Publishable Summary for 15HLT09 MetAMMI
Metrology for additively manufactured medical implants

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.

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.

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).

Progress beyond the state of the art

Currently AM is used mainly for prototyping purposes and the technology is not mature enough to prove its reliability to certified bodies in Europe for the final implants and guides used in surgery. This work went beyond the state of the art by developing robust routines for characterisation techniques as well as providing feedback to the manufacturing chain via protocols to validate these implants and guides. The current state of the art for production assurance of AM parts relies on the use of a combination of conventional tactile and optical coordinate measuring machines (CMMs), 3D scanners, and destructive sectioning required for measurements of the internal features as well as XCT. This project went beyond the state of the art by investigating alternative methods such as terahertz computed tomography (THz-CT), thermography and ultrasound (UT).

Results

Fabrication and characterisation of implants, guides, and standard objects

The requirements for medical devices (MD), as well as standard objects (SO), to validate the different measurement techniques, have been established for dense and lattice structures. With regards to SO, a way of introducing defects in the bulk has been established and types of designed defects suggested (missing struts/area, untreated material, closed cells, roughness). All these parts could be measured with the different characterisation techniques. The measurands had been discussed (defects, surface roughness, thickness, porosities, geometrical tolerances, sphericity, distortion, linearity, bending and elasticity) as well as the associated measurement uncertainties required. Several MDs have been fabricated by AM from different materials such as polymers, ceramics, and metals and circulated to the relevant partners. Several SOs, such as hole plates and miniature step gauges, have also been manufactured by AM and have been circulated to the relevant partners. Characterisations, of the available MDs and SOs, had been performed. These consisted of density, XCT, THz-CT, and surface measurements. The objective was achieved.

[Deliverable 2, and 5]

Validation of non-destructive characterisation techniques, development of traceable measurement capabilities and quantification of dimensional measurement errors

Discussions on the determination of the uncertainty of XCT and THz-CT techniques have led to the evaluation of dimensional measurements errors. Existing methods used for uncertainty determination have been used as a basis for evaluation of error on measurement. Also, discussions on the evaluation of performance parameters of clinical CT systems had been addressed. Phantoms, suitable to determine relevant parameters, have been chosen. The performance parameters of CT systems were determined using these phantoms. The objective was achieved.

[Deliverable 1, 3, 4, and 5]

Identification of metrology protocols for the detection and quantification of defects

Input on the design of reference parts containing the typical geometrical deviations for each technology has been provided, and several parts with defects were manufactured. The objective was achieved.

A data analysis procedure to assess the dimensional errors of AM parts using XCT has been developed. Routines for 3D quantification of delamination and 3D quantification of bulk defects are available. Simulation of industrial part XCT and simulations of the systematic effect of error sources on dimensional XCT measurements have been performed. A protocol to determine the uncertainty of XCT has been produced as well as a good practice guide for medical XCT image acquisition and analysis. In addition, three protocols on defect detection using alternative, less time consuming and expensive measurement methods have been investigated and described in the good practice guide on defect detection and prevention. The objective was achieved.

[Deliverable 6 and 7]

Quantification of the build-up of errors from each part of the whole implant and guide manufacture chain from medical imaging to clinical use

The screening of geometrical deviations in manufactured parts has been performed as well as the analysis of their origins in the process chain. Case studies have been performed to investigate and quantify the build-up of errors along the process chains. The objective was achieved.

[Deliverable 8]

These results are summarised in several deliverables:

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 material whereas THz waves can penetrate polymer and ceramic but are reflected by metal. THz-CT allowed the detection of defects and density changes but did not allow us to perform dimensional measurements from the 3D images. This was possible with XCT. Indeed, the spatial resolution of XCT images is higher than the spatial resolution of THz-CT images. However, measurements were possible from the 2D images with THz. This is an important new finding.

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

This deliverable describes briefly various NDT surface and volumetric methods, density, permeability, and mass measurements methods suitable to characterise AM parts. It provides their capability in terms of geometry and material that can be inspected and in terms of accuracy. It also gives the advantages and disadvantages of the methods as well as their efficiency (investigation time and cost). Finally, it presents commentary on some mechanical testing, microstructural characterisation and defect detection.

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. 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 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.

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 (dimensional measurement, geometrical deviation, defect detection).

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. The report also presents suitable reference standards to qualify XCT industrial systems.

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

This deliverable summarises the AM technologies and parts investigated in the project. The typical deviations on the manufactured parts according to the AM technology and material are listed 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, recommendations are given to prevent typical deviations. In annexes, four failure modes and effect analysis (FMEA) are presented.

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/surgical guides using three process categories. It details the medical purpose of the implant/surgical guide, its quality attributes with acceptable tolerances in its intended use as well as its fabrication. Critical steps along the manufacturing chain from the numerical design (CAD model) to final parts fabrication have been identified. Finally, it advises suitable measurands and suggests possible characterisation tools to monitor the manufacturing of the implant along the chain in order to produce reliable and defect free parts.

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
2. Dental guide
3. Pedicle screw drill guide and intervertebral body fusion cage
4. Cranial implant

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

Impact

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.

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

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