Masterclass:

Biomedical applications of Additive Manufacturing

Part 01: General considerations and clinical case studies

sirris
driving industry by technology

Materialise

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Masterclass:

Biomedical applications of Additive Manufacturing

Case Study 4: New features and functions in implants through an innovative design approach and Additive Manufacturing (Laser Beam Melting)

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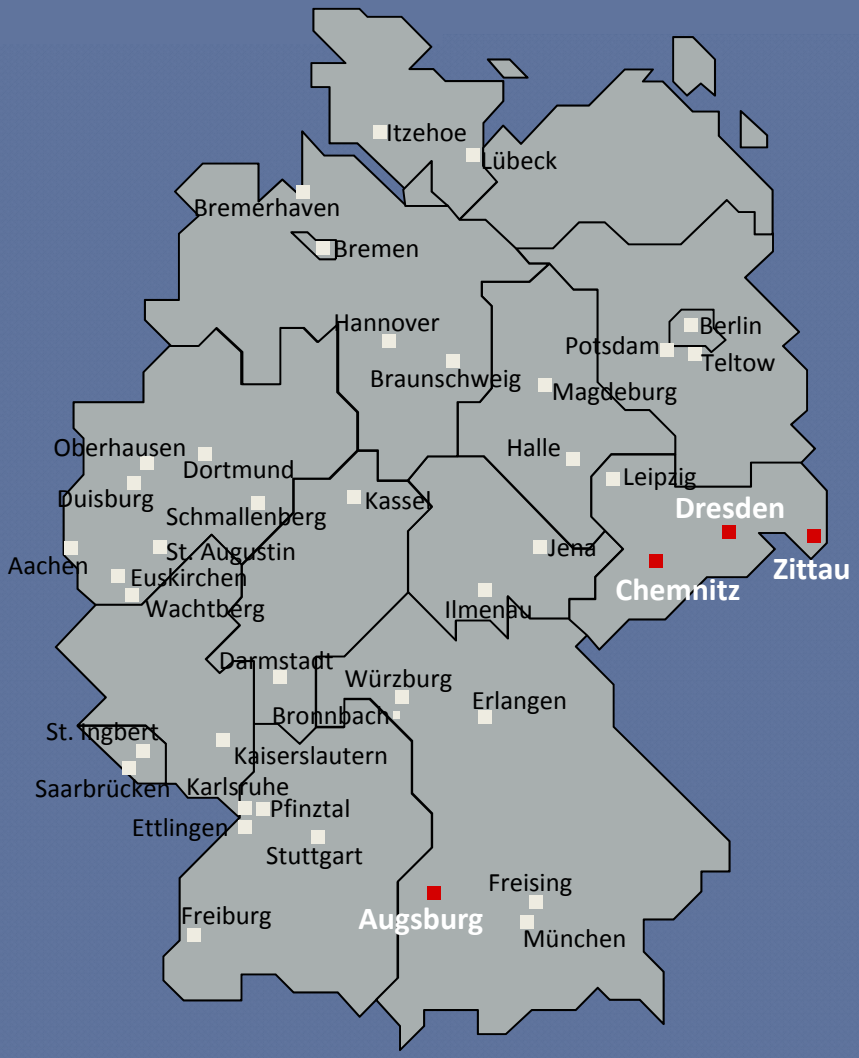
Fraunhofer IWU

Content

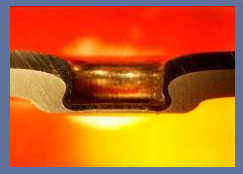
- The Fraunhofer IWU
- Motivation for biomedical Additive Manufacturing
- Laser Beam Melting
- Functional integration through Laser Beam Melting
- Active material combination for a non-loosening implant
- Conclusions

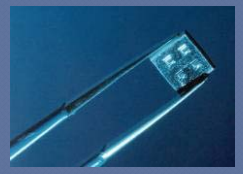
The Fraunhofer IWU - Locations

- founded on July 1st, 1991
- about 510 employees
- 29 million euro budget
- Project Group in Augsburg since January 2009
- Project Group in Zittau since October 2011



The Fraunhofer IWU - Profile





- **Fields of expertise**
  - Machine Tools
  - Mechatronics
  - Lightweight Construction
  - Forming Technologies
  - Cutting Technologies
  - Joining and Assembling
  - Production Management
- **in close cooperation with**
  - Chemnitz University of Technology
  - Fraunhofer-Gesellschaft
  - Machine tool industry
  - German and international automobile industry
  - Ancillary industry (forming, cutting, tool and die making)

Institutional Network Production Eng.
Chemnitz – Dresden

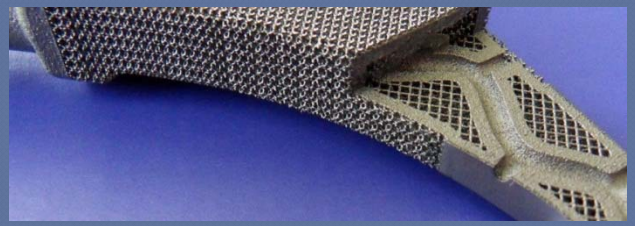
Fraunhofer IWU
Chemnitz location

Fraunhofer IWU
Dresden location

IWP
TU Chemnitz

The Fraunhofer IWU – Medical Eng.

- **Bio-mechanical characterization, design and numerical simulation**
- **Active materials for medical engineering**
- **Additive Manufacturing of implants with Laser Beam Melting**
- **Precision technology and micro-manufacturing**
- **Multifunctional light weight design and metal foam**
- **Bulk metal forming**
- **Based on clinical / medical demands and bio-mechanical analysis, we want to develop production technologies for functionally enhanced implants**



