A stomal sphincter configured from the rectus abdominis muscle in pigs. First results.

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Abstract

Our aim is to develop an artificial sphincter for use in stoma patients. Earlier experiments have demonstrated the anatomical feasibility for using the rectus abdominis muscle as an artificial sphincter in humans and pigs.
Three pigs were used to condition the rectus abdominis muscle and to create an artificial sphincter. Animals were implanted with stimulators and muscle conditioning started one week after implantation. After a conditioning period of 4 - 5 weeks animals were reanaesthetised and a final experiment was conducted. During this experiment two different sphincter configurations were tested and characterised.
A double wrap sphincter design was more effective than a single wrap design. A stimulation frequency of approximately 20Hz was required to generate fused contractions and sufficient pressure within the sphincter's lumen. Both continuous and intermittent patterns of stimulation of the muscle failed to provide long-term continence.
In the last animal the muscle was electrically divided into two parts, which were stimulated alternately with a short period of overlap. This protocol allowed the rectus abdominis muscle to function as a sphincter that was both continent and resistant to fatigue.
In a further series we will test this protocol in double wrap sphincters for continence over extended periods.

1 Introduction

Current estimates suggest that there are approximately 80,000 to 100,000 stoma patients in the UK. Additionally 12,000 to 15,000 new stomas are created every year [1]. Quality of life in these patients is seriously affected [2][3]. Konsten et al. examined the feasibility of using the rectus abdominis muscle as an artificial sphincter in pigs [4]. Bardoel et al demonstrated the anatomical feasibility in human cadavers [5]. Results based on an acute study in dogs were also encouraging [6][7].

2 Methods

All procedures were performed under general anaesthesia and carried out under the UK Animals (Scientific Procedures) Act 1986. Three pigs were used to assess the feasibility of conditioning the rectus abdominis muscle and to create an artificial sphincter. During a first procedure stimulators (Medtronic Itrel, bipolar output) were implanted so that the rectus abdominis muscle could be conditioned to become resistant to fatigue. Muscle conditioning started one week after the initial procedure by stimulation of the muscle at a constant frequency of 2Hz and 210µsec pulse duration. Stimulation amplitude was adjusted throughout the conditioning period of 4 - 5 weeks for muscle twitches that were easily palpable.

2.1 Surgical techniques

Anaesthesia was introduced with Stresnil and Propofol and maintained by volatile agents after endotracheal intubation.

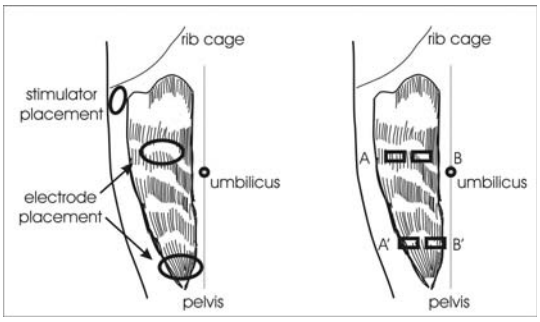

Figure 1: *Left side: electrode and stimulator placement during implantation; right side: electrode placement for alternating stimulation with muscle in situ.*

During stimulator implantation two wire electrodes were placed on the rectus abdominis muscle just beneath the covering epimysium. One electrode was placed close to the pubic insertion of the rectus abdominis muscle and the second electrode was implanted at the level of the umbilicus. The stimulator was positioned subcutaneously close to the animal's rib cage (Figure 1).

In the final experiment the muscle was carefully dissected through a midline incision and cut proximal to the upper electrode. Care was taken not to compromise the blood supply through the inferior epigastric artery. The sphincter was formed by rolling the cut end of the muscle around a piece of plastic tubing of 12-15mm diameter, which was then removed. 3-0 Dexon mattress sutures were used to hold the muscle together. In the third animal the rectus abdominis muscle was wrapped twice around the plastic tubing, creating a double-wrap sphincter (Figure 2). Finally, a condom or piece of small bowel was connected to a piston pump and placed inside the lumen of the sphincter and filled with saline (Figure 3).

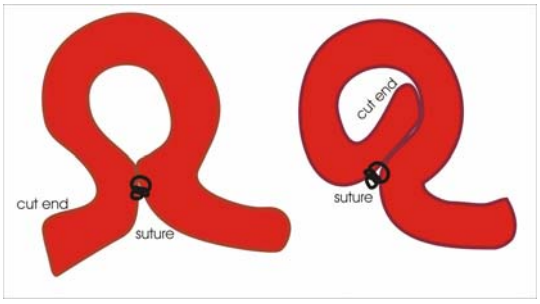

Figure 2: *Left side: single wrap sphincter; right side: double wrap sphincter.*

2.2 Terminal experiments

The terminal experiments were used to characterise the newly created sphincters. The pressure generated inside the lumen was measured in relation to the pressure just upstream the sphincter and the stimulation frequency. The maximum upstream pressure that the sphincter could contain was measured. Finally, the interaction between continuous stimulation, intermittent stimulation, alternating stimulation and fatigue was tested. Stimulation was delivered via two external stimulators (custom-built stimulator for RISE project, Department of Biomedical Engineering and Physics, Medical University Vienna and Devices Isolated Stimulator Mk IV).

