A HIGH PERFORMANCE BIDIRECTIONAL MICROPUMP FOR A NOVEL ARTIFICIAL SPHINCTER SYSTEM

A.Doll, S.Reimers, M. Heinrichs, F.Goldschmidtboeing, H.-J. Schrag+, U.T.Hopt+, P.Woias
Institute for Microsystem Technology (IMTEK), University of Freiburg, Germany
+Artificial Sphincter Study Group, University Hospital Freiburg, Germany
Georges-Koehler-Allee 102, 79110 Freiburg, Germany
doll@imtek.de

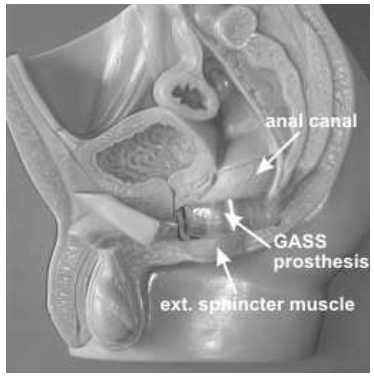
ABSTRACT

We present the design, fabrication and testing of a novel medical implant based on a high performance silicon micropump. An analytical model was exploited for further optimization of our micropump design. The experimental data obtained are in a good accordance to theory. Two sphincter prosthesises of different sizes were developed and tested. Their general medical capability as a prosthesis has been proven.

Keywords: sphincter prosthesis, micropump, active valves, bidirectional

INTRODUCTION

Anal incontinence is the loss of natural anal sphincter control and can lead to an unwanted loss of feces and gases. The fecal incontinence is a demoralizing condition that has a major impact on everyday living and the quality of live. Studies have estimated an incidence of 1-2 per cent in the total population and even up to 7 per cent in otherwise healthy adults over the age of 65 years [1]. The relevant clinical systems nowadays available are based on a circular compression balloon system (cuff) enclosing the anal canal. The compression cuff is connected to an external fluid reservoir and a separate pump mechanism that are implanted in different anatomical spaces. Complications and explantation rates of up to 40% combined with the high cost of the devices result in an expensive therapy.



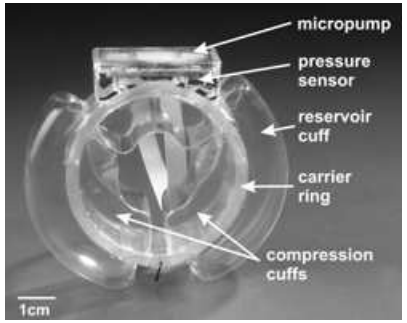


Fig. 2. *Prototype of the artificial sphincter prosthesis, human version*

THE GERMAN ARTIFICIAL SPHINCTER SYSTEM

The German Artificial Sphincter System (GASS) is a novel hydraulic muscle to treat major fecal incontinence [2,3]. The new concept benefits from a high integration of all functional components into one device. Thus, an easy surgical implantation technique and a low risk of infection can be achieved. The prosthesis is implanted around the debilitated sphincter muscle as shown in Fig. 1. It employs elastic compression cuffs inside a rigid carrier ring and reservoir cuffs at its outer side. A bidirectional micropump transports NaCl solution between both cuff systems (Fig. 2). The GASS is driven by an electrical control circuit that will be implanted as well and can be addressed by a telemetric interface from the outside of the body.

We have designed two different implant sizes, one for in-vivo animal case studies in mini-pigs and another one for human patients. The necessary inner diameters of the carrier rings were determined using magnetic resonance imaging (MRI). The prosthesis size for the mini-pig version was thus defined to 30 mm while the carrier ring of the human version has a diameter of 38 mm.

The compression cuffs and the reservoir cuff are connected over a fluidic network and a bidirectional micropump as shown in Fig. 3. By shifting the fluid between the reservoir cuff and the compression cuffs, the sphincter muscle can be compressed or relaxed and thus the state of continence can be controlled. In Fig. 4, the two stable states of operation that must be controlled by the micropump are shown. For the

