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Mechanical Extension Implants for Short-Bowel Syndrome

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Abstract

Short-bowel syndrome (SBS) is a rare, potentially lethal medical condition where the small intestine is far shorter than required for proper nutrient absorption. Current treatment, including nutritional, hormone-based, and surgical modification, have limited success resulting in 30% to 50% mortality rates. Recent advances in mechanotransduction, stressing the bowel to induce growth, show great promise; but for successful clinical use, more sophisticated devices that can be implanted are required. This paper presents two novel devices that are capable of the long-term gentle stressing. A prototype of each device was designed to fit inside a short section of bowel and slowly extend, allowing the bowel section to grow approximately double its initial length. The first device achieves this through a dual concentric hydraulic piston that generated almost 2-fold growth of a pig small intestine. For a fully implantable extender, a second device was developed based upon a shape memory alloy actuated linear ratchet. The proof-of-concept prototype demonstrated significant force generation and almost double extension when tested on the benchtop and inside an ex-vivo section of pig bowel. This work provides the first steps in the development of an implantable extender for treatment of SBS.

Keywords

Shape Memory Alloy; Medical Implant; Short Bowel Syndrome; Extension; SMA ratchet

1. INTRODUCTION

Short-bowel syndrome (SBS) is a devastating disease associated with mortality rates exceeding 30%¹. It is a condition where the small intestinal length is far less than required for proper nutrient absorption. This condition can occur in pediatric and adult populations, and may be due to congenital processes, or acquired through the loss of large amounts of small intestine due to inflammatory conditions or ischemic events^{1,2}. The syndrome prevents a self-sustaining absorption of nutrients from the intestine, and supplemental parenteral nutrition is required. An estimated 40,000 patients with intestinal dysfunction from SBS require parenteral nutrition³. Several long-term effects due to parenteral nutrition have been found to be harmful, such as sepsis, liver disease and bowel bacterial overgrowth; therefore this method can only be used as a short-term solution⁴. Care for SBS patients is in excess of \$200,000 per patient per year, and estimated costs in the United States have exceeded \$1 billion yearly¹.

A number of treatment procedures have been proposed to alleviate SBS. Some have tried using growth hormones along with specific nutrients known to stimulate bowel tissue growth⁵. This approach has limited effectiveness and several obstacles, including reversal of the adaptive process after termination of the hormones^{6–9}, lack of somatic muscle growth^{5,10}, and concerns about uncontrolled and tumorous growth. Another option is to surgically modify the organs to achieve an increase in intestinal length¹¹. With this approach, there is a risk of injury to the mesenteric vasculature, leakage of enteric contents due to a very long surgical connection, and the procedures can only be done if the intestine is overly dilated. Despite success in some patients, there is a very high failure rate up to 45% in some series^{12,13,14}. Finally, small bowel transplantation has been used for adults and children when other treatments have failed. Although a viable option, transplantation is very costly¹⁵. Patients require long-term immunosuppression and are at risk for infection and graft failure. Although early patient and graft survival are excellent, five-year graft survival is typically at the 50% level, and patient survival is approximately 60%¹⁶. Clearly, there is a great need for an alternative procedure to treat short bowel syndrome.

Recently, work has demonstrated that mechanical forces can be powerful regulators of tissue growth or regeneration. Through the process of *mechanotransduction*, the translation of mechanical signals to biochemical ones which affect cell function¹⁷, the response to the forces results in a cascade of actions which includes the activation of growth mechanisms^{18,19}. Numerous organs have been shown to be mechanoresponsive including bone, lung, and neural tissue^{17,18}. The effects of controlled mechanical stimulation to the small intestine are largely unknown. However, based on the response of these other organ systems, it is hypothesized that mechanotransduction of forces applied in a linear fashion to small bowel could help induce intestinal growth.

