Chapter 6

Dynamic Rectus Abdominis Muscle Sphincter for Stomal Continence: An Acute Functional Study in a Dog Model

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Introduction

With the anatomical study as a base we felt there was a need to first perform an acute functional study using this same rectus abdominis island flap design in an animal model before going on to chronic studies.

It is of importance how “tight” a muscle is wrapped. Tightness not only is of significance for the resting pressure but also is it directly related to the squeezing pressure. In an animal model Buie et al. wrapped sartorius muscles around stents with different diameters and measured resting and squeeze pressure. They found the tighter the wrap the higher the resting pressure and the higher the squeezing pressure. It must be taken into account that this cannot be done unlimited since the higher the resting pressure the more chance of getting venous congestion of the stoma and the more difficult it becomes to let stool pass through. Clinically the issue of the tightness with which to wrap the gracilis muscle around the anal canal in dynamic anal graciloplasty has not been resolved. At the present time, the most satisfactory course appears to be a “snug” wrap around the surgeon's contralateral index finger.

In pilot studies we found that wrapping the rectus abdominis muscle island flap around a segment of distal ileum into which a 1.0 cm diameter stent was placed was able to occlude the stomal lumen completely during electrical stimulation and was patent while resting. The purpose of this acute functional study was to determine whether the rectus abdominis island flap when made into the shape of a sphincter could function as such e.g. would be able to generate stomal pressures sufficient with stomal continence (60 mm Hg). In this acute functional study we first outlined what the generated intraluminal stomal pressures were using different stimulation frequencies and if these were consistent with stoma continence. In a second part we determined the ability of this rectus abdominis stomal sphincter to generate continence at different intraluminal bowel pressures.

Materials & Methods

Eight rectus abdominis island flap stomal sphincters were created around a segment of distal ileum in six dogs (two dogs had two rectus abdominis island flap stoma sphincters created and four dogs had one). Sphincter function was assessed by measuring peak pressure, fatigue rate and continence time (Fig. 1). Furthermore, the arterial blood flow to the rectus abdominis muscle island flap sphincter was measured before and during electrical stimulation.
Animal Care
Male mongrel dogs (23 to 27 kg) were used in these experiments. Prior to surgery, animals were housed in separate cages in temperature (22°C), light (12-hour light-dark cycle) and airflow controlled rooms. They were fed a commercial dog diet with ad libitum access to water. At the end of each experiment, dogs were euthanized using an intravenous overdose of Beuthanasia (390 mg of pentobarbital sodium and 50 mg/ml of phenytoin).

Figure 1
Experimental set-up in dogs. A rectus abdominis sphincter is constructed around a segment of distal ileum. A pair of stimulation electrodes is inserted into the muscle near the nerve entry zone. Stomal pressure and fatigue rate measurements are obtained using a microtransducer catheter placed into the stoma lumen encircled by the sphincter. To perform continence measurements, a catheter connected to a saline bag is inserted into the ileum 20 cm proximal to the stoma.
Acute Functional Study

sodium (Schering-Plough Animal Health Corp., Kenilworth, NJ). The protocol for the use of dogs in this study was approved by the Institutional Animal Care and Use Committee at the University of Louisville and adhered to the National Institutes of Health and APS “Guide for the Care and Use of Laboratory Animals”.

**Surgical Technique**

On the day of surgery, dogs were preoperatively medicated with atropine sulfate (0.1 ml/kg body weight; subcutaneously, Vedco, Inc., St. Joseph, MO.), and anesthetized using Pentothal (thiopental sodium, 6 to 12 mg/kg body weight; intravenously, Abbott Laboratories, Chicago, IL.). Animals were intubated and mechanically ventilated with a halothane/oxygen/nitrous oxide mixture (2:94:4, 0.2 liter/min/kg body weight, Halocarbon Laboratories, River Edge, NJ) to maintain a surgical level of anesthesia. An intravenous infusion of lactated Ringer’s solution (5 ml/kg body weight/hr) was maintained for the duration of the procedure with continuous monitoring of arterial blood pressure and heart rate.

