FUNCTIONAL INTEGRATION IN IMPLANTS THROUGH ADDITIVE MANUFACTURING TECHNOLOGY AND SMART MATERIALS

B. Müller, T. Töppel, C. Rotsch, A. Böhm, J. Bräunig, R. Neugebauer
Fraunhofer Institute for Machine Tools and Forming Technology IWU,
Chemnitz/Dresden (Germany)

EUROPEAN FORUM ON RAPID PROTOTYPING
Rapid Prototyping & Manufacturing

Content

- Fraunhofer IWU – Overview
- Medical Engineering at Fraunhofer IWU
- Motivation
- Functional Integration through Laser Beam Melting
- Active Material Combination for a Non-Loosening Implant
- Conclusions

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The Fraunhofer IWU
Locations in Germany

- founded on July 1st, 1991
- about 510 employees (together with IWP institute at University Chemnitz about 700)
- 29 million Euro budget
- Project Group in Augsburg since January 2009
- Project Group in Zittau since October 2011

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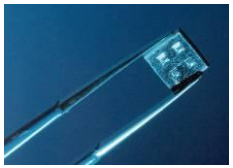
Fraunhofer IWU

The Fraunhofer IWU in Profile
Production Engineering









Fields of expertise

- Machine Tools
- Mechatronics
- Lightweight Construction
- Cutting Technologies
- Forming Technologies
- Joining and Assembling
- Production Management

in close cooperation with

- Chemnitz University of Technology
- Fraunhofer-Gesellschaft
- Machine tool industry
- German and international automotive industry
- Automotive suppliers (forming, machining, tool and die making)

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Fraunhofer IWU

Institutional Network Production Engineering
Chemnitz – Dresden

Fraunhofer IWU
Chemnitz location

Fraunhofer IWU
Dresden location

IWP
TU Chemnitz

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Fraunhofer IWU

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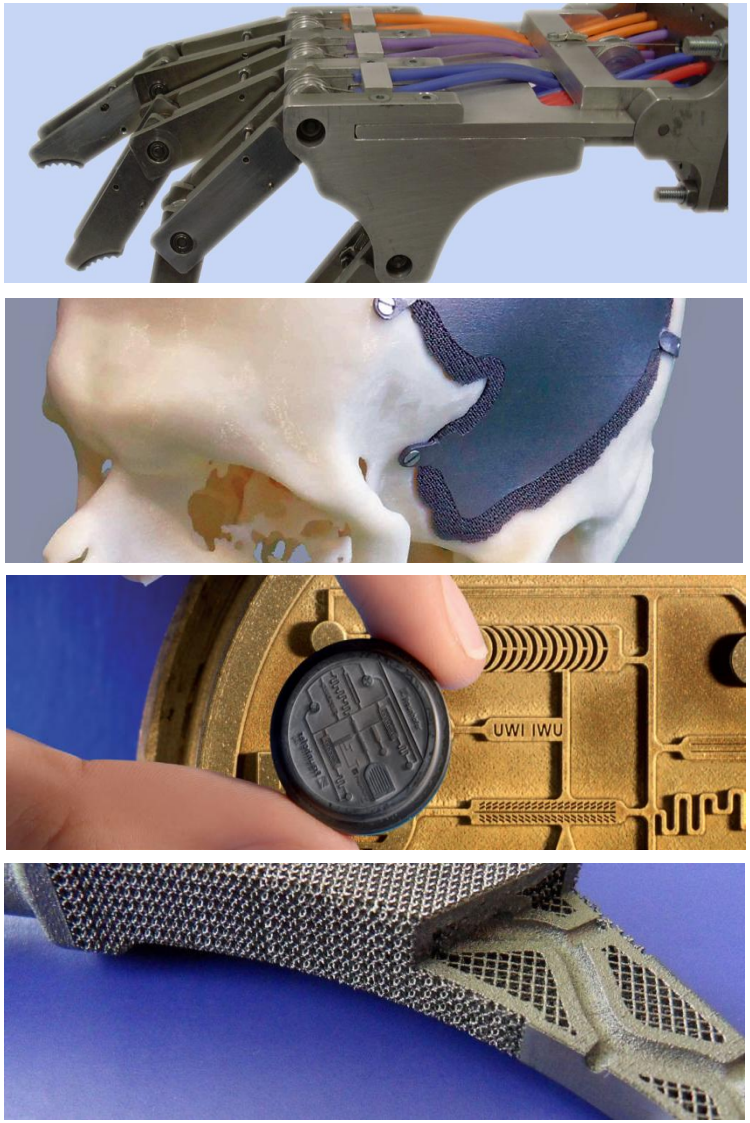
The Fraunhofer IWU
Topics Medical Engineering

Technology development and prototype manufacturing of medical device components within the following 4 topic areas:

- Conception, design and simulation
- Manufacturing technology and implementation
- Determination of key parameters
- Testing and integration

The Fraunhofer IWU
Technologies

- Active materials for medical engineering
- Design and numerical simulation
- Additive Manufacturing of implants with Laser Beam Melting
- Precision technology and micro-manufacturing
- Multifunctional light weight design and metal foam
- Bulk metal forming



Scientific Background
Fraunhofer IWU

- research group for medical technology established for more than 6 years
- in addition, a core team for medical technology co-ordinates all research activity and technologies with (potential) medical application (adaptronics, smart materials, AM, die forging, micro and precision machining etc.)
- cooperation with several medical companies including implant manufacturers, university hospitals and surgeons

Approach:

- Based on the **clinical / medical demands** and bio-mechanical analysis, we want to develop **production technologies** for **functionally enhanced implants**

