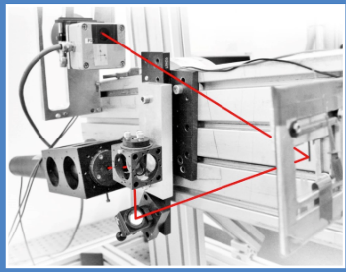
Prof. Bert Müller, Uni Basel

SmartSphincter

SMART MUSCLES FOR INCONTINENCE TREATMENT



Dr. Lukas Brügger

PD Dr. Philippe Büchler, UniBE

PD Dr. Franc Hetzer, Spitäler SH

Dr. Urs Sennhauser, EMPA

What it's about…

Realizing artificial muscles for the treatment of severe fecal incontinence by building hundred thousands of low-voltage, dielectric, electrically activated polymers layers with nanometer thickness.

Context and project goals

One of the largest markets, still under-developed by medical device companies, is the treatment of urinary (UI) and fecal incontinence (FI). The demographic changes in western countries will lead to a significant increase of incontinent people. For instance, FI affects nearly 10% of people over 60 years of age, and about 2 million people in Europe have daily severe FI, which is one of the most devastating of all physical disabilities, since it affects self-confidence and personal image, and usually leads to social isolation. The success of current treatments is disappointing because of numerous complications including infections that often require device removal and the extended use of diapers. The aim of the proposal is to realize prototype devices acting as artificial muscle, termed anal sphincter, to finally treat patients with severe FI. The device should replace the destroyed natural muscle function using low-voltage electrically activated polymers (EAPs) controlled by implemented pressure sensors and the patient.

The unique artificial fecal EAP-based sphincter system is driven by an integrated microprocessor, powered by an energy harvesting device and an implantable battery, rechargeable by transcutaneous energy transfer (TCT) controlling the fluid flow intentionally by the patient and automatically with pressure gauges. The remote control will allow the physician to perform patient-specific adjustments. The ring-like sphincters should be optimized with respect to its macroscopic shape concerning function and comfort applying statistical shape models, with respect to its surface architecture and chemistry to prevent infections and achieve implantation procedures as simple as possible.

In vitro and bench tests should verify reliability of the entire device before it will be implanted in minipigs. Histological investigations should demonstrate that the applied forces do not significantly affect the surrounding tissue. The expected benefits for the patient and their physicians are:

- recovery of continence
- short hospitalization periods because of the relatively simple treatment and post-op individual adjustments
- guaranteed reliability (minimal failure rates)
- electronically controlled by integrated sensors and managed by the patient.

The consortium is a competent, multidisciplinary team, distributed across Switzerland, active in fields ranging from medicine via microelectronics towards biomaterials science with recent experience in the development of sophisticated urinary sphincters.

How it differentiates from similar projects in the field

First, the researchers in the project carefully analyze the human anatomy to define the target specifications for a biomimetic design.

Second, they determine the biomechanical parameters using advanced experimental setups and sophisticated imaging and software tools.

Third, they include the time response to realize a nature-analogue implant.

Fourth, the implant design includes multiple actuators to allow tissue recovery in a periodical manner.

Fifth, the unique, low-voltage, dielectric actuators enable sensing and guarantee an energy efficient operation.

Quick summary of the project status

Main achievements so far include:

- Finding two promising alternatives to conventional stiff metal electrodes for the multilayer dielectric electrically activated polymer actuators (see Success Story below)
- Developing a cantilever bending method which verified the mechanical deformation of the first actuators as a function of applied voltage to a precision of 0.03 %
- Validating the ability to power the actuators for 10 days without recharge from available ISO-compliant lithium ion cells
- After receiving the approval of the ethical committee of the Canton of Bern for a full pilot study, ten healthy male volunteers and ten healthy female volunteers are going to be recruited in total. By the end of May 2015, ten male and one female have signed up for the study from which seven male subjects have been assessed. The analysis of the data has proven the conclusion drawn based on the pre-pilot study.

Looking towards the future, the team has designed a system for fabricating multiple layers of nanometer-thin actuators using physical vapor deposition in ultra-high vacuum, and is currently proceeding with its realization.

Success stories

At the start of the project the reviewers pointed out that the stiffness of the actuator (dielectric electrically activated polymer) is given by the nanometer-thin conductive (metal) layers and not by the stretchable elastomer layers, although the elastomer layer is typically an order of magnitude thicker. The team concurs with the reviewers that the stiffness of conventional metal electrodes makes achieving strains of 10 % a formidable challenge. Fortunately, it is now possible to see some promising alternatives to the gold films currently in use. During the first year, the PhD-student T. Töpper introduced liquid metals, which could master the challenge. Another PhD-student, Bekim Osmani experimentally realized parallel wrinkles to allow the actuator to stretch in one predefined direction.

Siloxane-based polymer thin films were produced by molecular beam deposition to realize dielectric electrically activated actuators (DEA), which operate between 1 and 12 V, qualifying the nanostructures for medical applications. Vinyl-terminated polydimethylsiloxane (PDMS) with molecular weights of 6`000 and 28`000 g/mol were evaporated under high-vacuum conditions at temperatures between 100 and 180 °C. The PDMS films were successfully polymerized via UV-radiation at the functional vinyl end groups of the chains, as confirmed by MIR-spectroscopy. The Young`s modulus of the polymer network was derived from AFM nano-indentation measurements. Asymmetric cantilever structures constructed from a 200 nm-thin film exhibit a bending characteristic, which, activated in the voltage range between 1 and 12 V, maintains the actuation efficiency compared to kV-operated DEAs based on micrometer-thick, spin-coated PDMS [1].

Presence in the media:

- Uni News 18.04.2013
- In TV documentation “Gesundheit heute: Mit Nanotechnologie gegen Arterienverkalkung“ of 04.01.2014 our PhD students Elisa Fattorini, Bekim Osmani and Tino Töpper were showing our laboratory.

Main publications

Florian M. Weiss, Tino Töpper, Bekim Osmani, Carla Winterhalter, and Bert Müller, Impact of electrode preparation on the bending of asymmetric planar electro-active polymer microstructures, Proc. of SPIE 9056 (2014) 905607.

Bekim Osmani, Tino Töpper, Christian Deschenaux, Jiri Nohava, Florian M. Weiss, Vanessa Leung, and Bert Müller, Micro- and nanostructured electro-active polymer actuators as smart muscles for incontinence treatment, AIP Conference Proceedings 1646 (2015) 91 .

Tino Töpper, Bekim Osmani, Florian M. Weiss, Carla Winterhalter, Fabian Wohlfender, Vanessa Leung, and Bert Müller, Strain-dependent characterization of electrode and polymer network of electrically activated polymer actuators, Proc. of SPIE 9430 (2015) 94300B.

Tino Töpper, Florian Weiss, Bekim Osmani, Christian Bippes, Vanessa Leung, and Bert Müller, Siloxane-based thin films for biomimetic low-voltage dielectric actuators, Sensors and Actuators A: Physical .

“Cutting-edge technology for the next-generation of artificial muscles”