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Non-destructive examination of additive manufactured acetabular hip prosthesis cups

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ABSTRACT

The application of Additive Manufacturing (AM) in medicine is extensive with the production of anatomical models, endoprosthetics, surgical guides, implants and scaffold implants. This is due to its design flexibility and cost effectiveness when geometrical complexity is required. Total hip arthroplasty is a common surgical procedure with a prevalence increase of 0.72% in 20 years that it is expected to grow faster in the next decades. The work presented demonstrates a novel non-destructive, non-contact examination method utilising X-ray Computed Tomography (XCT) and image processing. This method examines an AM bone-mimetic structure that enhances bone ingrowth and implant fixation of acetabular hip prosthesis cups. The results of the image processing analysis include information on the interconnectivity of the bone-mimetic structure, local thickness and spatial distribution.

Keywords: Computed Tomography, Computed Tomography, Image Processing, Non-destructive test

1. INTRODUCTION

Arthroplasty is a surgical procedure that replaces a damaged joint such as hip or knee to improve its functionality. Total hip arthroplasty (THA) is classified as a major surgery even though it is a common procedure.^{1,2} The prevalence of THA in 2010 in US was 0.83% that corresponds to 2.5 million patients. This demonstrates a continuous increase that leads to a 0.72% increase since 1980 when the prevalence was just 0.11%.³ The most common reasons that can lead to THA are osteoarthritis, rheumatoid arthritis, hip fractures and bone dysplasia among others.¹ A successful joint replacement should be painless, stable and provide freedom of movement with an acceptable service lifespan.^{4,5} The majority of THA are uncomplicated but complications such as dislocation, infection, intraoperative fractures, thromboembolic disease, bleeding, vascular injury, nerve injury are associated with it.² Wear of the components and aseptic or septic loosening are inevitable complications of THA due to the repeatable movement under constant friction. Numerous biomechanical studies examined design, mechanical and material properties to reduce the effect and occurrences of this complication and to improve the lifespan of the prosthesis. Bone mimetic biomaterials are proven to increase bone ingrowth and implant fixation.⁶ According to a recent study by Taniguchi et al,⁷ the pore size of a titanium lattice structure affect the bone ingrowth. The study examined three different lattice structures with pore sizes of 300 μm , 600 μm and 900 μm . The optimum bone ingrowth was achieved with pore size of 600 μm in comparison of pore sizes of 300 μm and 900 μm . The implant with pore sizes of 600 μm achieves compression strength and high fixation ability in the early period and deep bone ingrowth.⁶

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1.1 Additive Manufacturing in Healthcare

Different methods can be used to produce the controlled size of pores needed for optimum bone ingrowth such as space holder and additive manufacturing techniques.⁶ Additive manufacturing (AM) is defined as the process of joining materials to make objects from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing methodologies, such as traditional machining by ASTM.⁸ The continuous development of this technology is due to its advantages including reduction of fixturing, cutting tools and minimal post processing that lead to cost reduction and improves product development cycle time. The development advantages of AM include design flexibility for geometric complexity, assembly free designs and fast development and production for low part quantities.⁹⁻¹²

The application of AM in niche markets such as aerospace, biological systems and medicine is well known. AM and its application in healthcare can improve population wellbeing with customised medical products.¹⁰ These applications include maxillofacial prosthesis, dentistry, surgical guides and orthopaedic implants. AM is uniquely suitable in the production of healthcare products due to its capability to produce customised products based on the patients requirements.^{4,13-21} Furthermore, AM is applicable in producing bone mimicking biomaterials and specifically interconnected porous lattice structures with predictable and pre-determined unit cells. Metallic biomaterials are suitable for joint replacement prosthesis because of the similarities with the mechanical properties of bone. The mechanical properties of lattice biomaterials depend on the structure and shape of the pores AM can provide the required control to achieve the specific properties while ensuring optimum bone ingrowth and fixation. In particular, THA prosthesis requires maximum post-surgical bone density while ensuring stiffness and bone ingrowth.^{6,7}