Some initial work has been done towards the validation of this hypothesis and the development of techniques for bowel lengthening. In an early study, application of a screw like device in rabbits resulted in bowel lengthening albeit with a decline in absorptive enzymes²⁰. It has been questioned, however, whether the small amount of length increase in this study (only 10mm) was true bowel lengthening, or merely stretching of the bowel²¹. More recent results using a similar external screw device on a segment of bowel in rats have proven more successful. By manually advancing the screw device a few millimeters each week, a 149%²¹ to 200%²² increase in small bowel length was obtained, with either an increase or preservation of intestinal function. Such a device, however has marked disadvantages in the application to human patients. In particular, the structure of the device requires the mounting of large external structures to the abdominal wall, the exposure of the bowel segment to ambient air, and the immobilization of the subject during the process. These results do however, motivate the development of an implantable device more appropriate for use on human patients.

This paper presents the initial development of two implantable bowel extenders, a hydraulic and a shape memory alloy actuated device. The hydraulic extender, with its simple design and construction, serves as a first proof of concept of a bowel extender implant and the SMA extender provides functionality closer to that required from an actual clinical device. Since these were the first of their kind, preliminary experiments were conducted to establish safe

extender specification to which both devices were built and benchtop characterized. The hydraulic extender was tested in-vivo in several pigs and demonstrated significant bowel growth. The SMA extender, tested ex-vivo, successfully fit and operated within the bowel with the specified force levels. The results of this work provide the first steps in the development of an actual clinical device suitable for human patients.

2. BOWEL EXTENDER SPECIFICATIONS

Both the bowel extenders were designed to operate inside the human body cavity inserted in a section of bowel detached from the digestive tract but still attached to the vasculature. The remaining bowel is reattached, maintaining bowel function. The device extends gradually, and after treatment, the lengthened bowel segment is grafted back into the digestive tract. Eventually, it is foreseen that the power, monitoring, and automatic control components would be integrated within the implanted device, although they are not part of the preliminary devices presented in this paper.

For clinical use, the implant design must meet a set of specifications based on the mechanical and growth properties of the bowel itself and of the body cavity. To fit inside the bowel, the device must have an outside diameter no more than 15 mm. The device should be relatively smooth, made of biocompatible materials, and should not generate external temperatures greater than 37°C to avoid damaging the bowel tissue. The un-extended length of the device must be less than 10 cm to reduce the length of bowel section, which must be detached from the digestive tract upon implantation, and to accommodate the curvilinear nature of the bowel. Ideally, the implant should extend to a minimum of twice its initial length, although further extension is always desirable.

To determine the forces required to stretch the bowel and the maximum force to avoid bowel damage, mechanical tests were conducted on sections of pig bowel similar in dimension to human bowel. A series of tensile loads were applied to a set of 10 cm bowel segments taken from various locations along the bowel, and the relative change in length (strain) was measured. The force-strain relationships plotted in Figure 1 show a linear elastic region at loads below 10 gf (gram-force) above which the bowel becomes less stiff. Inspection of the bowel shows that no damage occurs at tensile loads below 20 gf and strains below 20%.

A key function of the device is to maintain the tensile force as the bowel grows, thus a static device is not sufficient because as the bowel grows it loses contact with the tissue. The extension rate of the device does not need to be fast to keep up with the growth of the bowel: at most 1 cm per day. This motion may be continuous, as does the hydraulic extender or it may be produced, in finite steps, as does the SMA actuated extender. For the finite step, after each step the device needs to hold the new length for a period of time such that the bowel can grow and “catch up” with the device before another step is taken. While the 20 gf safe limit allows a large, 2 cm step size, in practice, a smoother and slower lengthening is desired, with a 1 to 2 mm step size specification. A 2 mm step represents a 2% strain on a 10 cm bowel segment, with a corresponding tensile force of 1.4 gf. This, however, is simply the force required to stretch the bowel; additional force is required to push against the soft tissues surrounding the bowel. Therefore, the required extension force was set to 20 gf.

Since steps occur only between long intervals, the conditions under which a step is taken may be controlled such that the patient is still and relaxed at that time. At other times, however, the patient may be moving, such that when holding a position, the device must hold against forces from the surrounding tissues larger than those occurring during a step, with a specified retention force set to 200 gf. Finally, since the device is intended for single use, it need only extend – it does not need to retract itself. However, a method to manually retract the device is desirable to aid in its removal. These specifications are summarized in Table 1.