Medical Engineering

Process Chain at Fraunhofer IWU

Analyzation

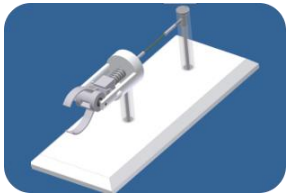
→ Bio-mechanical Characterization

Determination of key parameters
- Biomechanics / structural mechanics

Conception, Design, simulation

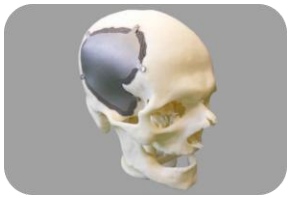
Active Materials

→ New functions and drive concepts



Additve Manufacturing

→ Patient / defect specific Implants

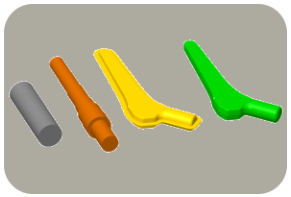


Micro and Precision technology

→ Micro implants, instruments

Bulk metal Forming

→ Resource-efficient mass production

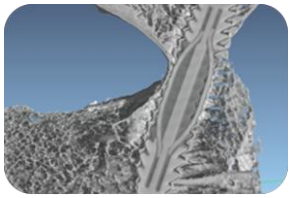


Production technology implementation, Process development

Testing and Integration

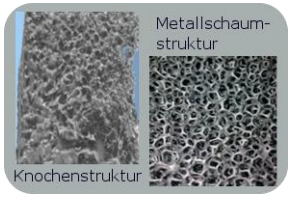
Testing

→ Verification



Metal foam

→ Lightweight design, bionic approach, bone replacement



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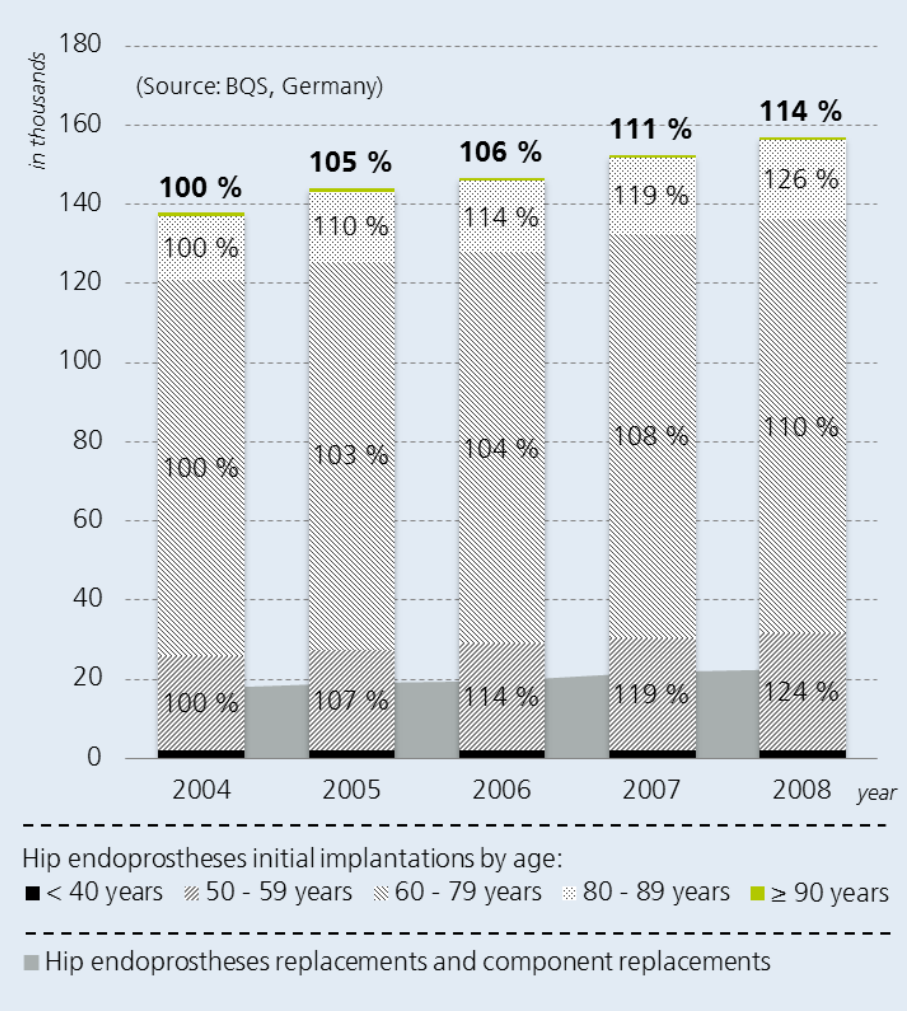
Motivation

- in Germany alone > 400.000 artificial joints (endoprostheses) implanted every year
- 90 % hip and knee joints
- main cause: arthrosis (wear of cartilage layer in joint)

- numbers are rising significantly (initial implantations as well as revision surgery) ➔ cost explosion
- ever younger patients
- high demand for innovative endoprostheses
(life cycle time ↑, complications ↓)



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Fraunhofer IWU

Motivation

Idea: New features and functions in implants through an innovative **design approach** and **additive manufacturing technology**
Together with surgeons / medical doctors **2 strategies** were developed:

Structured Implant

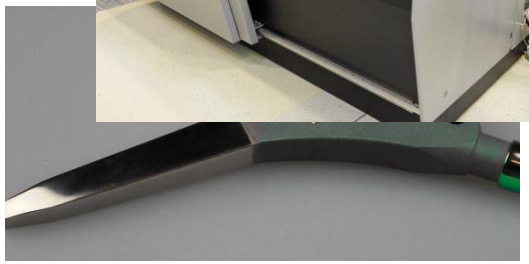
- Internal functional cavities
- Inner and surface structures

➔ Better ingrowth behavior (secondary stability)

Active Components:

- Shape M
  Increase
  ➔ Anchorin
  primary a

Lasers Beam Melting Machine „m2 cusing"