1.2 X-ray Computed Tomography

X-ray Computer Tomography (XCT) is mainly known for its medical application, however in recent years it has new industrial applications. The growing interest of this technology is due to its capabilities to examine materials, products and failures non-destructively.²² XCT utilises a few thousands of radiographs representing the examined object from different angles that are reconstructed to create a 3D volume. During the reconstruction, the 2D pixels of the radiographs are used to calculate the grey value of the equivalent 3D voxels. The reconstructed data provides information about the entire specimen, internal and external structure, in different grey values. Lighter grey values illustrate materials with higher attenuation and darker grey values exhibit materials with lower attenuation while the darkest values, black, demonstrate air/background.²³⁻²⁶ The volume can be segmented manually or automatically with several methods to separate the different materials and the background. The most basic segmentation method is surface determination in one material scans that separates the material from the background. XCT is undeniably a useful non-contact, non-destructive test that provides otherwise unreachable data, however further procedures and methods are required to provide dimensional measurements.

XCT systems include an x-ray source, a manipulator system and a detector in a radiation secured cabinet or room while some systems also provide temperature control. Based on the design of XCT systems, there are numerous factors that can affect the quality of the radiographs and the resulted volume.²⁷⁻³¹ These include the geometric hardware calibration and alignment, the chosen settings of the source and detector, the geometry, material and orientation of the examined object and the reconstruction and analysis methods. Even then, multiple scans of an examined object in the same XCT scanner with the same settings will differ due to image noise, filtration, pixel size changes and the characteristics of the radiation while any measurements will be suspect of the surface determination and any segmentation method.

The evaluation of any dimensions from any measurement equipment is required before their utilisation.³² CT measurements are not recognised yet as reliable due to the lack of task-specific measurement uncertainty.³³ Currently, there are no international standards for the metrological performance verification of CT systems. ISO TC 213WG 10 group is developing an ISO standard to ensure traceability and define the uncertainty of measurements.^{32,33} Since these standards are not available yet, the German VDI/VDE guidelines are the only existing reference to obtain reasonable results. According to these guidelines, there are four typical measurement processes that they utilise reference measurement data obtained by a traceable method or CAD model of the examined object. In all processes the CT volume is updated based on the pre-existing information by re-scaling its voxels.

The work presented here discusses the application of XCT in the examination of AM acetabular hip prosthesis cups and its bone-mimetic lattice structure. This method considers XCT limitations and identifies the measurement error with a repeatability study. The results of the volume analysis provide information on the local thickness of the porous structure examining the entire statistical population of pores and struts. This method was developed utilising a prototype and the results do not provide any conclusion on the quality of the manufacturing method, process, design of the component and material selection.

2. METHODOLOGY

This investigation examines AM acetabular hip prosthesis cups of titanium alloy Ti6Al4V produced with Electron Beam Melting (EBM) by Arcam EBM Q10 (A GE Additive Company). The aim of this method is to examine non-destructively the specimen, ensuring the quality of the main body and the required characteristics of the lattice structure. The equipment and software used in this investigation are provided in Table 1. The investigation initiated with the calibration of a reference object before XCT scanning. The measurements of the reference object were used to identify the measurement error. The reconstructed volume was analysed with image processing after it was exported in 2D DICOM images.

Table 1: Equipment and software used in this method

Machines & Software Used	Name	Producer	Year
X-ray CT scanner	X-TEK XT H 225/320 LC	Nikon Metrology, UK	
Optical CMM scanner	NEXIV VMA 4540	Nikon Metrology, UK	
CT Reconstruction software	CT Pro 2.4	Nikon Metrology, UK	2016
CT Inspection software	VG Studio Max 2.2	Volume Graphics GmbH, Germany	2016
Analysis Software	Matlab 2016b	MathWorks, USA	2017
	ImageJ 1.51k	Wayne Rasband	2017
	Avizo 9.0.2	FEI Visualisation Sciences Group	2017

2.1 XCT scanning

The XCT scanning was performed with the settings provided in Table 2 that were chosen based on the achieved grey values to provide sufficient penetration and minimise noise. All of the available guidelines³⁴ were followed ensuring the specimen remained in view in all projections. A reference object with three spheres was calibrated and then scanned with the examined object for 19 times to classify the measurement error. A physical filtration was used to reduce XCT common errors such as noise, scattering, beam hardening, cupping artefacts and scattering radiation effects. A beam hardening reduction algorithm with a standard second order polynomial correction filter³⁵ was used in the reconstruction to further reduce the common errors.

