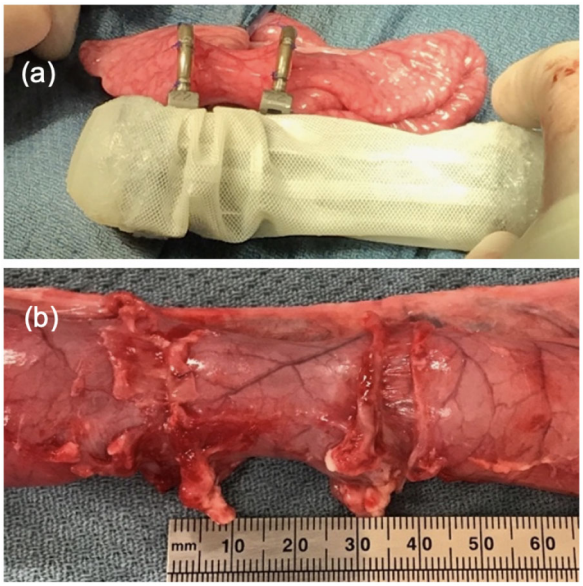

Fig. 6. Bowel lengthening using implant of [5]. (a) Implant sutured to bowel during implantation. (b) Lengthened bowel segment after removal of rings showing growth from 22 mm to 37 mm. Rings were attached at 0 and 37 mm with respect to the ruler in the image.

B. In Vivo Experiments 2 & 3: Non-Surgical Implant Removal

Two in vivo experiments were performed in which the device of Fig. 3 was implanted in 20kg pigs. The absorbable rings were sutured to a segment of bowel as shown in Fig. 7(a) using absorbable suture (5-0 PDS polydioxanone, Ethicon, Johnson & Johnson). This suture retains about 50% of its strength at four weeks and is completely absorbed in 6 months [20]. To ensure that the suture did not slide around the rings, the notches of Fig. 4 were replaced with holes through the rings (Fig. 7(a)). The radial force from the rings can be observed to prevent bowel obstruction.

The tether was tunneled out through the animal's flank and sutured to the skin to prevent accidental dislodgement (Fig. 7(b)). The two filament loops running from the rings through the tether were then connected to the control box. The loop from the sliding ring was fed onto the motor spool while the loop from the distal fixed ring was affixed to the box (Fig. 3(b)).

In these experiments, the rings were sutured to an initial segment length of 33mm. Traction began two days after implantation. On the first day of traction, a ring displacement of 15mm was applied. The displacement on each of the subsequent 10 days was 3.7mm such that the rings reached a maximum displacement of 85mm. Displacements were made at the same time each day and were commanded via Bluetooth from a laptop computer running a custom software interface. Each displacement was performed incrementally while monitoring the force measurement. If an incremental displacement resulted in a significant increase in force, the operator would wait until tissue relaxation reduced the force enough for the next increment to be applied. Fig. 7(f) displays ring displacement and force for a typical 24-hour period. When ring

