ADJUSTABLE BONE FIXATION OF AN ARTIFICIAL HIP STEM BY USING AN INTEGRATED SENSOR ACTUATOR SYSTEM

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AGENDA

- **Medical Background and Motivation**
- Actuator
- Sensor System and Energy Transfer
- Hip Stem Design
- Biomechanical Setup
- Results and Outlook

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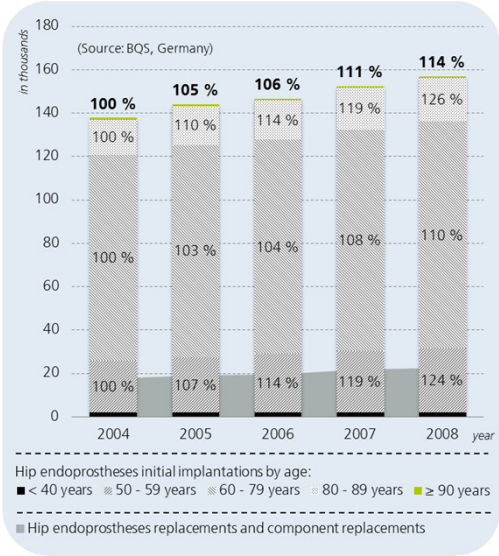
Medical Background and Motivation (1)

- **214,000** hip implantation per year (only in Germany)
- main cause: arthrosis (wear of cartilage layer in joint)
- numbers are rising significantly (initial implantations as well as revision surgery) cost explosion
- high demand for innovative endoprostheses (younger patients, lifecycle)
- Main Problems:
  - Exhaustion of the artificial hip joint in **4,700** patients per year
  - Implant loosening in approximately **15,000** patients per year



Source: PD Dr. Prietzel, Uniklinik Leipzig

Medical Background and Motivation (2)

- The main cause of failure of endoprostheses in 50 to 70% of cases is aseptic implant loosening
- Abrasion particles between the sliding joint partners → various cell and inflammatory reactions → osteolysis or implant loosening
- Other causes: Changes in bone tissue caused by different mechanical stiffnesses of bone (E-modulus bone ~ 1 to 17 GPa) and implant (E-modulus ~ 110 GPa)
- Degradation of bones at unloaded, non-frictional interfaces to the implant and thus a changed flow of force
- Possible end result: aseptic loosening, replacement of the implant necessary

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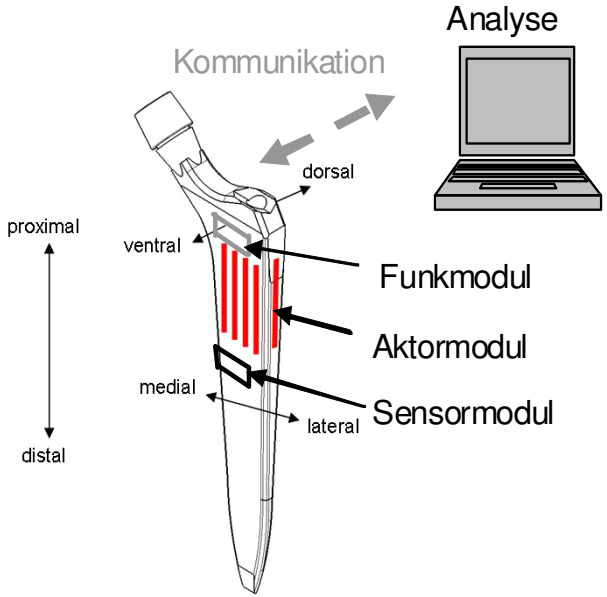
Medical Background and Motivation (3)

Aim of the project:

- Monitoring of ingrowth behavior and / or implant-bone interaction
- Influencing the implant-bone interface by integrated shape memory actuators
- Technology development and proof of concept



Laboratory FORBIOMIT, University of Rostock

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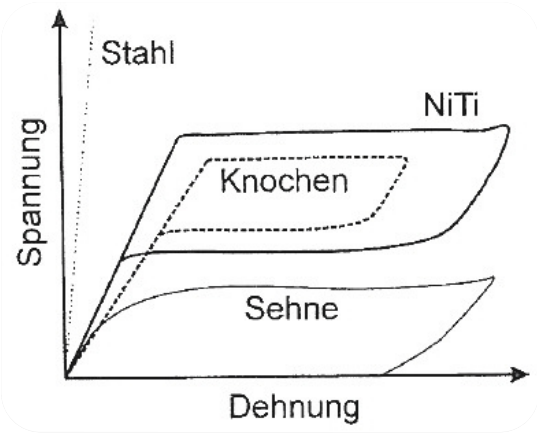
Actuator System (1)

