Chapter 1

General Introduction
Some life-saving surgeries result in the necessity to establish permanent stomas; this outcome has an undeniable physical and emotional effect on the patient’s life. For these patients the presence of the stoma and external pouching system may be lifelong reminders of the societal stigmas regarding elimination. The need to provide long-term physical and emotional support for many of these patients also has resulted in significant costs for the health care system. Although patients with permanent stomas reasonably adjust, complications that include peristomal skin irritation, pouching system dysfunction, stoma problems, renal deterioration (in patients with a urinary diversion), social inhibition, depression, and sexual dysfunction also have been reported.1-10

The underlying issue is continence: the ability to control and evacuate feces, flatus, or urine at socially acceptable times and places. In fecal incontinence the definition extends to being able to distinguish between gas and stool. Surgeries resulting in traditional abdominal stomas render the patient incontinent. The use of a pouching system provides a measure of continence or control over elimination. Even infrequent leakage and odor, however, are frank reminders of underlying incontinence. There remains a need to be continent. Research in this area also has been motivated by the prolonged survival of these patients. With operative survival routine and cure of cancer common, patients are living longer and therefore are willing to have a type of surgery that promises a more “natural” result. That is, patients no longer are universally grateful to be alive; they also seek an improved quality of life.

The quest for fecal continence has resulted in numerous non-surgical and surgical continent diversion techniques.11-32 The use of dynamic myoplasty is one of them. Dynamic myoplasty is a term given to the use of electrical stimulation devices to stimulate surgically elevated muscle flaps. Using new electrical stimulation devices and skeletal muscle flaps dynamic myoplasty has been used to treat fecal13 and urinary14 incontinence using a gracilis muscle flap neo-sphincter. Another clinical example is use of the lattissimus dorsi muscle to augment the pump function of the heart in patients with chronic heart failure.15 None of the attempted techniques to maintain stomal continence have enjoyed widespread use because of associated complications or because these techniques were not able to provide complete continence. Failure of the surgical techniques has been mainly due to foreign body related complications like wound infections or ischemic complications related to the surgical procedure.16,17,36,37 These eventually lead to necrosis of the stoma and peristomal area18,19 resulting in narrowing of the stoma. In dynamic myoplasty these complications should not occur since the stoma sphincter is constructed of innervated and vascularized autogenous skeletal muscle. However, like the many other attempts, the use of dynamic myoplasty to achieve stomal continence has also met with limited success. The results do not support

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dynamic myoplasty as being a better alternative treatment for fecal stomal incontinence than those methods already available. *Denervation* atrophy caused by flap elevation to construct the sphincter and early *muscle fatigue* caused by continuous electrical stimulation were responsible for these disappointing results and constitute the major obstacles standing in the way of dynamic myoplasty becoming an effective solution to stomal incontinence in the clinical setting.
Aim and outline of this thesis

Aim
The aim of this thesis was to create an abdominal stomal sphincter with an electrically stimulated skeletal muscle flap (dynamic myoplasty) in order to maintain long-term stomal continence.

The following questions were investigated in this thesis:
- Is it possible to use an innervated pedicled skeletal muscle flap, using local available skeletal muscle, for stomal sphincter construction?
- Which muscle flap design is the best for stomal sphincter construction while keeping its innervation intact?
- Is the developed muscle sphincter able to function as such, e.g. able to generate sphincter pressures that are consistent with stomal continence?
- Is it feasible to make the stomal sphincter fatigue-resistant by means of training resulting in long-term stomal continence?
- What type of electrical stimulation (intramuscular or direct nerve) is the best in terms of generating long-term stomal continence?
- What is the effect of chronic stimulation on the stomal sphincter muscle fiber type transformation, muscle fiber histology and its bowel wall morphology?

Outline
Based on previous reports on dynamic myoplasty for stomal incontinence and our laboratory success using dynamic myoplasty techniques\textsuperscript{39-41} it was believed that a continent stoma sphincter could be designed and could provide continence for at least several hours. A multiphase project was undertaken that was designed to solve the critical issues of denervation atrophy and early muscle fatigue.

Chapter 2 describes the types of intestinal stomas, epidemiology of stomas, problems associated with stomas and it focuses on the problem of stomal incontinence. Past and current treatment options for stomal incontinence are outlined in detail in this chapter.

The phenomenon muscle plasticity, dynamic myoplasty and its clinical applications are described in Chapter 3. This is followed by description of the former attempts in applying dynamic myoplasty to the problem of stomal incontinence.

In Chapter 4 the basic knowledge of physiologic and electrical muscle stimulation is described to better understand and approach the problems encountered with functional electrical stimulation (FES). The problem of muscle fatigue and methods of approaching it will be described in detail.
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The first phase of our multiphase study is described in Chapter 5. This first study addressed the problem of denervation atrophy. It involved identifying an ideal muscle to use as a stomal sphincter and determining the anatomical feasibility of using that muscle to wrap around a fecal stoma in fresh human cadavers. Two different flap designs were investigated.

The second phase is described in Chapter 6. The proposed rectus abdominis muscle island flap design, developed in the first study, was attempted in an acute canine model. The aim of this study was to determine if the elevated flap wrapped around a stoma would function as such e.g. would be able to generate stomal pressures sufficient for stomal continence.

In order to solve the problem of muscle fatigue we performed two chronic canine studies (third and fourth phase). In the first chronic study we defined a methodology for training the muscle sphincter. This study was designed to determine if the rectus muscle could be “trained” to become fatigue resistant in a chronic canine model. In the first part of the chronic study (Part I. Intramuscular stimulation) we investigated two training protocols (A and B). The best was defined to be the one that led to stomal continence for a couple of hours. The second chronic study (Part II. Direct nerve stimulation) involved the application of the best training protocol found in Part I with the use of nerve cuff electrodes instead of intramuscular electrodes. These chronic studies are described in Chapter 7.

In Chapter 8 the effect of chronic stimulation on sphincter muscle fiber type transformation and muscle fiber histology was analyzed. In addition the examination of the morphologic changes in the small bowel was investigated in this chapter.

Chapter 9 includes the summary and epilogue of this thesis.
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