Smart 4D-printed implants and instruments

Michael de Wild, University of Applied Sciences Northwestern Switzerland, FHNW, School of Life Sciences, Institute for Medical Engineering and Medical Informatics IM^2, Hofackerstrasse 30, CH-4132 Muttenz, Switzerland, michael.dewild@fhnw.ch
Sebastian Dany, University of Applied Sciences Northwestern Switzerland, FHNW, School of Life Sciences, Institute for Medical Engineering and Medical Informatics IM^2, Hofackerstrasse 30, CH-4132 Muttenz, Switzerland. Hochschule Hamm-Lippstadt, D 59063 Hamm, Germany
Christoph John, Department of Chemistry, University of Basel, Mattenstrasse 24a, CH-4058 Basel, Switzerland,
Felix Schuler, University of Applied Sciences Northwestern Switzerland, FHNW, School of Life Sciences, Institute for Medical Engineering and Medical Informatics IM^2, Hofackerstrasse 30, CH-4132 Muttenz, Switzerland

Selective laser melting (SLM) was used to manufacture smart programmed structures made of biocompatible NiTi shape-memory alloy. A series of helixes was produced with systematically varied SLM process parameters Laser Exposure Time in order to specifically change the thermo-mechanical material properties of the 3D structures. This innovation opens up the possibility to adjust the NiTi phase transformation temperature during the manufacturing process. This controllable property determines which of the two crystallographic phases martensite or austenite is present at a certain operating temperature and allows the mechanical properties to be adjusted: martensitic devices are soft and pseudo-plastic due to the shape-memory effect, whereas austenitic structures are pseudo-elastic. In a further step, the SLM process parameters were locally varied within 4D-printed twin-helixes. As a result, the phases, respectively the mechanical properties of a single component were adjusted at different locations. The amount of elastic or plastic deformation and the spring constant of the helix can be locally controlled. This allows, for example, the spatio-temporal programming of 3D-printed surgical instruments or implants that are stimuli-responsive.

Modeling of a Piezo-Electric Hearing Aid Device coupled to a Middle Ear Model

Dmitrii Burovikhin, Reutlingen Research Institute, Reutlingen University, Alteburgstr. 150, 72762 Reutlingen, Germany, dmitrii.burovikhin@reutlingen-university.de
Michael Lauxmann, Reutlingen Research Institute, Reutlingen University, Alteburgstr. 150, 72762 Reutlingen, Germany, michael.lauxmann@reutlingen-university.de

Introduction

The piezo-electric actuator (PEA) is one of the main components of an innovative type of hearing aid devices which are small enough to be worn directly on the tympanic membrane (TM). Compared to conventional hearing aid devices, which usually reach frequencies of 6-8 kHz, the PAE can transmit higher frequencies (up to 16 kHz) which is important for spatial hearing and the understanding of speech. By optimizing the mechanical design of the PEA, its performance with regard to feedback issues, sound transfer loss, energy consumption and sound fidelity can be improved. Therefore, a finite element (FE) model of the PEA coupled to a middle-ear model is developed and validated with the help of the Laser-Doppler-Vibrometer (LDV) measurements.

Methods

The middle ear and the PEA are modelled in ANSYS. The PEA is modelled using direct coupled equations for the piezoelectric effect. To validate the FE model, LDV measurements on the PEA and on temporal bones are performed. In case of the combined model the actual adhesive contact between the PEA and the TM is modelled simply as a bonded contact.

Results

The simulated transfer function (TF) of the PEA alone fits well to the measurements. Also, the simulated TF from an acoustic input pressure to the stapes motion in the middle-ear model fits well to the temporal bone measurements and within the range established by the ASTM standard. The combined model shows some deviations in the higher frequency range due to the simplified modelling of the adhesive contact between the PEA and the TM.

Conclusion

An FE model of the PEA coupled to the middle ear was developed. The simulated data for the actuator and the middle ear separately looks plausible compared to the LDV measurements, but further improvements in the contact formulation of the adhesive PEA-TM contact should be made for a more precise fit.