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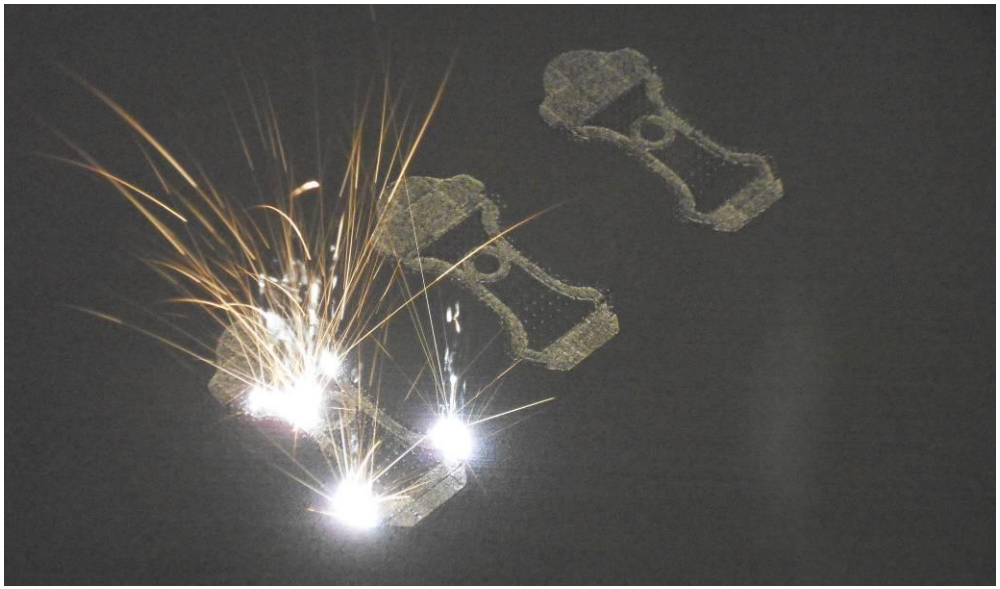
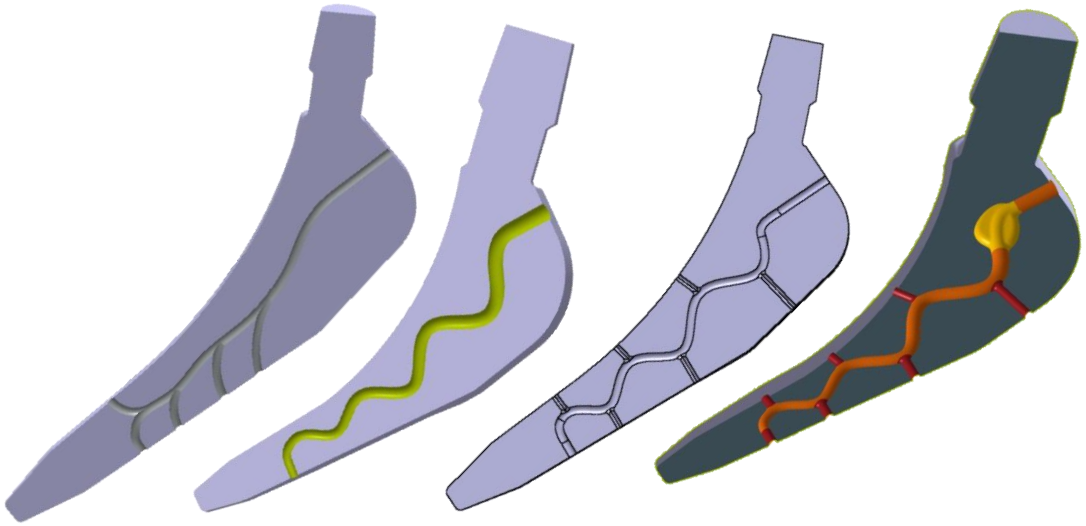
Implant with functional channels and cavities
Manufacturing

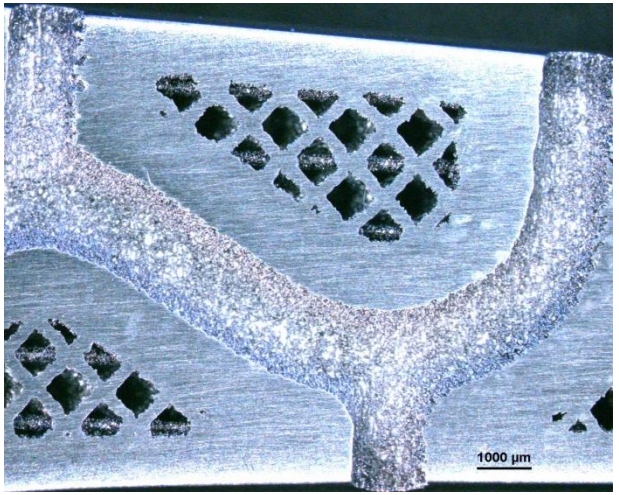
- Additive Manufacturing with Laser Beam Melting
- medically approved titanium alloy TiAl6V4
- other materials possible (pure titanium, cobalt-chromium, stainless steel)
- manufacturing possible individually or in series



Implant with functional channels and cavities
Design features

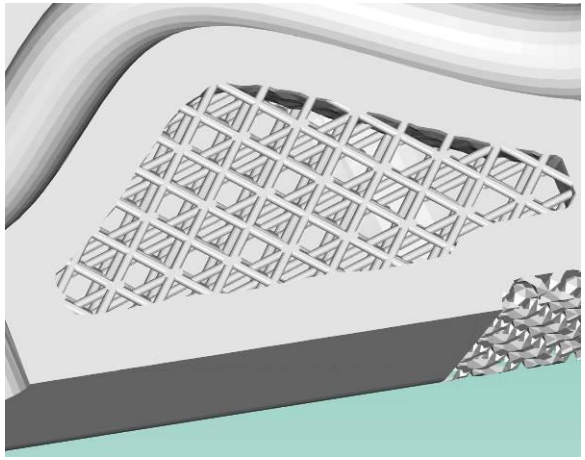
- **Inner functional channels and cavities**
  - virtually unlimited freedom of design in shaping the channels and cavities, depending on desired function
  - high material and structural quality assure strength and stiffness of implant despite weakened cross section

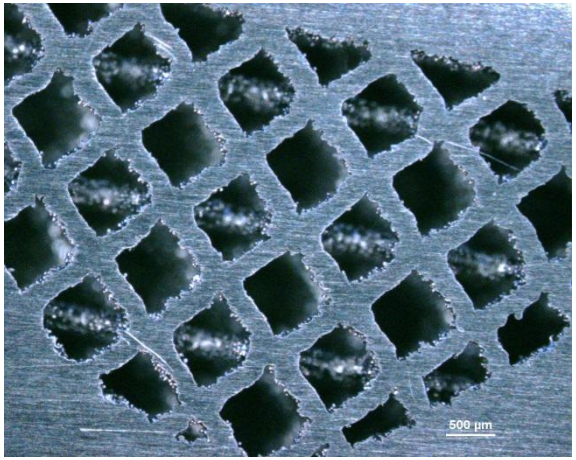




Implant with functional channels and cavities
Design features

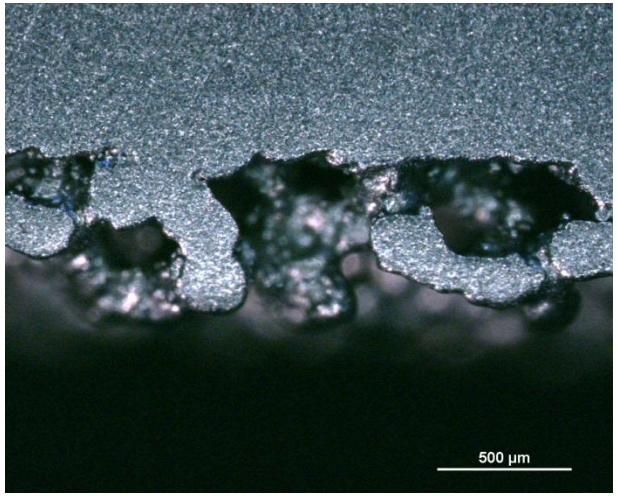
- **Inner lattice structure**
  - creation of periodic lattice structures in different shape and size
  - stiffness adaption to the bone
  - reduction of dead weight





