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Development of an Endoluminal Intestinal Lengthening Device Using a Geometric Intestinal Attachment Approach

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Abstract

Background—Distraction enterogenesis may provide a novel therapy for short bowel syndrome. Previously described methods have relied on isolated intestinal segments or transmural fixation due to ineffective endoluminal attachment. We hypothesized that a novel approach using geometric coupling between a tapering device and the mesenteric curvature would allow transstomal distraction enterogenesis.

Methods—A catheter device was designed with tapering stiffness, consisting of a stiff catheter with a taper to a flexible latex tip to prevent perforation. Yorkshire pigs underwent creation of a jejunal Roux limb with device placed via jejunostomy. Intestinal attachment was achieved without a substantial decrease in bowel perfusion as measured by laser Doppler. An external clamp was secured at the stoma to provide external fixation of the device. The catheter was advanced 1 cm/day for either 7 or 14 days before explant.

Results—After 7 days, the distracted segment achieved a mean±SD increase in length of 37±6% versus fed, nondistracted bowel, corresponding to an absolute gain of 10.6±1.7 cm (1.5 cm/day). After 14 days, the Roux limb achieved an 80±2% increase in length versus fed control bowel, corresponding to an absolute gain of 16.8±3.0 cm (1.2 cm/day). No perforation or stoma-related complication occurred.

Conclusion—We describe a novel catheter device with tapering stiffness allowing for endoluminal distraction enterogenesis via geometric coupling. This approach may allow

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development of clinically applicable technology for the treatment of patients with short bowel syndrome.

Graphical abstract

Keywords

distraction enterogenesis; mechanotransduction; pediatric device; intestine; short bowel syndrome

INTRODUCTION

Short bowel syndrome (SBS), where loss of small bowel length results in insufficient nutrient absorptive capacity for growth and development, is the most common cause of pediatric intestinal failure (1). Survival among patients with SBS is predicted by the length of the residual small bowel (2, 3), making the restoration of intestinal length an attractive strategy. Surgical lengthening procedures have been developed (4–6) but carry the risk of complications (e.g., infection, perforation, bleeding, and obstruction) and are limited to patients with favorable anatomy (e.g., dilated small bowel) (7–9). Small bowel transplantation has been employed less frequently in recent years, partially due to less than optimal outcomes, with graft failure and rejection approaching 60% at five years (10, 11). Therefore, therapy for SBS consists primarily of supportive therapy with supplemental or total parenteral nutrition (TPN), which carries risks of hepatic dysfunction, metabolic derangement, and sepsis (1).

Distraction enterogenesis may provide a therapeutic option for the treatment of SBS patients who otherwise face little chance of achieving enteral autonomy (12–14). Distraction enterogenesis is the use of mechanical force to induce small bowel lengthening, and has been shown in animal models to produce durable increases in length with preservation of intestinal function (15–17). Increased intestinal length is accompanied by mesenteric neovascularization, muscular hypertrophy, increased mucosal surface area, and increased epithelial cell proliferation (13, 18, 19).

While distraction enterogenesis has shown promise in animal models, it has yet to become a clinically applicable strategy. Prior methods of distraction enterogenesis have been limited

by the use of blind-ending intestinal segments (12, 13) or transmural sutures to allow attachment of the device, which is necessary for transmission of mechanical force to the intestinal wall (20). These methods of attachment require an implant operation to create the blind-ending segments or to place sutures, followed by a second explant operation to restore continuity. The restoration of intestinal continuity may result in the loss of gained intestinal length - up to 39% - due to the need for creation of a new anastomosis (21). In addition, SBS patients have been shown to mount a post-surgical inflammatory response (22), making multiple intestinal operations a high-risk proposition for such patients.

Our aim was to create a method of distraction enterogenesis using a fully endoluminal intestinal lengthening device. This approach would obviate the need for surgical placement of the device beyond the creation of an intestinal stoma (gastrostomy or enterostomy) – which many patients with SBS already have due to their underlying disease. In the present work, we describe the use of a novel catheter with progressive reduction in stiffness to allow endoluminal small bowel fixation. We hypothesized that geometric intestinal attachment would allow distraction and intestinal lengthening via a jejunostomy. Safety and efficacy of this approach were demonstrated in a well-established swine model.