Polymeric stents for the Eustachian tube: development and human cadaver study

Kerstin Schümann, Institute for Biomedical Engineering, Rostock University Medical Center, Friedrich-Barnewitz-Str. 4, 18119 Rostock, Germany, e-mail: kerstin.schuemann@uni-rostock.de
Tamara Wilfling, Gerrit Paasche, Robert Schuon, Thomas Lenarz, Department of Otorhinolaryngology, Hannover Medical School, Carl-Neuberg Str. 1, 30625 Hannover, Germany
Carsten Tautorat, Niels Grabow, Institute for Biomedical Engineering, Rostock University Medical Center, Friedrich-Barnewitz-Str. 4, 18119 Rostock, Germany
Klaus-Peter Schmitz, Institute for ImplantTechnology and Biomaterials, Institute for Biomedical Engineering, Rostock University Medical Center, Friedrich-Barnewitz-Str. 4, 18119 Rostock, Germany

Introduction

Impairment of Eustachian tube function with non-sufficient ventilation of the middle ear is a main cause for chronic otitis media. To provide an effective and safe therapy, the innovative concept of Eustachian tube stenting was established. Biodegradable polymeric stents are developed to restore impaired tube function and dissolve after fulfilling their supportive purpose.

Materials and Methods

To evaluate the applicability of biodegradable polymer stents in the Eustachian tube, prototypes made of poly(L-lactide) in conjunction with corresponding implantation instruments were tested in human cadaver studies. In the current examination two polymeric stents were implanted using cardiovascular balloon catheters to demonstrate structural access and feasibility of stent implantation. Radiopaque markers and a diaphanoscopic approach were tested as additional features to prove correct positioning of catheter and stent in the tube.

Results

The stents could be implanted in the Eustachian tube of human cadavers without difficulty. Correct positioning of the stents in the tube was proved by diaphanoscopy during intervention and postoperative tomographic and histological analyses. The visibility of the stents by means of the integrated radiopaque markers could be proved in postprocedural DVT images. Histological analyses showed, that the polymeric stents effectuate an opening of the Eustachian tube and adapt to the tube geometry without generating a complete circular cross-section.

Conclusion

Important insights regarding the access and feasibility of stent implantation in the Eustachian tube as well as tools for radiopacity and diaphanoscopy have been gained from the current study. Diaphanoscopy facilitates the implantation and provides the surgeon with security regarding correct insertion of the balloon catheter. Radiopaque markers enable the visualization of the stents offering the only control of the actual positioning of the stents. Once designs are optimized on basis of cadaver studies, preclinical safety and efficacy studies using animal models will be initiated.

Transcatheter mitral valve repair devices - *in vitro* studies on the influence of device-width on mitral regurgitation

Robert Ott: Institute for ImplantTechnology and Biomaterials e.V., Friedrich-Barnewitz-Str. 4, 18119 Rostock-Warnemünde, Germany, E-mail: robert.ott@uni-rostock.de
Swen Großmann: Institute for ImplantTechnology and Biomaterials e.V., Friedrich-Barnewitz-Str. 4, 18119 Rostock-Warnemünde, Germany, E-mail: swen.grossmann@uni-rostock.de
Alper Öner: Heart Center/Department of Cardiology, Rostock University Medical Center, 18057 Rostock, Germany, E-Mail: alper.oener@med.uni-rostock.de
Hüseyin Ince: Heart Center/Department of Cardiology, Rostock University Medical Center, 18057 Rostock, Germany, E-Mail: hueseyin.ince@med.uni-rostock.de
Michael Stiehm: Institute for ImplantTechnology and Biomaterials e.V., Friedrich-Barnewitz-Str. 4, 18119 Rostock-Warnemünde, Germany, E-mail: michael.stiehm@uni-rostock.de
Niels Grabow: Institute for Biomedical Engineering, Friedrich-Barnewitz-Str. 4, 18119 Rostock-Warnemünde, Germany, E-Mail: niels.grabow@uni-rostock.de
Klaus-Peter Schmitz: Institute for ImplantTechnology and Biomaterials e.V., Friedrich-Barnewitz-Str. 4, 18119 Rostock-Warnemünde, Germany, E-Mail: klaus-peter.schmitz@uni-rostock.de
Stefan Siewert: Institute for ImplantTechnology and Biomaterials e.V., Friedrich-Barnewitz-Str. 4, 18119 Rostock-Warnemünde, Germany, E-Mail: stefan.siewert@uni-rostock.de

Introduction

Mitral regurgitation (MR) is the most prevalent valvulopathy in the USA and the second most prevalent valvulopathy in Europe. Despite excellent clinical results of surgical mitral valve repair (SMVR), transcatheter-based mitral valve repair (MVR) procedures emerged as a feasible treatment option for surgically inoperable or high-risk patients suffering from clinically relevant MR. The current study investigates the impact of device-induced coaptation-width on the hydrodynamic performance of insufficient mitral valves (MV) during left ventricular (LV) systole.