3. HYDRAULIC BOWEL EXTENDER

As a first step towards a clinically appropriate implantable bowel extension device, a hydraulically actuated device was developed. While this device does not have the full functionality required of a clinically appropriate device, its simple design and operation provides a quick means to prove the concept of an implantable bowel extension device. This was carried out by in-vivo lengthening experiments in pig small bowel.

3.1. Device Architecture

Hydraulics provide a simple means of direct linear extension. In principle, a hydraulic piston can produce large motions with large forces as long as a high-pressure fluid source is available which is difficult to implant, requiring connection through the skin to an external fluid source. The overall motion of a hydraulic piston is limited by the length of the cylinder, and is reduced by the additional length required for piston seals and hydraulic connection ports. To overcome the effects of this extra overhead and come near to the goal of a length-doubling extension, a dual concentric piston design was developed which provides approximately twice the motion of a single piston in a similar package size.

The device (shown schematically in Figure 2 and in the photograph in Figure 3) consists of an outer syringe casing (cut from a 3 ml, 10.2 mm diameter medical syringe) through which a rubber plunger runs. The outer syringe rubber plunger is attached to and pushes forward an inner syringe (cut from a 1 ml, 6.4 mm diameter medical syringe) through which another rubber plunger runs. The inner syringe rubber plunger pushes forward a rod which extends to the forward end of the device. Silicone bumpers 16 mm in diameter on the back end of the outer syringe and the front end of the push rod apply extension forces against the ends of the bowel section. When saline fluid (chosen for biocompatibility) is forced into the device using a manually operated unmodified 10 ml syringe as a pump, pressure from fluid in the outer syringe pushes forward the outer syringe plunger. A hole through the outer syringe plunger allows fluid to flow into the inner syringe, pushing the inner syringe plunger (and the push rod) forward. The overall length of the device when retracted is 11.8 cm. The outer piston extends 5.7 cm beyond this length, and the inner piston extends an additional 4.5 cm, for a total extended length of 22.0 cm: an 86% increase in length.

3.2. Benchtop Characterization

Benchtop tests were performed to validate the basic operation of the dual hydraulic device and to determine both the forces on the actuation piston required to produce motion and the

holding power of the device. Because of the large diameter of the actuation piston, relatively large forces are required to actuate the device to overcome friction in the pistons and to produce motion. To measure these forces, the actuation piston was mounted vertically in a vice and increasingly large weights placed on the piston until motion was produced in the device. Since the outer piston diameter is larger than the inner piston diameter, the outer piston moved first, requiring a 2200 gf weight on the actuation piston. Once the actuation piston reached its full extension, weight was gradually added until a total of 6900 gf of weight caused the inner piston to move to its full extension. The 2200 gf weight corresponds to a fluid pressure of 103 kPa gage (15 psi), or a force of 640 gf on the outer piston to overcome friction. Similarly, the 6900 gf of weight corresponds to a fluid pressure of 324 kPa gage (47 psi), or a force of 648 gf on the inner piston to overcome friction. To measure the holding capacity of the device, when the actuation piston is left free to move, the device was pushed against a digital scale until each piston retracted. The inner piston retracted first, with a force of 400 gf, twice the required 200 gf, after which the outer piston retracted with a force of 900 gf.

3.3. In-Vivo Experiments

A population of 11 three year old pigs was implanted with hydraulic bowel extender devices. In each pig, two 11 cm lengths of bowel were isolated from the digestive tract, and the remaining bowel reconnected. Both segments had a hydraulic extender inserted, and the ends were oversewn. The tubing which connected to the actuation syringe was brought out through one end. One of the two segments acted as a control, and no fluid was pumped into the device. The other underwent an incremental lengthening (0.5 ml, or approximately 1.46 cm per day) over the course of seven days, until the device was fully extended (10.2 cm). All but one pig had a successful trial: the first pig developed an intestinal leak due to a buildup of mucus, which was drained on the remaining 10 pigs, and had to be sacrificed on the third day of extension.

After the extension procedure, the small bowel segment length, weight, and surface area were compared between the control segments and the extended segments in Table 2. The lengthened segments were significantly longer than the controls, by 69%, with a 69% increase in weight and an 88% increase in surface area. The mass per cm² decreased only slightly, by 15%, indicating that the lengthened bowel has potentially similar structure and function to normal intestine. Of particular importance, gross and microscopic inspection did not show evidence of mechanical injury to the lengthened segments of bowel.