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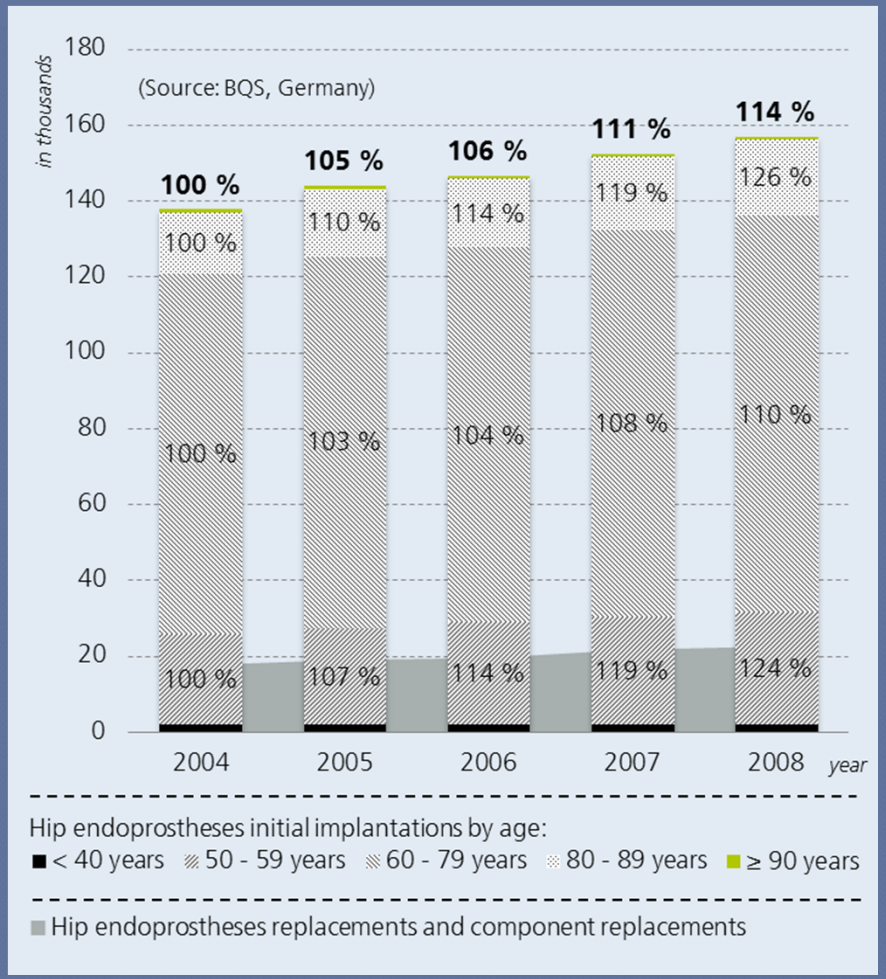
Motivation for biomedical AM

- 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 ↓)



Motivation for biomedical AM

- **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 implants:**
  - Internal functional cavities
  - Inner and surface structures
  - Better ingrowth behavior (secondary stability)

Motivation for biomedical AM

- **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:**

- **Active components:**
  - Shape Memory Alloy (SMA) to increase the implant stability
  - Anchoring function, better primary and secondary stability

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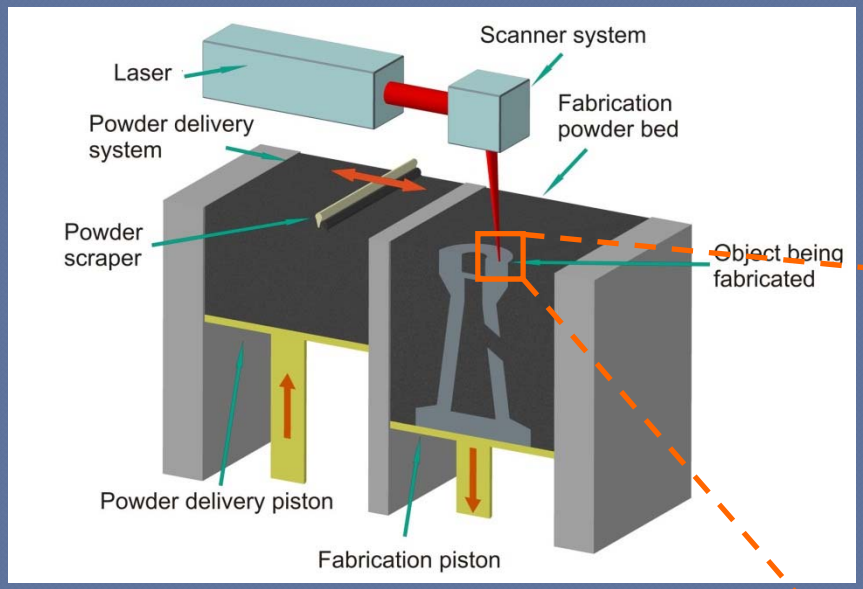
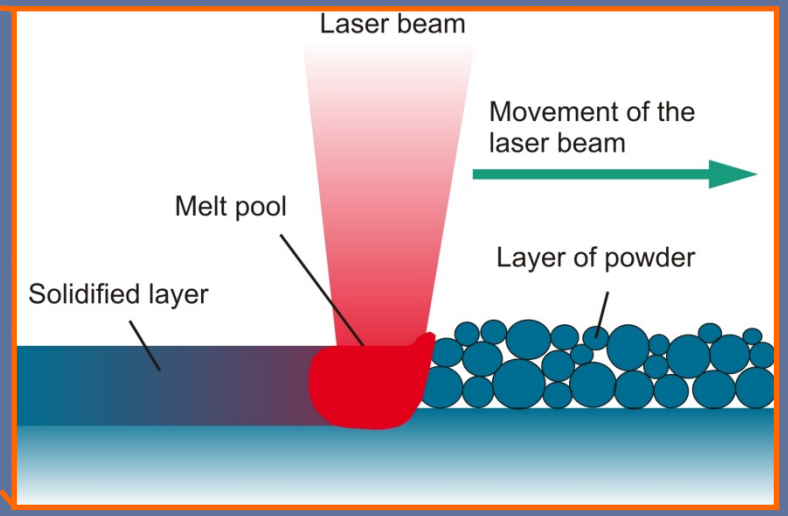
Laser Beam Melting - Principle

- **Direct, single step process, creating parts out of series-like metallic material**
- **Complete local melting of the metal powder to a 99.5 - 100 % dense microstructure**