Table 2: XCT scanning settings

CT scanning settings	
Voltage (kV)	215
Power (W)	33
Exposure Time (sec)	2.8
Gain (dB)	24
Voxel Size (μm)	43
Filter (mm Sn)	2

The calibration of the reference object was performed with traceable tactile CMM in a control environment with temperature of 20 °C. The machine was calibrated according to ISO 3650:1999 and ISO 10360-8:2013.^{36,37} The reconstructed volumes of the initial 19 scans performed to identify the measurement error were examined in a viewing software where measurements were taken from the reference object. Based on the results of these measurements, the measurement error was identified for this examination. The measurement error for each scan was calculated based on the known distances of the three spheres of the reference object. One of these distances was used for voxel rescaling and the other two distances were used to examine the deviation. The results are provided in Figure 1.

2.2 Image processing

The volume of the examined object was aligned, re-scaled and exported in DICOM images* for image processing. The surface determination was achieved with Otsu threshold selection.³⁸ The hemispherical shape of the acetabular hip prosthesis was segmented further to separate the lattice structure from the main body of the cup. Two hemispheres were placed on the top and bottom of the lattice structure to separate it from the main body of the examined object. Hough transform was used to identify the two circles in the 2D images and least squares method was used to calculate the hemispheres from the points of the circles. Extra protrusions were removed from the volume according to their geometry. Based on these results two new volumes were created, one for the struts and one for the pores, for 3D local thickness analysis. Statistical analysis of the local thickness was performed on the entire population of both struts and pores. The local thickness analysis was visually represented to assist in the identification of weak strut areas, smaller and larger than required pores. The selected tolerance limits were chosen based on the work of Taniguchi et al.⁷ Further information on this method is provided in Kourra et al.³⁹

3. RESULTS

The results of this analysis include qualitative and quantitative data for the lattice structure of the acetabular hip prosthesis cup. They provide the characterisation of the struts and porous structure that can ensure bone ingrowth and prosthesis stability. The quality of the scans was defined through the measurement error and image analysis provided the statistical data.

The measurement error of the results is required to demonstrate the limitations of this method and XCT. The calibrated referenced object was used in a repeatability study under the same conditions as the acetabular prosthesis to identify the measurement error of this method. The measurements taken after the voxel rescaling were compared to the traceable measurements. The measurement error was calculated according to the voxel size and is provided in Figure 1 demonstrating the magnitude of the error is lower than 30% of the voxel size throughout all of the measurements. A boxplot is provided and it demonstrates that the average measurement error is under 20% of the voxel size as suggested by Lifton et al.⁴⁰ and it can reach close to 30% of voxel size. More variables need to be identified and considered to define the measurement uncertainty. This repeatability study in combination with the voxel rescaling demonstrates the attitude of the issue that is acceptable for this study.

Data provided by the image analysis can demonstrate the quality suitability and be used for quantitative comparisons while in case a specimen does not meet the criteria, the qualitative information can assist in the illumination of the issues. Table 3 provides the quantitative data provided by the analysis, including the new voxel size after rescaling and statistical information such as mean and standard deviation. According to Taniguchi et al.⁷ that examined porous titanium structures with three different sizes, the optimum bone ingrowth in their study was achieved with pores of $632 \pm 171 \mu\text{m}$ and struts of $416 \pm 134 \mu\text{m}$. These numbers were used in this examination as tolerances to demonstrate the capabilities of the method. According to the results, the mean pore value is $452.91 \mu\text{m}$ and the mean struts value is $261.19 \mu\text{m}$, significantly lower than optimum value. Figure 2 shows the histogram of pores and struts and the red lines demonstrate the lower tolerance. The results confirm that the pores and struts do not have a normal distribution.