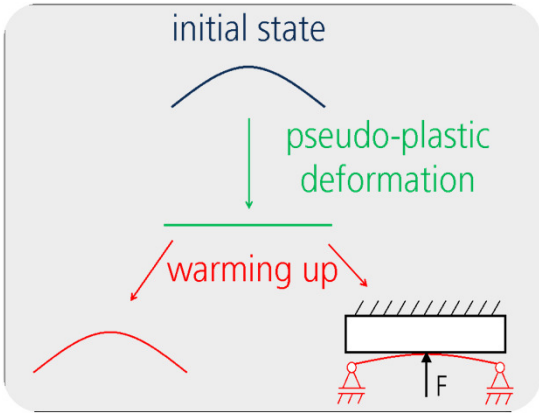
Background:

- Actuators based on SMA materials
- Thermal activation leads to the modification of geometry and stress ratios based on crystal structure changes

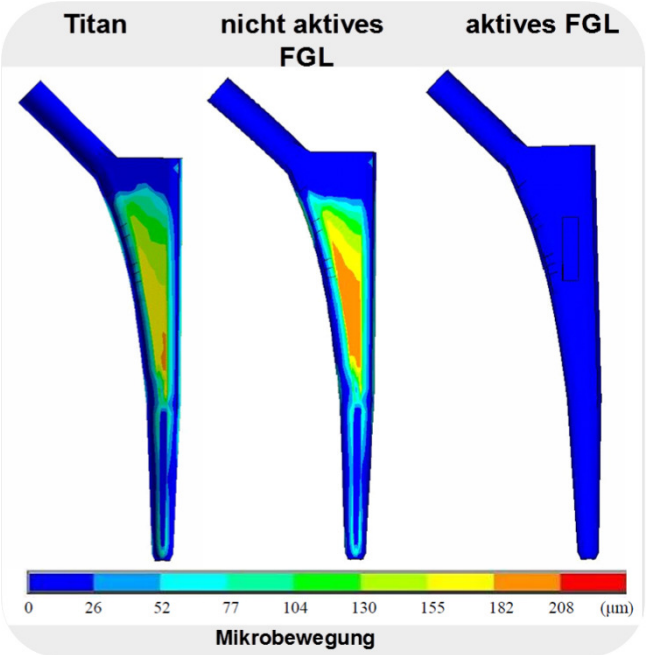


Objectives:

- External activation
- Adjustable tension or pressure level



Actuator System (2) – State of the Art (Example)



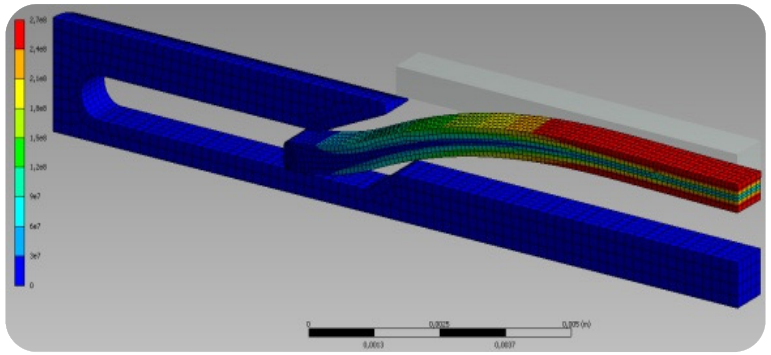
Higa, M., et. al: Possibility of Total Hip Arthroplasty Using Shape Memory Alloy, Journal of Biomechanical Science and Engineering, Vol.5 No.1, 2010

- Representation of the relative micro-motions at the bone-implant interface due to the joint contact force in a hip shaft made of titanium and with SM A anchoring elements
- Problem: punctual introduction of force, construction

Actuator System (3)

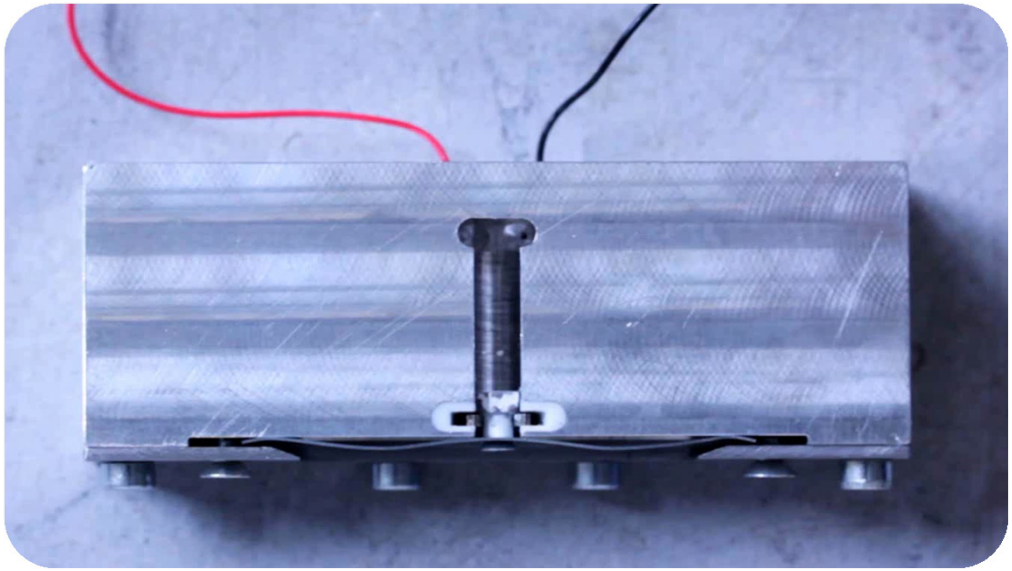
Former Projects at Fraunhofer IWU:

