FINAL PUBLISHABLE REPORT

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For JRPs:

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1 Overview

Additive manufacturing (AM) offers an effective solution in the medical sector. It enables the production, on demand, of customised implants which match the patient's anatomy, with grafts that promote bone growth, as well as surgical guides that help the surgeons. The objective of this project was to provide a comprehensive basis to enable the safe use of medical AM products. Therefore, within this project off-the-shelf medical devices, patient specific guides and implants manufactured from patient images or numerical models were qualified. This helps to guarantee their reliability to notified bodies and to facilitate acceptance of AM in the medical sector.

2 Need

The need for this project was justified by the fact that AM technology for medical applications has advanced at a much faster pace than regulations and quality controls. Patient specific implants (PSIs) and patient specific guides (PSGs) are to be used in highly critical applications governed by strict safety requirements from notified bodies and hence controlling the quality of the parts is of paramount importance. In order for the medical device industry to have confidence in the AM technology they need validated techniques to verify the finished parts and improve the process and the reliability of the manufacturing chain.

In order to validate these techniques, medical devices and standard objects, manufactured using different AM processes and materials, needed to be first fabricated and characterised. Relevant aspects that have to be taken into account for these characterisations were the dimensions of external and internal geometry as well as internal defects, roughness and porosity, which will also influence the mechanical properties of the medical devices. Work was required to a) determine the precision limits of dimensional measurements and the relative sensitivity of industrial and medical X-ray Computed Tomography (XCT), and to b) qualify alternative, faster and cheaper non-destructive characterisation techniques, for routine control.

The manufacturing process of patient specific medical devices with AM contains a number of steps, from the prior computed tomography (CT) scan of the patient to the final manufacture and clinical use, each of which can introduce errors. The material used also has an influence on the parts as well as on the category of processes used. Manufacturers need tools and protocols for the detection and quantification of defects so that the best material and manufacturing process can be reliably selected. It was therefore necessary to characterise the parts at various stages of the production and application process to quantify errors in the chain from medical imaging to clinical use.

3 Objectives

The overall objective of this project was to provide a comprehensive basis to enable the safe use of medical AM products. The scientific and technical objectives of this project are:

1) To fabricate and characterise industrial medical implants, guides, and standard objects using destructive and non-destructive techniques (such as Terahertz Computed Tomography (THz-CT), and XCT) and produce a good practice guide on the choice of a best suited characterisation technique. The implants, guides and standard objects will be made using different AM processes from materials such as polymers, ceramics, and metals and will be dense or lattice structures.
2) To validate non-destructive characterisation techniques, develop traceable measurement capabilities and quantify dimensional measurement errors in the whole process of personalised body part replication and standard production parts including image analysis.
3) To provide feedback to the manufacturing chain that enables process chain corrections to be implemented and manufacturing chain monitoring to be demonstrated. This will be done with the following:
    i. Metrology protocols that identify geometrical deviations between the numerical model and the part manufactured in the process chain;
    ii. Correlation of the geometrical deviations to their origin to optimise the process for personal and mass-produced implants and guides. For powder particles size a range of submicron (<1 µm) to 120 µm and for defects a range between 100 µm and 400 µm will be targeted.

4) To quantify the build-up of errors from each part of the whole implant and guide manufacturing chain from medical imaging to clinical use.
5) To facilitate the take up of the technology and measurement infrastructure developed by the project by the measurement supply chain (accredited laboratories, instrumentation manufacturers), standards developing organisations (ISO/TC261, CEN/TC438, ISO/TC119, etc.) and end users (implant manufacturers and clinicians).

4 Results

4.1 Objective 1

To fabricate and characterise industrial medical implants, guides, and standard objects using the destructive and non-destructive techniques (e.g. THz-CT and XCT), and produce a good practice guide on the correct choice of characterisation technique. The implants, guides and standard objects will be made using different AM processes from materials such as polymers, ceramics, and metals and will be dense or lattice structures. (WP1, WP2)

A total of 94 medical implants, 6 chirurgical guides, and 57 standard objects were manufactured using several materials and several AM technologies. Parts were produced in metals, ceramics, and polymers, with lattice and dense structures, as well as parts with defects. The AM categories of processes involved were: power bed fusion (PBF), binder jetting (BJ), material extrusion and vat photopolymerization. Thus, 157 medical implants, guides, standard objects, and test samples, in total, made of metal, ceramic, and polymer, with lattice and dense structures (instead of originally planned 82 parts) were manufactured by MetAMMI partners and provided to the WP2 leader for further use within the project. As an example, Fig. 1 shows a set of scaffolds with defects. All these parts are described in a table available on the MetAMMI website.

Fig. 1. Parts with defects: 1 without defects, 1 with filled cells, 1 with thicker struts, 1 with thinner struts, 1 with missing struts.

The AM objects manufactured in the frame of the MetAMMI project (i.e. medical implants, chirurgical guides and standard objects) were characterised by different destructive and non-destructive techniques such as volumetric techniques e.g. X-ray computed tomography (XCT), terahertz computed tomography (THz-CT), digital volume tomography (DVT); optical techniques e.g. fringe projection, focus variation; tactile techniques e.g. coordinate measurement machines (CMM), etc. In total, more than 200 measurements were carried out in different objects fabricated by different AM-technologies, see Table 1.

Table 1. Overview of all the parts manufactured in the frame of the MetAMMI project (medical implants, guides and standard objects), of all the characterisations performed on these parts and the name of the partners which performed these characterisations.

Standard objects

Object		Measurements							
Design	*Material*	*Tactile*	*Optical*	*CT/THz-CT*	*Archimede*	*Pycnometer*	*Mechanical test*	*Ultra-sound*

Hole plate	Ti	PTB, FAU	FAU	PTB				
	ABS	PTB, FAU	FAU	PTB, CNRS				
	Al_2O_3			PTB				
Calotte cube	Ti	NSAI	NSAI, PTB	PTB				
	TCP		PTB	PTB	LNE	LNE		
	ABS			PTB	LNE	LNE		
Step gauge	Ti	VTT	FAU	PTB				
	Al_2O_3	DTU	DTU,	PTB				
	ABS	VTT		PTB, CNRS				
	Nylon			PTB				
Plate with defects	Ti			BAM				BAM
	TCP			BAM				
	Al_2O_3			BAM				BAM
	ABS			BAM				
Roughness specimens	Si_3O_4		DFM					
	ZrO_2		DFM					
	Ti		DFM					
	CoCr		DFM					
Dense cubes	Ti				LNE			
Cubic scaffolds	Ti			PTB, BAM	LNE	LNE, NSAI		
				<u>Medical implants</u>				
Cylindrical scaffold	Ti		PTB, DTU, DFM	PTB BAM		NSAI	BAM	
	TCP			PTB	LNE, BAM			
	Al_2O_3			PTB			BAM	
	PMMA			PTB		NSAI	BAM	
	Resin		DTU	PTB		LNE		
	ATZ				LNE			
	CoCr			PTB			BAM	
Dental models			SKBS, Bego	PTB				
Dense spine implant	Ti			PTB, BAM				
	Nylon			PTB, UNOTT				
Scaffold spine implant	Nylon			PTB, UNOTT				LNE
Jaw implant	Ti			BAM				
Cranium Implant	Polymer		VTT	PTB, BAM, CNRS				
Hip cup implant	Ti			BAM				