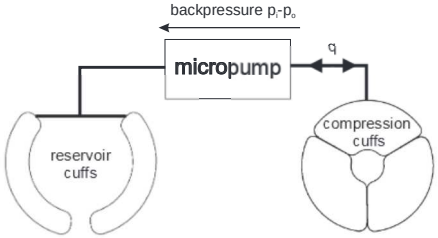


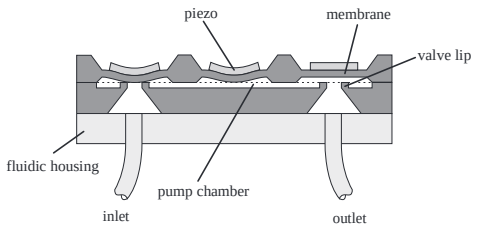
Fig. 3. *Principle interconnections of the fluidic network*

Fig. 4. *Both states of operation*

the reservoir and for an occlusion into the compression cuffs, respectively. The maximum fluid volume that can be filled into the compression cuffs is 9.5 ml for the small prosthesis version and 21 ml for the large one. The amount of fluid that has to be shifted to reach continence of the bowl depends on the pressure that has to be exerted on the sphincter muscle. Accordingly, the pressures were determined by a special bio-simulator using explanted porcine sphincter muscles [3]. The worst case is the simulation of diarrhea with e.g. water inside the rectum. It turned out that the worst case pressure inside the compression cuffs must be above 245 mbar to ensure the proper closing of the bowl.

THE MICROPUMP

The requirements to be fulfilled by the micropump can be derived from the specification of the cuff system. A high flow rate in both directions is needed to ensure fast defecations. Furthermore, the micropump must be able to build up pressures up to 30 kPa in the compression cuffs and sustain it for long periods of time. A schematic cross section of our micropump is given in Fig. 5. The pumping mechanism is based on the bending of three membrane actuators driven by the deformation of piezoelectric plates (PZT). The valve membranes seal a circular valve lip when actuated, whereby the pump membrane is free to move into the pump chamber.



In contrast to other micropumps this pump features active valves. The active valves enable the reversal of the pump direction by applying different driving schemes. Possible malfunction of the system or a lack of power supply results in a normally open state of the valves and consequently, in an open state of the bowl.

For the design of this micropump a theoretical model has been developed that predicts the pump performance over the whole frequency and backpressure range [4]. This lumped parameter model is based on electrical network analogies. Fig. 6 shows the setup of the fluidic network analogon. The pressure drop of a valve is represented by a resistor R_V, the fluidic capacities of the valve membranes by capacitors C_v and C_D for the driving membrane over the pump chamber. The resistances of the valves were approximated analytically by the flow through a slit of height h_0. This height was determined as a function of the pump chamber pressure and the corresponding deflection of the piezo-actuated membrane [4].

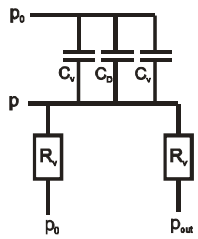
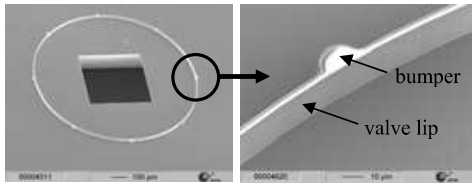


Fig. 6. *Lumped parameter model of the micropump*

The model predicts that the flow characteristics of the valves will mainly determine the pump rate. Possible optimization methods to increase the flow rate are the enhancement of the actuator membrane stroke, the reduction of the fluidic capacities and the miniaturization of the valve lip.

One of our design optimization strategies is to scale down the width of the valve lip [5]. Fig. 7 shows a scanning electron microscopic (SEM) image of the smallest realized lip. Here, bumpers were added to



enhance the mechanical stability and to absorb the mechanical impact of the valve membrane (Fig. 7, right).
The valve lip is fabricated using an optimized ASE process. With this an extremely narrow (3 µm) and high (40 µm) lip was fabricated. These lip dimensions are close to the technological limits that could be realized. Smaller lips would be destroyed when applying ultrasonic cleaning during manufacturing. The overall size of the micropump is 30 x 12 x 1 mm³.