Principle sketch of a Laser Beam Melting machine

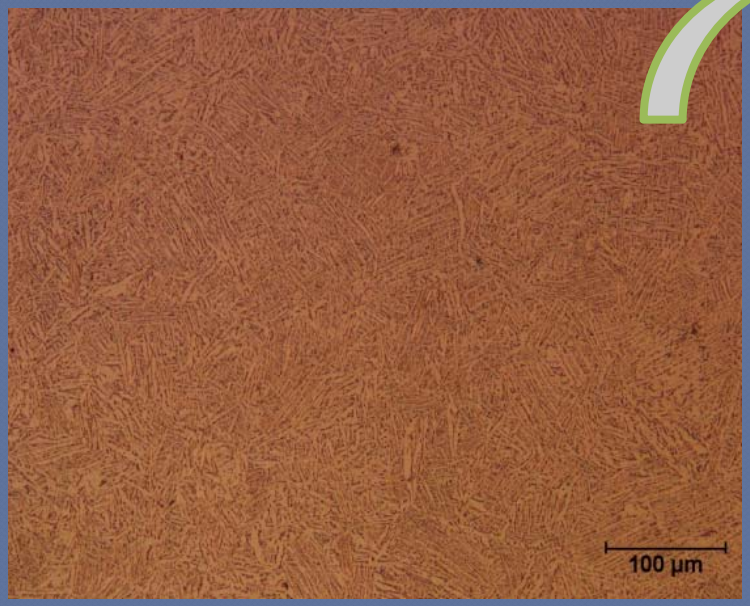


Schematic diagram of Laser Beam Melting

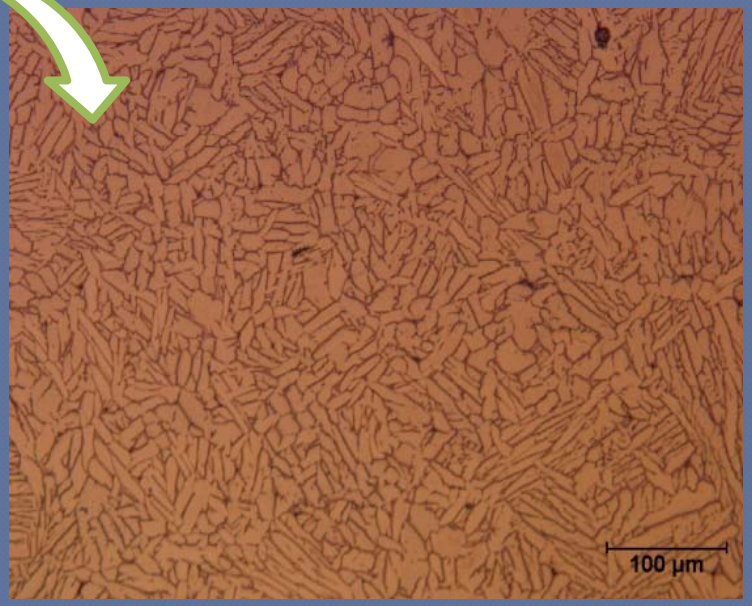
Laser Beam Melting - Principle

- **Fast cooling down of the melt pool up to 10^6 K/s**
  → characteristic lamellar micro structure of LBM

Heat treatment



Ti-6Al-4V lamellar micro structure
(condition as built)



Ti-6Al-4V duplex micro structure
(heat treated above beta transus temperature)

Laser Beam Melting - Advantages

time to product

- no tools needed
- no job preparation / technology planning
- no NC programming
- single step process

freedom of shape

- arbitrarily complex geometries
- undercuts
- internal geometric shapes
- delicate structures
- geometries not fabricable by cutting, forming or casting

material diversity

- aluminium
- titanium
- cobalt-chrome
- hot and cold work steel
- nickel-base alloy (Inconel)

lightweight construction / bionics

- hollow and lattice-like structures
- 100 % topology optimized parts
- bionic structures
- structures with graded porosity

Laser Beam Melting at IWU

Powder sieving machine

Heat treatment equipment

LBM machine M2 Cusing by Concept Laser

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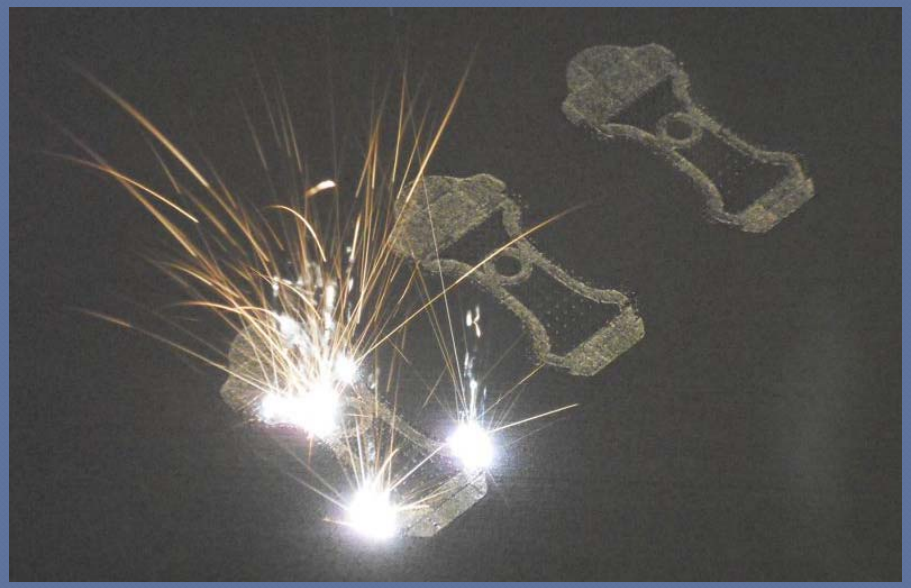
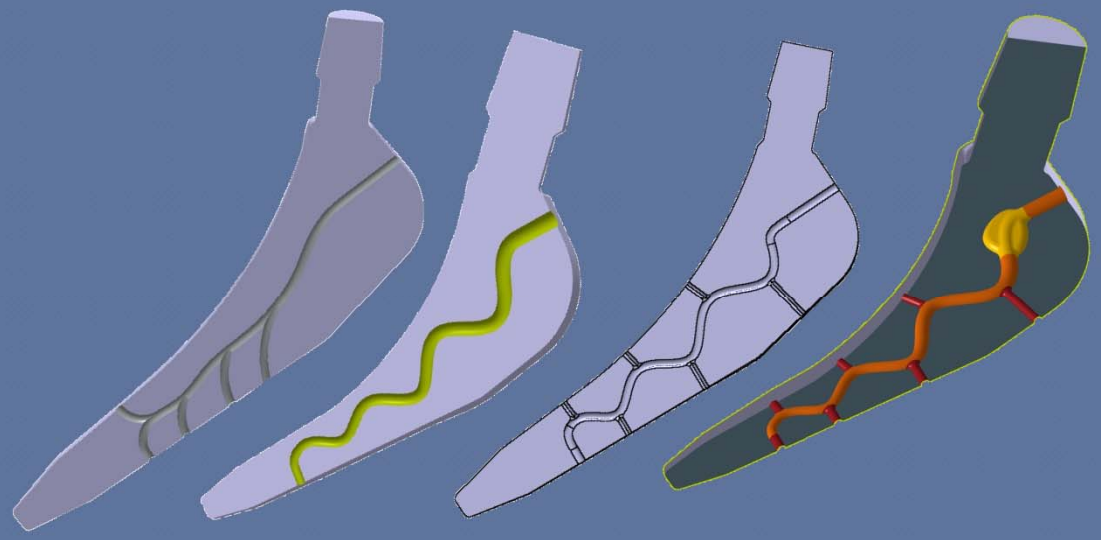
Functional Integration through LBM
Implant with functional channels and cavities