Methods

A non-calcified, pathological MV model (MVM) featuring a D-shaped MV annulus with an area of 7.6 cm^2 and a flail gap in the A2-P2 region was used. Pressure gradient-volumetric flow rate (Δp-Q) relations were investigated for steady-state backward flow with transvalvular pressure gradients ranging from ($0.75 \leq \Delta p \leq 177.36$) mmHg. Glycerol-water mixture (36 % (v/v) glycerol in water) at 37 °C with a density of ($1\,098.2 \pm 1.3$) $kg \cdot m^{-3}$ and a dynamic viscosity of 3.5 mPa·s was used as circulatory fluid. To determine the impact of the width of MVR devices during LV-systole, Δp-Q relations were investigated for three MVM-configurations: MVM without MVR device, MVM with one MVR device, and MVM with two MVR devices implanted in the A2-P2 region. The MVR devices were manufactured from steel sheets featuring arm lengths of 9.0 mm and a width of 5.0 mm.

Results

Investigations show that the implantation of MVR devices in the A2-P2 region prevents the manifestation of an A2-P2 flail gap and thereby effectively reduces the retrograde blood flow during the LV-systole by 13 % with one MVR device and 27 % with two MVR devices implanted.

Conclusion

The application of two MVR devices with a combined device-induced width of 10 mm results in a better MR reduction than the implantation of one MVR device with a width of 5 mm.

Development of a limbal fixation mechanism for a minimally invasive implantable glaucoma microstent

Stefan Siewert, Institute for ImplantTechnology and Biomaterials e.V., Rostock-Warnemünde, Germany, e-Mail: stefan.siewert@uni-rostock.de
Swen Großmann, Institute for ImplantTechnology and Biomaterials e.V., Rostock-Warnemünde, Germany, e-Mail: swen.grossmann@uni-rostock.de
Christoph Brandt-Wunderlich, Institute for ImplantTechnology and Biomaterials e.V., Rostock-Warnemünde, Germany, e-Mail: christoph.brandt-wunderlich@uni-rostock.de
Ariane Dierke, Institute for ImplantTechnology and Biomaterials e.V., Rostock-Warnemünde, Germany, e-Mail: ariane.dierke@uni-rostock.de
Olga Sahmel, Institute for Biomedical Engineering, Rostock University Medical Center, Rostock-Warnemünde, Germany, e-Mail: olga.sahmel@uni-rostock.de
Michael Stiehm, Institute for ImplantTechnology and Biomaterials e.V., Rostock-Warnemünde, Germany, e-Mail: michael.stiehm@uni-rostock.de
Sabine Kischkel, Institute for Biomedical Engineering, Rostock University Medical Center, Rostock-Warnemünde, Germany, e-Mail: sabine.kischkel@uni-rostock.de
Wolfram Schmidt, Institute for Biomedical Engineering, Rostock University Medical Center, Rostock-Warnemünde, Germany, e-Mail: wolfram.schmidt@uni-rostock.de
Thomas Stahnke, Department of Ophthalmology, Rostock University Medical Center, Rostock, Germany, e-Mail: thomas.stahnke@med.uni-rostock.de
Niels Grabow, Institute for Biomedical Engineering, Rostock University Medical Center, Rostock-Warnemünde, Germany, e-Mail: niels.grabow@uni-rostock.de
Rudolf Guthoff, Department of Ophthalmology, Rostock University Medical Center, Rostock, Germany, e-Mail: rudolf.guthoff@med.uni-rostock.de
Klaus-Peter Schmitz, Institute for ImplantTechnology and Biomaterials e.V. and Institute for Biomedical Engineering, Rostock University Medical Center, Rostock-Warnemünde, Germany, e-Mail: schmitz@iib-ev.de

Introduction

Glaucoma represents a chronic eye disease that becomes increasingly prevalent worldwide. Therapies are commonly based on the reduction of intraocular pressure. Implant devices for micro-invasive glaucoma surgery (MIGS) represent a promising therapy option in refractory cases but suffer from limitations in long term efficacy or from dislocation associated complications. Our approach of an innovative drug-eluting glaucoma microstent for MIGS was presented previously. Within the current work we developed concepts and prototypes of a mechanism for the fixation of our glaucoma microstent in the region of the corneal limbus.