- Hip stem with SMA and activation by body temperature after implantation
- No time-delayed activation possible
  Time-controlled thermal activation of the entire actuator



B. Müller, T. Töppel, C. Rotsch, A. Böhm, J. Bräunig, R. Neugebauer: New features and functions in implants though an innovative design approach and additive manufacturing technology, in: Ceretti, Elisabetta (Ed.) Proccedings of The 1st International Conference on Design and PROcesses for MEdical Devices, PROMED 2012, Brescia, pp 237-241, ISBN 978-88-6608-058-9.

Actuator System (4)



Initial state:

- Outer sheet is pre-stressed
- Locking by SMA actuator

- Thermal activation by electrical current (resistance heating)
- Reduction of actuator mass an thermal energy consumption
- The sheet metal is released and generates a variable pressure force

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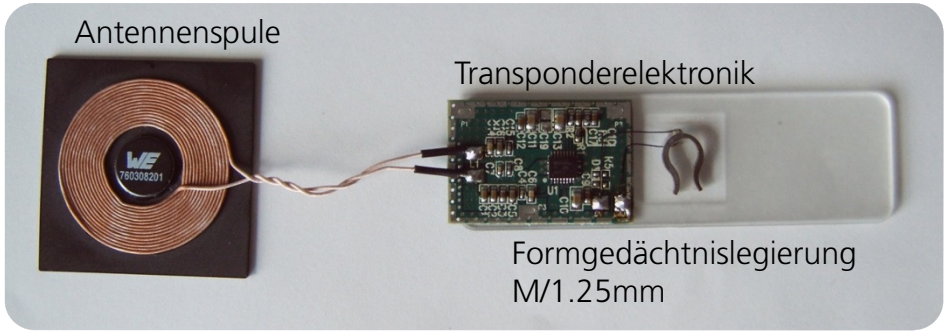
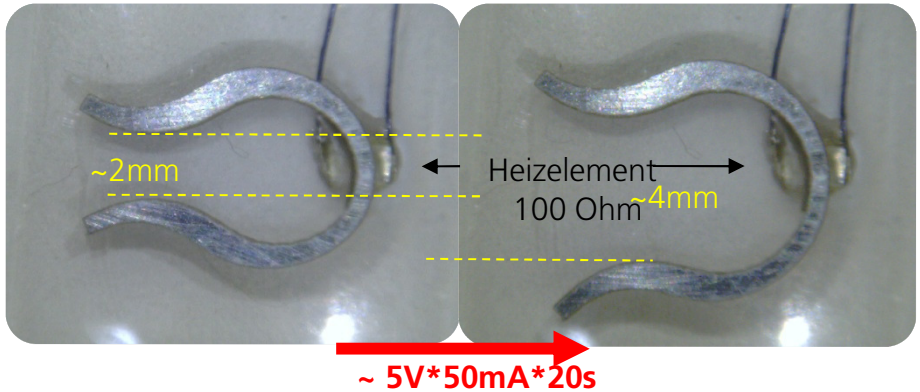
Sensor System and Energy Transfer (1)

- Different concepts were developed
- Example: Qi Standard /RFID 125 kHz
- Actuator can be released wireless
- Different external spool geometries





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Sensor System and Energy Transfer (2)

- Analog acceleration sensor
- Because of the small signals evaluating via lock-in amplifier necessary
- Approach: Insertion into the artificial joint ball is optimal