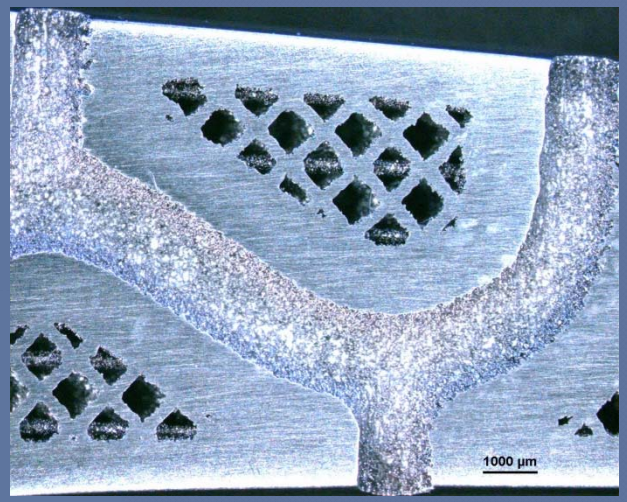
- **Manufacturing**
  - Additive Manufacturing with Laser Beam Melting
  - Medically approved titanium alloy TiAl6V4
  - Other materials possible (pure titanium, cobalt-chromium, stainless steel)
  - Manufacturing possible individually or in series



Functional Integration through LBM
Implant with functional channels and cavities

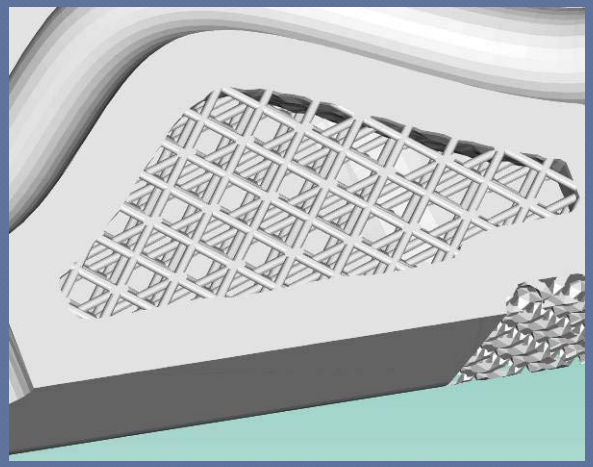
- **Design features – inner functional channels and cavities**
  - Virtually unlimited freedom of design in shaping the channels and cavities, depending on desired function
  - High material and structural quality assure strength and stiffness of implant despite weakened cross section

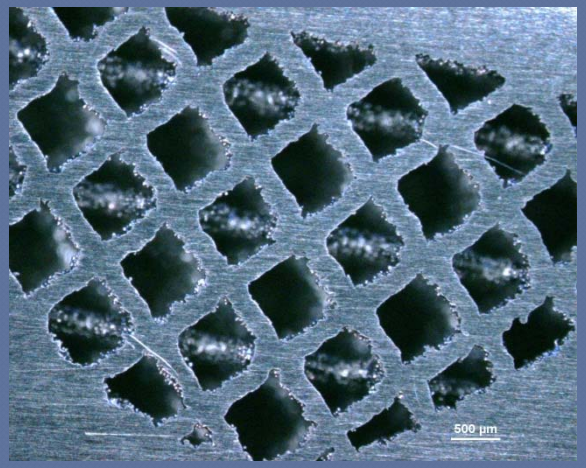




Functional Integration through LBM
Implant with functional channels and cavities

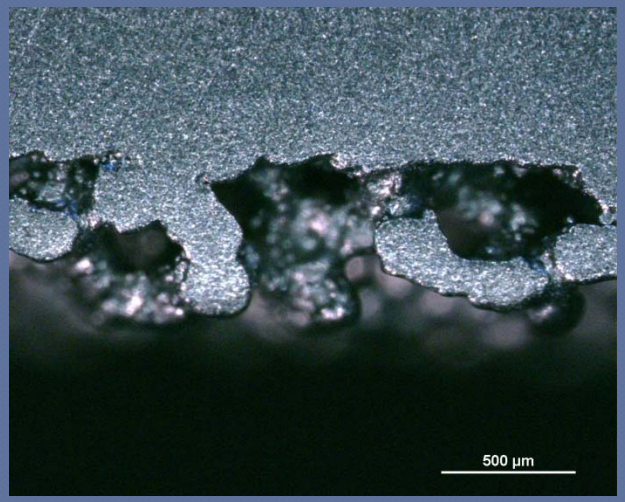
- **Design features – inner lattice structure**
  - Creation of periodic lattice structures in different shape and size
  - Stiffness adaption to the bone
  - Reduction of dead weight





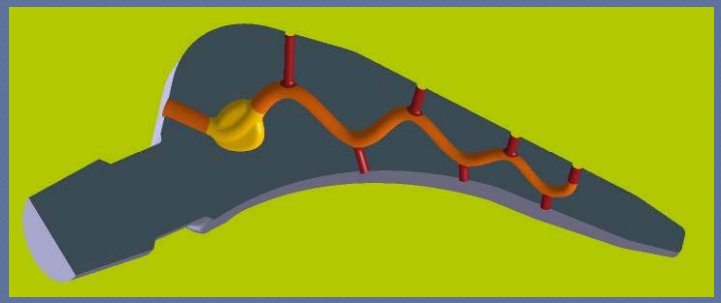
Functional Integration through LBM
Implant with functional channels and cavities

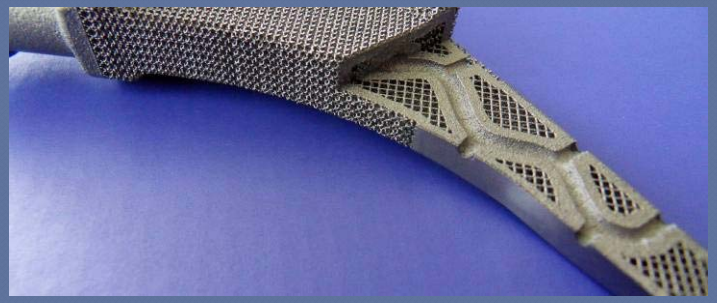
- **Design features – macro-porous surface structure**
  - Design of any desired surface structure
  - Creation of structures partially or on whole part
  - Depth/thickness of structure can be defined as desired
  - Better ingrowth