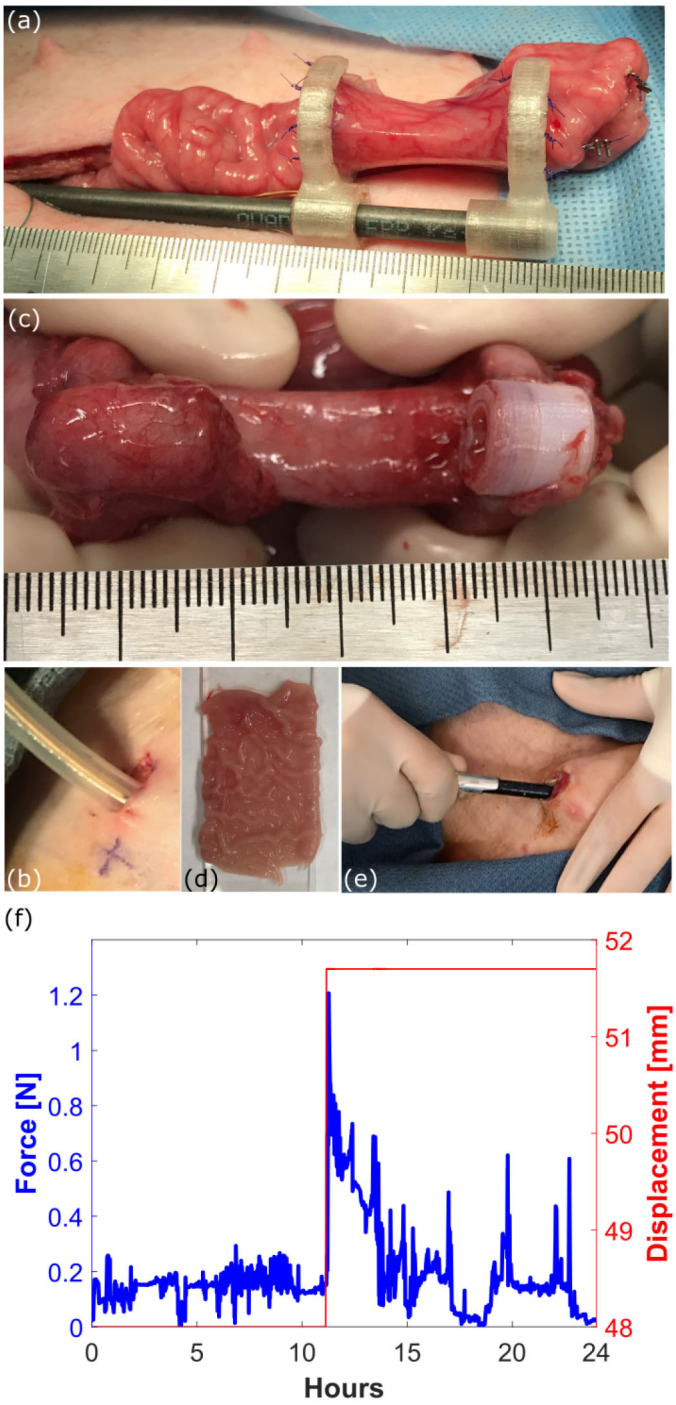

Fig. 7. Bowel lengthening with non-surgical implant removal. (a) Implant sutured to bowel during implantation. (b) Tether exiting animal's flank. (c) Bowel segment from Experiment 3 after removal of adhesions. (d) Mucosa (inner bowel wall) from Experiment 3. (e) Non-surgical removal of implant body. (See Video 1.) (f) Example of bowel force response to step change in ring displacement over 24 hour period.

displacement is increased, the force on the bowel increases simultaneously, but then falls off in an approximately exponential fashion as the tissue lengthens. The observed transient changes in bowel tension force correspond to changes in animal posture, e.g., standing up, lying down.

On the 13th day, the implants were removed as follows. The animals were first anesthetized and the sutures where the

tether entered the skin were removed. Next the control box was opened and the two filament loops passing through the tether to each ring were cut. To release the rings from the implant body, the loops were then completely removed from the body by pulling on one end of each loop. Finally, the implant body was pulled out of the body by its tether.

After implant removal, the skin was sutured closed. The animal was then observed for an additional eight days prior to sacrifice. Following sacrifice, the abdomen was opened so that the bowel segment with attached rings could be examined and measured.

Experiment 2: In this experiment, the control box malfunctioned after implantation and the desired traction displacements were not applied. The experiment was continued, however, in order to (1) provide additional data on non-surgical device removal and (2) as a control to evaluate the inflammatory response of the implant in the absence of traction. As in the first experiment, the animal tolerated the implant well and removal of the device on the 13th day was performed smoothly.

The animal was maintained for a week after removal and then sacrificed. In this case, it was observed that adhesions produced by the inflammatory response from the implant had constricted the bowel segment between the rings reducing its initial length from 45mm to 30mm. After dissecting the adhesions, the segment returned to approximately its original length and its exterior (Fig. 7(c)) and interior mucosa (Fig. 7(d)) had the appearance of healthy and functional tissue. This experiment points out the importance of considering the foreign body response to an implant as discussed further in the Conclusion below.