METHODS

Device Design

A specialized catheter device was designed and constructed so as to provide for a progressive tapering in the amount of stiffness. (Fig 1A). A 3.26 mm diameter stranded cable (8 AWG [American Wire Gauge]; Southwire, Carrollton, GA) served as the device base, consisting of 19 strands of 0.72 mm diameter copper wire. Each strand was trimmed at 1 cm intervals to decrease progressively the total strand count approaching the device end. The trimmed stranded cable was inserted into a latex sheath that tapered gradually over a length of 33 cm from a 24-Fr base to an 8-Fr end. The internal wire structure ended 14 cm proximal to the end of the latex sheath. The total device length was 80 cm. These materials and dimensions were chosen such that the most rigid end of the device (the fully stranded 8 AWG wire) was stiff relative to the bowel (i.e., if advanced ‘as-is’ into the small intestine via the stoma, it would eventually lead to a perforation). The end of the device, by contrast, was selected such that it was more flexible than the bowel itself (i.e., when an 8-Fr latex catheter was advanced ‘as-is’ in to the small intestine, it would conform to the intestinal curvature; Fig 1B). We found that if the end of the device was stiff relative to the bowel, it would exert focal radial force on the intestinal wall, which over time with distraction would lead to ischemia/perforation.

In addition to a flexible end, a gradual transition in stiffness along the length of the device was found to be important. If stiffness of the device decreased abruptly at any point along the device, the intestine would drape acutely over this abrupt transition. This ‘tip-effect’ resulted in a disproportionate amount of longitudinal distractive force being applied in a concentrated area of the bowel wall at that point of transition. In previous devices where such a tapered tip was not used, perforation occurred at the end of the device (23).

In order to fixate the device to the abdominal wall and allow transmission of the applied force to the targeted area for small bowel lengthening, a clamp (Fig 1C) was mounted on a 10 cm wide rubber base, which was sutured to the abdominal wall at the stoma site. After each advancement of the device, this clamp was applied to provide proximal fixation of the device at the level of the stoma.

Mechanical Characterization

To quantify the mechanical characteristics of the device, the bending stiffness of the catheter was measured along the length of its tapered portion. Bending stiffness is defined as the ratio between an applied bending moment, measured in N-m (Newtons-meter), and the resulting curvature (reciprocal of the radius of curvature, or 1/m) with resulting units of N-m².

Measurements of bending stiffness were performed by measuring the linear stiffness of a cantilevered section of the device (Fig 2A). The device was fixed horizontally in a V-groove clamp at a specified point along its length, and a series of weights (varying between 0.186 g and 250 g) were hung from a thread tied at a set test-length distance (ranging from 15 to 50 mm) from the clamp. The vertical deflection of the tip was measured as a function of load, where, according to classical linear beam theory (24), the bending stiffness is equal to one-third times the test length cubed times the ratio between the applied load and the tip deflection. The resulting bending stiffness ranged from a maximum of 1.89×10^{-2} N-m² at the proximal end of the device to 1.5×10^{-5} N-m² at the distal end (Fig 2B).

Another important mechanical property of the device which needed to be quantified was the maximum curvature that could be applied before the catheter was bent permanently due to the malleability of the copper. The curvature was measured by bending the device to a radius of curvature (relative to a set of printed concentric circles of known radius) and releasing, decreasing the radius of curvature progressively until the device no longer sprang back to its original straight configuration. This test was repeated at varying positions along the malleable portion of the device. The smallest radius which allowed complete spring-back (plotted as a function of position along the device – Fig 2C) varied from 200 mm at the proximal end of the device to 100 mm where the internal wire structure ended distally. This radius relates to the largest amount of bending moment the device can apply to the bowel before the device takes a permanent “pose,” conforming to the bowel, after which the residual force on the bowel takes on a maximum at the value required to bend the device into that pose.

Animal Model

The device was tested using our previously described swine model for distraction enterogenesis (20). Female Yorkshire pigs weighing 30–40 kg were used for each experiment (n=4), and the stated procedures were approved by the University of Michigan Animal Use Committee (#PRO00005005). Although the future clinical application is intended to be placed via a gastrostomy (or nasoenteric tube), the course of the porcine duodenum is far more tortuous than that of a human. Thus, the device was placed via a proximal jejunostomy. Through a midline laparotomy, a Roux limb was created 90 cm distal to the ligament of Treitz and the proximal end was brought out as a jejunostomy in the left abdomen. The jejunostomy was secured in three layers at the skin, anterior fascia, and

