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Fraunhofer Research Institution for Additive Manufacturing Technologies IAPT

Dr. Philipp Imgrund, Kevin Janzen, et al.

Development and evaluation of an automated design and binder jetting process for individual finger joint implants

Fraunhofer Research Institution for Additive Manufacturing Technologies IAPT

Hamburg, Germany

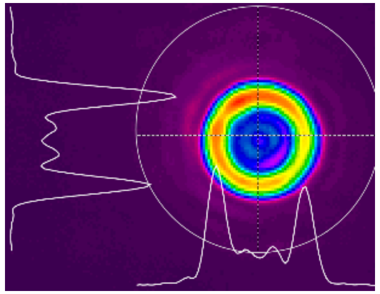
Fraunhofer IAPT

- Founded in 2018 as 70th Fraunhofer Institute
- Approx. 100 employees

- Research fields:
  - Process Qualification
  - Process Chain Automation
  - Virtualization
- Next generation topics:
  - Security/Defense
  - Energy
  - Mobility
  - Life Science

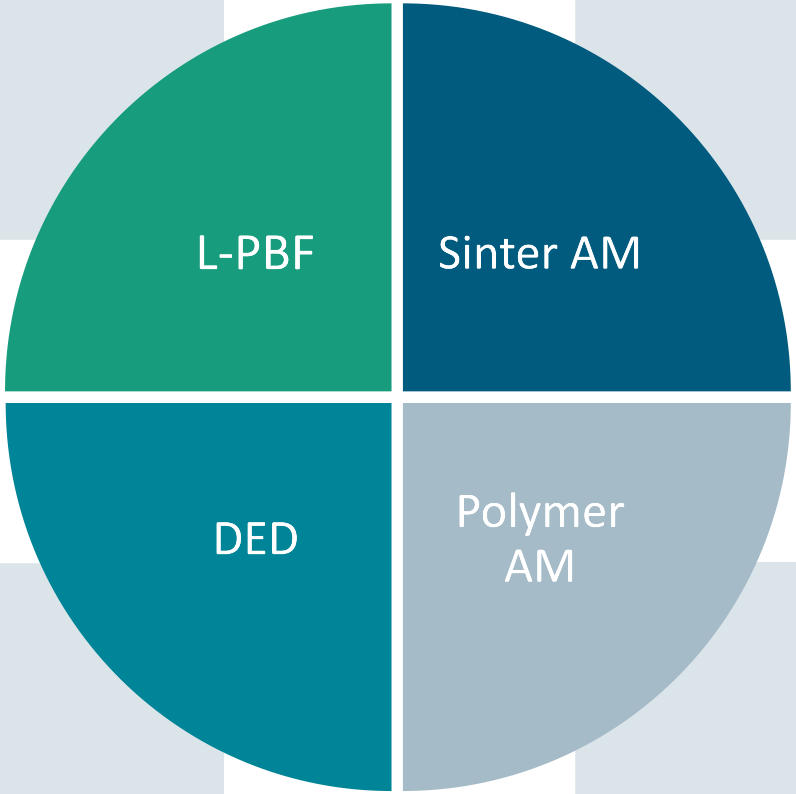
Process Qualification

Teams and competencies



- L-PBF process development for productive and resource efficient processes
- Material qualification
- Adaptive scan strategies

Team Lead: Dipl.-Ing. Philipp Kohlwes
Team: 7 scientists, 3 technicians



- Process development & qualification for Metal MEX, Metal BJT, Metal SLS
- Machine development for printing MIM feedstock

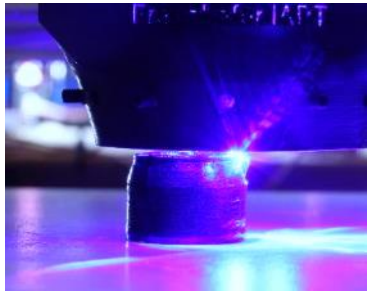
Team Lead: Dr.-Ing. Lennart Waalkes
Team: 3 scientists

Team Lead: M.Sc. Robert Lau
Team: 5 scientists, 1 technician

- DED process development & qualification
- Mobile DED solutions
- Large-scale Ti components

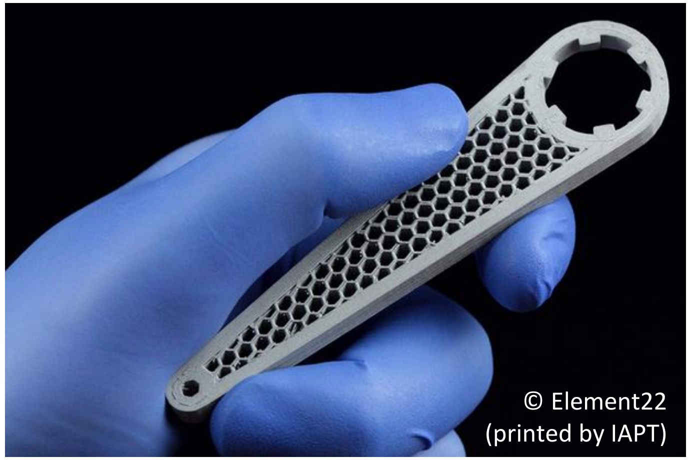
Team Lead: M.Sc. Paul Wegwerth
Team: 4 scientists, 1 project engineer