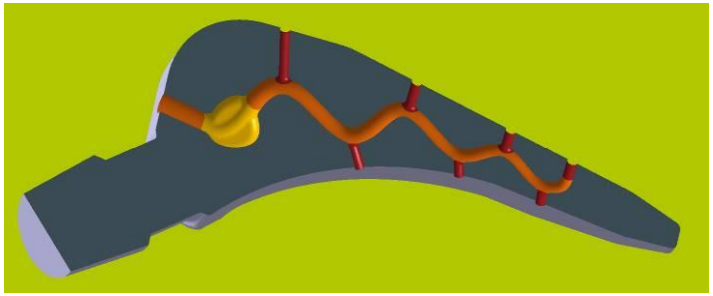
Implant with functional channels and cavities
Design features

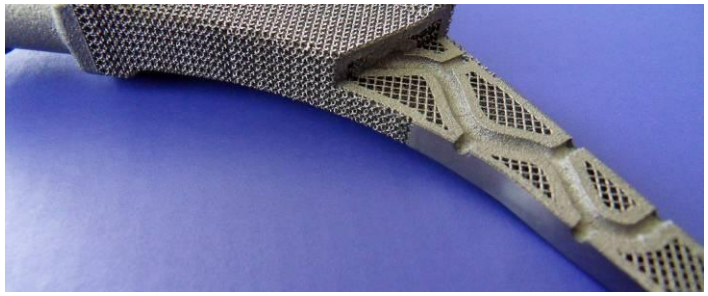
- **Macro-porous surface structure**
  - design of any desired surface structure
  - creation of structures partially or on whole part
  - depth/thickness of structure can be defined as desired
  - better ingrowth



Implant with functional channels and cavities
Functions

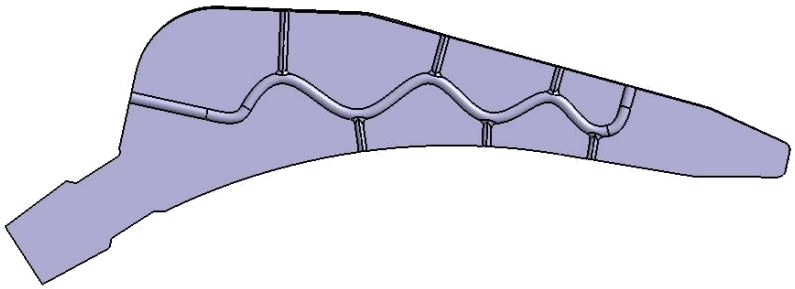
- **Drug depot inside the implant**
  - for post-surgery medical treatment of patient:
    - improving wound healing
    - promoting ingrowth
    - pain relief
    - preventing infections
  - with supply channels to implant-bone interface
  - dosis and time period for release according to doctoral precept

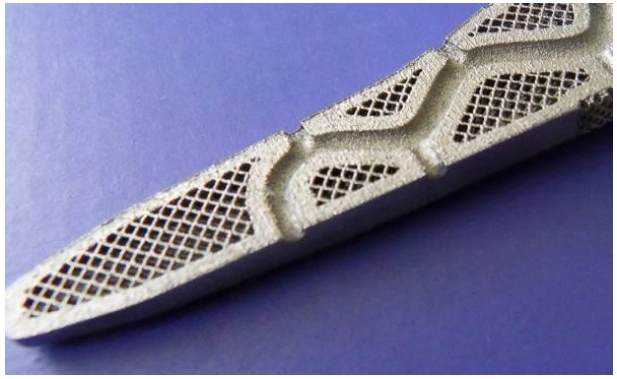




Implant with functional channels and cavities
Functions

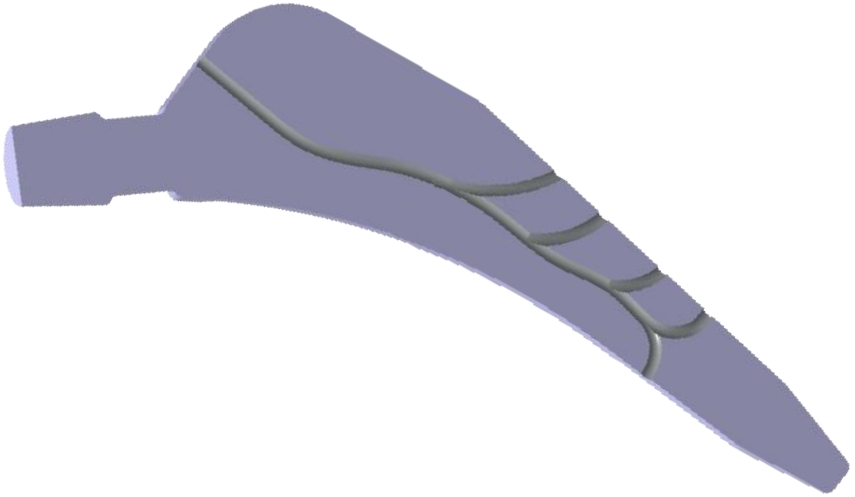
- **Supply & distribution of bio-resorbable filler or bone cement**
  - central ingate and numerous supply channels towards implant-bone interface
  - to bridge gaps between implant and bone due to:
    - fitting deficits of implant
    - unexpectedly bad bone conditions
    - already suffered loosening of implant
  - prevention & treatment of loosening even years after implantation, avoiding revision surgery