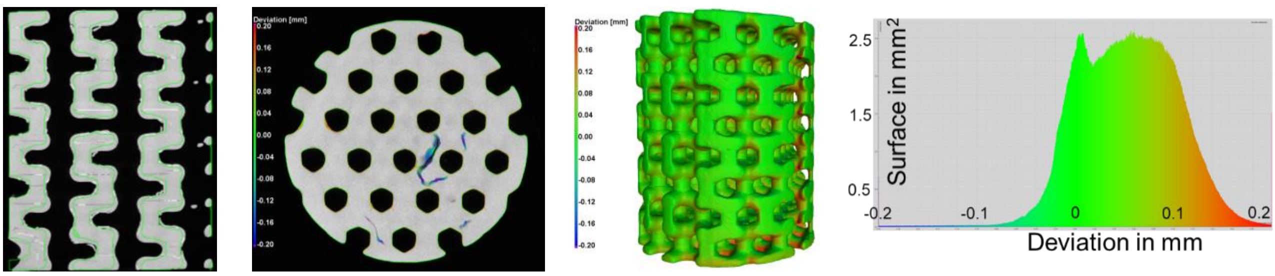
Endoscopy implant	Al_2O_3	PTB, CNRS
		Medical guides
Dental guide	Resin	PTB, CNRS, SKBS
Spine guide	Ti	PTB
	Nylon	PTB, UNOTT
Medical screws	ZrO_2	CNRS, BAM

The objective was to characterise AM-objects to obtain information about:

- Inner and outer geometries of the AM-objects;
- Additive manufacturing errors - object-wise (e.g. using nominal/actual comparison with the nominal CAD model)
- Defect analysis (e.g. cracks, missing regions, extra regions, pores/voids)
- Density, porosity
- Struts thickness (for cylindrical scaffolds)
- Surface characteristics (e.g. roughness, texture)
- Mechanical strength of the objects (e.g. tension, compression testing)

Regarding volumetric characterisation, three modalities of imaging techniques were included in the project: industrial XCT, dental DVT and THz-CT. Only using these modalities, more than 100 measurements were carried out.

Fig. 2 presents an example of an industrial XCT measurement of a TCP cylindrical scaffold. Already from the quick visual analysis of the industrial XCT data, it is possible to observe a (designed) missing region in an inner region of the scaffold, see Fig. 2-a. Also, delamination defects were detected in the scaffold, see Fig. 2-b. The overall manufacturing error could be evaluated by performing nominal/actual comparison, where the XCT dataset was compared with the CAD model used for the manufacturing process. The strut thickness of the scaffold was also measured using XCT by measuring the diameter of several (small) cylinders all over the scaffold, the strut thickness distribution was calculated and reported, see Fig. 3.



(a) (b) (c) (d)

Fig. 2. Industrial XCT measurement of the TCP cylindrical scaffold (a) lateral view of the XCT data; (b) top view of the CT data with some delamination defects visible; (c) complete nominal/actual comparison with the CAD file in colour code and (d) accumulated histogram of the nominal actual comparison.

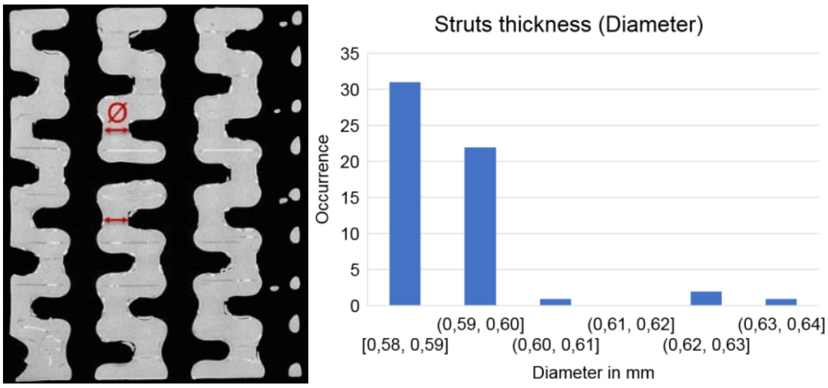


Fig. 3. Strut thickness measurement: (left) industrial XCT dataset and (right) strut thickness distribution.

Also, ceramic and plastic AM-parts were scanned by THz-CT, due to limitation of penetration of the THz waves in metals. The long waves-based technique was able to qualitatively determine the location and the size of defects but the measurement errors were much larger compared to XCT. A report on the THz-CT technique in comparison to XCT describes these observations (deliverable D1). An example of a THz-CT scan in a plastic cranium implant is given in Fig. 4.

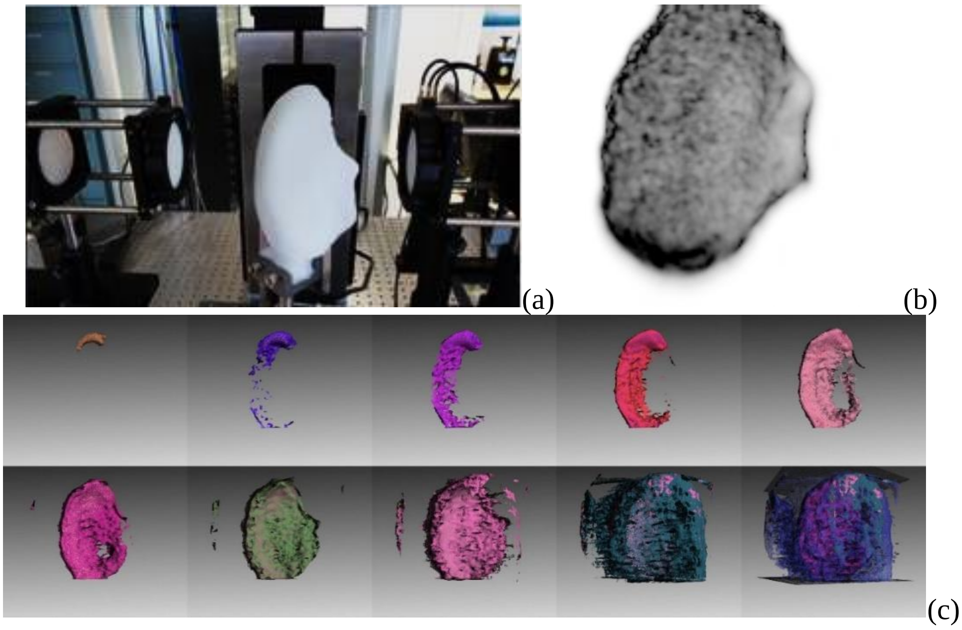


Fig. 4. THz measurement of a plastic cranium implant: (a) setup, (b) 2D image and (c) reconstruction and surface

Dental DVT systems were also used to characterise in particular AM dental guides, as this volumetric technology is being extensively used to plan dental guides in practice. Local and overall deviation of the final guide compared to the planed guide was the main characteristic to be evaluated, Fig. 5.

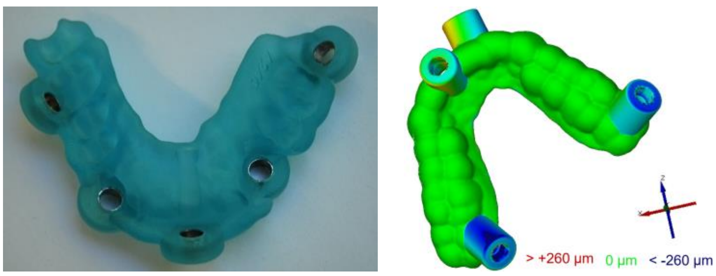


Fig. 5. DVT scan of the resin dental guide(left) picture of the dental guide, (right) DVT image of the guide.

Additionally, tactile traceable characterisations of AM and non-AM reference standards were carried out. An example of a tactile measurement of a metal standard object (Ti hole plate) is presented in Fig. 6. The scale error of the manufacturing process was characterised by the centre-centre distances between the holes, see Fig. 6-a and -b. To evaluate, how good the AM technology can create a regular geometrical form, i.e. a cylinder, roundness deviation measurements of the holes were carried out, see Fig. 6-c and -d.

