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 is 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 image or numerical model will be qualified. This will guarantee their reliability to notified bodies and facilitate acceptance of AM in the medical sector.

Need

The need for this project is 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 are 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 reliability of the manufacturing chain.

In order to validate these techniques, medical devices and standard objects, manufactured using different AM processes and materials, need to first be fabricated and characterised. Relevant aspects that have to be taken into account for these characterisations are 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 is required to a) determine the precision limits of dimensional measurements and the relative sensitivity of industrial and medical 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 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 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 is therefore necessary to characterise the parts at various stages in the production and application process to quantify errors in the chain from medical imaging to clinical use.

Objectives

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 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 manufacture 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 prototype purposes and the technology is not mature enough to prove its reliability for certified bodies in Europe for the final implants and guides used in surgery. This work will go beyond the state of the art by developing routine 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 CMMs, 3D scanners, and destructive sectioning required for measurements of the internal features as well as X-ray Computed Tomography (XCT). This project will go beyond the state of the art by investigating alternative methods such as Terahertz Computed Tomography (THz-CT), Thermography and Ultrasound (US).

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 can be measured with the different characterisation techniques. The measurands have been discussed (defects, surface roughness, thickness, porosities, geometrical tolerances, sphericity, distortion, linearity, bending, elasticity) as well as the associated measurement uncertainties required. The first set of MDs have been fabricated from different materials such as polymers, ceramics, and metals and circulated to the relevant partners. The first set of SOs, such as hole plates and miniature step gauges, have also been manufactured and have been circulated to the relevant partners. The first characterisations, of the available MD, have been performed. These consist of density, XCT and THz-CT measurements.

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

The first discussions on the determination of the uncertainty of XCT and THz-CT techniques have started. Existing methods used for uncertainty determination have been presented as a basis for further discussions. Also, first discussions on the evaluation of performance parameters of clinical CT systems have been addressed. Phantoms, suitable to determine relevant parameters, have been studied. The performance parameters of CT systems will be determined using the phantom that will be agreed on.

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 as well as for the CAD and the protocol is under development.

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

The work on this objective has not yet started.

Facilitation of the take up of the technology and measurement infrastructure developed by the project by the measurement supply chain, standards developing organisations, and end users.

The work on this objective has not yet started.

Impact

Partners have participated in several conferences (such as the 41st International Conference on Infrared, Millimeter, and Terahertz waves (IRMMW-THz) and Quality Control for Additive Manufacturing, Euspen) where the project and its results were presented. A few articles have already been written in order to disseminate the inputs of 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 and THz-CT are new technologies 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 and THz-CT measurements traceable and give valuable input to the evaluation of uncertainties thereby increasing 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.

Shapes of standard objects (SO), to validate the different measurement techniques, were discussed concerning dense and lattice structures. We agreed on the final shapes. These shapes have to be similar to the medical devices (MD) that will be studied. Then, the measurands were discussed (defects, surface roughness, thickness, porosities, geometrical tolerances, sphericity, distortion, linearity, bending, elasticity) as well as the associated measurement uncertainties required.

Still concerning SO, the way to introduce defects in the bulk was addressed and type of designed defects was suggested (missing struts/area, untreated material, closed cells, roughness). These parts should be fabricated using different AM techniques and be made of different materials. It was ensured that all these parts could be measured with the different characterisation techniques.

The first discussions on the determination of the uncertainty of XCT and THz-CT have been engaged. Existing methods of uncertainty determination has been presented. They will be followed to do a first evaluation of the uncertainty using a THz-CT.

In order to increase competencies at LNE on XCT as well as on metrological validation of CT in order to contribute to the metrological validation of the CNRS THz-CT, LNE worked, in collaboration with PTB, in their laboratory, for fifteen days.

Impact on industrial and other user communities

This will increase the uptake of the AM technology for manufacturing on demand and customised implants. This feedback provided to the manufacturing chain 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 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 will support their work and drive uptake of higher performance medical devices. Comprehensive regulations and pre-normative

measurement procedures will allow this robust growth to continue, which will increase the market acceptance of all manufactured parts.

Impact on relevant standards

The business case for all stakeholders is evident as standardisation will boost the application of this technology in critical sectors such as medical devices. The FP7 SASAM project has prioritised topics for AM standardisation: materials, processes/methods and test methods. The standardisation activity is expected to enlarge the existing AM business and will help to get acceptance in existing markets (medical and aerospace). This will be a big opportunity for innovation and economic growth in the European industry, which should enhance competitiveness and will therefore be instrumental to creating jobs in Europe.

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 of the project partners are already members of both the ISO/TC 261 and ASTM F42 AM committees, as well as ISO TC213 WG10 on XCT. The results from this project will be fed into either existing or new work items as appropriate.

Several partners have provided inputs to their standardization groups on additive manufacturing and on XCT. LNE has joined a work group specifically dedicated to medical applications for AM in order to increase the impact of the project into standardisation.

<table>
<tr><td colspan="2">Project start date and duration:</td><td>01/06/2016, 36 months</td></tr>
<tr><td colspan="3">Coordinator:
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<tr><td>Internal Funded Partners:
1 LNE, France
2 BAM, Germany
3 DFM, Denmark
4 NSAI, Ireland
5 PTB, Germany
6 VTT, Finland</td><td>External Funded Partners:
7 Aalto, Finland
8 CNRS, France
9 DTI, Denmark
10 DTU, Denmark
11 FAU, Germany
12 FH OÖ, Austria
13 Lithoz, Austria
14 Medicrea, France
15 SKBS, Germany
16 UNOTT, United Kingdom</td><td>Unfunded Partners:
17 Bego, Germany
18 PaS, Germany
19 Xilloc, Netherlands</td></tr>
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