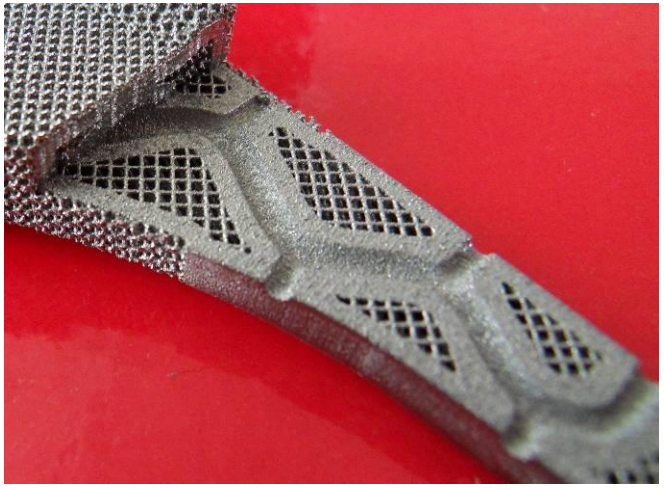




Implant with functional channels and cavities
Functions

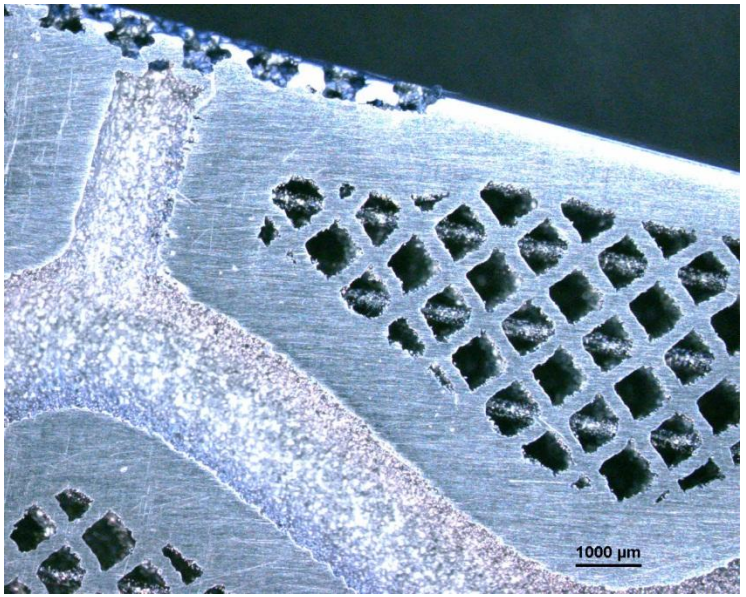
- **Endoscopic inspection through the implant's inner body**
  - central ingate and numerous outlets towards implant-bone interface
  - minimally invasive
  - alternative to CT and MRT for post-surgery monitoring





Implant with functional channels and cavities
Functions

- **Other potential functions**
  - post-surgery drainage of blood and wound ooze through the implant's body
  - support of revision surgery by feeding a medium for local dissolution of implant-bone joining for easier and faster explantation with less damage in sound bone structure



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Together with surgeons / medical doctors **2 strategies** were developed:

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- Internal functional cavities
- Inner and surface structures

➔ Better ingrowth behavior (secondary stability)

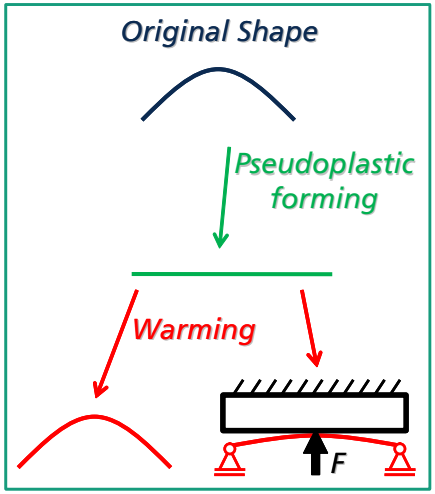
Active Components:

- Shape Memory Alloy (SMA) to increase the implant stability

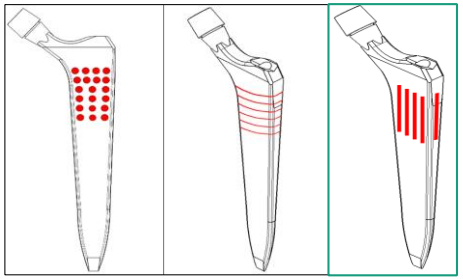
➔ Anchoring function, better primary and secondary stability

Active Material Combination for a Non-Loosening Implant

- **Aim:** homogeneous and stable fixation of cementless hipstems
- **Background:** osseous anchorage of the endoprosthesis often inadequate => differences in the mechanical strength and elasticity of bone vs. implant
  => main cause (aseptic) loosening of cementless hip implants (beside particle abrasion)
- **Solution:** increase the primary stability by an optimal force distribution at the bone hipstem interface using Shape Memory Alloy (SMA) elements
- SMA elements have similar mechanical properties comparing to bone material
- Development of design as a basis for further studies and expert interviews

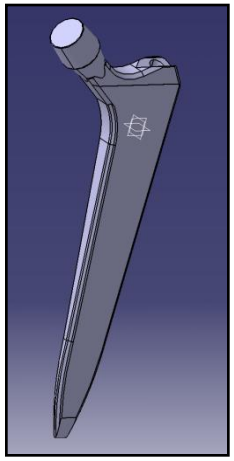


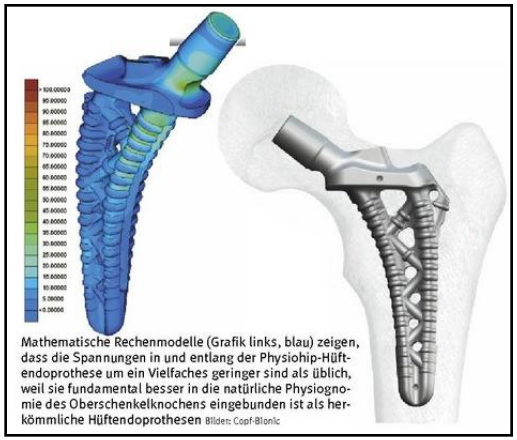
Supressed Shape Memory Effect


Designs, examples

Different Designs of the Implant

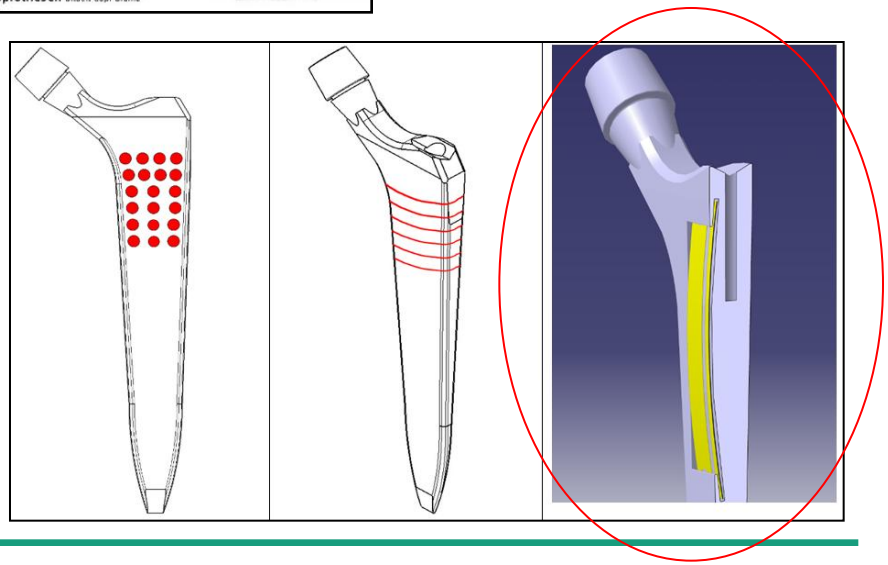
- Question: "traditional or modern" classical short stem prosthesis as prefered variant