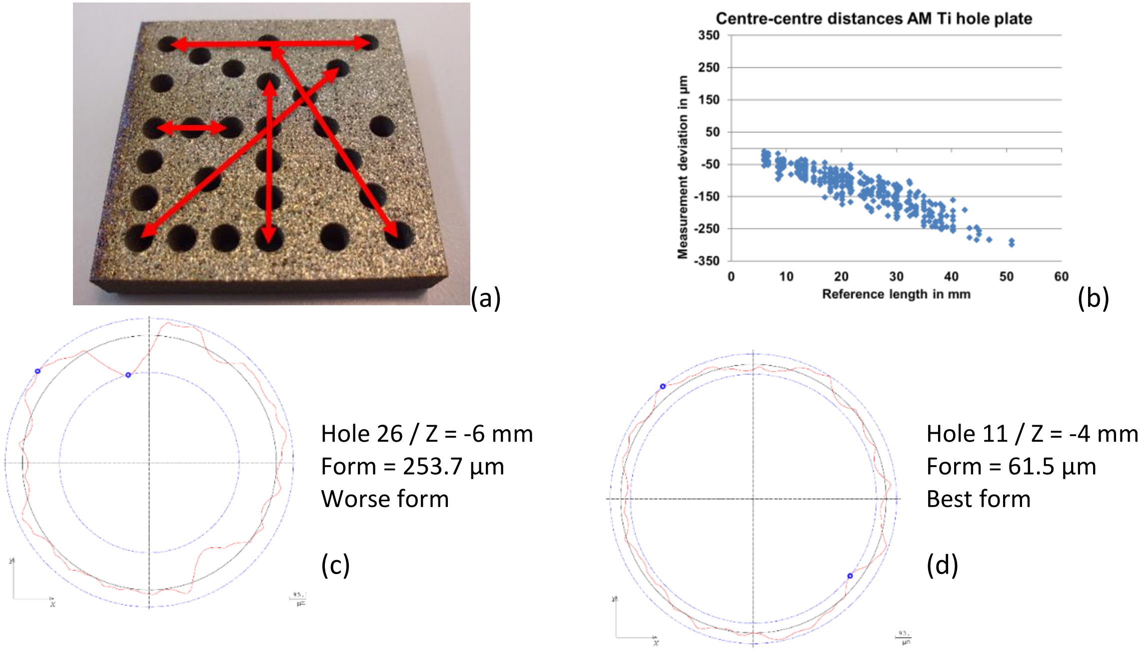


Fig. 6. Tactile measurement of the AM Ti hole plate: (a) picture of the AM Ti hole plate; (b) comparison between tactile measurement and CAD for centre-centre lengths; (c) roundness deviation in hole 26; and (d) roundness deviation in hole 11.

Dental and metrological optical systems were also used to characterise the AM-objects. Characteristics such as surface properties and outer dimensions could be evaluated by these systems. An example of characterisation of the overall manufacturing error of distances between planes of an AM Al_2O_3 step gauge being measured by 3Shape scanner is presented in Fig. 7.

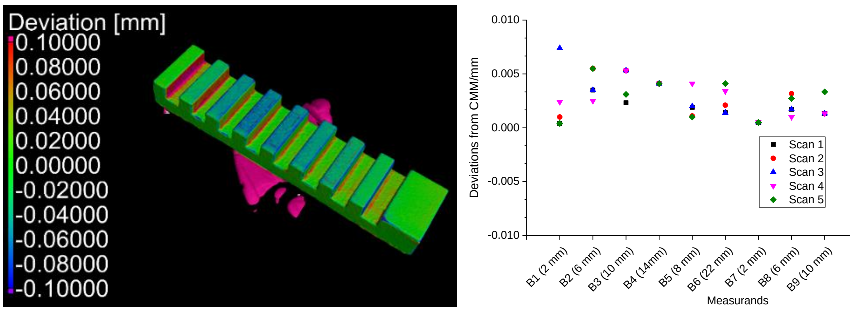


Fig. 7. Optical measurement of a AM Al_2O_3 step gauge (left) nominal/actual comparison of the optical measurement with the CAD and (right) distance between planes being compared with the tactile measurement.

More than 100 AM medical implants, guides and standard objects were successfully characterised by several imaging techniques, tactile systems as well as medical systems. Industrial XCT has shown to be an outstanding technology for the characterisation of AM-objects, however the high price and the complexity of the technology limits a broader use of it. THz-CT has been tested as a promising measurement technology. The results showed that THz-CT imaging is not yet in the measurement level (e.g. developments on reconstruction algorithms for a suitable reconstruction of THz dataset are still necessary). Measurement methods using THz 2D images have been developed during the project. However, the measurement accuracy is not yet comparable to the accuracy of tactile and industrial XCT systems. Optical systems presented very good results as a cheaper characterisation method when compared to industrial XCT. However, optical systems are limited to the outer geometry and surface and there is a stronger influence of the surface characteristics. Tactile CMMs are traceable characterisation techniques, however, the need of accessible geometries and the high roughness of the AM objects are limiting factors of using these systems. The expertise of the partners in the project was integrated and a good practice guide on how to select the best suitable characterisation technology for specific characterisation tasks, with pros and cons for each method, was developed.

A good practice guide (deliverable D2) on the correct choice of characterisation techniques compiles all the NDT surface and volumetric methods, density, porosity, permeability, and mass measurement methods but also destructive methods suitable to characterise AM parts. It gives a brief description of the methods, their capability in term of geometry and material that can be inspected, their accuracy, their advantages and disadvantages and finally their efficiency in term of investigation time and cost.

The objective was achieved.

4.2 Objective 2

To validate non-destructive characterisation techniques, develop traceable measurement capabilities and quantify dimensional measurement errors in the whole process of personalised body part replication and standard production parts including advanced (imaging) and routine (e.g. weighting, US measurements,…) characterisation. (WP3)

To fulfil this objective, the research efforts were focussed onto three different aspects:

1- The uncertainty evaluation
2- The error simulations
3- The image analysis

The aim of the uncertainty evaluation was to quantify the dimensional measurement errors and evaluate the uncertainties associated with the non-destructive characterisation techniques involved in the project. The assessment of measurement errors was done by comparing the measurement results from the respective non-destructive techniques, with that of reference data coming from tactile and optical CMM systems for standard reference samples. First, the measurement uncertainty of XCT and THz-CT techniques were determined. For industrial XCT, the determination covered length, diameter and form, structural resolution, porosity and small gaps using the objects presented in Fig. 8. For medical XCT, a specific phantom (details can be found in deliverable D5) was built with 15 SiN spheres arranged in 3 layers. The resolution was determined by a 4-step process:

1- Measurement of the line profile along 360 spokes for every sphere (Edge Spread Function)
2- Calculation of the first derivative of the 360 profiles (Line Spread Function-LSF)
3- Calculation of the Fourier transforms of LSFs
4- Determination of the resolution: the frequency value for which the FFTs (LSFs) drops to 0.1 is the image resolution

For THz-CT, the determination was limited to 2D images of polymer and flat-shaped ceramic parts. Second, XCT measurements were made on additively manufactured reference parts to compare the measurement errors to that of reference parts manufactured by standard production techniques (subtractive). Results demonstrate that the AM produced reference parts have a much greater measurement error, usually more than one order of magnitude greater than that of standard produced parts, and up to 100 µm (for length measurements between 30 to 60 mm).