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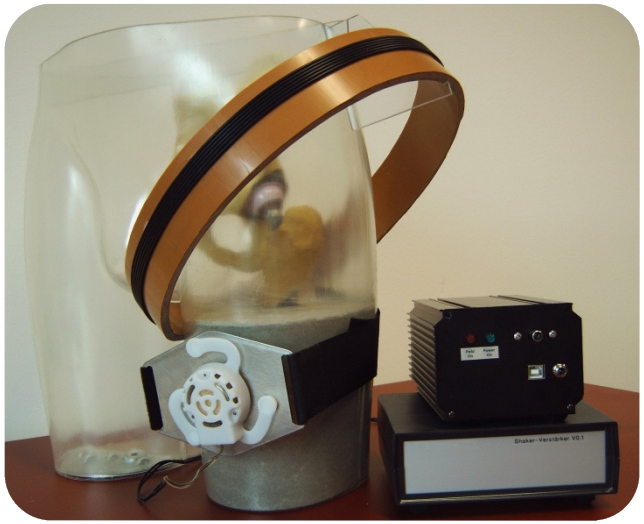
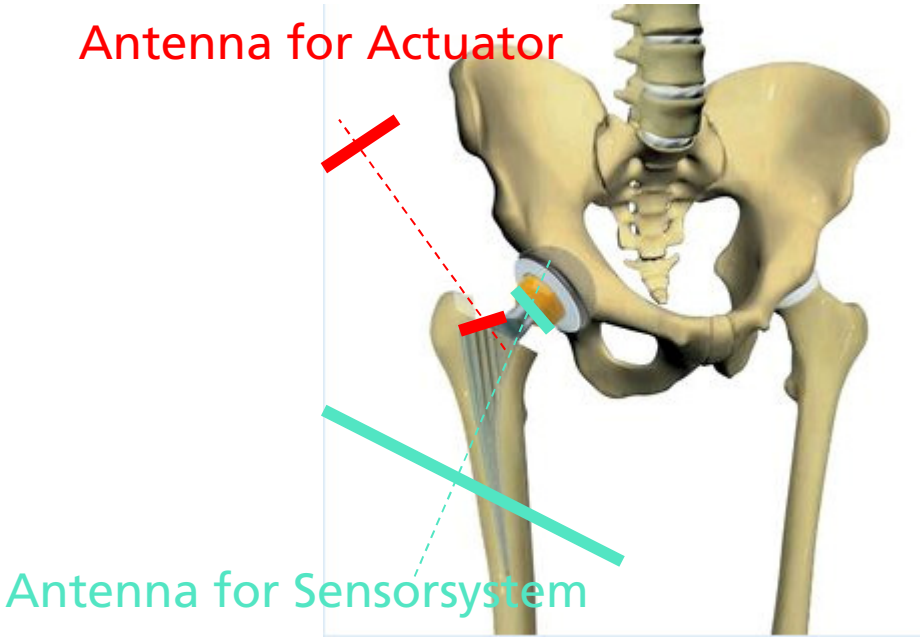


Sensor System and Energy Transfer (3)

- Different antennas for sensor system and actuator control



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Hip Stem Design (1)

Prevision® Modularer Hüftrevisionsschaft

By Aesculap AG

Influence of additional components regarding mechanical stability?

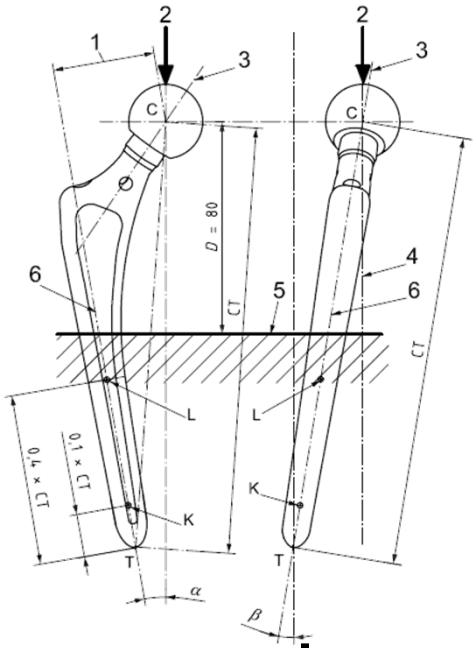
Hip Stem Design (2) – Finite Element Analysis

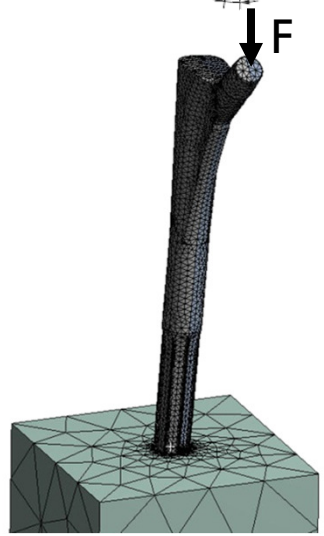
Table 1 — Parameters for test set-up

Parameter	Tolerance	Stem length		
CT (mm)	± 2	⩽ 120	120 < CT ⩽ 250	> 250
D (mm)	± 2	0,66 × CT	80	CT–100= **187**
α (°)	± 1,0	10	10	0
β (°)	± 1,0	9	9	4