Experiment 3: In this experiment, the rings were sutured to an initial segment length of 33mm. On the first day of traction, a ring displacement of 15mm was applied. The displacement on each of the subsequent 10 days was 3.7mm such that the rings reached a maximum displacement of 85mm. For the duration of the experiment, the animal continued to eat and pass stool normally. It also did not display any signs of discomfort or distress.

On the 13th day after implantation, non-surgical removal of the device was performed. It was possible to pull out the suture loops to release the rings and to retract the implant body by pulling the tether. See Fig. 7(e) and Video 1. After observing the animal for another week, it was sacrificed and a necropsy was performed. The bowel segment with attached rings was exposed and it was observed that the initial segment length of 33mm had increased by 52% to 50mm.

IV. Conclusion

This paper demonstrates a new concept for avoiding surgical removal of temporarily-implanted bionic devices. The concept relies on designing the implant from a combination of absorbable and non-absorbable components. At the time of removal, the absorbable components are released and the non-absorbable components are pulled out of the body by a tether. Avoiding a second surgical procedure to remove the device has benefits for patients that include reducing surgical and anesthetic risks. Such a device could likely be removed at the bedside with no sedation or minimal conscious sedation.

This concept was demonstrated in the context of a device that applies traction forces to induce small bowel lengthening. For patients with short bowel syndrome, a device that could safely and effectively lengthen the bowel would be of substantial benefit. Specific advantages include reduction of time on total parenteral nutrition (TPN), reduction of time to enteral autonomy and reduced exposure to complications of TPN.

While the non-absorbable implant body used here was a straight rod, the approach can be easily extended to 3D curved devices. For example, the body could be comprised of short cylindrical links connected by spherical joints comparable to the components of [21]. Internal tendons passing out through the tether could be used to control friction in the joints. Varying tendon tension could transition the implant body between a rigid curved shape and a compliant serial mechanism of short links. In the latter state, the device could be pulled out along a curved path in a follow-the-leader fashion.

There are two important research directions that should be addressed for the future development of this concept. The first is the engineering challenge associated with non-collocated actuation and sensing. To miniaturize the implant body, the motor, position sensor and force sensor were moved from the implant to the control box outside the patient's body.

This poses several challenges. Remote position sensing, for example, leads to uncertainty in measurement of ring separation distance. If the filament loop on the moving ring had broken, the motor encoder would have continued to report a ring separation distance. To eliminate this uncertainty, radiographic images were taken to verify ring spacing. Uncertainty in force measurement due to friction in the tether was an additional concern. The incorporation of biocompatible absorbable sensors is a possible approach to address these issues.

The second important research direction is the bioengineering challenge of optimizing the absorbable components to meet functional requirements while also minimizing inflammatory response. The application of bowel lengthening considered here is one of the most challenging owing to the difficulty and risks of re-surgical procedure as well as the foreign body sensitivity of bowel tissue. While the presented implementation achieved the goals of demonstrating non-surgical removal as well as growth, the absorbable PLA rings did appear to induce a greater inflammatory response and more fibrotic adhesive tissue than the titanium rings used in Experiment 1. In particular, Experiment 2 demonstrated that, without the application of traction, the inflammatory response and adhesive tissue actually shortened bowel segment length.

Overall lengthening appears to be a competition between the growth-inducing effect of traction and a constrictive effect of inflammation. Additional research is needed to identify absorbable materials that produce the minimal foreign body response for bowel while also providing the structural properties needed to apply traction.

While PLA was chosen for its low cost and availability, one alternative is to consider a copolymer such as PLGA (PLA combined with polyglycolic acid (PGA)). By varying

the ratio of polymers, it is possible to control the material stiffness, strength and absorption time [22]. Moreover, studies on abdominal biodegradable meshes found that PLA and PGA cause different inflammatory responses over time and that the area and density of adhesions were significantly lower in the PGA group than in the PLA group [23]. Therefore, a fine tuning of the polymeric ratio could result in a ring design with an improved inflammatory response as well as an accelerated absorption time.

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