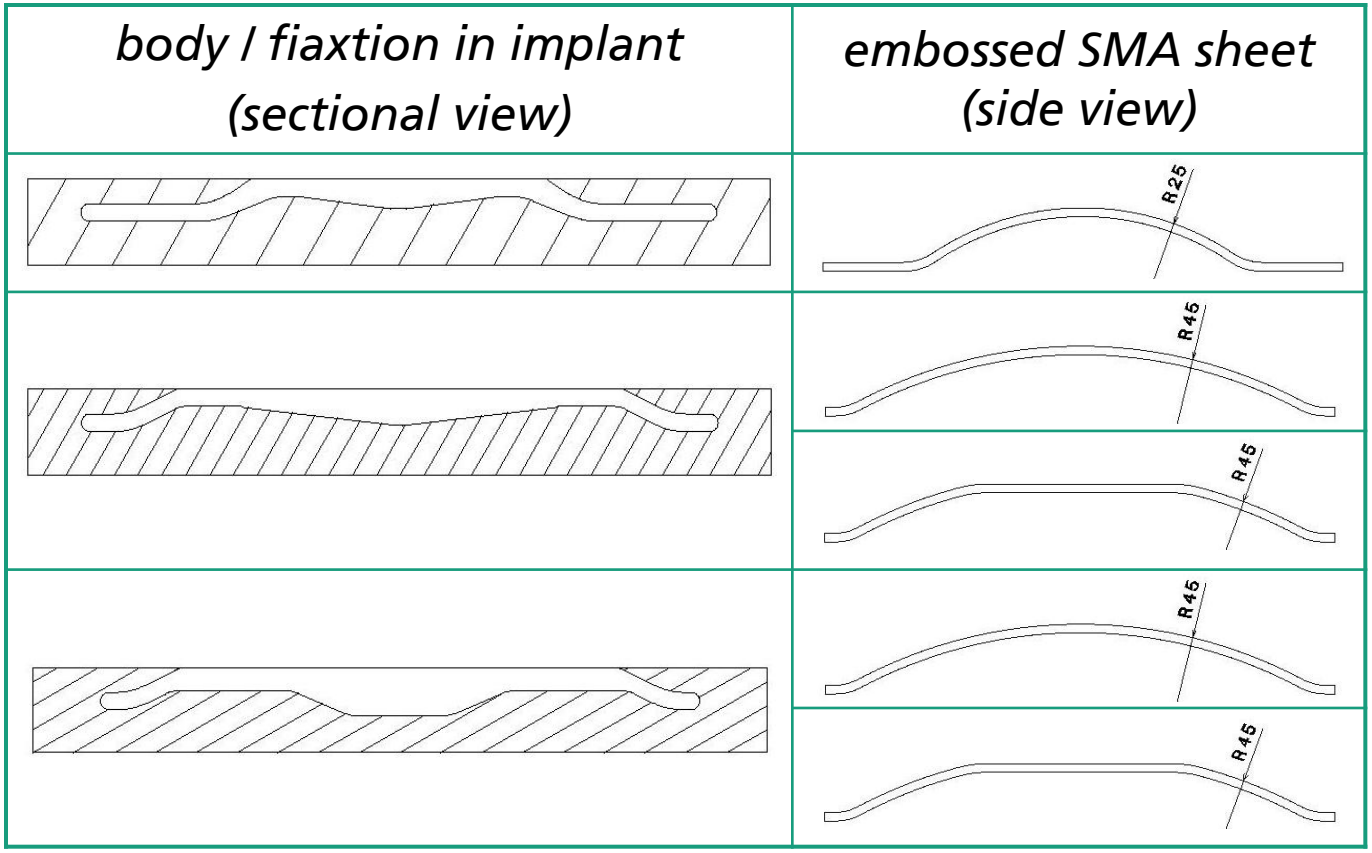


Mathematische Rechenmodelle (Grafik links, blau) zeigen, dass die Spannungen in und entlang der Physiohip-Hüftendoprothese um ein Vielfaches geringer sind als üblich, weil sie fundamental besser in die natürliche Physiognomie des Oberschenkelknochens eingebunden ist als herkömmliche Hüftendoprothesen Bilder: Copf-Bionic

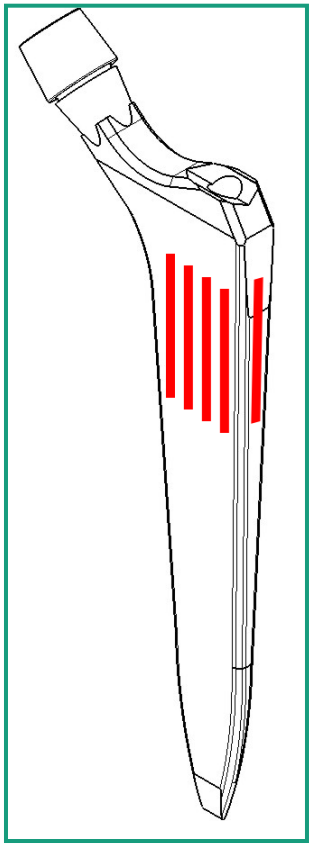
- Preliminary sketches for SMA-sheet integration as a basis for physician survey



Development of SMA embedding method- first-functional models

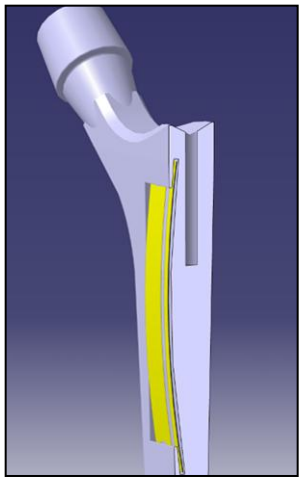


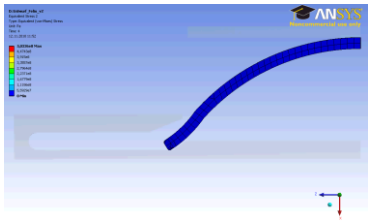
five variants of different geometry consisting of a base body and a SMA sheet



possible area of application in a hip stem

Principle

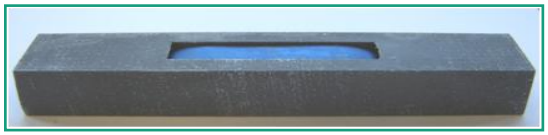




Hip stem with SMA elements => cool down

Implantation in Femur

Activation by body temperature



cooled

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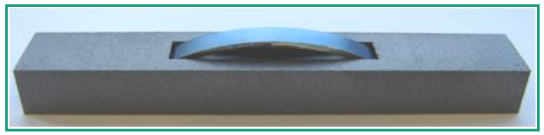