posterior fascia in order to prevent stoma retraction during distraction. An end-to-side anastomosis was created to form a Roux-en-Y jejuno-jejunostomy to restore intestinal continuity. The mesenteric defect was closed to prevent internal hernia. The clamp mount was sutured circumferentially to the abdominal wall at the stoma site. The device was inserted via the stoma into the Roux limb, advancing the flexible tip first. As the first mesenteric curve of the jejunal limb was encountered, the flexible tip of the device navigated this curve without bowel distortion (Video 1). With continued advancement of the progressively stiffer device, however, a point was reached where the device was no longer flexible enough to navigate the mesenteric curvature – thus, geometric fixation was achieved. The device was clamped at this depth. Silastic markers (vessel loops) were placed along the antimesenteric border of the Roux limb at 3 cm intervals. These markers allowed for accurate measurement of gain or loss of intestinal length at harvest. A 12 cm segment was selected 10 cm distal to the jejuno-jejunostomy to serve as a fed control and was marked similarly at 3 cm intervals, which allowed paired analysis of lengthening between the distracted and fed control segment from each animal. Separate control sham operations were not performed. The abdomen was then closed in standard fashion. All animals were fed a regular solid diet beginning on the first postoperative day until device explant.

Device Advancement

After a 24h recovery period, the device was advanced 1 cm/day by unclamping the stoma clamp to release the catheter, manually advancing the catheter 1 cm, and re-applying the stoma clamp. The portion of the device that remained exterior to the animal was coiled under a custom harness to prevent device dislodgement.

Morphology Assessment

At the end of the implant period, re-laparotomy was performed. The catheter was removed from the jejunostomy. Intervals between antimesenteric silastic markers were measured along the Roux limb and the control segment. The Roux limb was inspected grossly for evidence of mucosal damage or perforation. Full-thickness samples of the Roux limb at the contact areas with the device were resected and fixed in 10% formalin overnight. Samples were embedded in paraffin and stained with hematoxylin and eosin for histologic examination. Slides were visualized using a Nikon A-1 confocal microscope and assessed qualitatively for evidence of mucosal compromise, manifested as villus loss, mucosal sloughing, or changes in the submucosa or muscularis propria.

Tissue Perfusion Assessment

To characterize the optimal initial tension to apply, visual and laser Doppler assessment of tissue perfusion was performed at each implant. After device insertion into the jejunal Roux limb and advancement until the depth of geometric fixation, the device was advanced further to create longitudinal bowel tension until occlusion of vessels along the antimesenteric bowel wall along the first mesenteric curve was observed. The device was then retracted until vessel reconstitution was observed, and the clamp was applied at this depth. This established the initial insertion tension.

Blood flow to the antimesenteric bowel wall was measured using a Lisca PIM II Laser Doppler Perfusion Imager (Perimed AB, Stockholm, Sweden), placed 10 cm above the antimesenteric surface of the first mesenteric curve along the jejunal Roux limb. Perfusion patterns were analyzed using LDPIwin 2.3 software (Perimed AB) as described previously (25), using triplicate measurements of a 1 cm² tissue plane. Sequential measurements were taken at the same site with the device removed and with the device clamped at the initial insertion tension to quantify changes in tissue perfusion with distraction.

Analysis

All lengthening measurements were made along the experimental Roux limb relative to a fed control segment. This approach allowed correction for the confounding effects of post-laparotomy inflammatory changes on bowel length. A paired t-test was used to compare results from distracted and control segments from matched animals. Results were expressed as mean $\pm$ standard deviation unless otherwise specified. $P < 0.05$ was considered significant.

RESULTS

Lengthening

After 7 days, the distracted segment (measured after device removal) achieved a significant increase in length versus the fed, nondistracted bowel, without evidence of ischemia or perforation (Fig 3A). Bowel lengthening was noted from the stoma to the end of the device, which was initially placed to marker 12 (i.e., initially 3 cm intervals, for a total of 36 cm deep to the stoma). The distance between markers along the distracted segment increased relative to the spacing of markers on the fed control segment. The cumulative percent net lengthening of the bowel in contact with the device relative to fed control was $37 \pm 6\%$ after 7 days, and $80 \pm 2\%$ after 14 days of distraction (Fig 4A). Interestingly, while lengthening was seen throughout the distracted segment, the rate of lengthening increased sharply in the region of geometric attachment (the mesenteric curve). This rate increase was most notable after 14 days, where lengthening increased from 40% between markers 1–6 to 80% after marker 9. This change in lengthening efficacy may be due to additional distractive forces being applied in the region of the mesenteric curve, where the longitudinal distraction of the device is coupled with radial force applied by displaced elastic catheter on the bowel wall.

