Smart Artificial Sphincter
Biomechanical & Clinical Aspects

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Introduction

Fecal incontinence (FI) is a common disorder affecting up to 10 % of the population in Western society [1]. In Switzerland, 42 % of men and 49 % of women aged 65 years or older living in a nursing home suffer from FI [2]. To the present day there is no satisfactory implant-based surgical treatment option available for severe cases of FI. The main reasons for a poor outcome with current devices are high infection and revision rates. Therefore, the objective of this project is to develop an alternative device. In order to provide specific design requirements for the implant, **we are developing a patient-specific model of the human anal tissue.**

Biomechanical Model

The goal is the characterization of the anatomy and the biomechanical properties of the human continence organ in healthy and pathologic cases. Data collected in-vivo will be used to build biomechanical models of the tissue; both numerical and in-vitro. The knowledge and models achieved in this project are required to define the implant's geometry, improve the performance of the device to restore continence and improve the short- and the long-term success rate of the procedure.

The morphology will be determined using magnetic resonance (MR) and ultra sound (US) imaging whereas the mechanical properties will be extracted via high-resolution anal manometry (HRAM) and a functional luminal imaging probe (FLIP).

Each modality has strength and weakness. In detail, MR provides the complete pelvic floor imaging in a quantitative manner, and the spatial resolution is in the mm range. US yields distorted images of the sphincter anatomy with sub-mm resolution, but the contrast reduces with increasing depth. HRAM measures the active mechanical sphincter properties, whereas FLIP is used to assess the passive characteristics of the anal canal and sphincters.

The anatomical parameters measured are sphincter lengths, sphincter thickness, and sphincter volumes. Active biomechanically relevant parameters are anal canal length, resting, squeeze, and relaxation pressures, squeeze time, anal pressure in response to coughing, RAIR (percentage of anal relaxation), rectal volume filling to first sensation, urge and maximal tolerable rectal volume. Passive biomechanically relevant parameters are distension of the anal canal in response to different filling volumes in order to compute compliance and Young's modulus of the tissue.

Study Scheme


Experimental Results
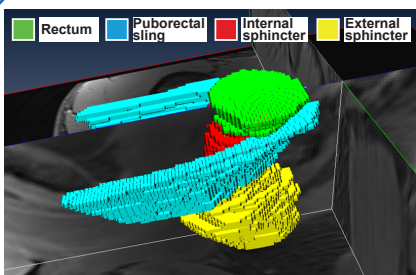
3D reconstruction of the anal sphincter complex. T1-weighted image with a voxel size of 1x1x1mm³ (Device: 3T Skyra, Siemens Erlangen).

Multiple segmented MR images are necessary to construct the Statistical Shape Model (SSM). To develop the envisioned biomechanical FE model mechanical properties have to be included in the SSM. Active muscle properties are assessed via HRM, whereas the passive tissue parameters are extracted from the FLIP measurement.
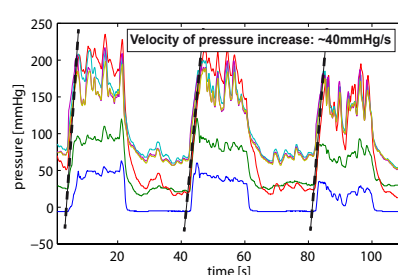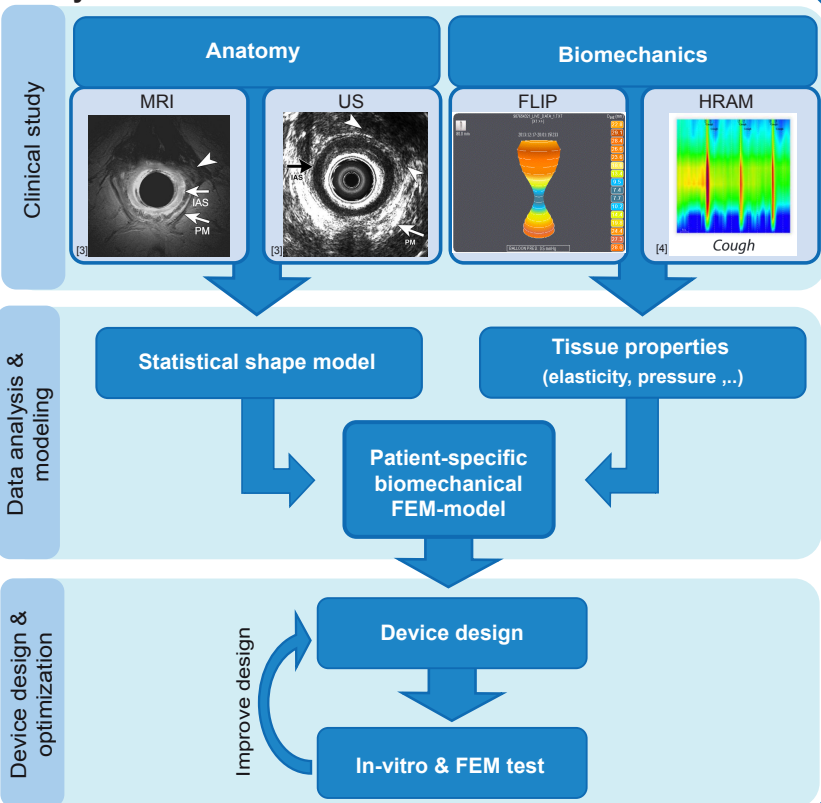
Response of eight pressure sensors in the anal canal to three squeeze of subject (Device: Solar GI, MMS, Enschede Netherlands).
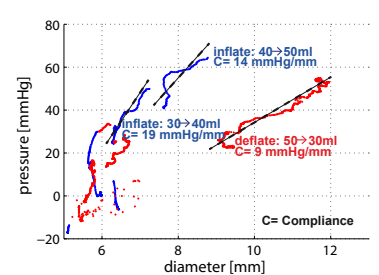
Anal canal diameter with respect to an applied pressure in the canal. (Device: EndoFLIP, EF-100, Crospon Ireland, Ireland).

Conclusion

The requirements of an artificial sphincter for fecal incontinence are determined using imaging techniques MRI and US as well as biomechanics tools HRAM and FLIP. The methodology to acquire morphometric and biomechanical information has been validated and is ready to be used in the first clinical study on twenty healthy subjects planned to start in August 2014.

[1] "Urinary and Faecal Incontinence", H-D. Becker et al., Springer-Verlag, Berlin Heidelberg (2005)

[2] http://www.bfs.admin.ch/bfs/portal/de/index/themen/14/02/01/key/07/04.html

[3] "External Anal Sphincter Defects in Patients with Fecal Incontinence: Comparison of Endoanal MR Imaging and Endoanal US", A.Dobben et al., Radiology (2007)

[4] Solar GI HRAM Brochure, Medical measurement systems (MMS)

[5] adapted from www.rcsed.ac.uk/fellows/kcattle/anatomy1.html