All measurements and control signals were processed via a National Instruments Data acquisition card (PCI-6035E) using custom-designed software written in Borland Delphi (v.7 Personal Edition).

Several pressures, piston position and the stimulation signal could be streamed to disk simultaneously. The software was also used to control the position of the piston and the delivering of muscle stimulation (Figure 3).

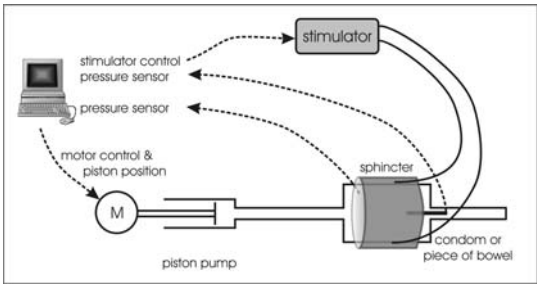

Figure 3: *Setup for terminal experiments.*

3 Results

All recorded pressure traces resembled the forces recorded under isometric conditions in other species. In all three animals the pressure generated seemed to be independent of the preload pressure prior to stimulation. Stimulation with a frequency below 20Hz failed to produce a fused pressure trace. All subsequent fatigue tests were consequently based on a stimulation frequency of 20Hz.

With continuous stimulation at 20Hz, the generated pressure fell to 80% of the initial value within 90 sec. With stimulation at 20Hz and an ON-OFF cycle of 5 sec ON – 5 sec OFF the generated pressure was unchanged after 360sec.

Despite a period of at least 30 days of conditioning, which we expected to induce slow contractile characteristics, intermittent stimulation resulted in a drop in the generated pressure to baseline even if the breaks in stimulation were as short as approximately 150ms (Figure 4).

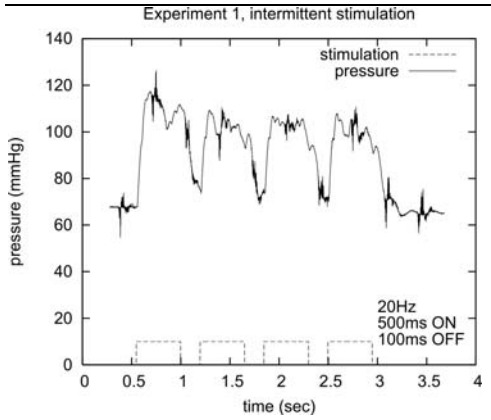

Figure 4: *Pressure generated in the lumen of the sphincter using intermittent stimulation.*

Observations in the literature suggested that an alternating stimulation protocol, using several segments of the muscle should be feasible [8]. In the third animal the sphincter was therefore split electrically into two longitudinal segments and the sphincter function was assessed. In addition a double wrap sphincter was constructed in this animal (Figure 1, Figure 2).

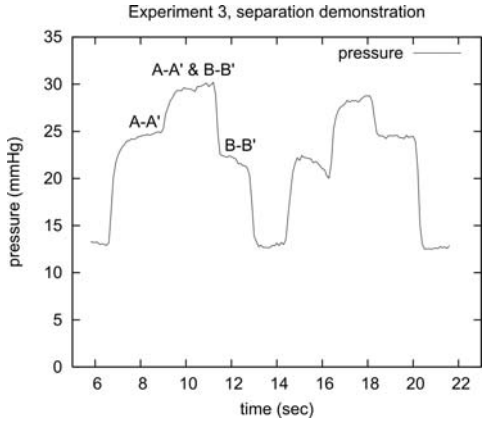

Figure 5*. Pressure recording of alternating stimulation.*

The measurements proved that it was possible to excite segments of the muscle independently by placing multiple electrodes on the muscle (Figure 5).

4 Discussion and Conclusions

A stimulation frequency of approximately 20Hz was required to generate sufficient pressure and a fused contraction. Neither continuous nor intermittent stimulation could be used to achieve long-term continence in an artificial sphincter.

It was however possible to use alternating stimulation by means of two sets of wire electrodes placed on the rectus abdominis muscle (Figure 1). A double wrap sphincter was more effective than its single wrap counterpart.

In order to validate these early findings we are currently conducting a second series of experiments to compare the conditioned right rectus abdominis muscle with the unconditioned left muscle of the same animal. Stimulation will be based on an alternating stimulation protocol. Sphincter function will be assessed over periods of several hours. Ultrasound imaging will be used to demonstrate the effects of stimulation on the lumen of the sphincter.

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