The net gain in length was dependent on the length of bowel with which the device interacted. The cumulative distance from the stoma to each bowel marker along the distracted segment was measured and compared to a group of control segment marker intervals at explant, extrapolated over the same number of markers(23) (Fig 4B). The gain in length of the entire distracted segment relative to the fed control segment was 10.6 ± 1.7 cm after 7 days, corresponding to an average lengthening rate of 1.5 ± 0.2 cm/day. Doubling the duration of distraction to 14 days resulted in additional lengthening, with a net gain of 16.8 ± 3.0 cm, and a slight decrease in daily gain to 1.2 ± 0.2 cm/day. Interestingly, the rate of lengthening consistently exceeded the 1.0 cm/day advancement of the device. This change in length is consistent with prior methods of distraction enterogenesis, where bowel lengthening exceeded device expansion.

Device Safety

No device-related perforation, bowel obstruction, or anastomotic complication occurred. Mucosa at device contact areas remained intact without ulceration. Histologic examination of the device contact areas revealed villus blunting with preservation of mucosal integrity as well as intact submucosa and muscularis propria (Fig 3B). No serosal or mesenteric damage occurred. Peri-stomal skin remained intact, and no stomal retraction occurred.

Laser Doppler measurements showed no significant decrease in tissue perfusion at the antimesenteric aspect of the geometric attachment site (0.95 ± 0.37 perfusion units (PU) vs 1.03 ± 0.49 PU; bowel at-rest vs device tension applied; $p=0.14$; Fig 5). Laser Doppler measurements were repeated at explant, confirming no compromise in perfusion after chronic implant (0.09 ± 0.23 PU vs 0.05 ± 0.13 PU; $p=0.07$). PU is a dimensionless unit used for laser Doppler measurement. Environment-specific calibration prevents comparison of measurements at implant and explant.

This device employed continuous distraction via daily advancement into the abdominal cavity. At explant of the 14 day implant group, the mesenteric curve of the distracted bowel was noted to abut the contralateral abdominal wall. Further device advancement was thus constrained by abdominal domain. No compression of surrounding organs was noted.

DISCUSSION

Clinically applicable distraction enterogenesis requires maximizing bowel length gain while minimizing the morbidity of the distraction therapy. A fully endoluminal device may achieve this goal by allowing distraction without multiple operations. This study demonstrates a method of endoluminal distraction enterogenesis using an indwelling, semi-rigid device with an atraumatic geometry of the end of the device. This strategy provides an effective method of intestinal attachment via geometric coupling of the device and mesenteric curvature. In addition, this geometry may improve the safety profile of any endoluminal device that is stiff relative to the bowel. Because the small intestine is non-linear in orientation with the mesentery tethering the bowel in a curved course, an endoluminal device must conform to this curvilinear shape. Devices which are stiff relative to the bowel, therefore, exert outward radial force on the small bowel and its mesentery (unless constructed to exactly match the bowel radius of curvature). At the end of a semi-rigid device, the bowel bends sharply over the device tip. This bending may create a focal point of radial force on the bowel, potentially inducing focal bowel ischemia and perforation. This phenomenon has been noted in a prior, catheter-based endoluminal distraction enterogenesis device (23), and it may explain reports of delayed perforation from the ends of enteric feeding tubes (26, 27). The gradual taper in stiffness of this device allowed for the catheter to exert progressively less radial force on the antimesenteric bowel wall as it approached the end of the device, preventing a sharp bend in the bowel over the end of the device, thereby decreasing the risk of perforation.

This method of distraction enterogenesis required an enterostomy for device insertion. Trans-stomal distraction enterogenesis has been described (13), though this technique relied on end-abutment of a stiff device on a surgically created intestinal blind end. While such anatomy is not frequently encountered clinically, enterostomies and/or mucus fistulae are

often present in patients with SBS. Trans-stomal distraction enterogenesis using geometric attachment may be a viable method of increasing residual bowel length in these patients. For example, such a device may be placed for a course of distraction therapy prior to takedown of the enterostomy in a patient who has undergone massive bowel resection and is at risk of SBS. This approach may allow the reversal of disuse atrophy if employed via a mucous fistula, may induce substantial gain of length prior to takedown of the enterostomy with re-anastomosis, and would not require additional operative maneuvers.