- Industrial FFF processes
- Powder bed polymer processes
- Material and system adaptions for FFF and SLS



Sinter AM Team

Process overview



Metal Material Extrusion (MEX)

- Machine development for piston-based feedstock fabrication (PFF)
- Process development for well-known and cheap MIM feedstock systems

Metal Selective Laser Sintering (SLS)

- Evaluation of the technology's potential compared to other AM processes
- Optimization of green part properties as a significant process advantage

Metal Binder Jetting (BJT)

- Process development for low-cost steel powders in the automotive industry
- Process chain adaptations for reactive metals such as Ti-6Al-4V

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FingerKIt project: Motivation and goals

Rheumatoid arthritis → Stiffening of finger joints
→ Reduced mobility and quality of life
Stress for the patient during diagnostics (CT)
Limiting factors for implant design: manual effort, time and costs in the design of custom implants

Goal 1:

AI-based, automated implant design

Frequent failure of standard implants due to insufficient individual mechanical balance and osseointegration
High manufacturing effort and costs for individual implants made of metal and ceramics

Goal 2:
Material qualification and near net shape forming

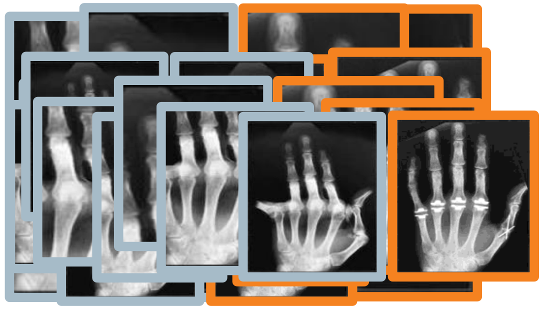
Complex testing for biological and biomechanical properties
Questions about documentation, technology and standardization for AI that cannot be answered from the market

Goal 3:
Certification compliant evaluation

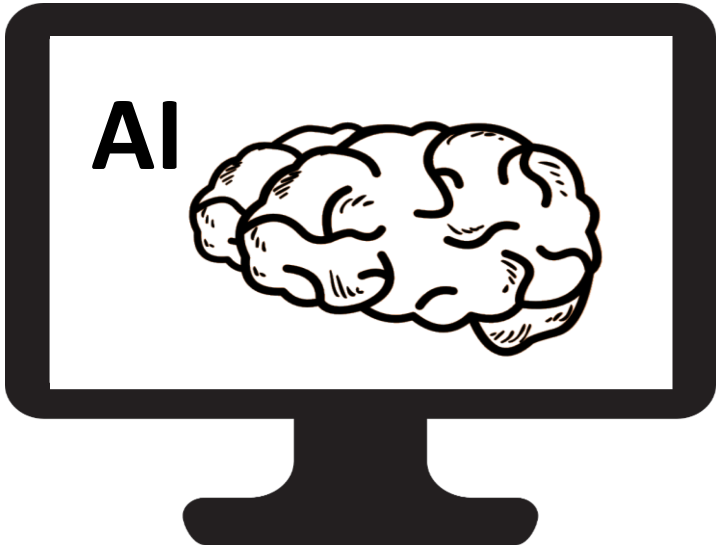
Artificial intelligence @ FingerKIt: from X-ray image to implant

Training phase (MEVIS, IAPT):

- Training on many X-ray images and matching implants
- AI system learns the relationship between joint model and implant
- Training database for defining individual gold standards



Data base



Autogeneration (IAPT):

- Trained algorithm can automatically design patient-specific implant

Input:

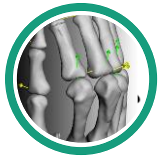
X-rax image

Output:

Implant design

Automated implant design

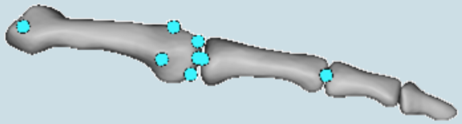
Medical Imaging



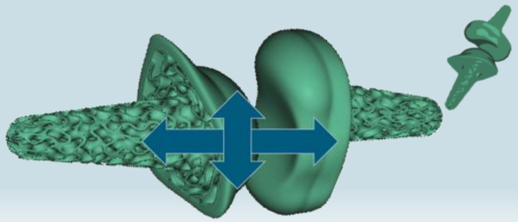
Reconstructed 3D model

Characterization of patient data

- AI-supported identification of patient-specific characteristics



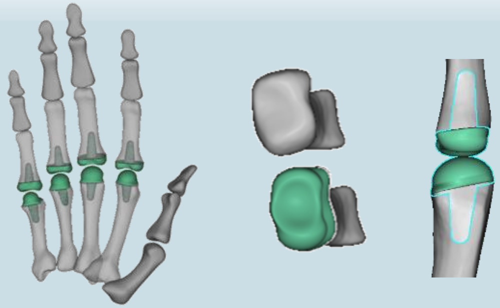
- Generic Definition of Implant Macrostructure and Mesostructure

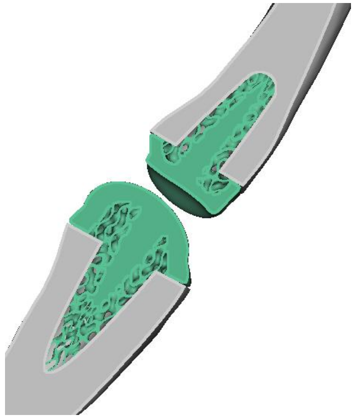


Basic design model

- Medical and technical requirements
- Certification Requirements
- Biomechanical Simulation

