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Overview of the EMPIR project: Metrology for additively manufactured medical implants

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Abstract

With the ability to produce on demand, in mass, complex specific patient medical devices such as implants and chirurgical guides, the additive manufacturing technology is of growing interest for the medical sector. As the technology developed at a much faster pace than regulations or quality control, there is currently a lack of validated techniques to inspect the finished parts. The objective of the European MetAMMI project (MetAMMI stands for "Metrology for additively manufactured medical implants") intended to reduce these gaps in order to increase the medical device industry confidence in the AM technology as well as for the certified bodies. This paper presents an overview of this project.

Metrology, additive manufacturing, medical devices, implants, chirurgical guides

1. Introduction

Additive manufacturing (AM) offers an effective solution, particularly for the medical sector. Indeed, the key advantage of this technology is to produce on demand, in mass, customised complex medical devices for specialities such as orthopaedic, spinal, cranial, maxillo-facial, and dental surgery. It also provides grafts that promote bone growth which match the patient's anatomy [1]. These medical devices can be either implants or chirurgical guides which help the surgeon in his work to place the implant. In such a critical sector, the integrity of the parts needs to be ensured in order for the parts to be certified. This implies that quality controls and metrology are required. The project MetAMMI (15HLT09) for "Metrology for additively manufactured medical implants" [2], which received funding from the EMPIR programme co-financed by the Participating States and from the European Union's Horizon 2020 research and innovation programme, addresses the metrology aspects of AM medical devices such as implants and chirurgical guides. It started in June 2016 and ended in May 2019.

In this paper an overview of the project is presented: the partners involved, the objectives as well as the outputs.

2. Partners involved in the MetAMMI project

The MetAMMI project, coordinated by LNE, involves eighteen partners from seven European countries (table 1):

- six National Metrology Institutes (NMI): LNE from France, PTB and BAM from Germany, DFM from Denmark, VTT from Finland and NSAI from Ireland;
- seven academic partners: DTU and DTI from Denmark, University of Aalto from Finland, IMS from France, FAU from Germany, University of Upper Austria and University of Nottingham from UK;
- three industrial partners from the medical sector: Lithoz from Austria, Bego from Germany and Medicrea from France;
- two partners from the health sector: Klinikum Braunschweig and Praxis am Sande from Germany.

Table 1 Parterns involved in MetAMM project

	Affiliation	Country	Name of the participant	
WP leader	BAM	Germany	Janka Wilbig Fabien Léonard Christian Gollwitzer	Jens Gunster Giovanni Bruno
	DTU	Danemark	Leonardo De Chiffre	Alessandro Stolfi
	LNE	France	Anne-Françoise Obaton	Charles Cayron
	PTB	Germany	Fabricio Borges de Oliveira Christian Rothleitner	Ulrich Neuschaefer-Rube
	VTT	Finland	Bjorn Hemming	Jan Akmal

Affiliation	Country	Name of the participant	Affiliation	Country	Name of the participant
Aalto	Finland	Mika Salmi	IMS	France	Patrick Mounaix Jean-Paul Guillet
Bego	Germany	Torsten Bahr	Lithoz	Austria	Martin Schwentenwein
DFM	Danemark	Jørgen Garnæs	Medicrea	France	Alexandre Baelde
DTI	Danemark	Olivier Jay from	NSAI	Ireland	Rory Hanrahan
FAU	Germany	Patrick Zippert	SKBS	Germany	Markus Borowski Lukas Pirl
FH OÖ	Austria	Sascha Senck	UNOTT	UK	Donal Mcnally Xiaobing Freng

3. Objective of the MetAMMI project

The overall objective of the project was to provide a comprehensive basis to enable the safe and cost efficient use of AM products within the medical sector in order to guarantee their reliability to notified bodies and facilitate acceptance of the AM technology which has proven clinical advantages.

The project was divided into five technical work packages (WP).