*Digital Imaging and Communications in Medicine (DICOM)

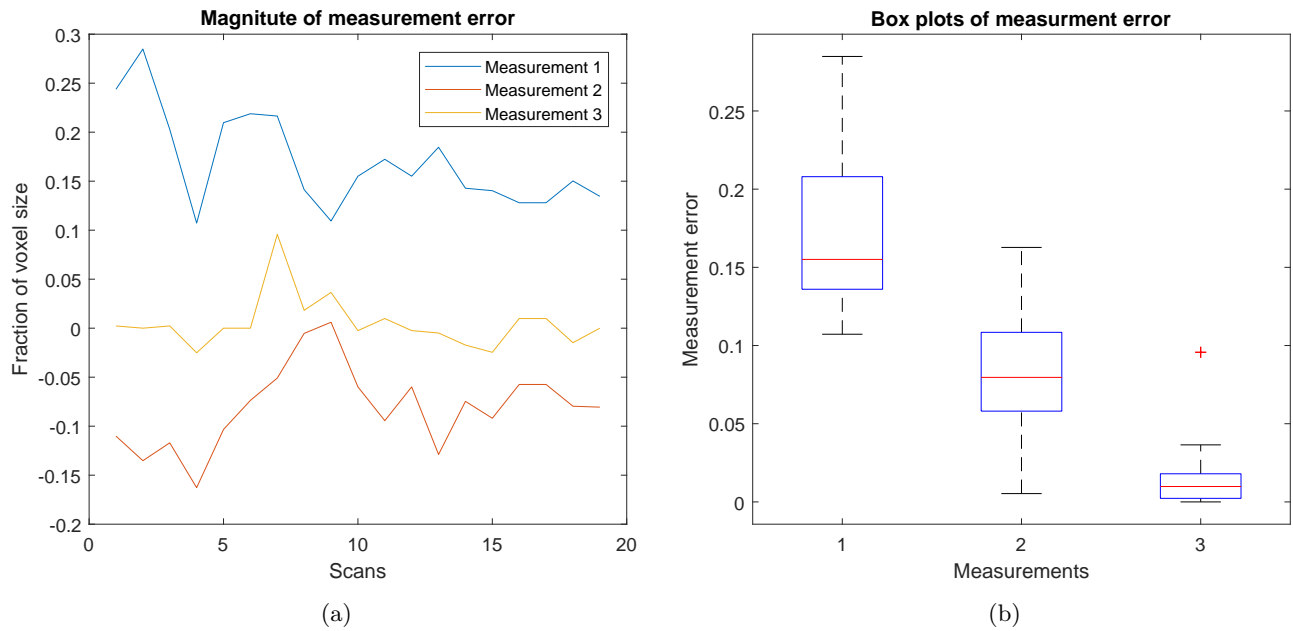


Figure 1: The measurement error of this method was identified through a series of scans, the result demonstrate the magnitude of the error in (a) and its statistical characteristics in (b)