This device achieved lengthening rates that compared favorably to serial transverse enteroplasty (STEP) outcomes (28). Seven days of distraction produced $37 \pm 6\%$ lengthening versus nondistracted fed bowel. This is similar to the current standard of care for patients with medically refractory SBS, the primary STEP procedure, which has been reported to produce a 22% to 43% increase in bowel length (28–31). It is important to note, however, that STEP results are measured at a single operative setting, while distraction enterogenesis requires interval measurement of lengthening after a set distraction period. In addition, lengthening via distraction occurs only in the length of intestine that contacts the device, whereas enteroplasty may be employed throughout the remaining bowel.

Importantly, this study demonstrated that prolonging distraction therapy results in continued intestinal lengthening, with 14 days of therapy producing approximately 80% lengthening – more than doubling the current rates of operative lengthening procedures. Future work must investigate how long enterogenesis can be maintained, and how its efficacy changes with time. In the current study, for example, the lengthening rate decreased slightly from 1.5 ± 0.2 cm/day to 1.2 ± 0.2 cm/day as distraction duration increased from 7 to 14 days. It is possible that more efficient enterogenesis may be maintained during prolonged therapy by increasing distractive force with time, or by the addition of a trophic growth factor during the period of distraction enterogenesis (15, 32). It is unclear whether ongoing distraction will produce indefinite lengthening, because the maximum duration over which enterogenesis can be achieved has not been evaluated to date. With the current device, however, prolonged distraction beyond 14 days may be limited, because ongoing catheter advancement may be constrained by limited abdominal domain.

The percent length gain of the full distracted segment demonstrated limited variance, with a standard deviation of $<10\%$ after 7 and 14 days of distraction. It is notable, however, that the variance in lengthening was considerably greater along the length of the Roux limb, with percent lengthening ranging from 25% (marker 2) to 84% (marker 9) at different points along the bowel. However, after the 10th marker, all Roux limbs had completed their first mesenteric curvature, which may explain why the variance in lengthening outcomes decreased abruptly after this point.

The current method of distraction enterogenesis demonstrated a favorable safety profile with no intestinal ischemia, perforation, or obstruction. Histologic examination of the mucosa at device contact sites did show villus blunting, which may suggest some degree of mild injury, however this histologic finding may simply reflect the fact that the device was employed in unfed intestine. Restoration of feeding after distraction has been shown to restore villus height (16), and these changes may be prevented if distracting fed bowel.

Defining parameters of safe distraction will be necessary before clinical use. We verified a safe level of initial distraction using laser Doppler measurement of tissue perfusion along the antimesenteric border of the intestine in the region of device attachment. We found no decrease in perfusion at the time of initial placement of the device or at explant. While laser Doppler flowmetry has been used to measure acute changes in intestinal tissue perfusion in animal models, it is most sensitive when applied to direct mucosal measurement (33), which was not possible in this study during device actuation. Direct measurement of tissue perfusion was possible only at the time of implant and explant, when the serosal surface of the intestine could be accessed. While measurement of perfusion at implant was used to set the initial tension of the device, we could not verify that this tension was maintained after closure of the abdomen. Therefore, we used a distance-based distraction regimen of 1 cm advancement of the device per day, which was chosen based on success with prior end-abutment devices (15, 19, 20). A more robust parameter of distraction would be direct measurement of applied bowel tension, which could be used to guide safe clinical use. For example, development of a pressure sensor to provide continuous measurement of force applied to the bowel wall would allow nasoenteric or trans-stomal placement of a distraction enterogenesis device and nonoperative calibration of distractive force throughout therapy.

The animal model used in this study had the advantage of being similar in size to the human equivalent of a 25–50 kg child with SBS; however, the model was limited by requiring a laparotomy for implantation. This model differed from the envisioned clinical use, wherein creation of an enterostomy would be performed as indicated for the clinical scenario, and placement of the device via the stoma would be performed at a later time. In this model, however, the device was placed at the initial laparotomy in order to place bowel markers for measurement of lengthening outcomes. At the time of explant on either postoperative day 7 or 14, generalized formation of intraperitoneal adhesions had occurred. Therefore, lengthening outcomes were measured relative to a marked fed control segment which was exposed to the same postoperative peritoneal environment in order to control for changes in bowel length due to postoperative inflammation. In future studies and clinical use, markers may be replaced with serial contrast studies to measure the outcomes of enterogenesis.