Functional Integration through LBM
Implant with functional channels and cavities

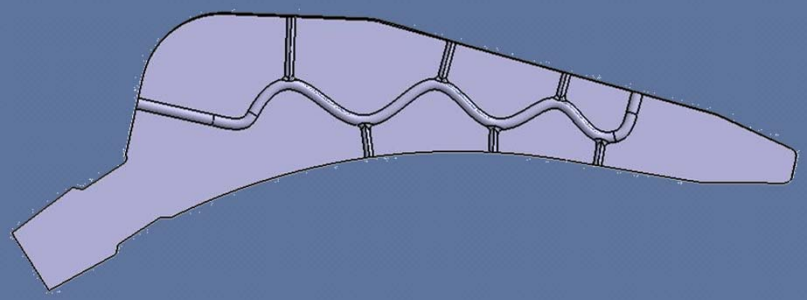
- **Functions – drug depot inside the implant**
  - For post-surgery medical treatment of patient:
    - Improving wound healing
    - Promoting ingrowth
    - Pain relief
    - Preventing infections
  - With supply channels to implant-bone interface
  - Dosis and time period for release according to doctoral precept

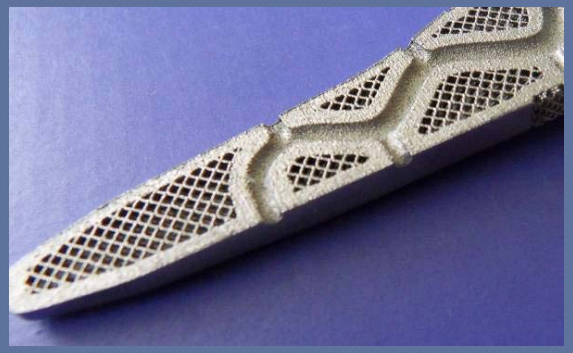




Functional Integration through LBM
Implant with functional channels and cavities

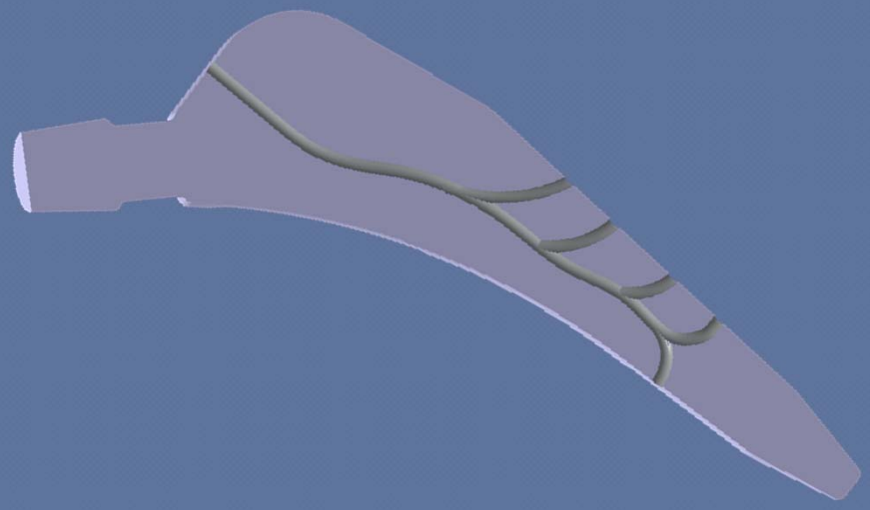
- **Functions – supply & distribution of bio-resorbable filler or bone cement**
  - Central ingate and numerous supply channels towards implant-bone interface
  - To bridge gaps between implant and bone due to:
    - Fitting deficits of implant
    - Unexpectedly bad bone conditions
    - Already suffered loosening of implant
  - Prevention & treatment of loosening even years after implantation, avoiding revision surgery





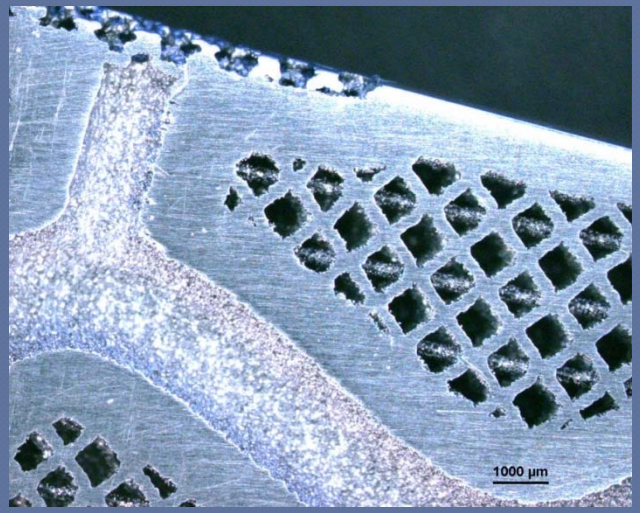
Functional Integration through LBM
Implant with functional channels and cavities

- **Functions – endoscopic inspection through the implant's inner body**
  - Central ingate and numerous outlets towards implant-bone interface
  - Minimally invasive
  - Alternative to CT and MRI for post-surgery monitoring



Functional Integration through LBM
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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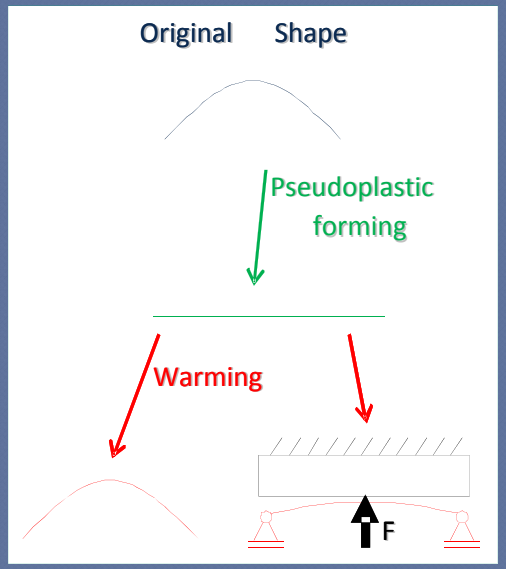
Active material combination for a non-loosening implant