Methods

A tripod and a haptics design of the fixation mechanism were developed and manufactured. Semifinished products were tested with regard to dimensional stability and mechanical properties according to the standard ANSI Z80.27-2014. Considering the mechanical properties of ocular target tissues, a gelatin based in vitro model for the measurement of microstent retention force was developed.

Results

Microstent base bodies with reproducible inner and outer diameter (0.20 ± 0.00) mm and (0.36 ± 0.02) mm (n = 17) were manufactured. Fixation fibers with diameters ranging from 50 µm to 150 µm were provided. Immersion of microstents in 0.9% NaCl for 14 days at (35 ± 2) °C according to ANSI Z80.27 shows negligible influence on dimensional stability and mechanical properties. Using the gelatin based in vitro model, a retention force of (22.5 ± 10.7) mN and (14.8 ± 4.3) mN was measured for microstent prototypes with and without a fixation mechanism (n = 3), respectively.

Conclusion

Retention force testing of microstent prototypes in vitro resulted in a proof of concept for the fixation mechanism. Future studies will focus on the use of smaller fixation fibers, for example commercially available suture material, and on an overall miniaturization of the fixation mechanism enabling the use of our applicator device with a 22Gx1½” cannula.

A pilot study: development of bone-preserving-biomimetic artificial femoral head cover

Nad Siroros: Department of Orthopaedic Surgery, RWTH Aachen University Clinic, Pauwelsstraße 30, 52074, Aachen, Germany. E-mail: nsiroros@ukaachen.de
Yu Liu: Department of Orthopaedic Surgery, RWTH Aachen University Clinic, Pauwelsstraße 30, 52074, Aachen, Germany. E-mail: yliu@ukaachen.de
Sophie Lecouturier: Department of Orthopaedic Surgery, RWTH Aachen University Clinic, Pauwelsstraße 30, 52074, Aachen, Germany. E-mail: slecouturier@ukaachen.de
Markus Tingart: Department of Orthopaedic Surgery, RWTH Aachen University Clinic, Pauwelsstraße 30, 52074, Aachen, Germany. E-mail: mtingart@ukaachen.de
Jörg Eschweiler: Department of Orthopaedic Surgery, RWTH Aachen University Clinic, Pauwelsstraße 30, 52074, Aachen, Germany. E-mail: joeschweiler@ukaachen.de

Introduction

Patients with hip arthrosis are increasing each year where total hip replacement is an effective solution when other non-invasive or surgical methods are no longer an effective solution. A pilot study of a new bone-preserving-biomimetic artificial femoral head cover was initiated. The purpose of the new implant is to be an alternative to the current hip arthroplasties.

Methods

A special polyurethane femoral head cover was mechanically tested. Experiments were performed to investigate the implants mechanical behaviour and response to tensile load and study on the locking mechanism design concept of the prosthesis. The femoral head cover had a 45 mm outer diameter. Two suture techniques were selected to represent possible locking mechanisms. The experiment consisted of five cyclic loadings followed by a pull-to-failure test.

Results

The results show that each specimen has a consistency response and different suture technique results in a different outcome. Specimens with simple interrupted suture has the largest average peak force at the end of each cyclic load followed by uncut specimens and specimens with running subcutaneous suture, respectively. From visual inspection was observed that during subjected to tensile loading the running subcutaneous suture kept the cut closer than the simple interrupted suture.

Conclusion

This experiment intended to study the response of specimens as a whole part, not the material itself. Factors are influencing the outcome such as the femoral head cover positioning and suture rupture pattern. From this pilot study, some points need to be further considered such as outer surface friction, the bone-prosthesis interaction, and locking mechanism development. The information obtained in this experiment would influence further development achieving towards the goal of this alternative hip arthrosis treatment.