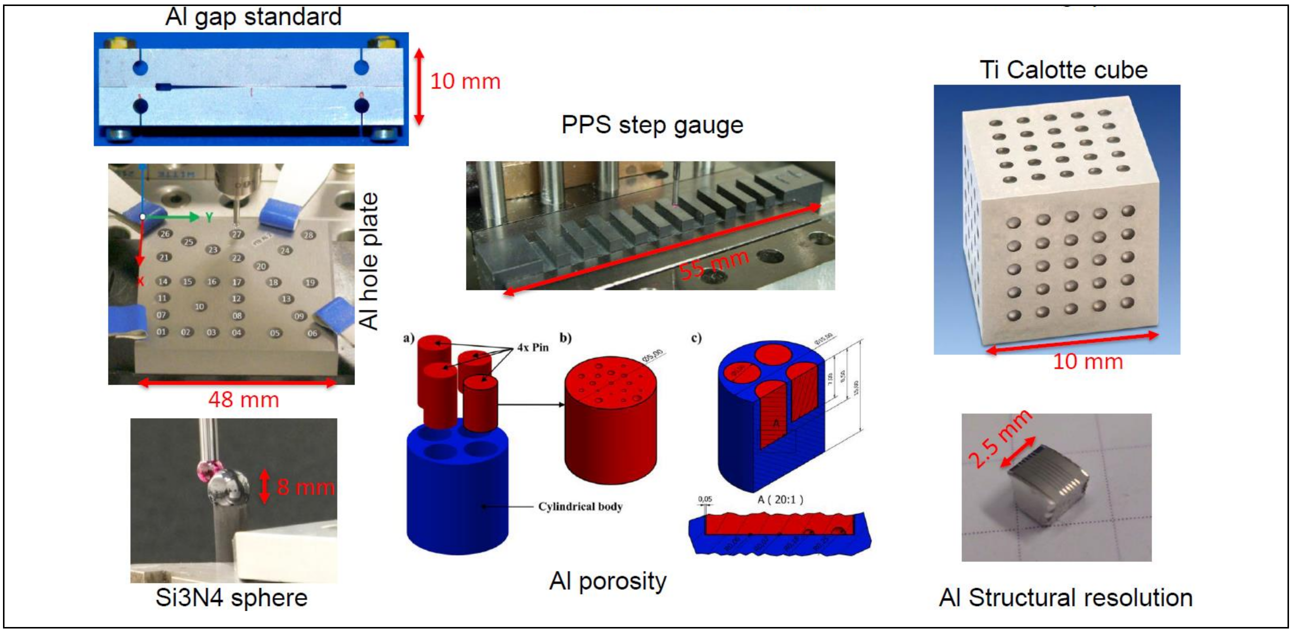


Fig. 8. Objects used for XCT measurement uncertainty evaluation.

Another important aspect of uncertainty was the uncertainty on the surface extraction from medical and industrial volumetric XCT data. Comparison with CMM data for a dry teflon rod showed that industrial XCT data were within +/- 100 µm from the CMM data, whereas the 3 clinical XCT systems investigated were within +/- 350 µm from the CMM data. In addition, the single point uncertainty was also assessed by repeated measurements (20 scans) on both industrial and clinical XCT systems, the results are presented in Fig. 9.

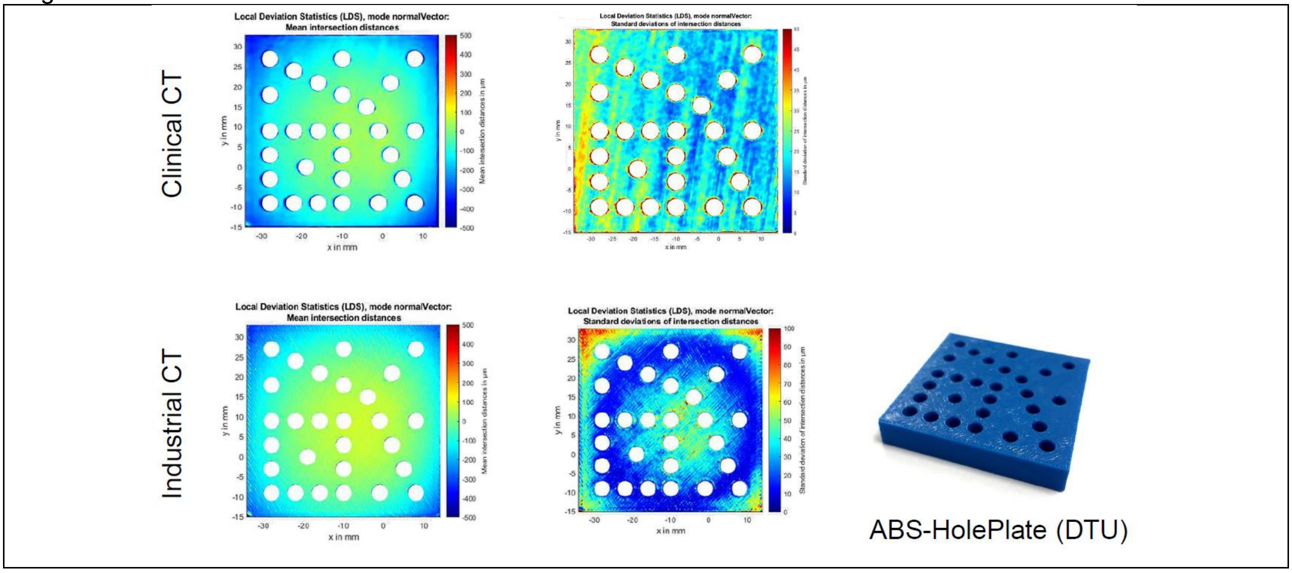
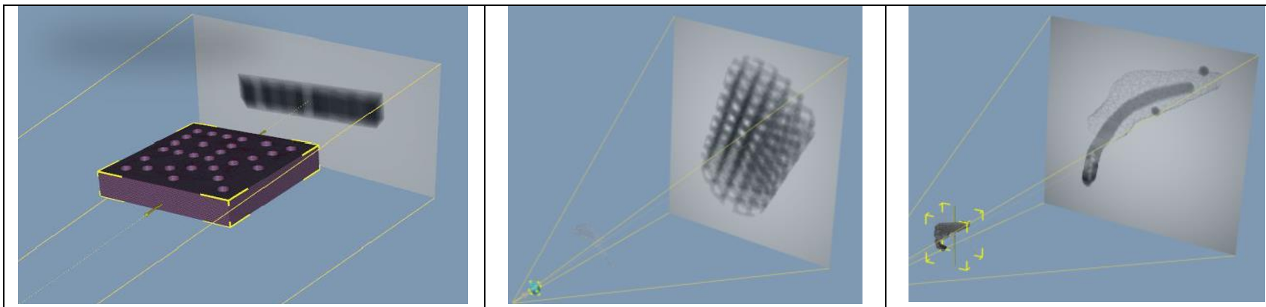


Fig. 9. Single point uncertainty for 3D printed ABS hole plate.

The aim of the error simulation was to estimate the influence of factors inherent to additive manufacturing techniques (such as surface roughness, waviness…) as well as typical measurement artefacts of the XCT technique (beam hardening, partial volume effects…), on dimensional measurements. These factors lead to errors in the surface determination step of the XCT data workflow and therefore influence dimensional measurements and associated tolerances. The influencing factors investigated within the frame of the project were: the part material, beam hardening, partial volume effect and surface roughness.

The aRTist simulation package from BAM was used to generate the XCT data (both raw 2D projection data and 3D reconstructed data) based on a CAD file of a given part, then the 3D reconstructed XCT data was compared to the CAD file used as an input in aRTist. This comparison, called nominal-actual comparison, was performed using VGstudio 3.2 software from Volume Graphics.

