European Metrology Programme for Innovation and Research

Delivering Impact

Measurement traceability for 3D printing

Implanted medical devices that replace, repair or support the normal function of the body were one of the greatest medical successes of the 20th Century. Additive manufacturing, commonly known as 3D printing, could offer high-quality, affordable medical devices specifically tailored to a patient. However, this technology lacked the knowledge of the build-up of errors that can occur from production to clinical use; required for quality controls and patient safety.

Europe's National Measurement Institutes working together

The European Metrology Programme for Innovation and Research (EMPIR) has been developed as part of Horizon 2020, the EU Framework Programme for Research and Innovation. EMPIR funding is drawn from 28 participating EURAMET member states to support collaborative research between Measurement Institutes, academia and industry both within and outside Europe to address key metrology challenges and ensure that measurement science meets the future.

Challenge

More than 500 000 medical devices are on sale in Europe, generating around €51 billion annually and accounting for one third of the market worldwide. This sector could potentially benefit from the rapidly expanding additive manufacturing (AM) industry. Commonly known as 3D printing this technique could allow the low-cost fabrication of parts for such things as implants for facial reconstruction, knee joint replacements or grafts that promote bone growth, that are specifically tailored to a patient's needs. However, the layer-wise manufacturing method this process uses, combined with the often-high roughness, complex geometries, materials and internal structures of AM products, makes acquiring accurate data challenging. This can lead to final parts that do not meet the initial patient-specific specifications, which had restricted its uptake by manufacturers of medical implants as they required SI traceable techniques for quality control to verify the finished product. Validated measurements were therefore needed covering the entire manufacturing chain - from the initial medical scans to the final implantation of the printed part into the patient.

Solution

The EMPIR project *Metrology for additively manufactured medical implants* brought together experts from national metrology institutes (NMI), industry and academia to address the need for AM measurement traceability. More than 100 medical implants, guides and standard objects were fabricated using different 3D printing technologies with a range of internal structures composed of materials such as polymers, ceramics, and metals. These were characterised for density, porosity, surface roughness and defects using over 200 destructive and non-destructive measurement techniques. A detailed analysis was performed using X-ray or terahertz computed tomography (CT), which provide a volumetric (external and internal geometries) three-dimensional image of an object, and coordinate measurement machines, that measure the external geometry of objects using tactile probes. The quantification of manufacturing errors was examined for pedicle screw drills used in spinal surgery, maxillo-facial implants for cheekbone reconstruction, dental guides and cranial implants. This resulted in the first ever knowledge of the build-up of measurement uncertainties across the whole AM chain; from the scan of the patient to eventual clinical use, with full traceability to the SI.

Impact

Since its founding in 2011, the company Lithoz has become the world market and technology leader for 3D printers, materials and solutions for the industrial production of high-performance ceramics. As a project partner the company was involved with the fabrication of AM parts. They are now passing on the knowledge gained - especially for non-destructive computed tomography measurements – to their customers who are now using this information to feed into their production environments. Furthermore, overcoming the measurement challenges that Lithoz faced during the project has played a part in stimulating the development of their new database driven CeraFab Control software. This allows complete traceability, quality assurance and intelligent data analysis to give greater efficiency in AM for ceramic parts. As a result of the more stable and robust processes developed in the project Lithoz has also seen an increase in customer confidence in the use of AM for production.

For the first time measurement traceability is available for 3D printed medical implants. This will enable the medical technology sector to benefit from this innovative manufacturing technique, an important step towards increased access to high-quality, low-cost medical devices across Europe.

Measurements for 3D printing

The EMPIR project *Metrology for additively manufactured medical implants* fabricated more than 100 medical devices by different additive manufacturing (AM) techniques including power bed fusion, binder jetting, material extrusion and vat photopolymerization. Made from materials such as polymers, ceramics, and metals they were characterised with over 200 destructive and non-destructive measurements including volumetric, optical and tactile techniques.

Three good practice guides were produced; one for medical XCT image acquisition and analysis, one for the detection and prevention of geometrical deviations in AM Medical Implants and one on how to select the best technology for specific characterisation tasks. Full AM chain monitoring was demonstrated in case studies on pedicle screws, maxillo-facial implants, dental guides and cranial implants and over a dozen papers were published in scientific journals. Project outputs will enable the medical sector to benefit from this innovative manufacturing technique, an important step towards increased access to high-quality, affordable medical devices across Europe.

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EMPIR EURAMET

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