Another limitation of the surgical model used was the placement of the device into an unfed segment of the jejunal Roux limb. Though the target patient population for distraction enterogenesis will be dependent on parenteral nutrition, it will be critical to demonstrate that a clinically applicable device can produce intestinal lengthening in non-diverted bowel without causing obstruction. Future work may establish the efficacy of this approach via delayed placement of the device into a fed intestinal segment. In prior studies using the current model, a segment of unfed intestine without distraction was used as a secondary control (20, 23). This approach was not performed in this study, because the device occupied the length of the Roux limb. In this study, distracted bowel was unfed, while the control bowel was fed. Therefore, it is possible that distraction of the fed intestine may result in even greater gains in length in the future.

A potential limitation of this study was the small number of animals which underwent device implantation. The lengthening outcomes of this approach were reproducible, with limited variation in percent length gain between animals. The consistent performance of this

device allowed for the demonstration of substantial length gains, despite the limited number of animals.

While trans-stomal distraction enterogenesis via geometric attachment was shown to be effective, this strategy may be applicable clinically in only select scenarios. First, this device requires direct enteral access to the segment of intestine to be distracted. In contrast to a more flexible device with focal intestinal attachments, the current approach would not be applicable via trans-gastric or trans-oral placement (23). Also, this method of intestinal coupling relies on the mesenteric curvature of the small bowel. In patients with severely shortened bowel, the remaining small intestine may not include a mesenteric curve to allow device attachment. In addition, pre-existing adhesions may fix the bowel in a linear orientation, preventing geometric attachment. Focal intestinal attachments, where the specific site of device anchoring can be selected, may be preferable in these scenarios.

In conclusion, this study demonstrated a trans-stomal endoluminal intestinal lengthening device. Intestinal lengthening was achieved using a novel method of geometric device attachment, with outcomes comparable to surgical lengthening. This is an important component in the design of a device for treating patients with SBS.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1. Device components. (A) The catheter device tapers in stiffness to a flexible end (arrow). A stoma clamp (triangle) is used to secure the device. (B) The gradual increase in stiffness with insertion of the device allows geometric coupling with the mesenteric curvature of the jejunal Roux limb. (C) The stoma clamp provides external fixation.

Figure 2.

Mechanical characterization of catheter. (A) Weights (W) were hung from the device at a set distance (L) from a v-groove clamp at select points along the device. The vertical deflection (d) was measured and used to compute the bending stiffness at that point along the device. (B) Bending stiffness of tapering catheter device. The applied moment (N-m) per resulting curvature (1/m) achieved at select points along the device, as measured in cantilevered beam bending tests. (C) Minimum bending radius of the device before permanent bending measured at select points along the portion of the device containing malleable copper wires. This radius relates to the maximum force applied by the device to the bowel when it takes a permanent pose, conforming to the bowel. The end of the device without a wire skeleton (Elastic portion) was not malleable.

Figure 3.

Explant findings. (A) Silastic markers placed initially 3 cm apart demonstrated a significant increase in spacing after 7 days of distraction. The distracted segment (arrow) and fed control (triangle) are shown without tension with the device removed. (B) Representative histologic section of the distracted jejunum, derived from the contact surface of the device along the first mesenteric curve. Hematoxylin and eosin staining demonstrates villus flattening with intact mucosa. Scale = 500 μ m.

Figure 4.

Lengthening results. (A) The % increase in distance from the stoma to each marker is shown (relative to fed control), with the region of geometric fixation (the first mesenteric curve of the jejunal Roux limb) indicated. (B) The increase in distance from the stoma to each marker is shown for the distracted segment relative to fed control. Control segments were extrapolated over the same number of markers to compare total bowel length gain. Each marker was initially placed 3 cm apart, beginning at the stoma. All measurements were taken at explant after device removal.

Figure 5.

Laser Doppler measurement of tissue perfusion. Perfusion scans of the antimesenteric serosal surface of apex of the first mesenteric curve of the jejunal Roux limb without the device in place (No Device) and with the device inserted and applying tension (Device) demonstrate no obvious decrease in tissue perfusion.