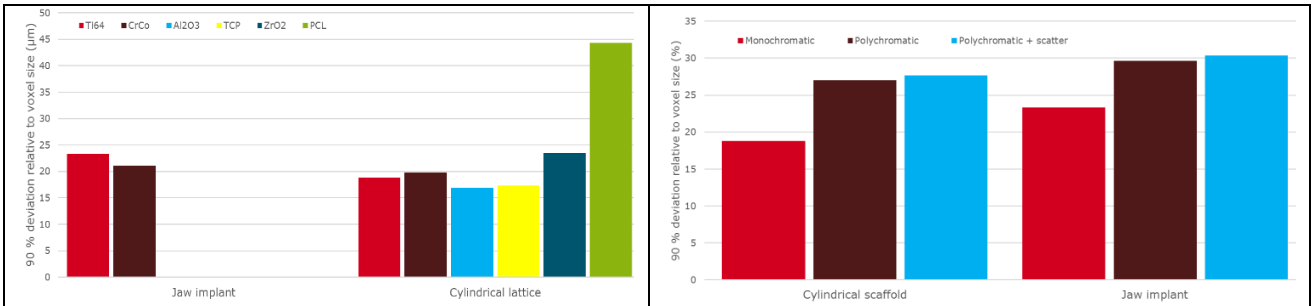
For all influencing parameters, both standard objects and implants were simulated, as shown on Fig. 10. Regarding the part material, metal, ceramic and polymer materials were covered: Ti, Cr-Co, TCP, Al_2O_3, ZrO_2, ABS, nylon, and PCL for the cylindrical scaffold; Ti and Cr-Co for the jaw implant; ABS and Ti for the hole plate. The results (Fig. 11 a) showed that as long as the contrast on a 2D projection is sufficient, the deviation in the dimensional measurements stays below the voxel[1] size.



a) *Hole plate*	b) *Cylindrical scaffold*	c) *Jaw implant*

Fig. 10. Example of parts simulated with aRTist simulation package.

For the beam hardening, which is one of the main artefacts in XCT, the simulations were run for a monochromatic beam, a polychromatic beam without scattering of the sample, and a polychromatic beam with scattering of the sample. The simulations with monochromatic beam (single energy) were free from beam hardening artefacts, and therefore acted as reference measurements. The simulations with polychromatic beam (wide spectrum of beam energies) but without scatter were used to single out the influence of the beam hardening, whereas the simulations with polychromatic beam and scatter were used to investigate the combined effect of beam hardening and scatter. As Fig. 11 b shows, the monochromatic beam simulation has the lowest deviation, whereas there is a slight deviation increase when using a polychromatic beam. The effect of scatter is small, due to the fact that the samples are relatively small and therefore far from the detector. Overall, for this parameter too, the associated dimensional deviations remain well below the voxel size.



a) *Influence of part material*	b) *Influence of beam hardening and scatter*

Fig. 11. Influence of part material and beam hardening on dimensional deviation.

For the influence of partial volume effects, the parts were simulated at different magnification and hence, different voxel sizes in the 3D reconstructed XCT datasets. A total of 11 voxel sizes, ranging from 10 up to 175 µm (10, 20, 30, 40, 50, 60, 80, 100, 125, 150, and 175 µm) were simulated. Results showed that the dimensional deviations increased linearly with the increase in voxel size, but that relative to the voxel size, the dimensional deviations always remain well below half the voxel size.

Finally, for the surface roughness, a new plug-in for aRTist was developed to be able to simulate the surface roughness of a part. The plug-in works by defining a layer thickness and a layer shift in order to generate a displacement between the different layers of a 3D printed part, and hence a surface roughness. Fig. 12 a) and b) shows the differences in a CAD file between an ideal part (smooth surface) and a real part (rough

[1] Voxel: 3-dimensional equivalent of one pixel.

surface), the results of the simulation, respectively Fig. 12c and d, and the good agreement of the simulation with XCT measurements on a real 3D printed ABS hole plate Fig. 12 d.

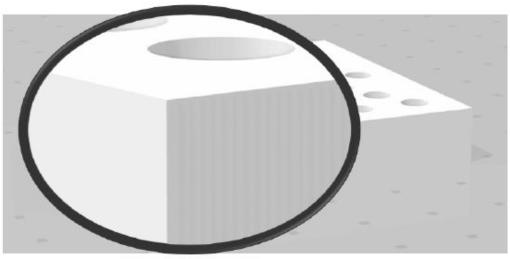
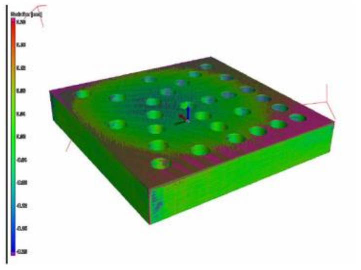
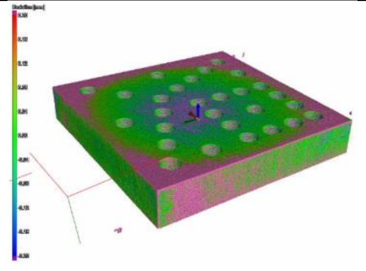
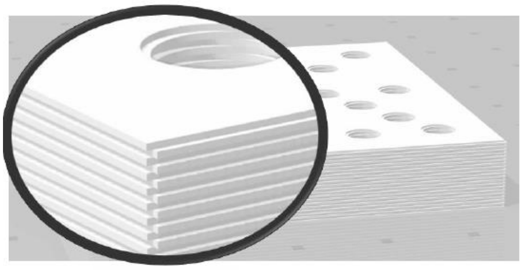
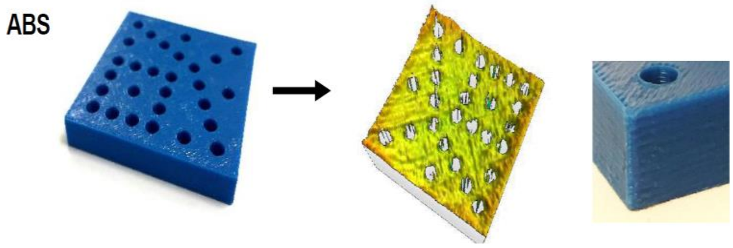
		
a) Ideal part simulation (no roughness)	*c) Ideal part simulation results*	*d) Real part simulation results*
		
b) Real part simulation (roughness)	*e) XCT measurements on real part (good agreement with d)*	

Fig. 12. Influence of part roughness on dimensional errors.

The aim of the image analysis was to establish robust routines for quantitative image analysis of clinical and laboratory XCT data. For clinical XCT, the focus was on image quality, in particular resolution, distortion and the influence of exposure and reconstruction parameters. A large number of scans (> 100) were performed, with several phantoms (3) being scanned by several clinical modalities (5), as detailed in Fig. 13. Overall, the results obtained here, in conjunction with some results from Work Package 5, were gathered to produce deliverable D3, a “Good practice guide for medical XCT image acquisition and analysis”, which gives general recommendations for both conventional computed tomography and dental cone beam CT on resolution, geometric distortions, artefacts, and data handling.

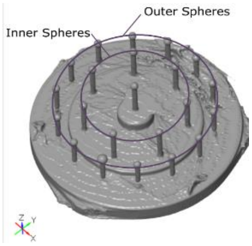
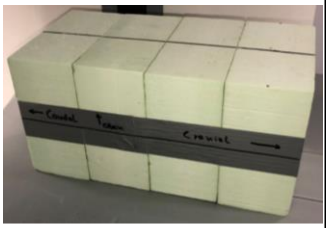
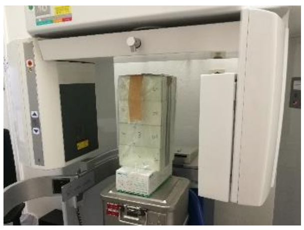
			
a) Multisphere standards for geometric distortion	*b) Homemade sphere phantom for resolution via 2D MTF*	*c) ACR 464 Phantom for electron densities*	*d) 16 Slice vintage CAT Scanner, Somatom Sensation 16*
			
e) 320 Slice modern CAT Scanner, Aquillion One	*f) C-Arm with DVT function, Artis Zee df*	*g) Dental DVT, VeraView Epocs R100*	*h) Dental DVT, Kavo 3D Exam*

Fig. 13. Phantoms and clinical modalities employed.