With dogs in the supine position, a longitudinal midline abdominal incision was made to expose the rectus abdominis muscle. The anterior rectus fascia was incised along its medial border and reflected laterally. The rectus abdominis muscle was elevated while preserving the integrity of the posterior fascial sheath. Marking sutures were placed at the tendinous insertion and at the most caudal intersection, so that after it was detached from its distal insertion the muscle could be extended back to its original resting length. The deep inferior epigastric artery and veins were dissected to the external iliac vessels. The two most caudal intercostal nerves were dissected out taking care to avoid excess traction on the nerves.

To determine which nerve innervated which part of the caudal segment, the two most caudal intercostal nerves were individually stimulated using a bipolar stimulating electrode cuff (model 4080, Medtronic, Inc., Minneapolis, MN). The part of the muscle that contracted when stimulating the most caudal nerve was tailored (4 cm width) into the final flap. The rectus abdominis muscle was then transected 12 cm from the pubic symphysis leaving the most caudal nerve and the deep inferior epigastric artery and veins intact. The rectus abdominis muscle flap was then dissected from the pubic bone incorporating a strip of periosteum.

The distal ileum was identified and transected, leaving two blind ends into which a rubber stent (diameter, 1.3 cm) was placed. The rectus abdominis muscle island flap was then snuggly wrapped around the end of the transected ileum and fixed to itself with two rows of 3-0 Dexon mattress sutures. Prior to electrical stimulation the stent was removed from the bowel lumen.
Sphincter Stimulation and Functional Measurements

Two stimulation electrodes (temporary myocardial pacing lead electrodes, model 6500, single lead, Medtronic, Fourmies, France) were placed 1 cm cranial and 1 cm caudal from the nerve entry into the flap and were connected to an electrical stimulator (A 310 Accupulser, World Precision Instruments, New Haven, CT).

The intensity of stimulation was normalized to motor threshold (MT) for all sphincters. MT was defined as that stimulus intensity which induces minimal muscle contraction as determined by visual inspection. The stimulator was then set at 4, 6 and 8 times motor threshold to determine the optimal current for maximal force contraction. All further muscle stimulation was performed at the optimal current, with a 270 µsec pulse duration. The resting time between stimulations was 10 min. or until the muscle’s bloodflow reached its resting value.

To determine rectus abdominis muscle sphincter function, the peak pressure, fatigue rate and continence time were measured. All measurements were performed using a microtransducer catheter (Millar®, Millar Instruments, Houston, TX, 1.67 mm diameter) placed into the lumen of the bowel wrapped by the rectus abdominis muscle sphincter. The microtransducer catheter was connected to a computer-based data acquisition system (CED 1401 PLUS interface and a 1902 signal amplifier, Cambridge Electronic Devices, U.K.).

Peak Pressure, Fatigue Rate, Continence Time & Blood Flow Measurements

Peak pressure in the stomal lumen (encircled by the rectus abdominis sphincter) and fatigue were measured at stimulation frequencies of 20, 30, 40 and 50 Hz. Peak pressure was defined as the maximal pressure generated (in the stoma lumen) by the sphincter during stimulation. Fatigue rate was defined as the time required for the maximal sphincter pressure generated during stimulation, to decline by half.

Continence time was defined as the amount of time (seconds) the rectus abdominis muscle sphincter could retain saline at different intraluminal bowel pressures. The continence time started with stimulation of the rectus abdominis muscle sphincter and ended at the instant when saline started leaking out of the stoma. The rectus abdominis muscle sphincter was stimulated at a frequency of 30 Hz at a pulse duration of 270 µsec at different (30, 65 and 100 mm Hg) intraluminal bowel pressures. Pressures were altered by varying the height of an infusion bag of saline. To prevent the retrograde flow of saline, away from the sphincter, a clamp was placed on the ileum 20 cm proximal to the sphincter. During filling intraluminal bowel pressure was monitored using a microtransducer catheter placed between the sphincter and the clamp (Fig. 1).
To measure blood flow to the rectus abdominis muscle sphincter, a blood flow probe (1.5RB; T206, Transonic Systems Inc., Ithaca, NY) was placed on the deep inferior epigastric artery. Measurements were performed before and during stimulation at the predetermined stimulation frequencies (see above). The change in the mean arterial blood flow over baseline was determined and recorded during stimulation.

**Statistical Analysis**  
Results are presented as mean ± standard error of the mean (SEM). We used a one-way repeated measures analysis of variance (ANOVA) and the Tukey post-hoc test. A value of p<0.05 was considered to be significant.