Body temperature

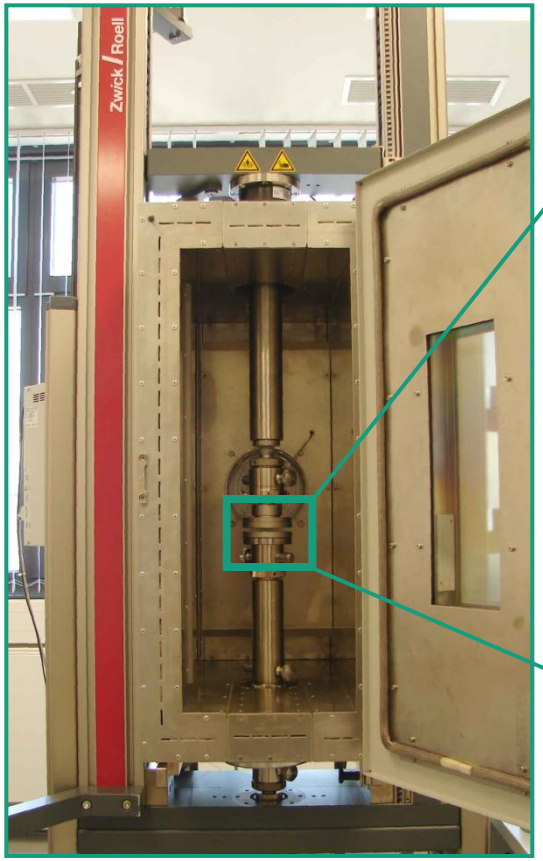
Generating an additional force in the contact area of the SMA sheets between hipstem an femur

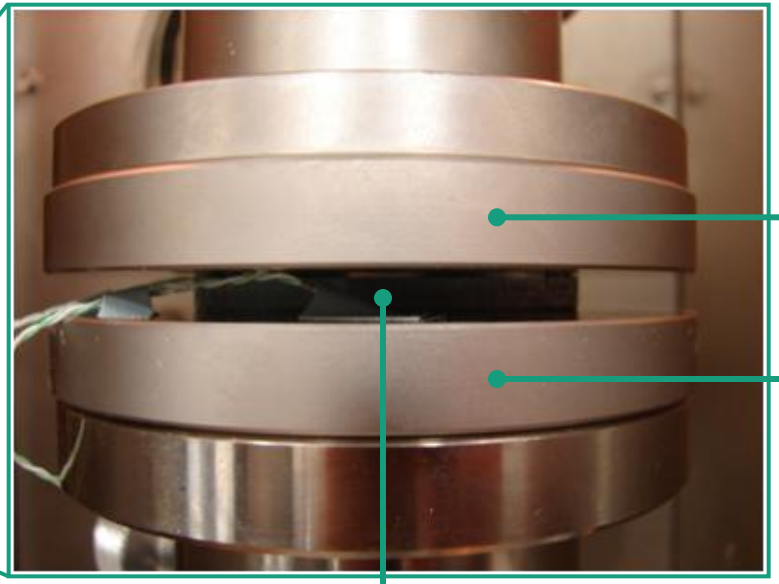
Aim: Stabilization of cementless hip stem

Determination of the forces

experimental setup

- *Z020 universal testing machine Zwick / Roell with integrated temperature chamber*
- *Heating up to body temperature and measuring of the transmitted power*





upper pressure plate

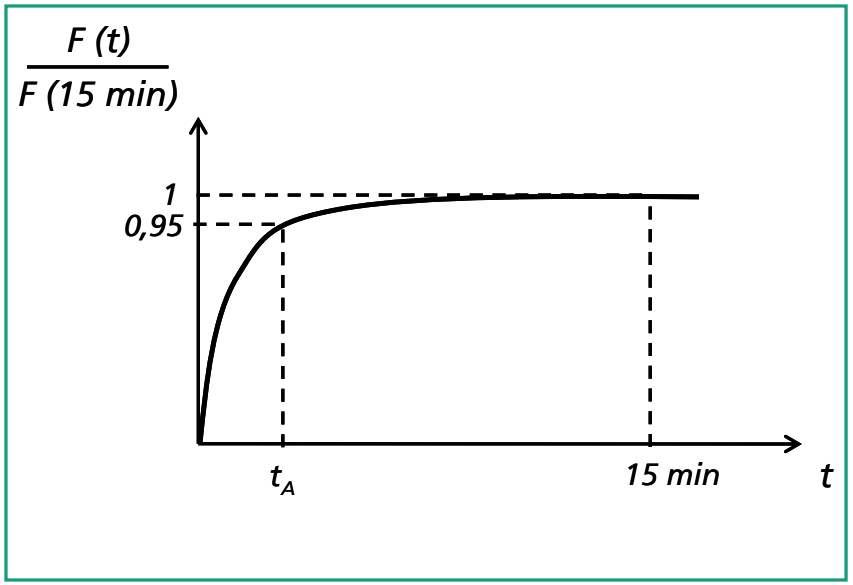
lower pressure plate

functional model

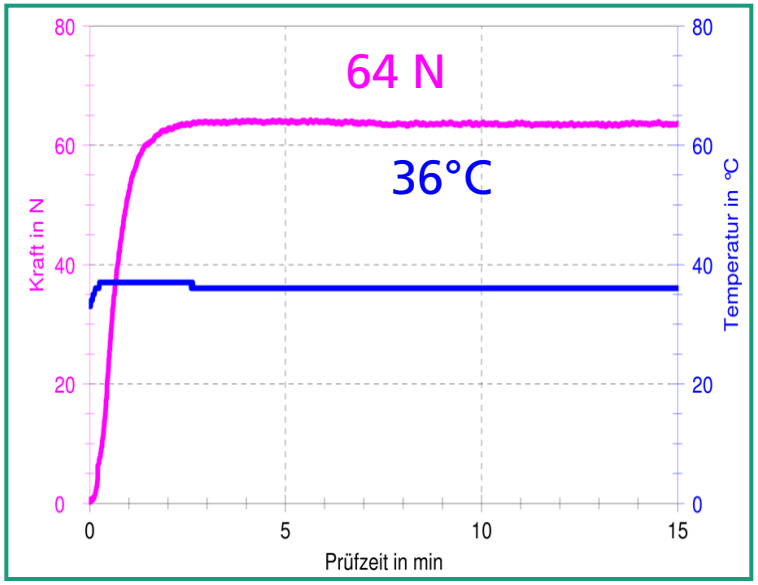
Proof of efficacy - experimentally obtained results