Autogeneration of the individual implant





Material and process development for additive manufacturing

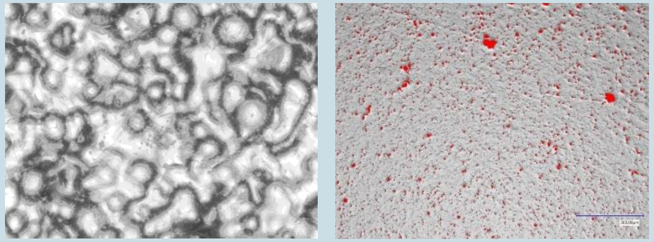
3 Ti-Variants

Additive Manufacturing

- Metal FFF and Metal Binder Jetting

Sample condition

- Surface quality and density

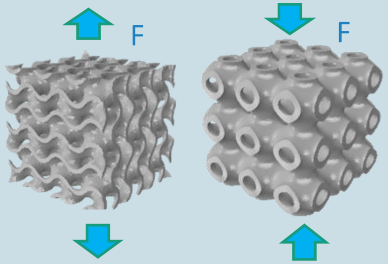


Biocompatibility

- In-vitro testing
- in-vivo testing

Mechanical testing

- Hardness testing
- Tensile testing
- Compression testing
- Push-out testing



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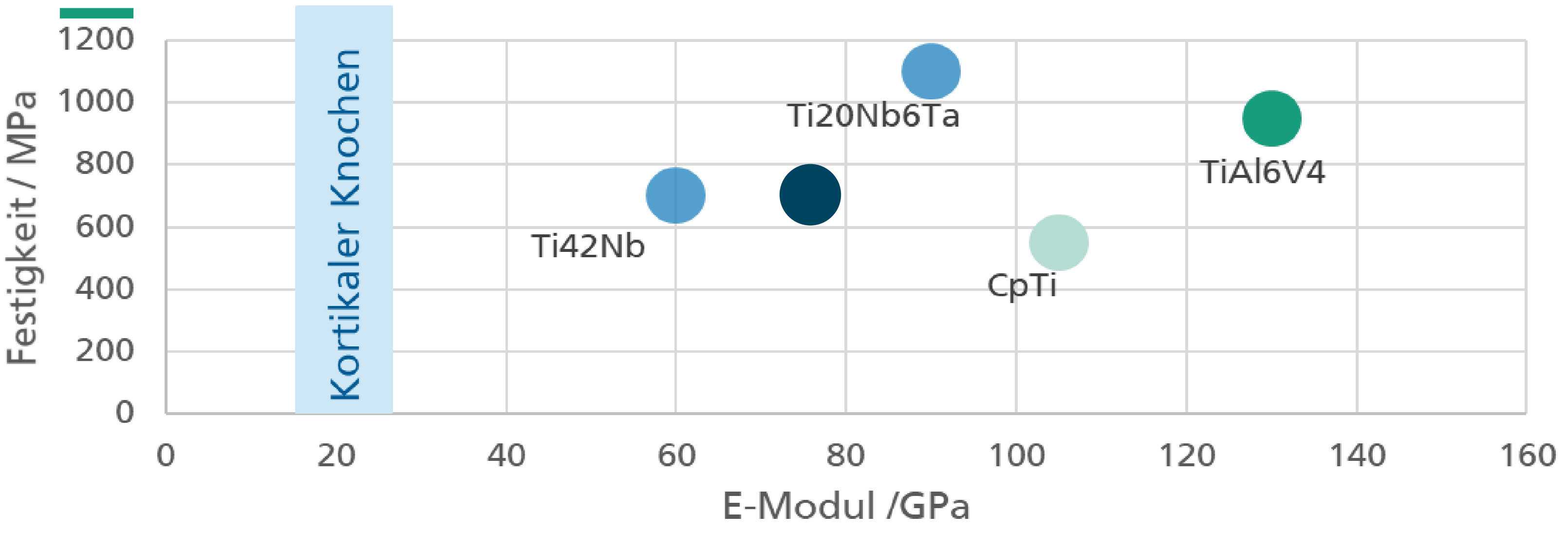
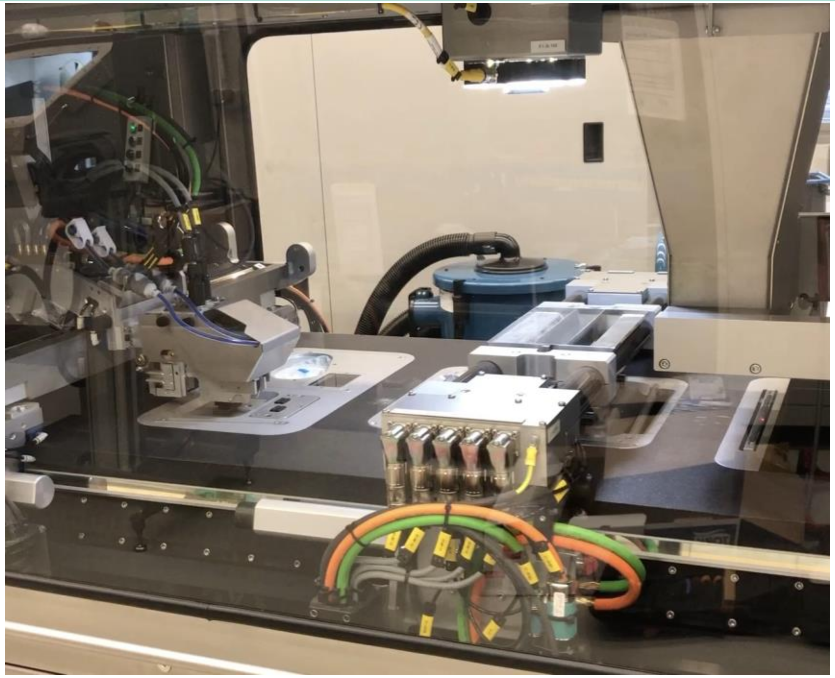
Material selection (preliminary investigation, m-FFF)