**Results**

**Sphincter Peak Pressure and Fatigue**  
The peak pressures at 20, 30, 40 and 50 Hz were 124.2 ± 11.8 mm Hg, 183.0 ± 14.6 mm Hg, 192.5 ± 14.5 mm Hg, and 238.8 ± 16.7 mm Hg, respectively (Fig. 2). The increase in peak pressure rate was significant (p<0.05) when comparing 20 with 30 Hz, 20 with 40 Hz, 20 with 50 Hz, 30 with 50 Hz and 40 with 50 Hz. Fatigue rates at 20, 30, 40 and 50 Hz were 92.5 ± 10.6

**Figure 2**  
Rectus abdominis muscle sphincter peak pressure (mm Hg) generation in the stomal lumen. Data (n = eight sphincters) are presented as mean ± SEM. All the peak pressures between the stimulation frequencies are significant (p < 0.05 by Tukey posthoc test), except the comparison indicated by the bracket. ns, non significant.
seconds, 41.0 ± 4.1 seconds, 27.8 ± 1.8 seconds, and 20.4 ± 1.8 seconds, respectively (Fig. 3). A significant decrease in fatigue rate was observed when comparing stimulation frequencies of 20 with 30 Hz (\(p < 0.001\)), 20 with 40 Hz (\(p < 0.001\)) and 30 with 50 Hz (\(p < 0.04\)).

**Sphincter Continence Time**

The rectus abdominis muscle sphincter (stimulated at 270 µsec and 30 Hz) was able to maintain continence of saline at pressures of 30, 65 and 100 mm Hg for durations of 165.5 ± 15.8 sec, 62.7 ± 5.2 sec, and 37.1 ± 2.4 sec respectively (Fig. 4). Continence times decreased significantly at intraluminal bowel pressures of between 30 and 65 mm Hg (\(p < 0.001\)) and 30 and 100 mm Hg (\(p < 0.001\)).

**Blood Flow to Sphincter**

The decrease in the mean arterial blood flow to the rectus abdominis muscle flap over baseline during different stimulation frequencies is shown in figure 5. At the start of stimulation the bloodflow decreased at all tested stimulation frequencies, the speed of which depended on the stimulation frequency used. At a stimulation frequency of more then 20 Hz there was a larger drop in bloodflow. Although not statistically significant there was a tendency for bloodflow to recover faster towards baseline when using higher stimulation frequencies.

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**Figure 3**

Rectus abdominis muscle sphincter fatigue rate (seconds). Data (\(n = eight\) sphincters) are presented as mean ± SEM. All of the fatigue rates between the stimulation frequencies are significant (\(p < 0.05\) by Tukey posthoc test), except the comparisons indicated by the brackets. ns, non significant.
Figure 4
Rectus abdominis muscle sphincter continence time (seconds). Data (n = eight sphincters) are presented as mean ± SEM. All of the continence times between the different intraluminal bowel pressures tested are significant (p < 0.05 by Tukey posthoc test), except the comparison indicated by the bracket. ns, non significant.

![Figure 4](image)

Figure 5
Mean arterial blood flow (ml/min) to the rectus abdominis muscle sphincters (n = eight sphincters) during stimulation using different stimulation frequencies. The x-axis represents the time (seconds) after the start of stimulation.

![Figure 5](image)
Chapter 6

Discussion

There is no muscle or structure in the human body that has a more keenly developed sense of differentiation and accommodation than the anal sphincter. It can discriminate between solid, fluid and gas stool consistencies as well as standing, sitting or reclining postures all the time maintaining varying pressures consistent with continence. The normal anal sphincter contains an internal smooth muscle component and an external striated muscle component. The former allows it to contract involuntarily while the latter is voluntarily controlled. The interplay between these two is complex and controlled by feedback mechanisms through reflex neural pathways that result in reflex contraction of the anal sphincter. An ideal stomal sphincter would incorporate as many of the above qualities and functions as possible.