While further study is required to determine the function of the lengthened bowel relative to normal intestine, the hydraulic extender clearly demonstrates that an implantable extension device has the potential to become a useful clinical device for treatment of short bowel syndrome, and is worthy of further development and testing. The hydraulic extender itself, however, has several important shortcomings for its use in human patients. First, it cannot be fully implanted because the necessary fluid pump and source is too large. Second, large variability in friction between the pistons and syringes make the applied force and motion irregular and unpredictable. Third, no failsafe exists in the device to prevent overextension in the bowel. Fourth, the extended length cannot be directly controlled, and fifth, due to

compliance in the hydraulic system, the device cannot precisely maintain a position under changing load. To overcome these drawbacks, a more sophisticated device was pursued using Shape Memory Alloy (SMA) actuation.

4. SMA BOWEL EXTENDER

Due to the compactness and implantability requirements of this application, conventional approaches are not viable due either to a) the external equipment necessary to drive them as in the case of hydraulics, or b) to their large size as in the case of electromechanical actuators. SMA is an attractive alternative because it is unmatched on specific power ($>100\text{kW/kg}$) and specific work (up to GJ/m^2), and simultaneously produces high strains (3–8%) and high stresses (up to 50 GPa), which is necessary for very compact actuation systems as required in the bowel extender^{23,24,25}. SMA also operates at safe levels of voltage and current to activate via resistive heating, is relatively inexpensive, and extremely biocompatible and corrosion resistant. The main disadvantage of SMA is its inherent slowness, typically only a few hertz, resulting from the heating and cooling activation cycle. Fortunately, in this case, the desired response is slower than this and the heat can be mitigated via a thin layer of thermal insulation. The challenge in the design of the SMA based bowel extender is to transform the relatively small strains (3–8%) into a long, continuous motion (over many cm). To achieve this, a ratcheting approach based upon many cyclic steps was pursued.

4.1. Device Architecture

The basic design of the SMA bowel extender is a concentric tubular linear ratcheting mechanism (Figure 5), where a steel threaded push rod slides inside a stainless steel outer shell, which has a ratchet flap which engages in the push rod threads. A stainless steel movable collar slides on the outer shell and also has a ratchet flap which engages in the push rod threads. These flaps are designed such that they allow motion of the push rod only in the extension direction (to the right in the figure). An SMA (Nitinol) wire is used as the actuator which, upon heating to the Austenite phase, can contract by 3–8% of its initial length. The SMA works against a reset spring which, when the SMA cools, stretches the SMA back to its initial length.

The resulting cyclic linear motion is used to actuate a ratchet as shown in Figure 6. During the forward motion, the Austenitic SMA wire (a) pulls the movable collar forward (b) relative to the outer shell, and pushes the push rod along with it due to the collar ratchet flap engagement (c), while the shell ratchet flap disengages (d), allowing the rod to slide forward (e). This motion compresses the reset spring (f). When fully actuated, both the collar and the push rod have moved forward a distance Δ , the spring is fully compressed (g), and the shell flap reengages (h). As the SMA cools (i), the return spring stretches it back out, pushing the movable collar back relative to the outer shell (j). During this motion, the shell ratchet flap (k) holds the push rod in place (l) while the collar ratchet flap disengages (m), allowing the collar to slide back to its original position, after which the collar flap reengages (n) and the spring is extended back to its original length. The net effect of this motion is to incrementally move the push rod forward by one or more thread teeth relative to the outer

shell. The front end of the push rod and the rear end of the outer shell thus push against the ends of the bowel segment, extending it.

4.2. Device Design

In the device design, it is critical to balance the SMA wire and spring. During actuation, the SMA wire must be strong enough to compress the spring, overcome friction in the mechanism, and apply the specified 20 gf bowel load. During reset, the spring must be designed to be just strong enough to stretch the Martensitic SMA and overcome friction in the mechanism. While the friction force varies as the tooth engages and disengages with the ratchet, a maximum 379 gf load was measured and will be used as a conservative value for design purposes. An 8 mil diameter SMA wire was chosen since it was experimentally determined to be capable of producing over 1600 gf of force. The 90 mm length of this wire was selected to be as long as could be reasonably mounted in the device.