Material	Density in % (metallographic)	Hardness HV10	Strength in MPa (mathematically from B3B test)
Ti42Nb	97,14	148 ±6	400
Ti20Nb6Ta	97,49	230 ±10	750
TiAl6V4	99,15	318 ±11	900

Binder Jetting Process



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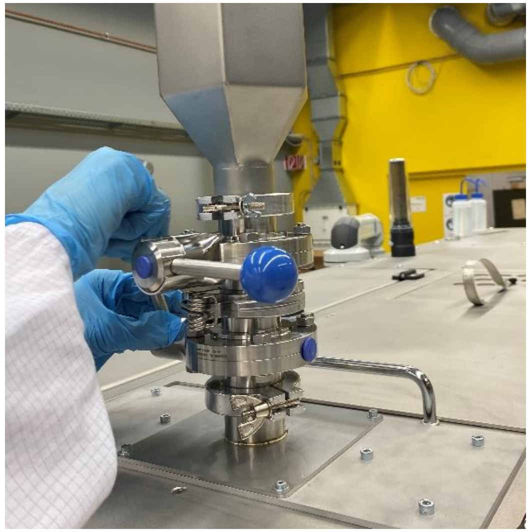
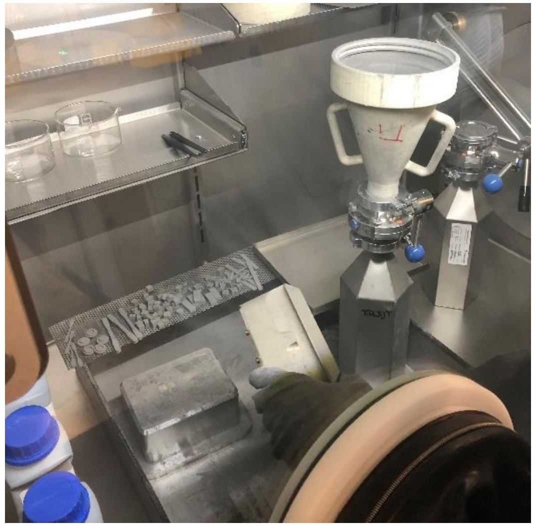
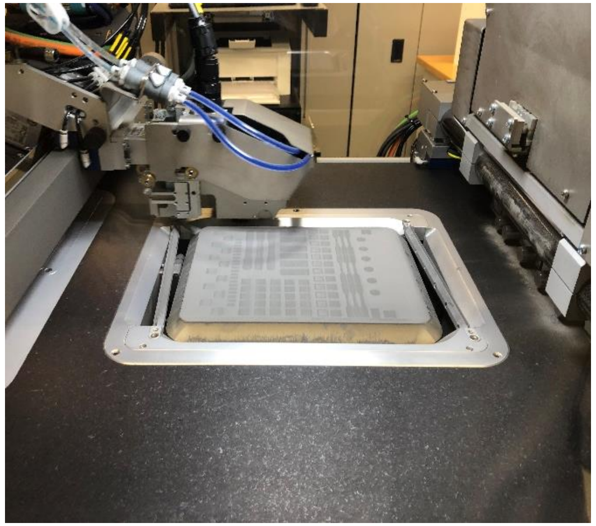
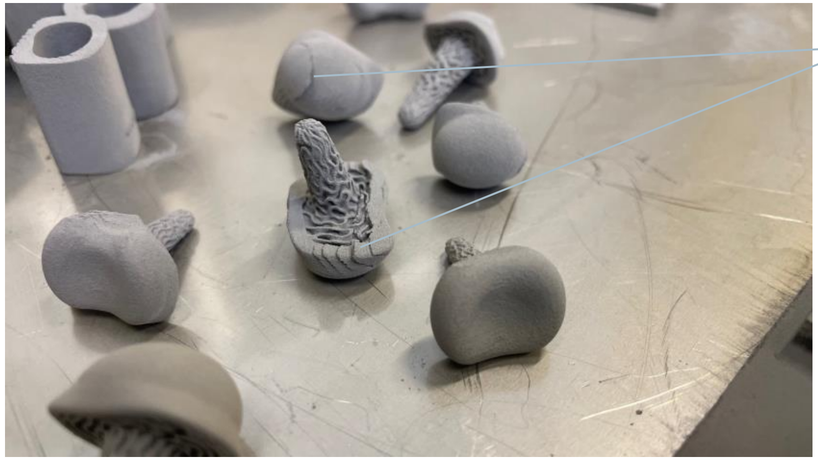
Adaption of Experimental Environment to Metal Binder Jetting of Ti-6Al-4V