RESULTS

The micropump

In Fig. 8 the flow rate of a micropump with a 5 µm wide valve lip (inner radius = 665 µm) is plotted over the driving frequency at different backpressures. As

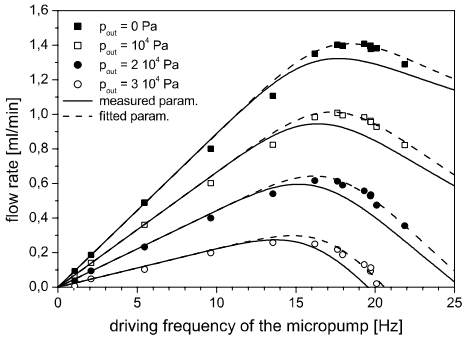


Fig. 8. *Flow rate versus driving frequency. Experimental data (dots) and theory (lines)*

can be seen, the flow rate first increases with the driving frequency. Above an optimum frequency the flow rate decreases. The frequency with the highest flowrate depends on the backpressure exerted at the outlet of the micropump. Our analytical model can predict this behavior. In Fig. 8, the experimental data are plotted. The straight lines are our model prediction for this pump design. If we take measurement inaccuracies of the parameters that enter the calculation into account (e.g. width of the valve lip ± 0.8 µm, membrane deflection ± 0.2 µm) the micropump behavior can be described even more accurately. The thus adapted model curve is represented by the dashed lines in Fig. 8. The maximum flow rate of this micropump is 1.4 ml/min at an operating frequency of 17 Hz for water media. This pump can build up a backpressure of 40 kPa.
The flowrate versus backpressure characteristics of our latest micropump design with a 3 µm thick valve lip (inner radius=665 µm) is given in Fig. 9 for different frequencies up to 27.8 Hz. Higher frequencies result in a decrease of the maximum backpressure and flow rate and are not plotted for clarity. This micropump can build up and maintain a backpressure of 60 kPa and shows a maximum flow rate of 1.8 ml/min at 27.8 Hz

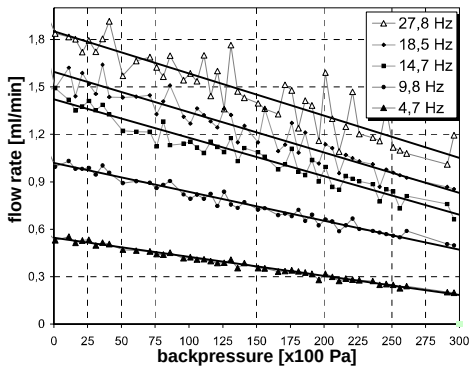


Fig. 9. *Flow rate of our latest micropump versus backpressure for different driving frequencies*

points for higher flow rates originates from the measuring setup.
Our micropumps work self-priming and are absolutely bubble tolerant, i.e. fluid, gases and mixtures of both can be pumped without a breakdown of the flow.

Testing of the large prosthesis version

We have tested the general ability of the prosthesis prototype to build up the appropriate pressures. Therefore, we have assembled the system around a bowl simulator object that shows higher resistance to deformation than the later sphincter muscle does. The pumping was started and the pressure behavior inside the compression cuffs was measured by an integrated pressure sensor. Figure 10 shows the pressure inside the compression cuffs of the large cuff version over pumping time. As can be seen, the needed worst case pressure of 245 mbar (threshold of continence) can be built up inside the compression cuffs in less than 15 min for this specific experiment. Here, the filling of the compression cuff is denoted as occlusion, while the relaxation of the pressure, i.e. pumping the fluid backwards into the reservoir is denoted as defecation.

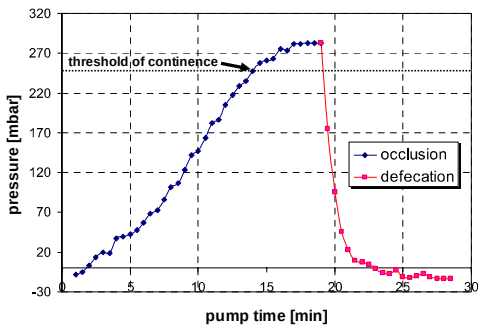


Fig. 10. *Pressure versus pump time characteristics of the compression cuff with sphincter resistance simulation (large cuff*

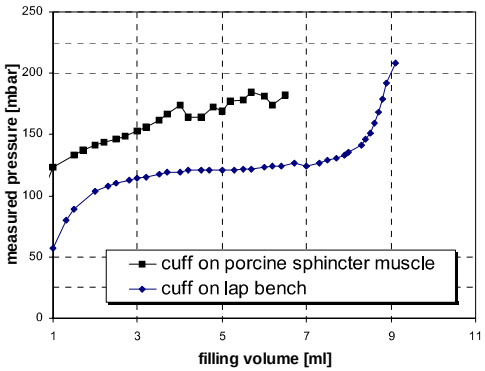


***Fig. 11**. Typical volume to pressure characteristics of the compression cuffs without external resistance and with the resistance of a living mini-pig sphincter muscle (small cuff version)*