The device motion and state is given in Figure 7. The SMA material lines were measured by gradually applying a tensile load and measuring deflection of both a cool (Martensitic) wire and an electrically heated (Austenitic) wire. A stock 53.6 gf/mm compression spring was selected with 9.14 mm diameter and 28.6 mm uncompressed length capable of producing forces up to 800 gf. The preload on the spring was selected to stretch the wire to a maximum of 4% strain (requiring 137 gf), for a total force of 546 gf including friction and bowel load. After a 15% safety factor in reset was added, a 17 mm compressed length was used.

Three system lines were generated: one from the spring (with specified preload) plus the 20 gf bowel load, and two others which include the maximum 379 gf friction both added to and subtracted from the spring/bowel line. Upon actuation, friction adds to the spring and bowel load, and the Austenitic wire comes into equilibrium with the system load at point A at a strain of 1.7%, or 1202 gf. When the wire cools, the friction subtracts from the spring force available to stretch the wire, and equilibrium is reached at point B at a (designed) strain of 4% or 137 gf. The difference between 4% and 1.7% strain on a 90 mm wire produces a net motion of 2.28 mm. Because several conservative approximations were taken in the design, this is a minimum stroke length obtained by the actuator. In particular, the friction force produced in the ratchet mechanism generally reaches its maximum only in the middle of the motion when the flap is transitioning between teeth. This is shown in Figure 7 by the dashed orange and cyan lines which come tangent to the corresponding friction-offset load lines in the middle of the motion, but also come tangent to the frictionless load line when the ratchet flaps snap into place, and friction is greatly reduced (or assumed eliminated in this illustrative example). These modified load curves intersect the SMA curves at a wider strain range (at point C, and a point off the graph to the left), and thus, larger step sizes are expected in practice than what was designed for, where the device may even take multiple steps at each activation.

4.3. Prototype

A dimensioned photo of the completed device with major features labeled is shown in Figure 8. The collar and outer shell were constructed from 0.25 mm wall thickness stainless steel tubing with flaps and tabs cut in. The push rod was cut from standard 6.35 mm (0.25

in) diameter 1.27 mm (0.05 in) thread pitch (and equivalently single step size) stainless steel threaded rod. The SMA wire was attached at the leading edge of the outer shell and at the trailing end of the collar. At the leading edge of the collar, a flap was bent up to which the SMA wire was soldered using Nitinol Flux 400™ from Shape Memory Applications Inc., electrically connecting it to the bulk of the device. Since the two ends of the wire must be electrically isolated, at the trailing end of the collar the SMA wire slips through a small slot in an additional Teflon collar and attaches to a rectangular brass crimp at the end of the slot, providing interference. This Teflon collar is the largest diameter feature on the device with an outer diameter of 10 mm. Electrical connection wires were soldered to the solder joint at the leading edge and to the brass crimp at the trailing end. Lumps of epoxy were attached to the front end of the push rod and the back end of the outer shell to provide smooth pushing surfaces. In Figure 8, the device is shown before the electrical connections and epoxy lumps were added.

The retracted length of the device, and consequently both the push rod and outer shell, is 10 cm. Since the compressed spring length was selected to be 17 mm, the stainless steel collar takes the remaining 73 mm of length. While ideally, the full extended length of the device would be equal to the push rod length plus the outer shell length (a total of 20 cm) the push rod must remain engaged with both the shell and collar flaps, noting that the collar flap lies behind the 17 mm compressed spring. Also, to maintain structural rigidity, the push rod must be partially retracted into the outer shell. Thus, a certain degree of overhead is required and a full doubling in length is not possible. In this case, an 18 mm overhead length was required, allowing the device to extend to at maximum length of 18.2 cm, or 82% longer than its initial length.