- System modification for safe powder handling
- Depowdering under nitrogen
- Parameter development at 36 and 42 µm layer thickness for low PSD (<25 µm)
- Thermal debinding and sintering at low temperature (<1,100°C)

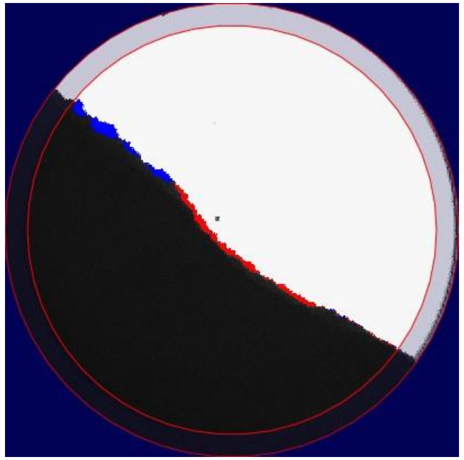





Initial printing results and discussion

- First printed samples show defects due to poor coating characteristics
- Observation could be validated by rotating drum analysis
  →Very poor flowability
- Longer drying cycles before printing could improve flowability (24h @80°C vs. 48h @80°C)



First printed samples of Ti-6Al-4V



Angle of first avalanche in rotating drum analysis

Printing of Ti-6-4: powder conditioning setup

Problem

- Due to the required sintering kinetics of the green parts, Ti-6Al-4V powder with a grain size of 5-25 µm PSD leads to insufficient flow properties

Challenge

- No findings on the influence of powder moisture of recycled or new powder
- No specific conditioning recommendation from the manufacturer
- New powder is dried in a convection oven for 48 hours at 80 ° before the first build job as standard
- Even with dried powder, there are still problems with the quality of the component and print bed

Solution

- Development of new conditioning and especially drying strategy

Used vacuum furnace from Memmert (VO49) as well as measuring setup for Karl Fischer titration for the determination of powder moisture

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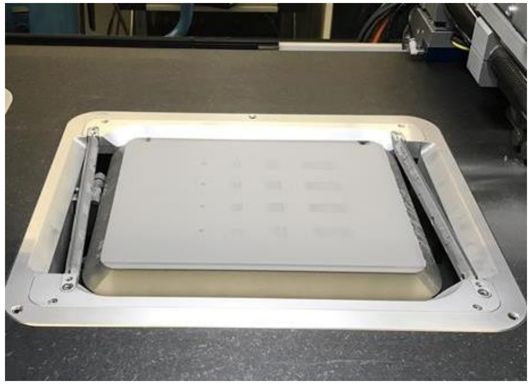
Printing of Ti-6-4: powder conditioning results

General findings

- New powder from the manufacturer has the same water content as powder stored openly in room air (approx. 50ppm)
- Drying in the powder bottle in a convection oven is significantly less efficient than drying in a vacuum oven

48 h 80 °C Convection oven	3 h 60 °C Vacuum oven	8 h 200 °C Vacuum oven
34,5 ppm	31,4 ppm	12,2 ppm



