

Smart Artificial Sphincter

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INTRODUCTION



Disorder of continence is a common (up to 10% of the population in western community [1]) devastating physical disability often accompanied with social isolation. Regarding demographic changes and consequent increasing cases of faecal incontinence (FI), treating FI has great potential for the MedTech market. Actual invasive treatments (left Fig. [2]) of FI show a high rate of revision surgery and morbidity often due to tissue erosions, atrophy or infections [1]. We intend to develop a device based on low voltage dielectric electrically activated polymers (EAP) which can be used in an actuator and in a sensing mode eliminating therefore the causes of failure of the actual treatments.

MyoPowers SA

MyoPowers is currently developing superior medical devices for treatment of urinary incontinence.

MyoPowers envisions that the research of the consortium for the development of an artificial fecal sphincter lead to superior improvements of incontinent treatments. This development could also be applied to the urinary sphincter. MyoPowers supports the scientific activities of the research consortium by allowing access to its proprietary technology platforms for artificial muscle development including technical support and the knowhow of its clinical and scientific advisory board.

<http://www.myopowers.com>

Empa

Electronics and power supply of the actuator

- Estimation and optimization of power consumption of the electrical activation of the EAP actuator, the electronic sensing and control system
- Development of an implantable sensing system
- System integration of all components and testing of the reliability and functionality under characteristic conditions (37°C in phosphate buffered saline (PBS))
- Design of an EAP-actuator based, electrically controlled "Smart muscle"-prototype with related pressure sensors

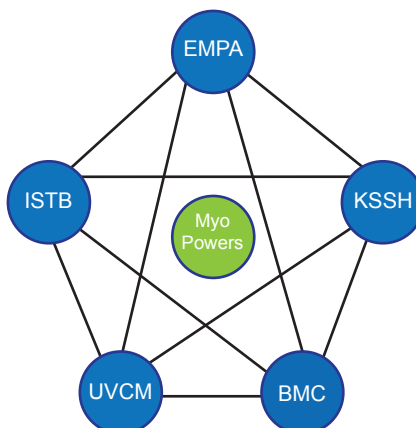
<http://www.empa.ch> - Abteilung Sennhauser

ISTB, University of Bern

In vitro reliability testing

- Determination of statistical shape model from collected medical data (incl. biomechanical behavior of the anorectum tissue)
- Design requirements/improvements from in vitro tests
- Finite element modeling
- Definition of appropriate testing conditions for the implant materials and electronics
- Testing and modeling implant long-term fatigue behavior

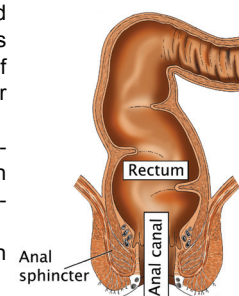
<http://www.istb.unibe.ch>



Spitaler Schaffhausen

Device definition and design

- Awareness of the needs (conformation of continence organs (right Fig. [3]), continence ranges, pathophysiology of FI) and the surgical feasibility from the clinical point of view → Development of a device that meets clinical demands from the beginning
- Development of realistic and clinically relevant models (e.g. in vitro) for the testing of the artificial fecal sphincter (AFS)
- Finding an optimized procedure to implant the AFS in selected animals and subsequently in patients
- Finally, patient evaluation and selection for the AFS



<http://www.spitaeler-sh.ch>

Bern University Hospital

In vivo study

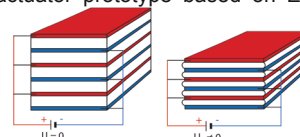
- Evaluation of animal models optimized to test the AFS and determination of evaluation parameters (e.g. bowel habits, pudendal nerve terminal motor latency)
- Test of occlusion function, sensor/remote control function, fail save system, energy consumption and biocompatibility of the AFS in a short time (3 days) animal model (minipig)
- Evaluation of optimal positioning and function/biocompatibility in a short time (1 week) animal model with debilitated anal sphincter function (Botox)
- Evaluation of bowel function/remote control function, fail save system, energy consumption and biocompatibility in a 3 months animal model

<http://www.insel.ch>

Biomaterials Science Center

Electrically activated polymer (EAP) nanostructures for the actuator

- Selecting the promising and innovative materials for the active elastomers and conductive layers thus, realizing a physical vapour deposition (PVD) technique for thin film nanostructures
- Realizing a molecular beam deposition under ultra-high vacuum conditions, a multilayer deposition procedures for EAP actuators with integrated in situ measurement of film thickness, surface morphology, strains and forces generated by the produced EAP structures
- Designing a actuator prototype based on EAP multilayer structures for clinical tests



www.bmc.unibas.ch

[1] "Urinary and Faecal Incontinence", H-D. Becker, A. Stenzl, D. Wallwiener and T. Zittel, Springer-Verlag, Berlin Heidelberg (2005).

[2] http://artisaglik.com/english/Artificial_Sphincter_Anal_Band.html

[3] Adapted from www.rcsed.ac.uk/fellows/kcattle/anatomy1.html