For industrial XCT, data analysis procedures were developed for specific tasks such as dimension, dimensional error, and 3D bulk defect assessment. The procedure for dimensional error determination is presented as an example in Fig. 14. A report on validated protocols for medical device characterisation along the AM process chain, based on advanced and routine characterisation has been written (deliverable D4). It gathers validated protocols to perform defect detection, dimensional measurements and dimensional error determination by XCT; dimensional error determination with a CMM; volume and density measurements using a pycnometer and by Archimedes' method; and mass measurements by weighting. These protocols now provide manufacturers and end users with clear and robust workflows for obtaining relevant quantities of interest (porosity and pore orientation, amount of defect and inclusions, extension of delamination regions…) or extract quantitative surface data for further use (dimensional metrology, simulations).

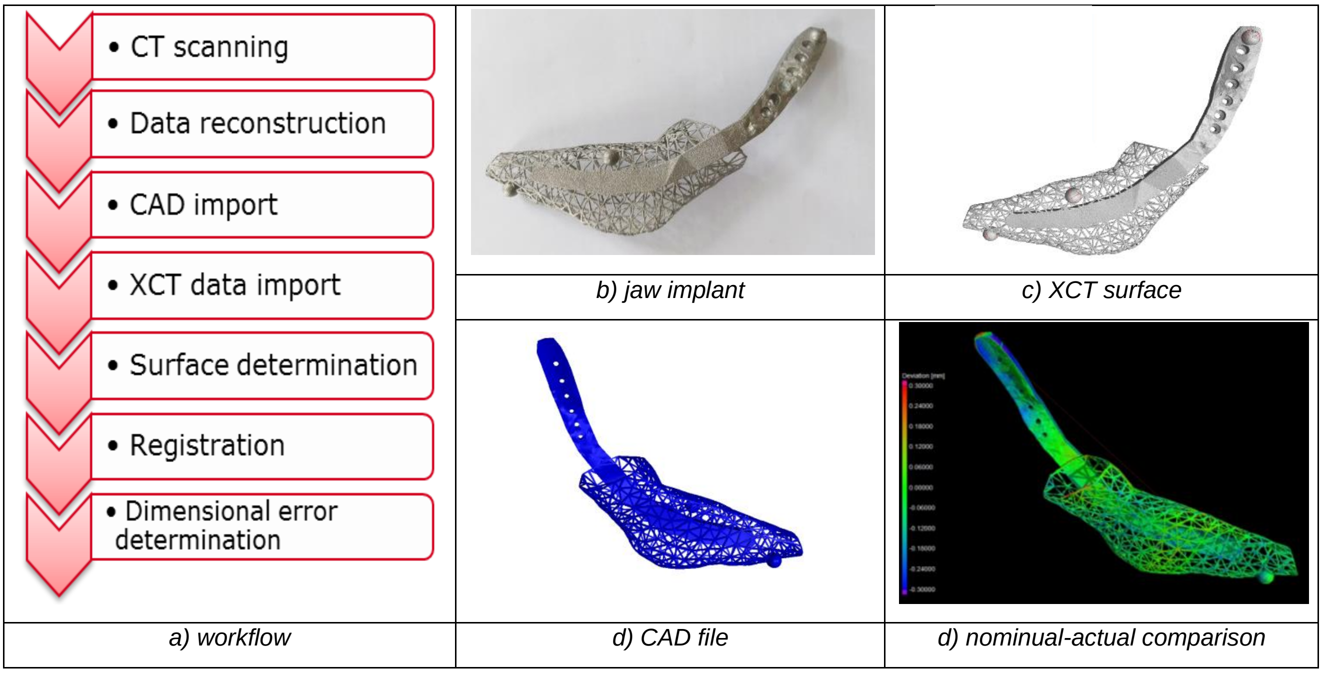


Fig. 14. Overview of procedure for dimensional error determination.

As THz-CT is a relatively new technique but with significant potential for AM applications, the assessment of samples is challenging for industrial XCT, *e.g.* flat polymer or ceramic parts, was performed by THz-CT. Results demonstrated that measurements were possible with the 2D images obtained by THz waves with samples having thicknesses limited by the Rayleigh criterium. In that case, with multispectral analysis, center of holes distances on a hole plate type standard sample could be localised with λ/10 precision.

The objective was achieved.

4.3 Objective 3

To provide feedback to the manufacturing chain that enables process chain corrections to be implemented and manufacturing chain monitoring to be demonstrated. This will be done with the following:

- *Metrology protocols that identify geometrical deviations between numerical model and part manufactured in the process chain;*
- *Correlation of the geometrical deviation to their origin to optimise the process for personal and mass produced implants and guides. For powder particles size a range of submicron (<1 µm) to 120 µm will be targeted and for defects a range between 100 µm and 400 µm will be targeted. (WP4)*

This objective is addressed mainly by two of the outputs of the MetAMMI project, which is a good practice guide on defect detection and prevention (deliverable D6) as well as a report presenting possible full manufacturing chain monitoring on four specific examples (deliverable D7).

In the good practice guide, typical deviations occurring in an AM part compared to the designed part have been collected and described along with recommendations for the identification and prevention of defects.

For the generation of the document, the parts produced within the MetAMMI project have been scanned and analysed by XCT and compared to the respective nominal CAD model, to identify typical defects occurring during manufacturing. Parts produced by binder jetting (BJ), laser-based powder-bed fusion (LBPBF) and material extrusion (FDM) have been investigated as well as parts manufactured using vat photopolymerization (SLA) and lithography-based ceramic manufacturing (LCM). Liquid, solid and powdery feedstocks were processed to fabricate metal, polymer and ceramic parts with dense and lattice geometries. The top view of a lattice design, also referred to as scaffold, produced with the different AM technologies within the project is presented in Fig. 15.

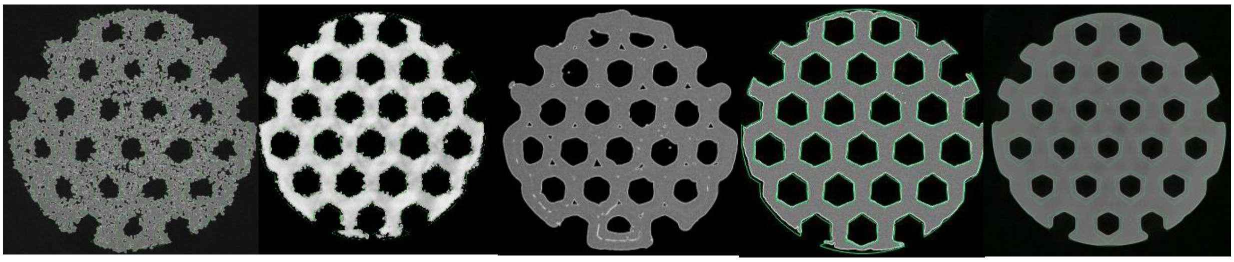


Fig. 15. XCT images of scaffolds printed by BJ (TCP), LBPBF (CoCr), FDM (ABS), SLA (Resin), LCM (TCP).

For the identification of origins of deviations in the respective AM process chain as well as possible measures for their prevention, the approach of a Failure Mode and Effect Analysis (FMEA) has been applied. For every AM method involved in the project, the manufacturer performed a FMEA analysis, which shows the single process steps, errors than can occur in each process step and related measures for detection and prevention. The results are summarised in the good practice guide.

Based on the measurement methods involved in the project, an analytical toolbox has been developed, which recommends possible measurement methods for the detection of a certain type of defect. The ability of different measurement methods to detect a specific type of defect has been investigated by inspection of parts with intentionally introduced typical defects.