Print bed with vacuum-dried titanium powder

Key findings from the experimental design

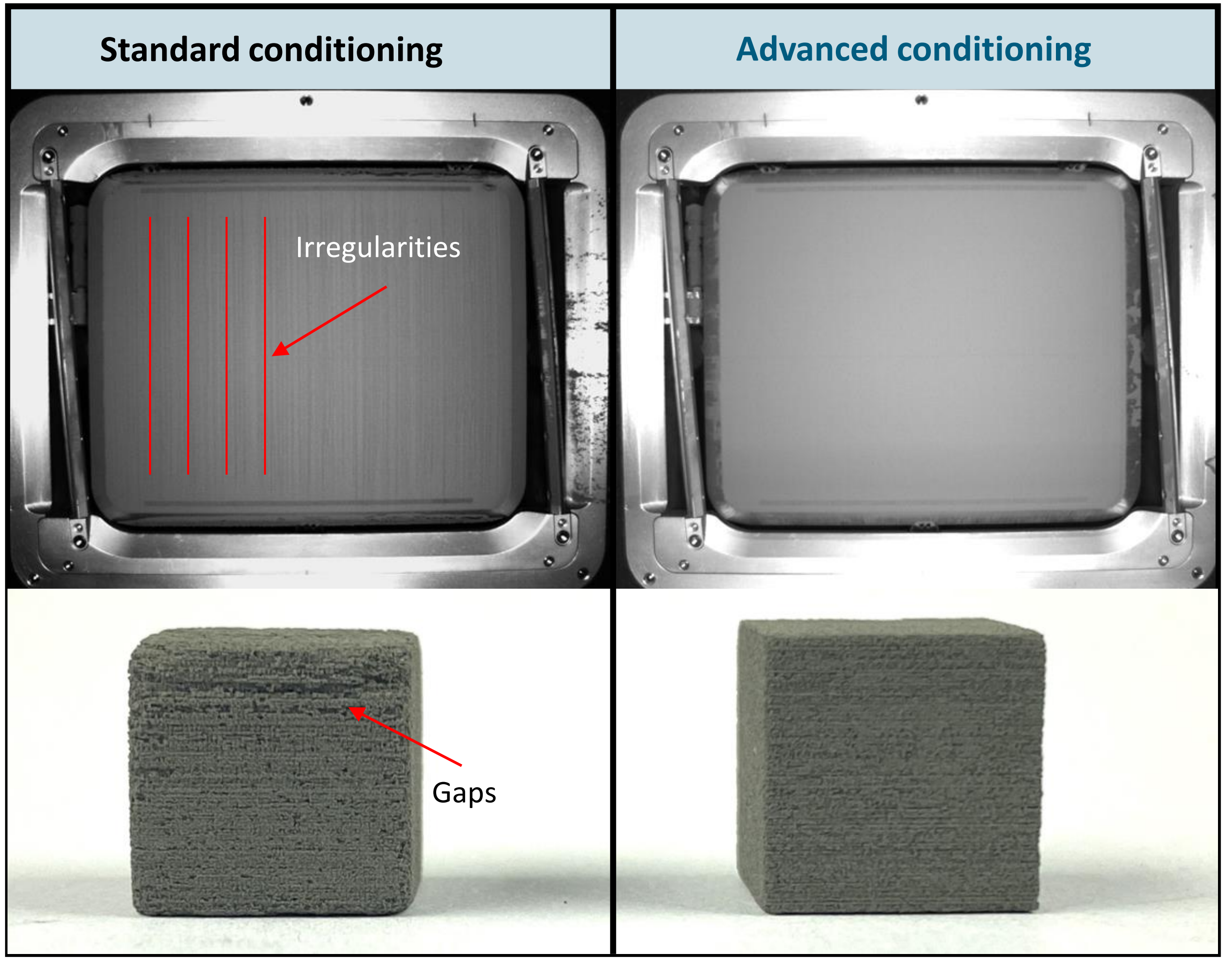
- Temperature has a greater effect on moisture reduction than time
- Flowability (angle of repose in Granudrum) increases proportional to decreasing moisture of the powders
- No increase in oxygen or nitrogen could be detected in the powder
- A visual improvement in the quality of the print bed and green parts could be observed
- Improved dimensional accuracy and enhanced surface quality of green parts were measured

Advanced powder conditioning - summary

Ensuring flowability through powder conditioning for **Metal Binder Jetting**

- Case study **Ti-6Al-4V**
  - **PSD < 25** µm for higher sinter kinetics and more advantageous microstructure
  - Flowability has been improved to such an extent that **powder can be processed with enhanced process stability**

Janzen, K.; Kallies, K.J.; Waalkes, L.; Imgrund, P.; Emmelmann, C.
Influence of Different Powder Conditioning Strategies on Metal Binder Jetting with Ti-6Al-4V. *Materials 2024*, 17, 750.
https://doi.org/10.3390/ma17030750

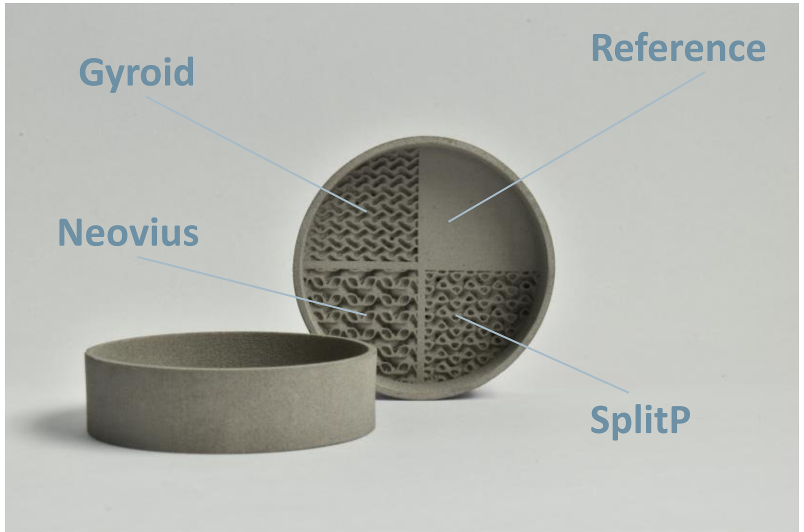


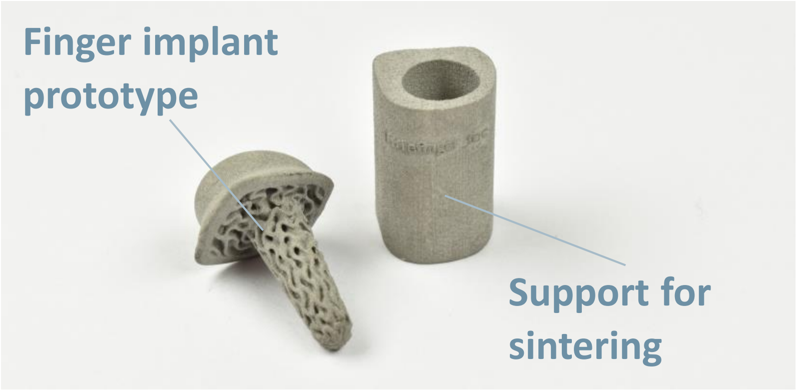
- Sa = 51 µm
- Sa = 12 µm

Titanium Finger Implants made by Metal Binder Jetting

Process stable production of finger implant prototypes and TPMS samples

- Case study Ti-6Al-4V
  - ✓ **TPMS-Structures** for biocompatibility testing
  - ✓ Finger implant prototypes with **high accuracy**





