Chapter 9

Summary & Epilogue
Summary

The key elements to creating a continent fecal stoma are voluntary control and a dynamic muscle sphincter that is resistant to fatigue and that is able to generate contraction pressures great enough to prevent the inadvertent leakage of stool. Additionally, the design of the sphincter muscle must be relatively straightforward, require no special devices, and preferably would not involve microsurgical techniques. A few attempts at creating a continent stomal sphincter using dynamic myoplasty have been reported but to date this remains an illusive goal. Denervation atrophy and early muscle fatigue have plagued all reported attempts to make a continent stoma a reality. It was our goal to see if we could make an abdominal stoma continent using dynamic myoplasty. A multiphase project was undertaken that was designed to solve the critical issues of denervation atrophy and early muscle fatigue.

Before starting with the description of the experimental studies, background information was given on the three research fields relating to this thesis, to better understand and approach the problems encountered in the experimental studies. I. Intestinal stomas and their associated problems, with focus on stomal incontinence and its treatment options (Chapter 2). II. Dynamic myoplasty, its clinical applications and the former attempts in applying dynamic myoplasty to the problem of stomal incontinence (Chapter 3). III. Functional electrical stimulation (FES), including the basic knowledge of physiologic and electrical muscle stimulation and with focus on the problem of muscle fatigue and methods of approaching it (Chapter 4).

To solve the problem of denervation atrophy an anatomic feasibility study was undertaken in fresh human cadavers (Chapter 5). This first study was designed to determine which local muscle could serve as an innervated and well-perfused muscle flap. The rectus abdominis muscle (RAM) was found to be ideal. This muscle has a dominant vascular pedicle in the deep inferior epigastric vessels, its elevation can be performed without dividing the intercostal nerves, and the sphincter can be created without the need for a microsurgical anastomosis. Additionally, the muscle location makes creating a sphincter in the lower abdominal quadrants relatively straightforward. Of the two RAM stoma sphincter designs the island flap was found to be superior to the peninsula flap design.

The next phase of the study was to identify an animal suitable for the development of a model for stoma sphincter design. After reviewing several potential animal models and doing several pilot studies, the dog was found to be appropriate. In an acute canine study, it was determined that the RAM island flap sphincter design used in human cadavers could be applied to the dog (Chapter 6). In this study an end ileostomy was created around which the muscle flap was wrapped. Using an electrical stimulation device, the muscle
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was able to be stimulated and to generate peak pressures well above 60 mm Hg (pressure needed to maintain fecal continence in humans). Muscle fatigue was found to be directly proportional to the stimulation frequency and continence was provided at all the tested bowel pressures (30, 65 and 100 mm Hg).

These promising acute functional study results paved the way for the initiation of chronic trials incorporating survival operations in dogs. In the first chronic study (Chapter 7, Part I. Intramuscular stimulation), it was revealed that the sphincter design was fatigue-resistant for 4 hours up to three months post-op with one of the two training protocols tested. Although preliminary, a continence time of up to five and one half-hours has been achieved with a pressure in excess of 60 mm Hg in one animal.

In addition, a second chronic study (Chapter 7, Part II. Direct nerve stimulation) was undertaken to test whether direct nerve stimulation, as opposed to intramuscular stimulation, would render more favorable results. Although the numbers were too small there was a tendency that the sphincter could be trained faster with direct nerve stimulation. However, electrode failure (displacement and lead fracture) led to a non-functioning sphincter in 63% of the cases when using direct nerve stimulation.

Analysis of fibertype transformation, as described in Chapter 8, revealed that a significant fiber type conversion was achieved in both training protocols (as used in Chapter 7, Part I. Intramuscular stimulation), with a greater than 50% conversion from fatigue-prone (type II) muscle fibers to fatigue-resistant (type I) muscle fibers without evidence of muscle fiber damage or significant fibrosis. The bowel wall within the functional dynamic stomal sphincter did not exhibit any significant architectural changes related to ischemic fibrosis or mucosal damage. This suggests that our anterior abdominal wall dynamic island-flap stomal sphincter, which generates a contractile force over the bowel wall capable of producing enough stomal pressure to achieve fecal continence, is not intrinsically harmful to the bowel that it encircles.
Summary and Epilogue

Epilogue

Fecal and urinary stomal continence remains an illusive goal for the hundreds of thousands of individuals who have to live with the loss of bowel and urinary continuity. The exciting results reported here bring us closer to achieving what has been an objective, stomal continence. By combining a local muscle flap design and dynamic myoplasty technology, impressive continence times have been achieved in our chronic dog model. What remains to be determined at this time is the durability of the design with focus on the stimulation electrodes, the ability of the design to function around a functioning end ostomy, what the potential complication rates may be, and who the best candidates are for this technique. These issues are currently being addressed with ongoing trials in our laboratory. By addressing the aforementioned issues, clinical trials in patients may be forthcoming in the near future.

Ultimately the introduction of a physiologic feedback loop would most closely simulate the anal sphincter. With a feedback system (using bowel pressure sensors to indicate the need to increase muscle tone), the sphincter would adjust the magnitude of its contraction according to the amount of backpressure exerted on the stoma. The sphincter would therefore only contract with a force sufficient to maintain continence at any given moment based on the physiologic demands placed on the stoma sphincter. With a feedback system, muscle work would be reduced and the rate of fatigue minimized. Currently there are commercial products for electrical stimulation with feedback capabilities as well as pressure sensors available.

Other options to prolong the durability are to use pulse generators in which one can change the stimulus waveforms to ones that are more favorable to use in terms of muscle fatigue and muscle and/or nerve damage. Taking into account that by training the muscle sphincter the time to relaxation increases, one could consider to introduce a resting period of 0.5 seconds every ten seconds of stimulation. The advantage of this is that the generated force will be still sufficient for maintaining continence but at the same time provides the muscle a period of relaxation. Simultaneously the charge built up at the level of the contact points of the electrodes can be reversed. Both proposals could not be investigated in our studies because of limitations of the pulse generator we used.