Testing of the small prosthesis version

The pressure sensor inside the prosthesis system delivers information about the actuation pressure inside the compression cuffs, i.e. the pressure exerted on the sphincter muscle. From the internal pressure of the compression cuff, the filling volume inside the cuffs can be deduced, presumed that the volume to pressure characteristics of the cuff in its specific application area is known. Figure 11 shows typical pressure characteristics of the small, mini-pig cuff model. One measurement was made on the lap bench, i.e. without any resistance between the compression cuffs but the cuff behavior itself, the other data was won directly on a porcine sphincter muscle from a truly implanted system. Here, the directly measured pressure including sensor peripheral offset is shown. The shifting of the complete fluid volume (9.5 ml) from the reservoir cuff inside the compression cuffs and vise versa can be realized in less than 5 min.

DISCUSSION

The measured data of the micropump performance show a good accordance to theory. Based on the established lumped-parameter model, further flow rate optimization steps were conducted. We could enhance the flow rate of our micropumps for about 30 % by miniaturizing the valve lip dimensions. A technological and mechanical limit has been reached for this step. The future optimization strategy must therefore concentrate on the stroke of the valve membrane actuator and the fluidic capacities of the membranes.

The two prototypes of the prosthesis system were tested and have proven their general ability to build up appropriate pressures to enable a proper operation of the prosthesis.

Figure 12 shows the first prototype of the small mini-pig prosthesis and the sealed driver-electronics with integrated internal power supply. In a first in-vivo experiment we could obtain the volume to

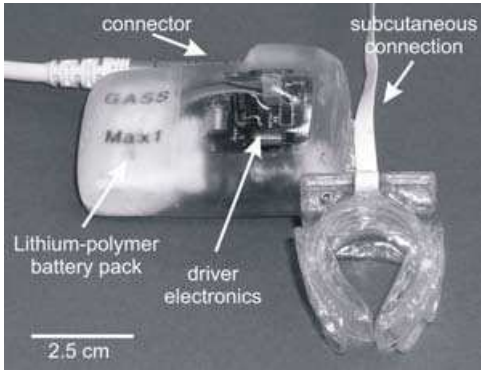


***Fig. 12.** The first prototype of the prosthesis and the driver electronics ready for implantation into a mini-pig*

around the sphincter muscle of a mini-pig. Further case studies and long time in-vivo experiments are planned in the near future.

CONCLUSION

The first step towards a novel artificial sphincter prosthesis powered by micromechanical components is accomplished. The technical concept is capable to fulfill the medical requirements. Future effort must be made to proof the reliability and the biocompatibility of the whole device.

AKNOWLEDGEMENT

We gratefully acknowledge the financial support of the “Forschungskomission” of the University Clinic of Freiburg and the German Ministry for Science and Education (BMBF). The silicon chips were fabricated by the Clean Room Service Center of the Institute for Microsystem Technology (IMTEK) Freiburg.

REFERENCES

[1] J. Rothbarth et al, ”What is the impact of fecal incontinence on quality of life?”, *Diseases of the Colon and Rectum*, **44**, 1, pp. 67-71, 2001

[2] H.J. Schrag, German patent: DE10023634, 2003

[3] H.J. Schrag, F.F. Padilla, F. Goldschmidtböing, A.Doll, P. Woias, U.T. Hopt, “German Artificial Sphincter System “GASS”, First Report of a novel and highly integrated sphincter prosthesis for the therapy of major fecal incontinence”, *Biomed.Tech.*, **49**, pp. 274-278, 2004

[4] F. Goldschmidtböing, A. Doll, M. Heinrichs, P.Woias, H.-J. Schrag, U. T. Hopt, “A generic analytical model for micro-diaphragm pumps with active valves”, *J. Micromech. Microeng.* **15** No 4, 673-683, 2005

[5] A. Doll, F. Goldschmidtböing, M. Heinrichs, P. Woias, H.J. Schrag, U.T. Hopt “A piezoelectric bidirectional micropump for a medical