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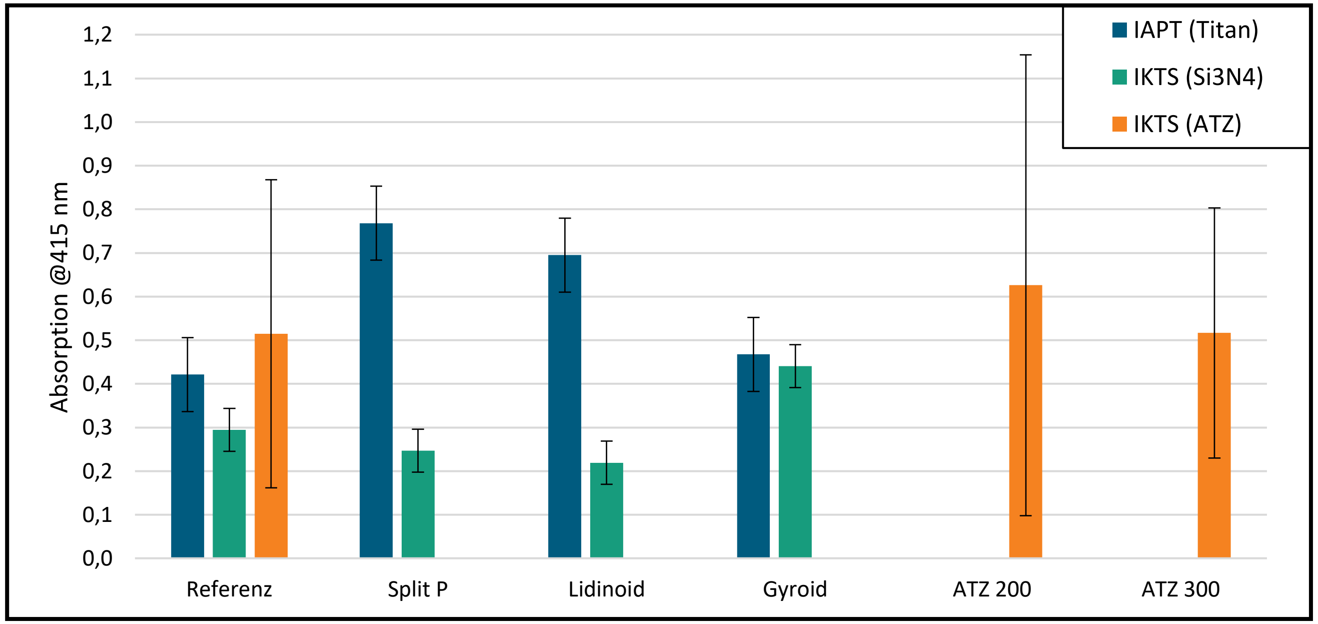
Osseointegration testing

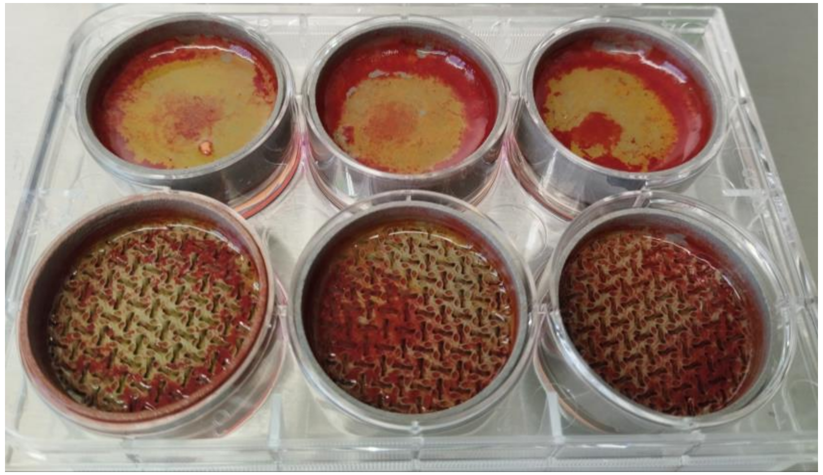
Mineralization test for biological testing of osseointegration

In vitro mineralization studies

- Osteogenic differentiation (duration 28 days)
- Alzarin-Red Tests to Determine Calcium Content
  → Statement about differentiation ability to osteoblasts or bone synthesis ability
- Key result: Titanium test specimen show highest calcium content

Form / Material	Glatt	Lidinoid	SplitP	Gyroid	Glatt	200 µm Gitter	300 µm Gitter
ATZ							
Titan							
Si_3N_4							





Regulatory strategy for the finger joint implant FingerKIt

1 **Purpose:** anatomically adapted replacement and restoration of joint function of a destroyed finger joint (remaining in the body > 30 d)