To evaluate the defect detection in lattice parts, a scaffold geometry has been designed with nominal height and diameter of 8.5 mm and 6.8 mm. The same structure was modified, four kinds of defects were intentionally introduced and printed as well. Typical defects in such filigree parts, when produced with AM are for example closed cells due to remaining material. Further possible defects as identified within the project are overall thicker or thinner struts in the final structure, which could influence the mechanical stability but also missing features, which can occur during handling of these delicate parts. Fig. 16 shows the top view on the scaffolds with intended defects. The part without defects is presented compared to 20 % thicker struts, 20 % thinner struts, two filled cells and one membrane and missing struts.

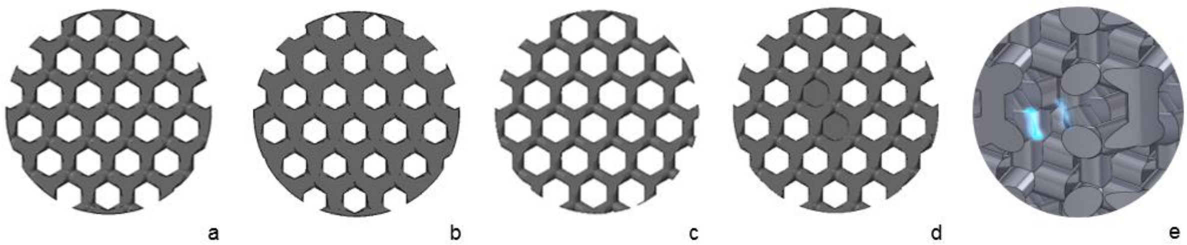


Fig. 16. Scaffold without intended defects (a) compared to thicker struts (b), thinner struts (c), filled cells (d) and missing struts (e). One representative slice of CAD file is shown for each designed object.

From the CAD files of the parts, the expected volume and also the expected mass of the parts can be determined, considering possible shrinkage of parts. Compared to the volume of the reference part without defects, the designed defects lead to changes in the parts volume of around 30 % for thicker and thinner struts and of less than 2 % for the parts with filled cells and missing struts. Thus, major and minor defects have been simulated. By XCT measurement the defects have been verified in the printed parts, before different alternative measurement methods have been applied to the parts.

Measurement protocols for defect detection by simple weighing, by volume determination using Archimedes method and by resonant acoustic testing have been demonstrated.

In conclusion, the results showed that both weighing, and Archimedes measurement to determine the volume can be simple, cost-effective methods for an in-line quality control. They allowed to distinguish between parts without defects and parts with defects leading to changes in mass and volume of around 20 % and more. Detection of minor defects using these methods is limited and depends on the reproducibility of the respective AM process.

Resonant acoustic testing is a volumetric global method, comparative to reference components, which consists of measuring the component's mechanical resonances in air and to compare them to the mechanical resonances of reference components defined as "good parts". A shift in frequency will be observed in the mechanical resonances of a "bad part". The method enables to detect the component's structural characteristics: flaws, process variations in manufacturing of the component etc. Anything that will cause a shift to the mass, stiffness, and damping of a component can cause a shift in the resonant frequencies.

To show possible applications of the measurement methods investigated, the process chains for the manufacturing of four different products relevant to the medical device industry have been reported with possible monitoring methods along the process chain. For each of them the specific medical application was described and resulting from these, specific requirements that need to be reached. Acceptance criteria and tolerances for the particular intended use were defined, the process flow chart presented, and critical process parameters identified as well as suitable measurands and measurement tools to control the process.

In a first example, a possible process chain for a ceramic lattice implant with a geometry as presented in Fig. 17 for bone substitution intended for the treatment of osteochondrosis dissecans and manufactured by LCM technology was elaborated by BAM, Lithoz and Mathys. As second example, the production of a surgical guide (dental drilling guide) as visible in Fig. 10 made of resin with the BEGO Varseo printing system (stereolithography process) has been investigated and also the process chain for the production of a metal spine implant manufactured by Medicrea (**Error! Reference source not found.** 11). Finally, the process chain for the manufacturing of a porous ceramic implant for bone substitution realized by binder jetting was presented.

Fig. 17. Scaffold.

Fig. 18. Surgical guide.

Fig. 19. Spine cage.

In all cases, possible monitoring methods along the process chains were identified, based on the manufacturer's already implemented methods as well as possible new methods investigated within the frame of MetAMMI. Focus in this report is on control of material, process parameters and especially sample properties by non-destructive testing methods.

The good practice guide on defect detection and prevention, and the report on full manufacturing chain monitoring provide recommendations both for defect detection and process chain corrections to prevent them, thereby meeting the objective initially described.

The objective was achieved.

4.4 Objective 4

To quantify the build-up of errors from each part of whole implant and guide manufacture chain from medical imaging to clinical use. (WP5)

Four cases were studied:

Case 1: Maxillo-facial implant (VTT, Aalto)

Case 2: Dental guide (SKBS, PAS, PTB, BEGO)

Case 3: Spinal implant (UNOTT)

Case 4: Cranial implant (SKBS, PTB)

To assess this objective, PTB, SKBS and FAU evaluated the performance of different medical-based XCT systems and DVTs related to system distortion and surface characterisation, varying scanning parameters in each system. This data was partially the basis for the report on the design, the traceable characterisation (surface and dimension) and the use of several standard objects for characterisation / clinical phantoms (deliverable D5). Besides this, PTB and SKBS assessed the error propagation of case 2 “Dental guide” by quantitatively assessing each step of the process chain of dental implantation. In this study, the conventional impression / cast method and the digitalised method of dental implantation were evaluated. For the conventional method, PTB performed XCT measurements of the intra-oral-based and sphere model-based dental guides, dental impressions, dental casts, as well as tactile reference measurements of the sphere model. Also, different impression materials (e.g. alginate, polyether) were scanned and the influence of different impression materials was evaluated. The influence of different design and materials of impression spoons on the dental implantation chain was investigated. A comparison between the standard metal spoon and the personalised polymeric spoon has been performed. In addition to that, three different cast gypsums were tested. For the digitalised method, the performance of DVT and optical scanners were evaluated based on implantation in training models. SKBS with assistance of PTB wrote a good practice guide on the entire dental implantation process chain.

SKBS decided with PTB the parameters to be evaluated for case 4 “Cranial implant” and evaluated the fit of 5 AM-cranial implants in clinical CT scans of real patients (real case). PTB provided reference data of in-vitro phantom for the study of the surface extraction of cranial scans.

VTT and Aalto performed uncertainty analysis for the skull and implant in clinical skull case. Scans of pig head and phantom were performed with a medical XCT's at the Helsinki University hospital (Fig. 20).

Fig. 20. XCT scan of pig head at the Helsinki University hospital.

Depicting a cranio-maxillo-facial deformity, a titanium implant (Fig. 21) was additively manufactured through laser-based powder bed fusion method. Both head and phantom were measured also measured by CMM and optical fringe projection instruments (Fig. 22). Based on these data VTT and Aalto performed an uncertainty analysis. It revealed that inaccuracies increased at each process step, totalling a cumulative error of -0.269 mm and a combined standard uncertainty of 0.784 mm for the 56.852 mm long freeform end-use implant.