Force profile during thermal activation

Theory

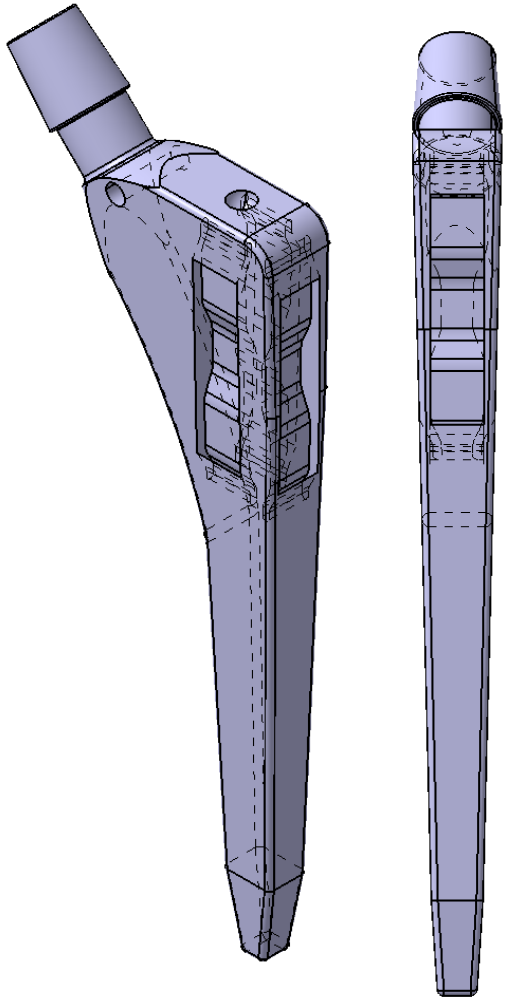


Example: Experiment

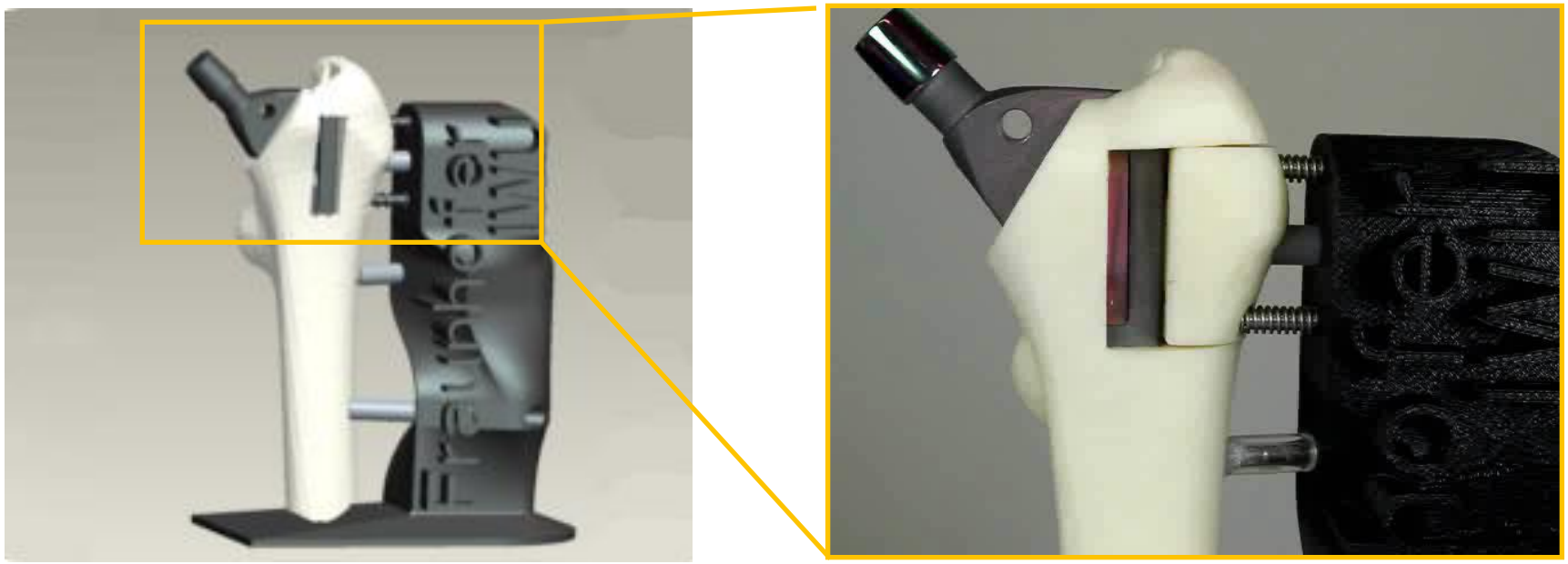


Activation time t_A = 62 s, contact forces up to 80 N

Hip Stem and SMA-actuators – final Design



Functional Demonstrator



Demonstrator – Hip Stem Implant with SMA Sheet Actuators

Hip stem with SMA actuators

- Standard stem prosthesis with SMA elements support a homogenous force distrbution on the stem – bone – interface
- Hip stem manufactured by AM in TiAl6V4
- Cone with standard size (12/14)
- lower end of the shaft polished = > only axial guiding
- SMA elements:
  - NiTi alloy, biocompatible
  - Activation at body temperature
  - biocompatible coating of prosthesis and SMA elements (Fraunhofer FEP, Dresden)

Summary

- Additive Manufacturing of implants with Beam Melting Technology enables unforeseen freedom in implant design
- besides patient-specific design and surface structuring, the integration of functions and added value in implants is another, new field of application for Additive Manufacturing technology in endoprosthetis
- inner functional channels and cavities supply implants with completely new and additional functions
- AM enables the integration of active SMA elements
- added value of these implants satisfy higher manufacturing costs?!
- less revision surgery, lower inter- and post-operative risks, more comfort for patients

What's next?

- further development of the implant prototypes
- In-vitro and in-vivo tests
- goal: introduction of MUGETO® implant and active implant as medically approved product to be implanted in humans
- partners wanted to reach that goal!

Thank you for your attention!

Dr.-Ing. Bernhard Mueller
Group Manager »Additive Manufacturing Technologies«

Fraunhofer Institute for Machine Tools and Forming Technology IWU

Postal address:
Reichenhainer Str. 88
09126 Chemnitz
Germany

Visitor address:
Noethnitzer Str. 44
01187 Dresden
Germany

Phone: + 49 (351) 4772-2136
Fax: + 49 (351) 4772-2303

E-Mail: bernhard.mueller@iwu.fraunhofer.de