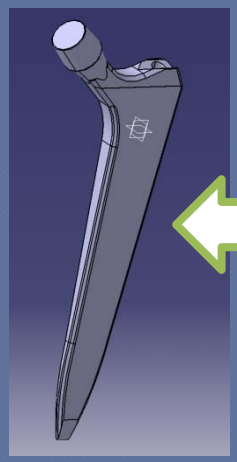
- **Background: (aseptic) loosening of cementless hip implants caused by differences in the mechanical strength and elasticity of bone vs. implant**
- **Aim: homogeneous and stable fixation of cementless hip stems**
- **Solution: increase the primary stability by an optimal force distribution at the bone hip stem interface using Shape Memory Alloy (SMA) elements**
  - Similar mechanical properties of SMA compared to bone material
  - Development of design as a basis for further studies and expert interviews

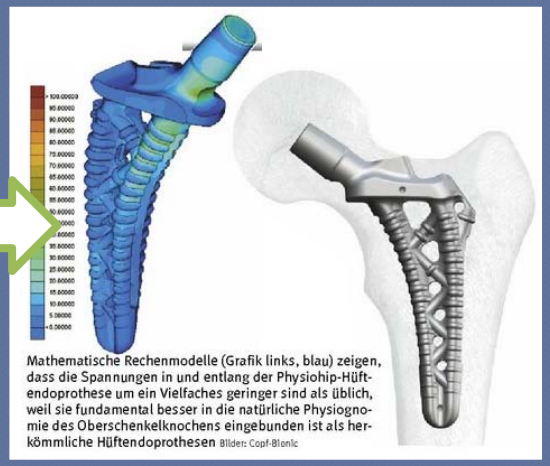


Supressed Shape Memory Effect

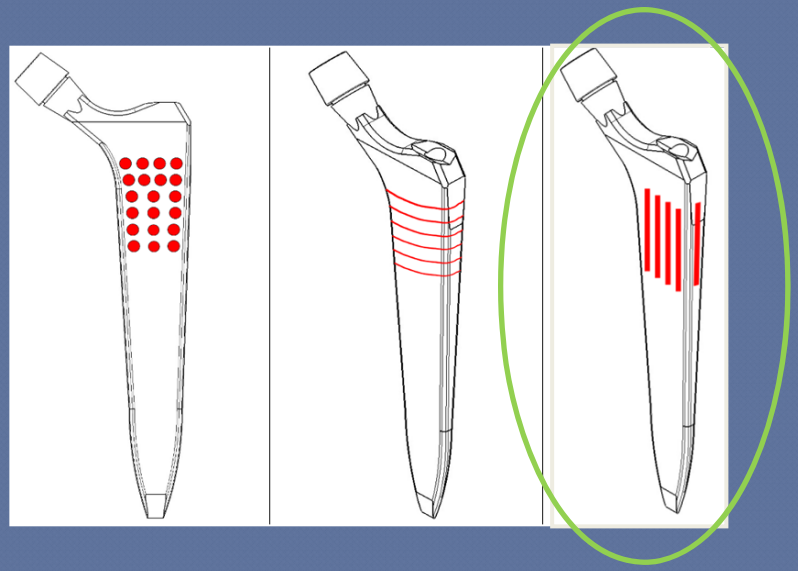
Active material combination for a non-loosening implant

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





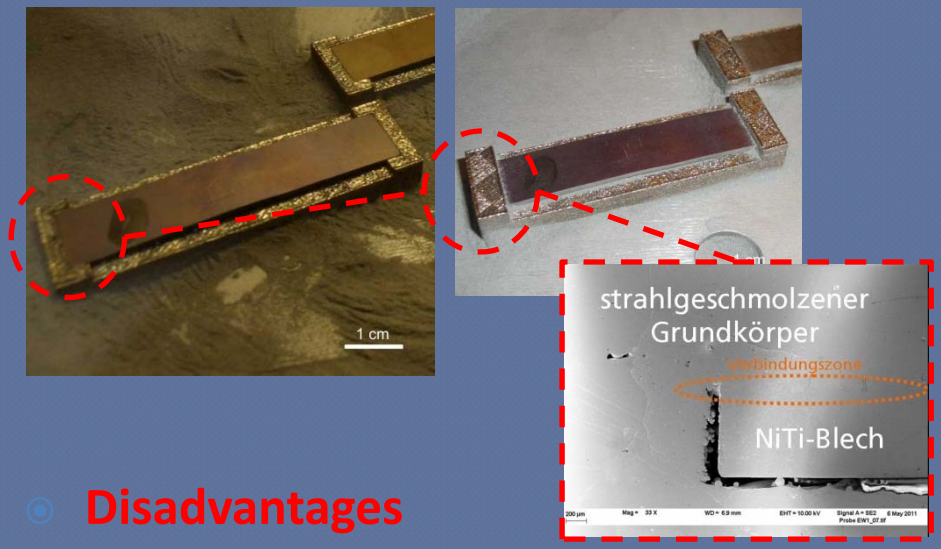
- **Preliminary sketches for SMA element integration as a basis for survey among surgeons**



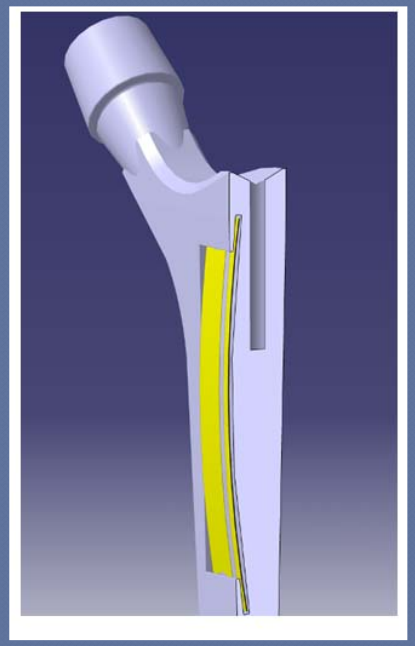
Active material combination for a non-loosening implant