3.1. WP1: Realisation of AM implants and guides, and traceable standards

The aim of this WP was to provide industrial medical implants and guides, as well as traceable standard objects, fabricated with different AM processes such as powder bed fusion, material extrusion, binder jetting and vat photopolymerisation, from materials such as polymers, ceramics, or metals (Fig. 1). The main challenges of this WP were related to the manufacture of the implants and guides that fulfil medical specifications in terms of dimensional, geometrical and surface accuracy as well as material quality. But also to fabricate standards objects suitable to metrology validated the characterisation, methods proposed in the project.

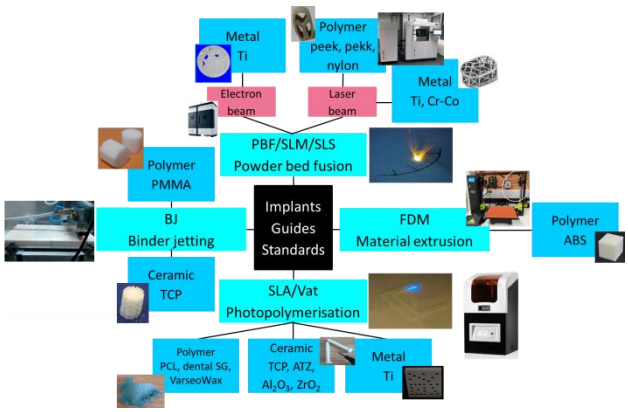

Figure 1. Categories of AM processes and material investigated in MetAMMI

3.2. WP2: Characterisation of AM implants and guides, and traceable standards using non-destructive and destructive techniques

The aim of this WP was to characterise the medical implants, the chirurgical guides and the standard objects manufactured in the frame of the project. The characterisation included inner and outer geometry, surface characteristics, porosity, density, defects and mechanical properties (Fig. 2). The main challenges of the WP were the special characteristics of AM parts (e.g. high roughness, density variations, internal defects, porosity) and the variety of characteristics to determine.

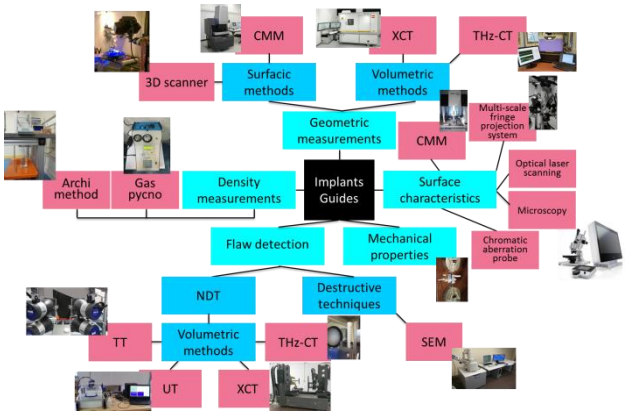

Figure 2. Characterisation methods investigated in MetAMMI
TT stands for thermographic testing, UT for ultrasonic testing, XCT and THz-CT for X-ray and terahertz computed tomography respectively, SEM for scanning electron microscope and CMM for coordinate measuring machine

3.3. WP3: Uncertainty and errors on reference object dimensional metrology

The aim of this WP was to validate the non-destructive characterisation techniques proposed, to develop traceable measurement capabilities and to quantify dimensional measurement errors in the whole process of personalised body part replication and standard production parts.

3.4. WP4: Manufacturing chain-errors (Patient image to final AM part)

The aim of this WP was to identify metrology protocols for the detection and quantification of defects so that feedback can be provided to the manufacturing chain, and to provide information to formulate rules of design.

3.5. WP5: Clinical case studies

The aim of this WP was to quantify the build-up of errors from each part of whole implant and guide manufacturing chain from medical imaging to clinical use (Fig. 3) so that the confidence in AM can be improved.