Table 2 — Parameters for testing

Kind of stem	Short, monobloc, modular neck, modular femoral		
CT (mm)	⩽ 120	120 < CT ⩽ 250	> 250
F_D (N)	1 200[a]	2 300[b]	1 200[c]
Number of cycles	~~5×10^6~~		
Number of unbroken specimens	6		



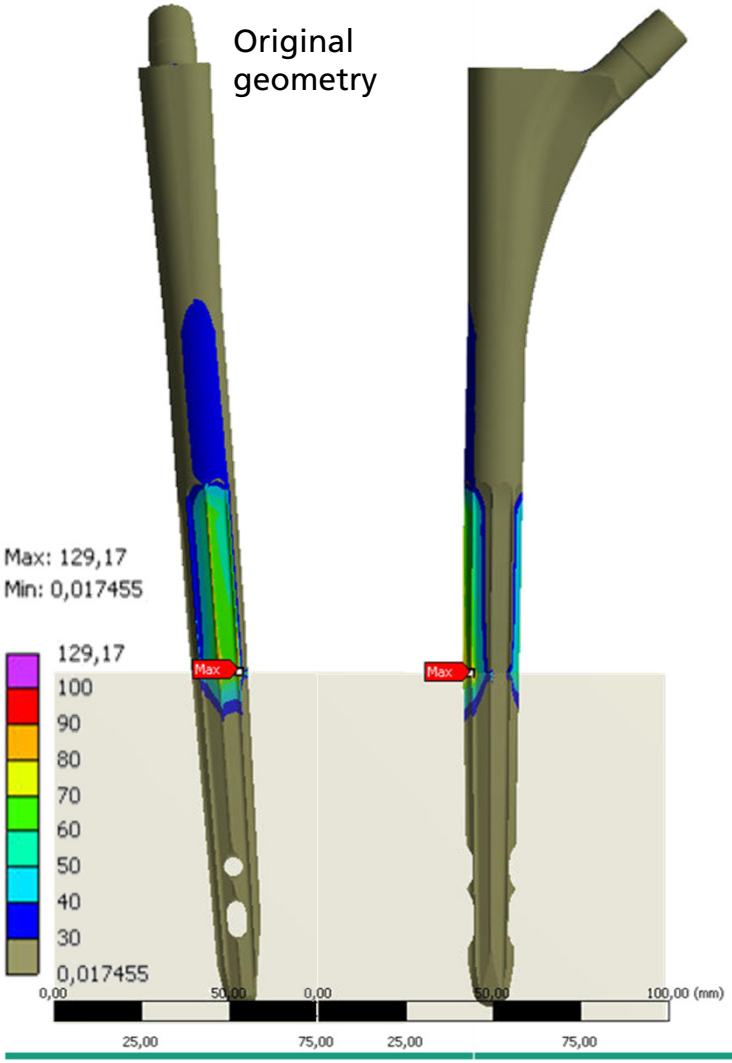


E-Modul des Einbett-materials = 4000 MPa

- Based on ISO 7206 Standard

Hip Stem Design (3) – Finite Element Analysis

- Comparison of the utilization rates in% (fatigue strength)



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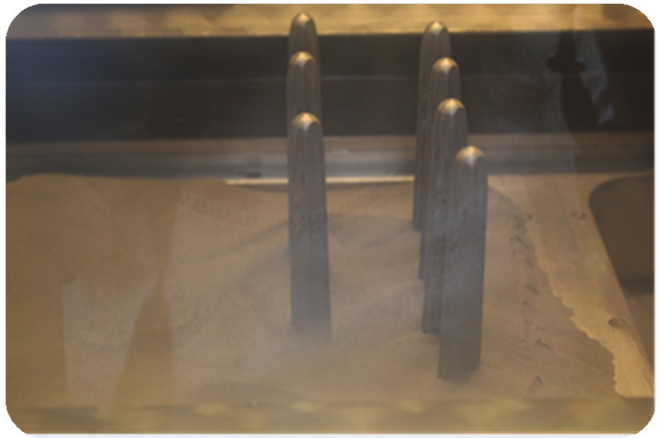
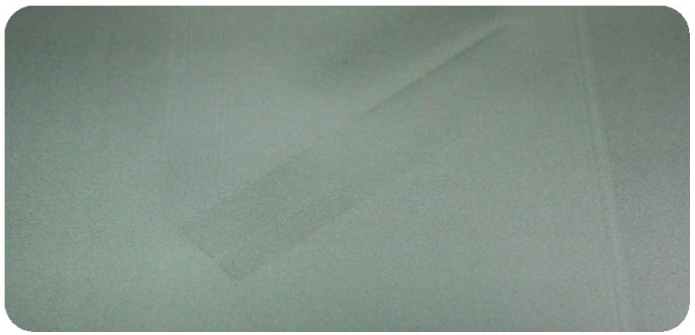
Hip Stem Design (4) – Technical Realisation