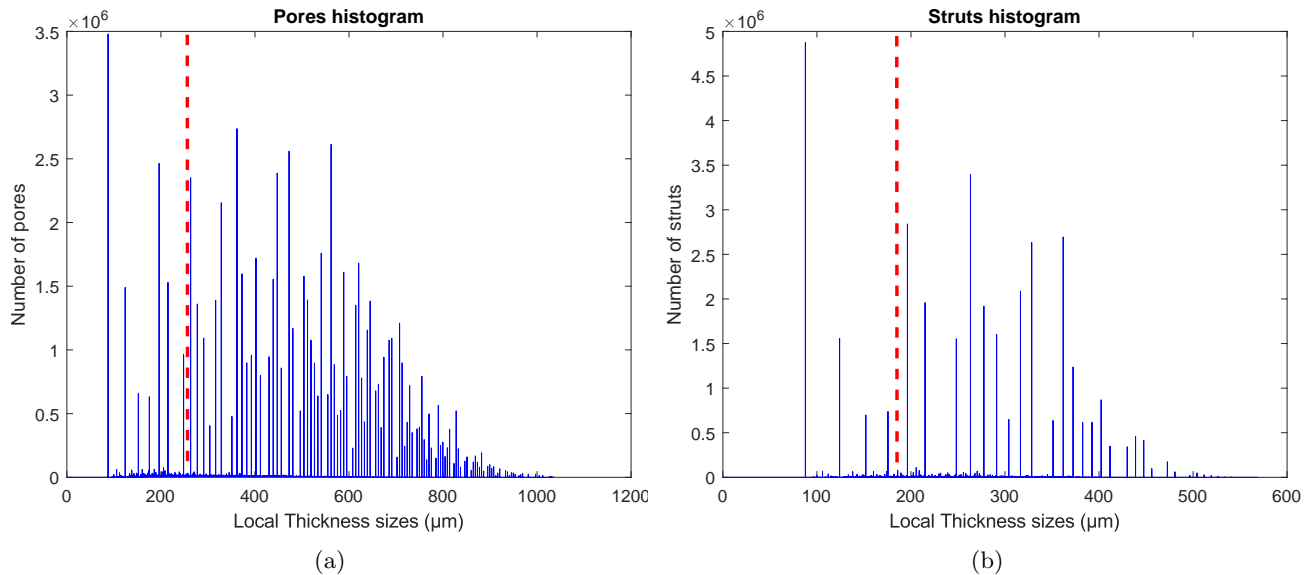


Figure 2: The number of occurrences of each pore and strut size are presented in histograms, (a) pores and (b) struts. The lower selected limit is shown in the red dotted line.