Figure 3. Manufacturing medical AM process chain

4. Output of the MetAMMI project: deliverables

Eight technical deliverables were written as outputs of the MetAMMI projects:

4.1. A report on the THz-CT technique in comparison to XCT

This deliverable reports on a comparison, performing dimensional measurements, between two computed tomography (CT) systems using two different probe waves: X-ray (XCT) and terahertz (THz-CT). The principle of these two CT systems is similar. It involves three steps: scan, reconstruction and analysis. However, X-ray can penetrate any type of materials whereas THz waves can penetrate polymer and ceramic but are reflected by metal.

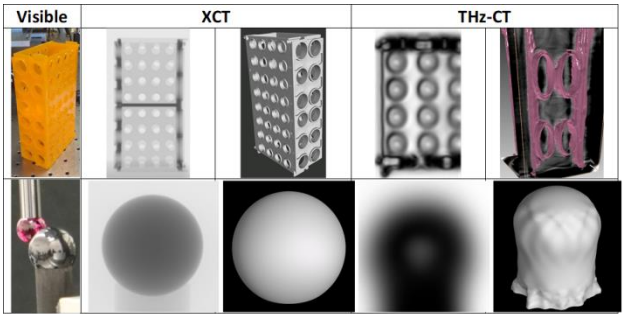

Figure 4. Comparison between optical, XCT and THz-CT images of the same objects

THz-CT allowed to detect defects and density changes but did not allow to perform dimensional measurements from the 3D images. It was possible with XCT. Indeed, the spatial resolution of XCT images is higher than the spatial resolution of THz-CT images (Fig. 4). However, measurements were possible from the 2D images with THz. This is a real new result.

4.2. Good practice guide on the correct choice of characterisation technique depending of the level of accuracy needed and the type of measurement required

This deliverable describes briefly various NDT surface and volumetric methods [3], density, permeability, and mass measurements methods suitable to characterise AM parts. It provides their capability in term of geometry and material that

can be inspected and in term of accuracy. It also gives the advantages and disadvantages of the methods as well as their efficiency (investigation time and cost). Finally, it presents some mechanical testing (Fig. 5), microstructural characterisation and defect detection.

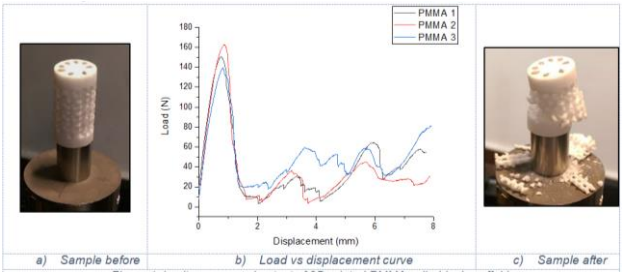

Figure 5. In-situ compression test of AM PMMA cylindrical scaffold

4.3. Good practice guide for medical XCT image acquisition and analysis

This deliverable explains the difference in principle between two CT devices: a conventional medical CT scanner and a cone beam CT (CBCT) scanner used respectively in medicine and in dentistry (Fig. 6). It goes further in proposing recommendations for acquiring data with these two systems. In particular, it points out the XCT set up parameters that need to be considered to increase the image quality in term of resolution, geometric distortions and artifacts. Finally, this deliverable gives recommendations on how to handle the medical images acquired in order to extract, performing segmentation, only the region of interest required to design the AM implants.

Figure 6. Medical conventional CT system (left) and cone beam CT system (CBCT) used in dentistry (right)

4.4. Validated protocols for medical device characterisation along the AM process chain, based on advanced and routine characterisation

This deliverable suggests protocols for the different non-destructive methods investigated in the frame of the project depending of the type of inspection needed (measurement, geometrical deviation, defect detection). An example of such protocol to perform dimensional measurements using XCT is presented in figure 7.

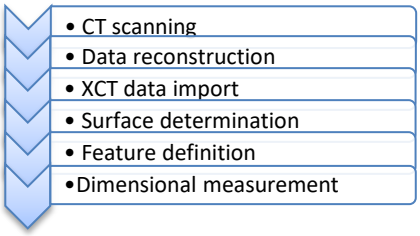

Figure 7. XCT protocol to perform dimensional measurement with a XCT

4.5. Report on the design, the traceable characterisation (surface and dimension) and the use of several standard objects for characterisation/clinical phantoms.