- Manufacturing by SLM (Concept Laser Machine), Material TiAl6V4





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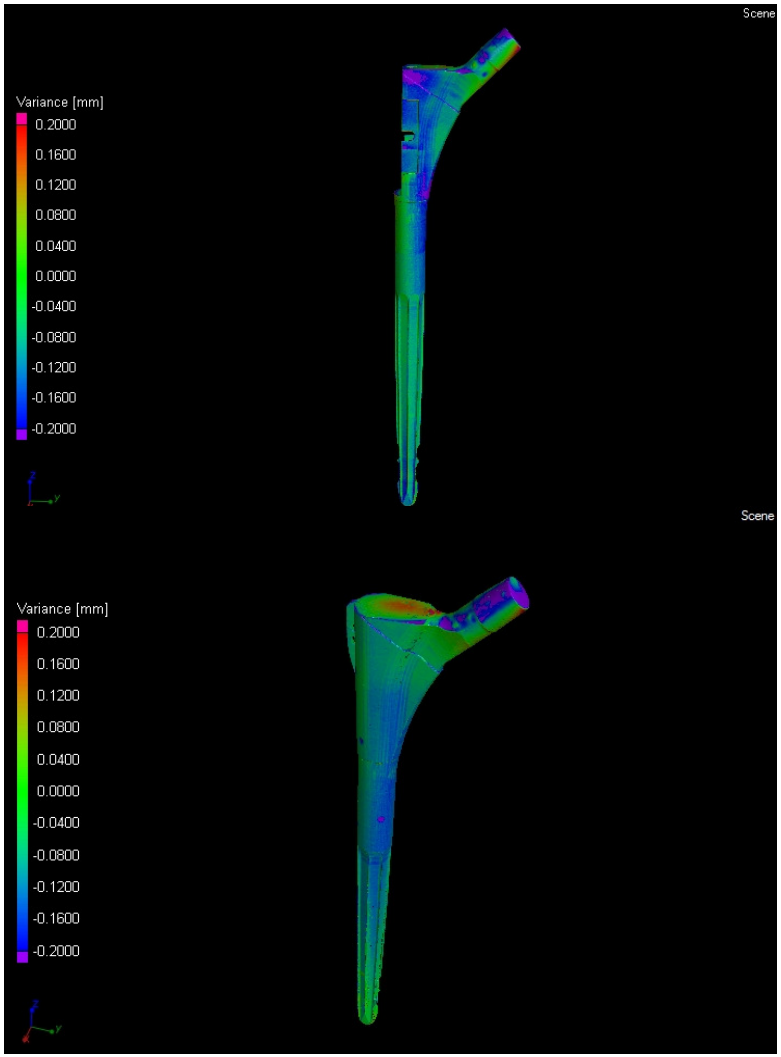
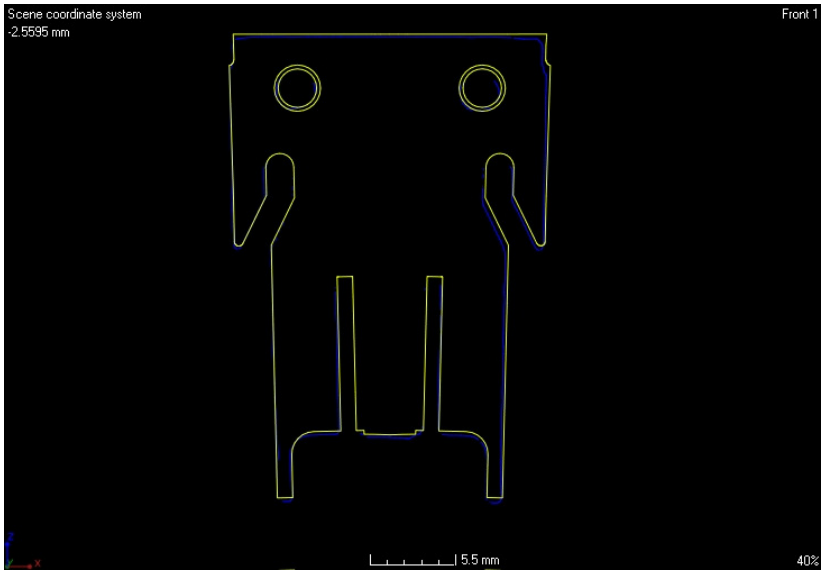
Hip Stem Design (5) – Technical Realistion