4.4. Experimental Setup

To validate the design and performance of the device, the prototype was tested to evaluate its ability to produce step motion under load. The test stand shown in the schematic and photo in Figure 9 allows the application of specified compressive loads to the end of the device while activating it and measuring its motion. The prototype device rests horizontally on a nylon bearing cylinder with the trailing end butted against an aluminum bracket. A variable weight hanging over the edge of the bench applies a compressive load to the device via a wire routed over a pulley and looped over the leading end of the push rod. A non-contact MICROTRAK 7000 laser displacement sensor measures the deflection of the end of the push rod. The data from the displacement transducer is recorded by a PC running Labview by means of an MIO-16E I/O board. Current is applied to the SMA wire from a KEPCO programmable DC power supply. The power supply was programmed to apply a square pulse in current of specified amplitude and time, and both the power input and the device motion were measured. The 0.8 A current used was determined empirically as the smallest current over which no addition motion occurs, fully transitioning the wire. Sequential steps were applied by cycling the current on for 10 seconds and then off for 20 seconds, giving plenty of time for the SMA to both heat and cool. Two sets of experiments were run to validate the operation and performance of the device. First, external loads similar to those seen in stretching the bowel (0 to 50 gf) were applied and the stepping

performance evaluated. Second, the ability of the device to step under larger loads (0 to 400 gf) was evaluated to determine the overall characteristics of the device.

4.5. Benchtop Results

When actuated, the device pushes forward until the wire is fully heated. This position may be somewhat ahead of a ratchet tooth such that when cooled, the device relaxes back to the previous tooth. Figure 10 shows the motion of the push rod over time during the course of two heating/cooling cycles. At the end of 10 seconds of heating, under loads in the range of 0 to 50 gf (in steps of 10 gf), the device moved forward to a position which was independent of the load, varying by at most 2.8% around an average value of 2.52 mm. This position happened to be just past a ratchet step such that at the end of 20 seconds of cooling, the device relaxed back to an average position of 2.47 mm (with a variance of 4.6% over load). In both the heated and cooled cases, there was no significant trend over load: noise and randomness in friction outweighed the loading effects. After a second, and further repeated heating/cooling cycles, the device displayed similar performance. The heated step motion was 10.5% larger than the predicted 2.28 mm heated step size. This difference can be attributed to the conservativeness of the prediction. Given that the 2.52 mm heated step size is equal to twice the 1.27 mm tooth spacing (within measurement error), the device took two ratchet steps rather than one, where each thread is 1.27 mm. This double-stepping would not cause a problem in the application because it is repeatable and because the double step size generates an elastic bowel force well below the 20 gf safety limit. Thus, it is demonstrated that the device has both the force and motion authority for the bowel application.

Under larger loads, ranging from 0 to 400 gf in steps of 50 gf, the motion was strongly dependent on the load (Figure 11) and fell into three categories: double steps, single steps, and no steps. From 0 to 150 gf, performance was similar to that in the application load range, and the device moved just past the second tooth and took a double step. As the load was increased from 0 to 150 gf, the actuated motion was largely independent of the load, decreasing by only 7.5% (from 2.53 mm to 2.34 mm) as shown by the pink line in Figure 11. This relative non-dependence on load is likely due to the fact that the ratchet tends to snap forward into place when approaching the next tooth (a behavior not predicted by the conservative model) bringing the mechanism farther forward than the SMA could do alone. From 200 to 350 gf, the device moved past the first tooth, by an amount dependent on the load, and relaxed back to a single step. Since the actuated motion in this range does not bring the ratchet near to a tooth (except at the high load end), the load dependence of the motion is much larger, decreasing by 43% (from 1.94 mm to 1.36 mm) as the load was increased as shown by the light blue line in Figure 11. This test result validates that the device can reliably take steps against loads much higher (by a factor of 17.5) than the designed load of 20 gf. From 400 to 500 gf, the device could not generate much motion at all and took no steps, moving at most 0.16 mm when heated. While the SMA should have been able to generate motion in this range, the load was too high for the ratchet mechanism which slipped, not allowing the collar to push the rod forward. Thus, the holding power of the ratchet was the force limitation, not the SMA.