This deliverable is related to reference standards to qualify medical and industrial XCT systems. It describes the design and the use of a suitable reference standard to qualify medical XCT to perform dimensional and surface measurements (Fig. 8). The report also presents suitable reference standards to qualify XCT industrial systems.

Figure 8. Sketch of a medical phantom designed for the evaluation of the dimensional error and resolution of medical CT systems.

4.6. Detection and prevention of geometrical deviations in additively manufactured medical implants

This deliverable summarizes the AM technologies and parts investigated in MetAMMI. The typical deviations on the manufactured parts according to the AM technology and material are listed (Fig. 9) and the geometrical deviations have been quantified. Several characterisation methods are proposed to identify the defects and deviations as well as to perform measurements. Finally, some recommendations are done to prevent the deviations. In annexe, four failure modes an effect analysis (FMEA) are presented.

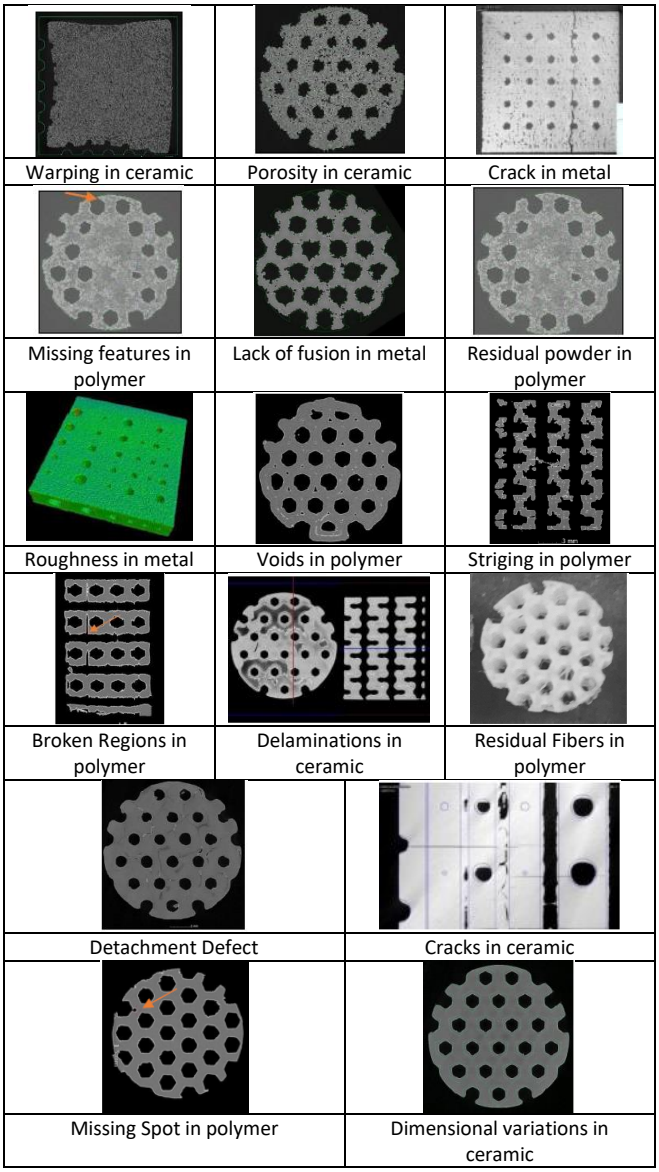

Figure 9. Organic defects in AM parts

4.7. Demonstration of full manufacturing chain monitoring for additive manufacturing of medical Implants and guides

This deliverable presents the process flow charts of the fabrication of four implants using three process categories (Fig. 10). It details the medical purpose of the implant, its fabrication and its acceptance criteria and tolerances in its intended use. Then it identifies the critical steps along the manufacturing chain from the numerical design (CAD model) to final parts fabrication. Finally, it advices suitable measurand and suggest possible characterisation tools to monitor the manufacturing of the implant along the chain in order to produce reliable and defect free parts.