- Comparision between CAD and manufactured geometry



Hip Stem Design (5) – Final Demonstrator

- Hip Stem manufactured by SLM
- Actuator System based on SMA
- Wireless thermal activation
- Sensor System in the ceramic ball
- Coated SMA components (Ni- Ions)

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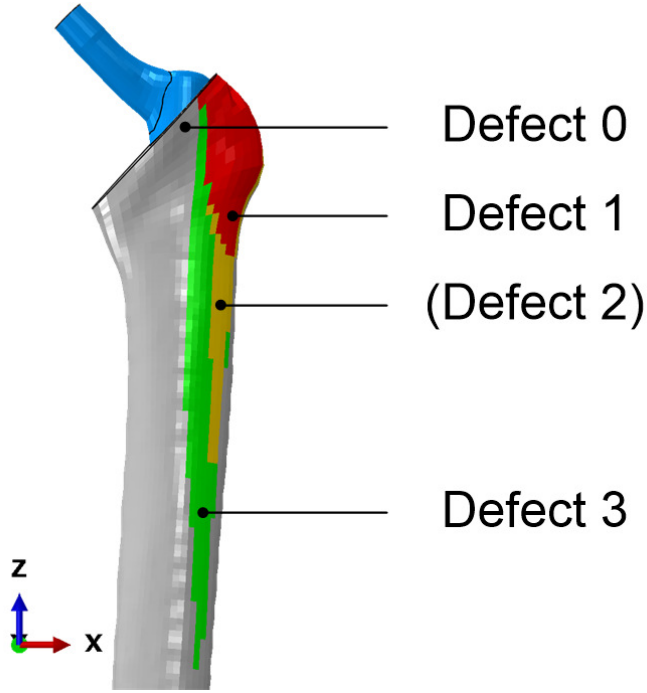
Biomechanical Setup (1)

- Bone defects regarding Paprosky et al.
- Comparison of implant stability with and without actuators
- Tests with artifical bone
- Implantation of the hip stem by surgeon



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[1] Paprosky et al. 2004

Biomechanical Setup (2)

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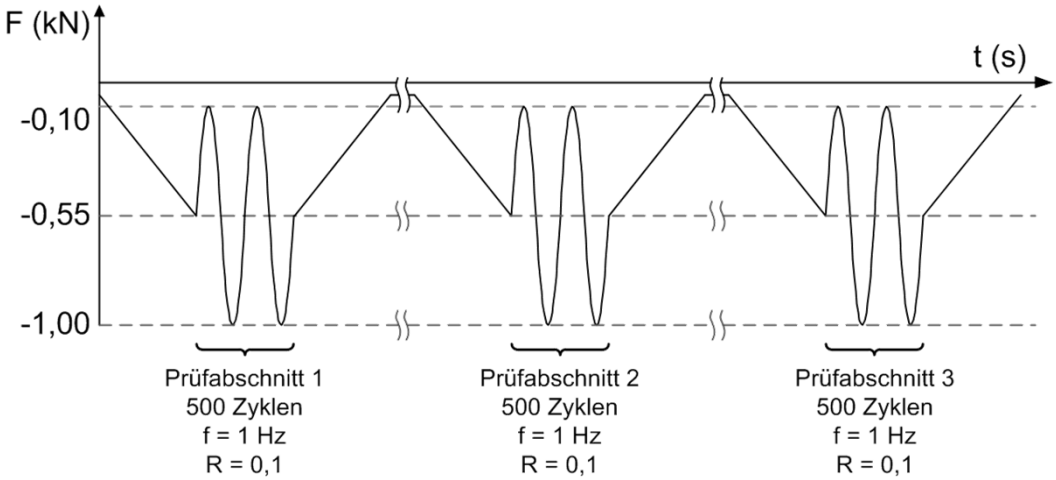
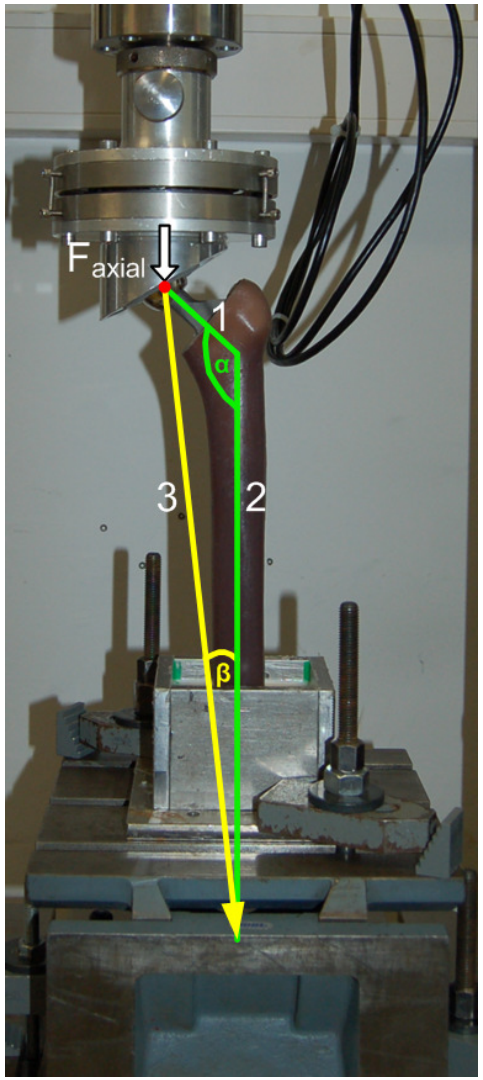
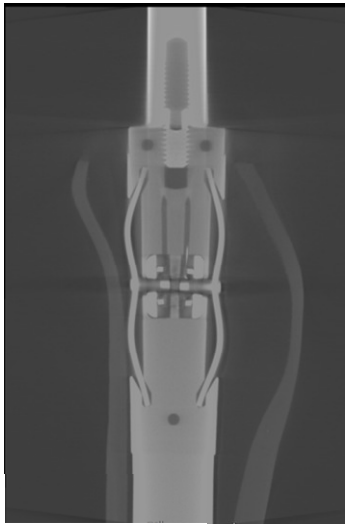
- Axial load introduction in the center of rotation of the hip head
- Samples preloaded with 50 N preload
- Threshold load between 100 N and 1000 N
- 3 test sections with 500 load cycles each
- Measurement of micromotion