- **2 principles of integrating SMA elements were investigated**

- **Joined integrally within LBM process**



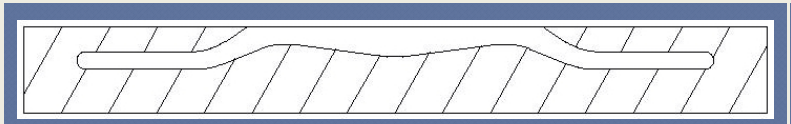
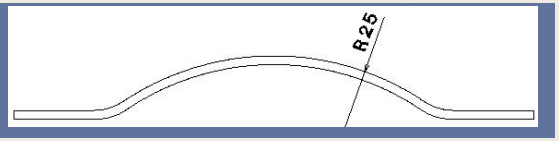
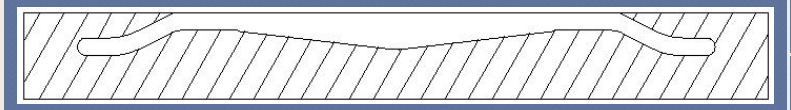
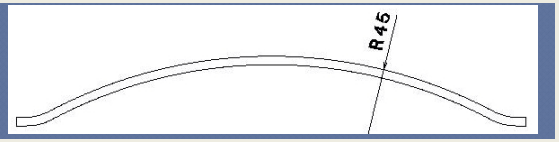
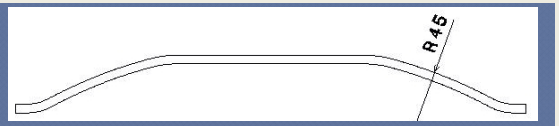
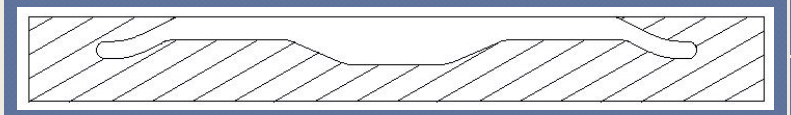
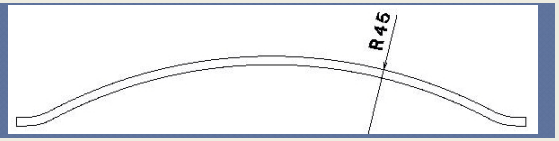
- **Mounted with positive locking**



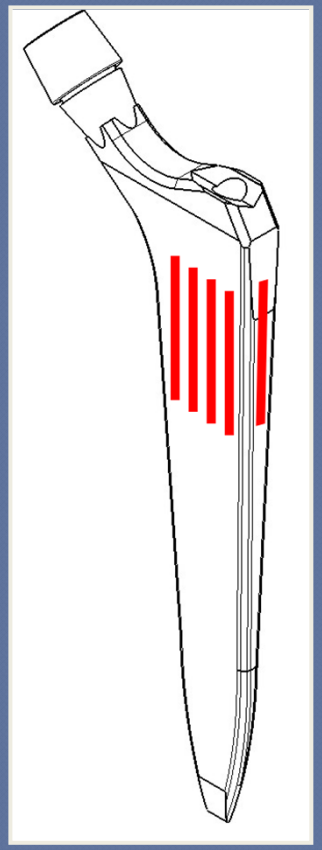
- **Disadvantages**
  - Limited freedom of design
  - Cleaning issues

Active material combination for a non-loosening implant

- **Development of SMA mounting method – first functional models**

body / fixation in implant (sectional view)	mounted SMA sheet (side view)
	
	 
	

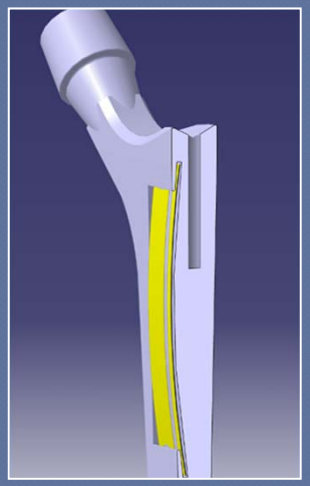
Five variants of different geometry consisting of a base body and a SMA sheet



Possible areas of application

Active material combination for a non-loosening implant

- **Active principle:**



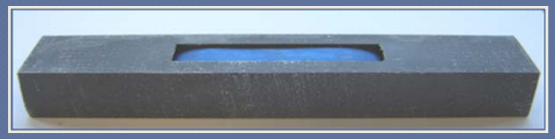
Hip stem with SMA elements → cool down ≤ 0 °C

↓

Implantation in femur

↓

Activation by body temperature



Cooled

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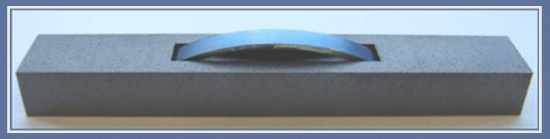


Body temperature

↓

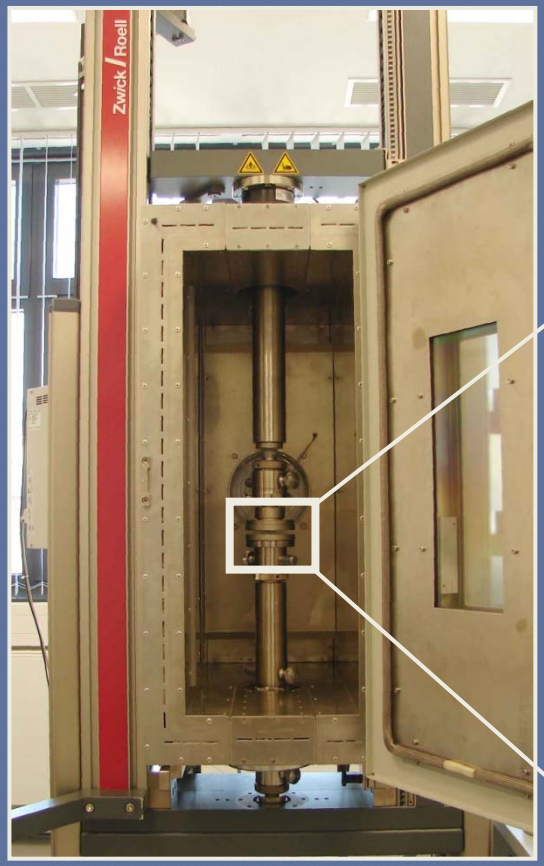
Generating an additional force in the contact area of the SMA sheets between hip stem and femur

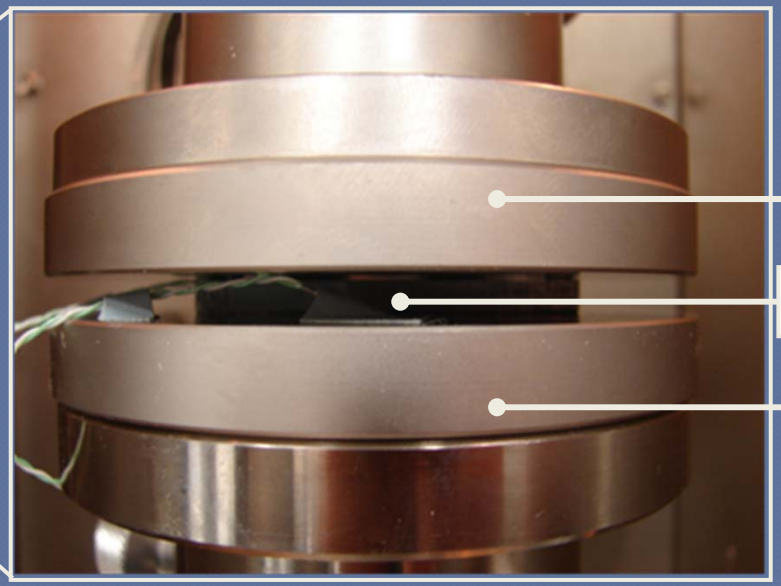
↓

Aim: Stabilization of cementless hip stem

Active material combination for a non-loosening implant

- **Determination of the SMA induced forces – experimental set up**
  - Z020 universal testing machine Zwick / Roell with integrated temperature chamber
  - Heating up to body temperature and measuring of the transmitted forces