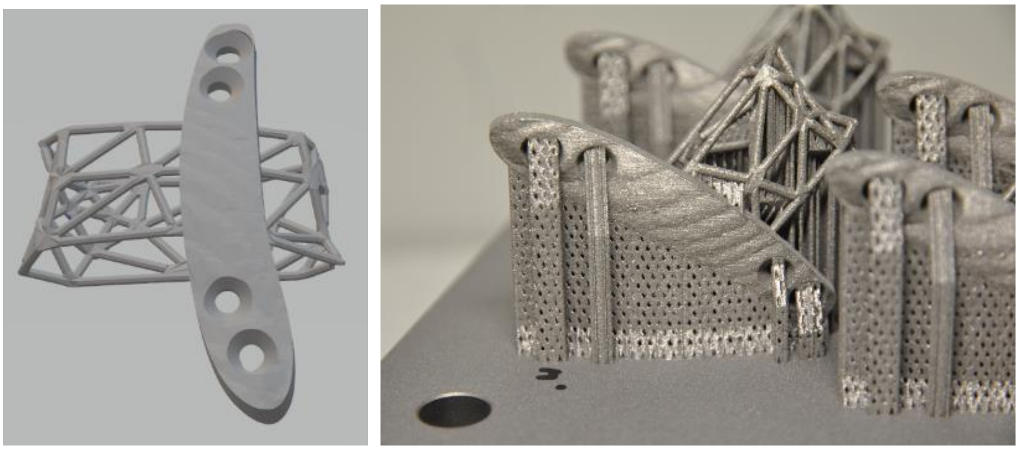


Fig. 21. Design of implant (left) and printed implant with support structures (right).

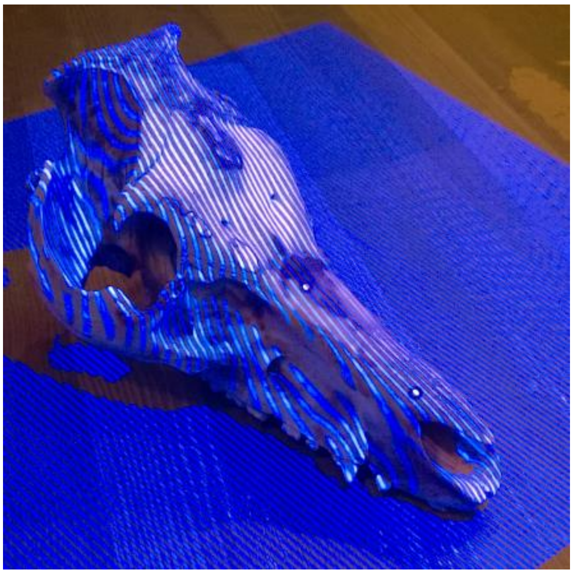


Fig. 22. Scan of pig head using fringe projection.

VTT and Aalto together with Helsinki University (Hospital District of Helsinki and Uusimaa, HUS) wrote an article with title: “Cumulative inaccuracies in implementation of additive manufacturing through medical imaging, 3D thresholding and 3D modelling of an end-use implant: a case study” which was submitted in May 2019.

All these case studies are summarized in a report entitled “Report on case studies: demonstrating the errors related to each manufacturing step from medical imaging to patient application” (deliverable D8). The biggest error sources were the XCT thresholding error of the segmentation process followed by the error of additive manufacturing. The volumetric error of the XCT was only a minor error.

Furthermore, a good practice guide for medical XCT image acquisition and analysis (deliverable D3) was provided in the frame of the MetAMMI project which 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. 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 terms of resolution, geometric distortions and artefacts. Finally, this report 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.

The objective was achieved.

5 Impact

Dissemination activities

Partners have participated in several conferences where the project and its results were presented. BAM organised a three-day workshop in Berlin in May 2019 where all the partners presented the more relevant results of the project to an audience of over 80 attendees, covering the entire AM process chain. The whole project as well as the results will be presented at the joint special interest group meeting between euspen and ASPE advancing precision in additive manufacturing in September 2019. Furthermore, eight articles have been written in order to disseminate the inputs of the project (3 published, see reference below, 4 submitted, 1 in draft).

Impact on industrial and other user communities

The results of the project will increase the uptake of the AM technology for manufacturing on demand and customised implants. This feedback provided to the whole additive manufacturing chain (from imaging to post processing) by the guides developed and studies conducted in this project will give the healthcare industry the opportunity to manufacture guides with higher accuracy, which will enable accurate cutting and placement of implants and thereby reducing the operating time as well as customised accurate implants that meet the patient’s anatomy and thus reduce the recovery time after surgery.

The clinical dental based study resulted in a good practice guide that has to be communicated and disseminated in the relevant scientific community, e.g. by presentations on relevant conferences like the annual conference of the German Society of Medical Physics.

The good practice guides developed within this project and the input to standards will provide notified bodies evidence of the improved reliability of AM. The cost of each surgical operation will be reduced as accurate guides reduce operating time and on demand accurate and customised implants will reduce the requirement for a large inventory of different sizes and sterile storage. The reduction in operating time will therefore allow more patients to be treated since operating room time is often the limiting resource.

The reduction in inventory will reduce the amount of manufacturing required, thereby having a positive impact on the environment. In addition, in some AM processes, the raw feedstock is recycled so there is no waste matter.

European companies are at the forefront of medical device development; this project supported their work and drove uptake of higher performance medical devices. Within the framework of the project, additively manufactured scaffolds for osteochondral defects in the knee joint for example have been evaluated together with Mathys Orthopädie GmbH, Germany. Regarding this bone defect, the project will help additively manufactured scaffolds to find their way into application. Comprehensive regulations and pre-normative measurement procedures will allow this robust growth to continue, which will increase the market acceptance of all manufactured parts.

Several partners propose new calibration services based on the techniques developed in the project.

Impact on the metrology and scientific communities

The qualified and traceable 3D volumetric non-destructive techniques (e.g. XCT) developed in this project for dimensional measurements will enable the metrology community to characterise the geometry of complex objects manufactured using AM. Furthermore, XCT is a new technology in the area of metrology. Thus, geometrical measurements are lacking traceability to SI and documented uncertainty assessments. The activities in the project will contribute to the work of making XCT measurements traceable and give valuable inputs to the evaluation of uncertainties that will be used in the JRP 17IND08 AdvanCT. This will increase the number of NMIs able to obtain these systems. By publishing material on traceable measurements of AM parts, the importance of metrology and measurement uncertainty will be brought to a wider scientific audience.

Impact on relevant standards

Several of the project partners are members of both the ISO/TC 261 and ASTM F42 AM committees, as well as ISO TC213 WG10 on XCT and VDI/VDE-GMA FA3.33 on coordinate metrology using CT. The results from this project were fed into either existing or new work items as appropriate.

The development of standards will help the AM industry demonstrate, to other industrial sectors, that it is a mature production technology that has the expected quality assurance and can be considered for production. Several partners have provided inputs to their standardization groups on additive manufacturing and on XCT.

Longer-term economic, social and environmental impacts

The identification of errors along the manufactured chain, from medical scan of the patient to, the final surgery of the patient, to place the implant, will help the medical sector. AM customised implants will benefit the patients in terms of better recovery and shorter recovery times.

6 List of publications

A-F. Obaton, J. Fain, M. Djemaï, D. Meinel, F. Léonard, E. Mahé, B. Lécuelle, J-J. Fouchet, G. Bruno, "In vivo XCT bone characterization of lattice structured implants fabricated by additive manufacturing: a case report", Heliyon 3 Aug 2017, DOI: 10.1016/j.heliyon.2017.e00374.

A-F. Obaton, M-Q. Lê, V. Prezza, D. Marlot, P. Delvart, A. Huskic, S. Senck, E. Mahé, C. Cayron, "Investigation of new volumetric non-destructive techniques to characterise additive manufacturing parts", Welding in the World, Vol. 62, Issue 5, pp. 1049-1057, 2018. https://doi.org/10.1007/s40194-018-0593-7.

F. Wohlgemuth, E. Haltenberger, C. Klein, T. Hausotte, "Numerical determination of task-specific measurement uncertainty using a virtual metrological X-ray computed tomography system", VDE Verlag GmbH. **Print ISBN:** 978-3-8007-4683-5