Recent technological advances in the field of electronics have made available electrical stimulation devices that are small, implantable, have long battery lives and can be programmed to respond to the body’s own feedback stimuli. The latest technology utilizes sensors that sense pressures, electrical impulses, movement etc. and according to preset parameters use these to control the degree of stimulation and thus create closed feedback loop mechanisms. These advances have given rise to a whole new field known as dynamic myoplasty. Dynamic myoplasty is a term given to the use of electrical stimulation devices to stimulate skeletal muscle in situ or as surgically elevated muscle flaps. Using these new electrical devices and skeletal muscle flaps dynamic myoplasty could be used to provide many of the characteristics of an anal sphincter. In cardiomyoplasty the latissimus dorsi muscle flap is wrapped around the myocardium and made to contract in synchrony with the beating heart. This is accomplished using a closed loop feedback mechanism whereby the electrical stimulating device utilizes ventricular electrical activity as a stimulus to drive its stimulation pattern. In graciloplasty for anal and urinary incontinence gracilis muscle flaps are constructed into the shape of sphincters. Using an electrical stimulation device the gracilis muscle is made to contract to generate average pressures of 60 cm H2O for maintaining anal continence and 40 cm H2O for maintaining urinary continence.

To avoid fatigue in all these applications, the skeletal muscle used must be trained prior to being asked to perform its definitive function. An electrical stimulation protocol lasting eight weeks is used to transform the muscle into a fatigue resistant fiber type. During this period the muscle is stimulated using a graded incremental training regimen until continuous stimulation is achieved. In creating a stomal sphincter using dynamic myoplasty techniques the goal is to create a stomal sphincter that simulates an anal sphincter. Such a sphincter would be located in the lower abdominal quadrant (where most stomas are placed), be able to generate sphincter pressures that are consistent with...
stomal continence, be fatigue resistant (to sustain elevated pressures for prolonged periods) and that could be regulated by stomal pressures. Proven technology is available to provide all these features.

The purpose of this study was to take a step toward achieving the above. In previous anatomical studies in human cadavers our group determined that a rectus abdominis muscle island flap was an ideal muscle flap design based on location, innervation and vascularity. In the present study we wanted to determine if the rectus abdominis muscle island flap, constructed into the shape of a sphincter could generate pressures consistent with those needed to maintain stomal continence. In humans anal sphincter pressures sufficient to maintain continence range between 40 to 60 mm Hg. In a clinical study Akwari et al. found that continence was maintained in a continent ileostomy and a conventional ileostomy at intraluminal peak pressures of approximately 50 cm H2O and 60 cm H2O respectively. Based on this information 60 mm Hg was set as the target pressure needed to achieve continence in our rectus abdominis stomal sphincter design. We found that in all cases the canine rectus abdominis stoma sphincter generated peak pressures well above this 60 mm Hg mark. As anticipated we found that there was a drop in the bloodflow after the start of electrical stimulation followed by a recovery in bloodflow. The speed of recovery towards baseline was dependent on the stimulation frequencies used.

The best function of the stoma sphincter would be achieved if the rectus abdominis muscle contracted in a smooth fashion without rhythmic excursions in generated pressure, since this would result in immediate incontinence. To obtain such a contraction the fusion frequency of the muscle must be found. The fusion frequency is the minimum stimulation frequency that results in a smooth fused plateau in the pressure signals, implying a tetanic contraction. Stimulating the rectus abdominis muscle sphincter using 20 Hz did not yield a tetanic contraction in all the tested sphincters. However, 30 Hz gave the desired tetanic response. Using 30 Hz as stimulation frequency our rectus abdominis muscle sphincter was able to occlude the stomal lumen completely and maintain it continent for all the three intraluminal bowel pressures (30, 65 and 100 mm Hg) measured.

Based on our findings from the initial anatomical study and this present acute functional study we will conduct chronic functional studies to determine if this sphincter design with the stimulation parameters tested here are capable of providing a non-fatiguing stomal sphincter. In these studies we will test our ability to train the rectus abdominis stomal sphincter to achieve prolonged continence. These future studies will bring us closer to establishing a stomal sphincter with capabilities similar to that of an anal sphincter.
Chapter 6

In conclusion, this study describes the acute functional characteristics of an electrically stimulated rectus abdominis muscle island flap wrapped around a stoma in a canine model. We demonstrated that by electrically stimulating the rectus abdominis muscle island flap stomal sphincter, sufficient contraction pressures could be generated to provide stomal continence. These findings contribute to the goal of using dynamic myoplasty as an alternative treatment for millions of patients with incontinent ileostomies or colostomies.

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