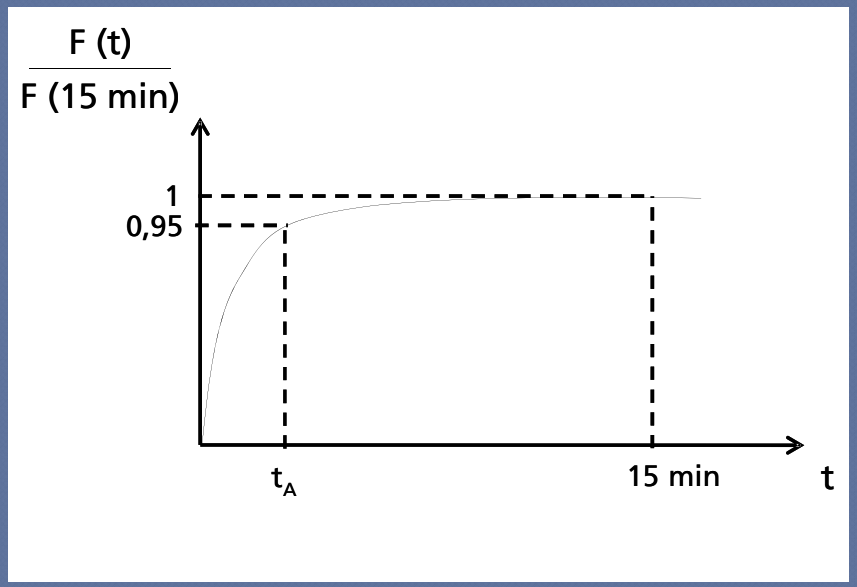




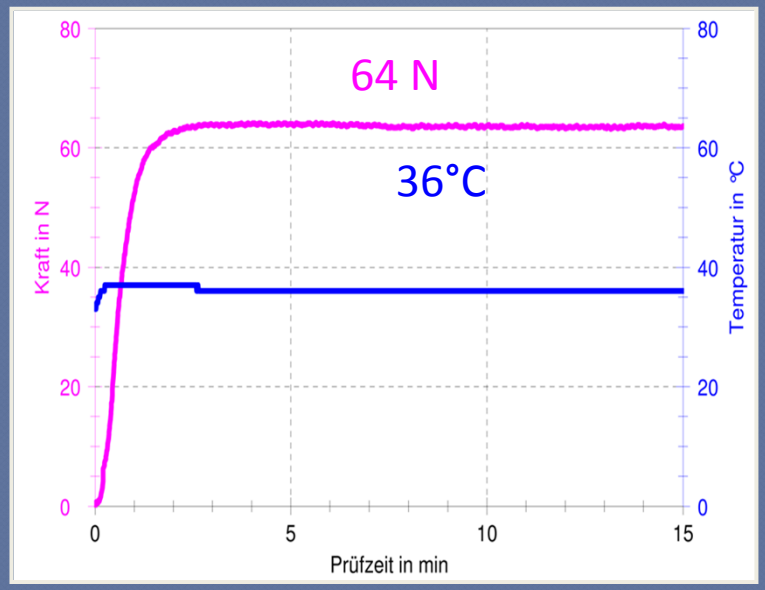
Active material combination for a non-loosening implant

- **Determination of the SMA induced forces – forces during and after thermal activation**

Theory



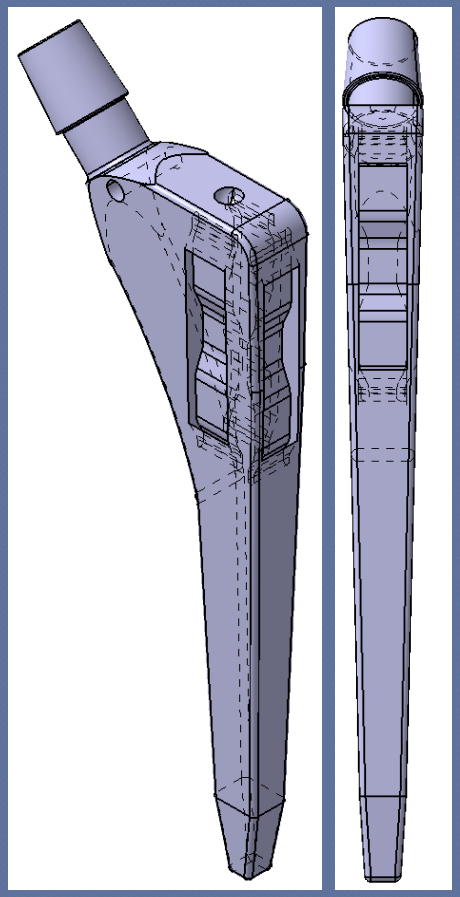
Experiment



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

Active material combination for a non-loosening implant

- **LBM manufactured hip stem with SMA sheet actuators – final design**



Active material combination for a non-loosening implant

Hip stem with SMA actuators

- **Demonstrator – femoral hip stem with SMA sheet actuators**
  - Standard stem prosthesis with SMA elements support a homogenous force distribution on the stem/bone-interface
  - Hip stem manufactured by AM in Ti-6Al-4V
  - Cone with standard size (12/14)
  - Lower end of the shaft polished → only axial guiding function
  - SMA elements:
    - NiTi alloy, biocompatible
    - Activation at body temperature
    - Biocompatible coating of prosthesis and SMA elements (Fraunhofer FEP, Dresden)

Content

- The Fraunhofer IWU
- Motivation for biomedical Additive Manufacturing
- Laser Beam Melting
- Functional integration through Laser Beam Melting
- Active material combination for a non-loosening implant
- Conclusions

Conclusions

- 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 endoprosthesis
- 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 implant with functional channels and cavities (MUGETO®) and active implant as medically approved product to be implanted in humans**
- **Partners wanted to reach that goal!**

Thank you for your attention!

Questions?

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