4.6. Ex-Vivo Experiments

To further validate the capabilities of the implant prototype and to provide insights into the performance, additional tests were run with the device inside an actual bowel section. A section of bowel slightly longer than the 10 cm retracted length of the device was removed from a pig. The entire device was enclosed in a loose latex bag to protect it from fluids and to both electrically and thermally insulate the SMA. The device was placed inside the bowel section as shown in Figure 12, left, and the ends of the bowel section tied closed to fit snugly against the ends of the device. The open end of the latex bag extended through the tied end of the bowel, the tie keeping both the bowel and the bag closed, through which the electrical connection wires ran. The device was actuated using the KEPCO power supply, applying a step sequence of 0.8 A for 10 seconds with 15 seconds between steps.

The test showed promising results in that the implant successfully elongated inside the bowel section, acutely stretching the bowel as shown in Figure 12, right. Because the steps were taken quickly (over 10 minutes), and because the bowel section was ex-vivo, the bowel could not grow along with the device, causing the tension to increase as the device extended. The tension was particularly large due to the mesentery (vasculature) being attached to the bowel, and after extending by 38 mm, a 38% increase in length, the bowel tension was too large for the ratchet mechanism, which slipped when actuated. These tests demonstrate that the device fits into and operates in the actual intraluminal environment of the intestine. Were the bowel allowed to grow as the device extended over a longer period of time, it is believed that the forces would have remained well within the capabilities of the device, allowing the device to extend to its full 82% capacity.

5. CONCLUSION

Two devices developed as proof of concept for an implantable solution to bowel extension for the treatment of SBS have been successfully demonstrated. Using a simple hydraulic device, promising results in a study using pigs has validated the viability of the use of mechanotransduction as a means to induce bowel growth. A shape memory alloy based ratcheting device has demonstrated the possibility of a fully implantable motion-controllable device. While taking these devices to the level where they can be used to help human patients will require a great deal more study into the design of devices as well as the mechanisms of mechanically induced growth, these devices provide the first steps towards a life-saving, minimally invasive treatment procedure.

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Figure 1.
Strain vs. tensile force for various pig bowel sections.

Figure 2.
Schematic of the hydraulic bowel extender in the partially extended position.

Figure 3.
The prototype dual hydraulic piston fully extended.

Figure 4. Bowel segments at the end of the lengthening period

Two isolated segments of pig small bowel 7 days after the lengthening was initiated. Both segments contained a lengthening device. The Stretch segment shows a marked difference in size from the control (non-lengthened) segment.

Figure 5.
Schematic of SMA bowel extender device.

Figure 6.
Operation of the SMA bowel extender ratchet mechanism.

Figure 7. Three system load lines plotted against the actuator curves in force-strain coordinates Directional dependence of friction gives three load curves: without friction (middle, green: spring and bowel force only), during reset (lower, cyan: friction takes away from spring force), and during actuation (upper, orange: friction adds to spring force). Dashed load curves show a more realistic representation of friction forces as the ratchet flaps engage and disengage with the teeth.

Figure 8.
Final prototype, partially extended, alongside a disposable pen (for reference).

Figure 9. The benchtop experimental setup

A schematic (left) and a photo (right) show the prototype (extending to the left) subjected to a load applied by a weight hanging over a pulley while a laser displacement transducer measures the motion.

Figure 10.
Stepping performance under application loads.

Figure 11.
Net stepping performance under larger loads.

Figure 12. In-bowel tests

The prototype device was enclosed in a latex bag and placed inside a section of pig bowel (left). Part of the total 38% extension achieved is shown (right).

Table 1

Engineering specifications for bowel extender implant.

Size	Max Outside Dia.	15 mm
	Max Initial Length	10 cm
	Min Extended Length	~20 cm
Force and Motion	Max Extension Rate	1 cm/day
	Step Size	1–2 mm
	Min Extension Force	20 gf
	Min Retention Force	200 gf
External	Retraction	Manual Only
	Texture	Smooth
	Max External Temp.	37°C
	Materials	Biocompatible

Table 2

Comparison of bowel segments after extension.

Group	Length (cm)	Wet Weight (g)	Surface area (cm ²)	Mass/cm ²
Control	10.4±3.2	17.4±4.5	46.1±13.7	0.33±0.04
Stretch	17.6±2.4*	29.4±2.3	86.7±19.8	0.28±0.03
Change	69%	69%	88%	−15%