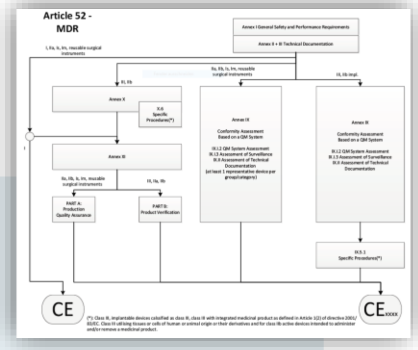
2 **Risk class:** Medical device class III (Rule 8, indent 8)

3 Regulatory classification as a patient-specific medical device: **Patient-matched device (PMD)**

(customized design based on general design)

4 **Conformity assessment process**

(Assumption: EU is planned sales market)



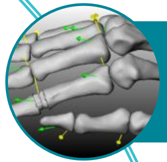
5 **Regulatory requirements:** MDR (EU Regulation 2017/745), ISO-14971, ISO-10993 series of standards, IEC-62366-1/-2;

EU-AIA + IEC 81001 + EN 62304 for AI production equipment;

ISO 17296 series of standards + ISO 52900/02/03/04/07/10/11/21/24/25 for additive manufacturing process

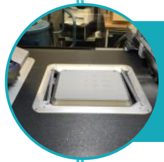
  Public

Summary / conclusions



Individual implant designs successfully derived from 3D-shape model

Printing setup adapted for Titanium binder jetting



Flowability and print bed quality for fine powders optimized by vacuum drying

Proven biocompatibility and osseointegration *in vitro*

Regulatory documentation and classification prepared for transfer to product

For more insights, please stop by:

Here: booth 2-111 (Fraunhofer ADDITIVE)

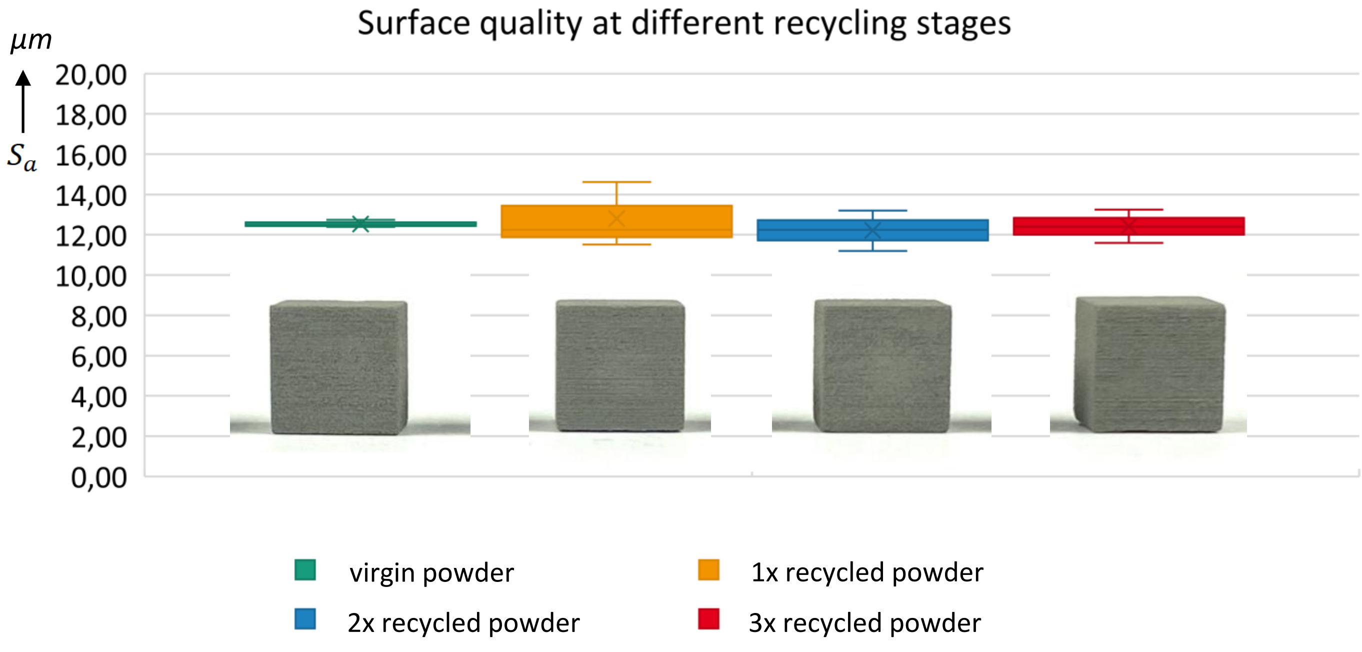
Online: www.iapt.fraunhofer.de

E-Mail: Philipp.imgrund@iapt.fraunhofer.de

Effects of powder recycling

Investigation of the effects of handling and thermal influences during **powder recycling**

- Gas atomized Ti-6Al-4V powder as reference
- Recycling four times leads to a slight change in particle size distribution and an improvement in flow properties
- Quality of the components practically unchanged
- No increase in oxygen or nitrogen even after repeating thermal conditioning/curing 16 times



K. Janzen, K. J. Kallies, L. Waalkes, P. Imgrund, C. Emmelmann: **Recycling of Ti-6Al-4V powder in metal binder jetting**, WorldPM2024, *Abstract accepted*.

Talk to our sinter-based AM team at World PM 2024!

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Thank you for your attention

.. and thank you to the whole FingerKIt project team!

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