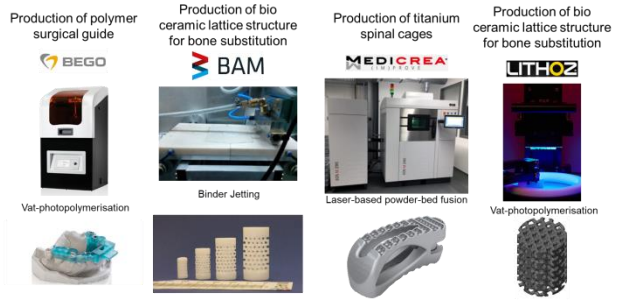

Figure 10. Four different flow charts studied in MetAMMI

4.8. Report on case studies: demonstrating the errors related to each manufacturing step from medical imaging to patient application

This deliverable presents four case studies:

1. Maxillo-facial implant (Fig. 11)
2. Dental guide (Fig. 12)
3. Pedicle screw drill guide (Fig. 13) and intervertebral body fusion cage
4. Cranial implant (Fig. 14)

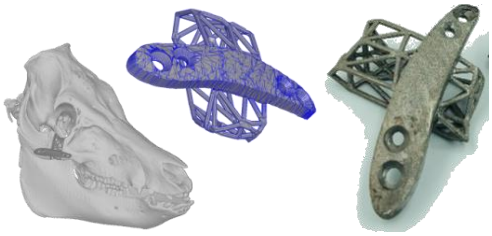

Figure 11. Maxillo-facial implant (VTT, Aalto)

Figure 12. Dental guide (BEGO)

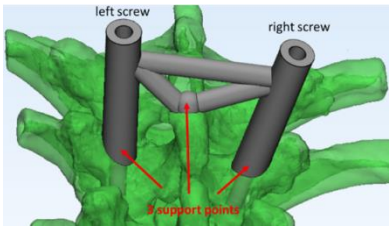

Figure 13. Pedicle screw drill guide (UNOTT)

Figure 14. Maxillo-facial implant (SKBS)

These cases show up and quantify the error related to the different steps within an implantation workflow, from medical imaging of the patient to the final clinical surgery (Fig. 15).

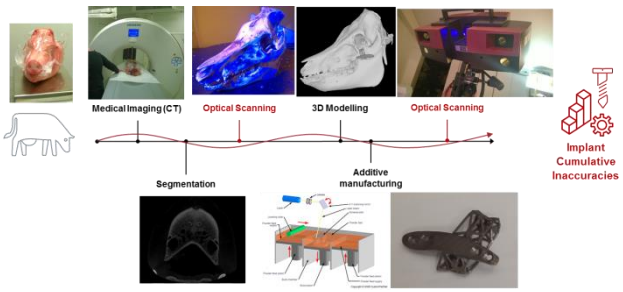

Figure 15. Implantation workflow, from medical imaging of the patient to the final clinical surgery

The typical medical steps in body part replication are:

1. Medical imaging;
2. Segmentation of relevant tissues for 3D model reconstruction;
3. Selection of implant/guide material, type and structure;
4. 3D modelling for implant/guide and preoperative model;
5. Additive manufacturing and finishing of printed parts;
6. Clinical use.

The errors are mainly erasing during the manufacturing process and the segmentation. The errors on the other steps are negligible.

References

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[2] http://projects.lne.eu/jrp-metammi/

[3] Obaton A-F, Lê M-Q, Prezza V, Marlot D, Delvart P, Huskic A, Senck S. Mahé E, Cayron C. 2018 Investigation of new volumetric non-destructive techniques to characterise additive manufacturing parts, *Welding in the World*, Vol. 62, Issue 5, pp. 1049-1057