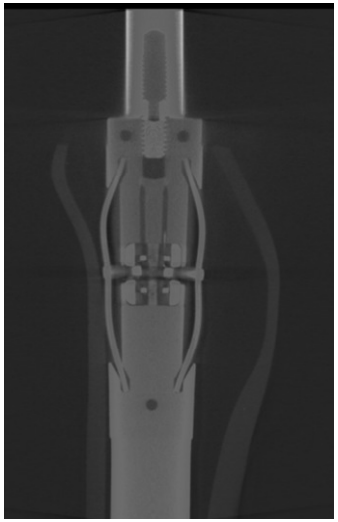


Biomechanical Setup (3)

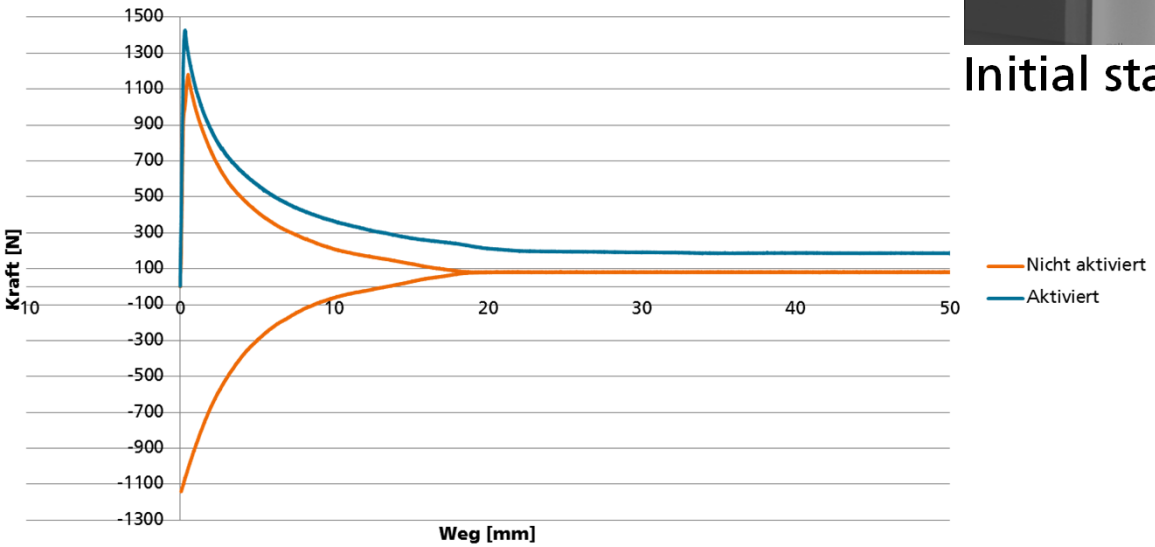
- Visual characterisation of actuator functionality by µCT
- Pull- out tests



Initial state



activated



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Results and Outlook

- Hip Stem implant with integrated sensor and actuator system was developed as demonstrator
- Proof of concept was done by first mechanical and biomechanical tests
- Results of pull out test are promising
- A possible process chain was developed

In the future

- other defect model
- Implantation in human bone model
- Further investigation of implant behavior
- Preclinical trials (Clinical trials)

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Thank you for your Attention!

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