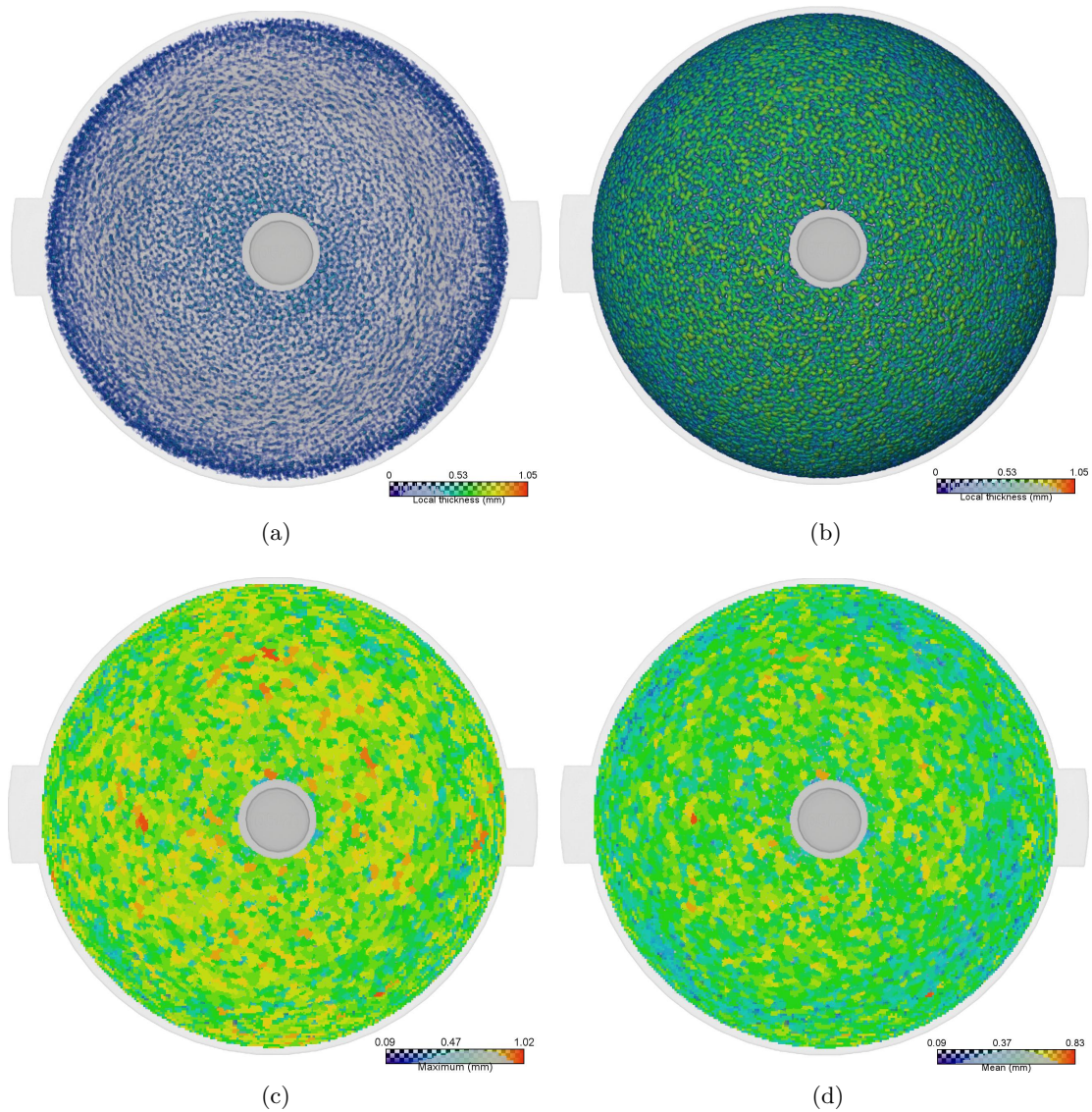


Figure 3: The results of the image processing analysis are demonstrated in 3D models for the better understanding of the issues and their location, (a) and (b) demonstrate the local thickness per pixel in different colours for struts and pores respectively for the same specimen, (c) shows the maximum and (d) the mean values of the local thickness at each point of the pore analysis.

Table 3: Pores and struts statistics for the established voxel size. The size limits shown in percentages are selected based on Taniguchi et al.⁷

Measurements (μm)			
Original voxel size	43.004	Rescaled voxel size	43.875
Pores	$\pm 3 \mu\text{m}$	Struts	$\pm 3 \mu\text{m}$
Maximum (μm)	1034.9	Maximum (μm)	568.87
Mean (μm)	457.92	Mean (μm)	261.19
Minimum (μm)	87.75	Minimum (μm)	87.75
Standard Deviation	163.21	Standard Deviation	90.19
% <225 (μm)	14.55	% <173 (μm)	17.96
% >1158 (μm)	0	% >811 (μm)	0

Figure 3 demonstrates volumetric representations of the results of the local thickness analysis of both struts and pores. The mean and maxima of the local thickness of the pores are also provided for better identification of the distribution. These results can assist in the identification of weak areas in production studies to optimise manufacturing settings.

The results of this analysis provide information for the characterisation of the lattice structure with a defined measurement error. The entire population of struts and pores was examined and it is demonstrated that they don't follow a normal distribution. The examined acetabular prosthesis is a prototype and the results are not representative to the design, manufacturing method and material selection.

4. CONCLUSIONS

The application of AM in healthcare can improve population wellbeing by providing customised products and biomimetic materials. Total hip arthroplasty is a common surgical procedure with continuous increasing prevalence and even though most procedures are uncomplicated, the complications can be severe and affect the lives of patients for long periods. The method presented here provides qualitative and quantitative results of an AM acetabular hip prosthesis cup, including statistical information and visual representation of local thickness analysis. The results were obtained with the combination of XCT and automated image processing to minimise human error.

The results for both struts and pores are demonstrated in histograms, 3D representations and tables demonstrating the characteristics of the lattice structure. This in-depth analysis is provided because of the unique capabilities of XCT and it is unreachable with other non-destructive methods. The industrial applications of this technology are not established yet because of lack of internationally accredited standards. In this investigation, the measurement error of the method is demonstrated through a repeatability study and it is below the required AM industrial limits.

Further investigations will continue to improve the accuracy and determine the uncertainty of XCT and this method. Future studies are planned to examine the effect of different variables and to better define the metrological limitations of this method. XCT is undeniably a useful tool that it can provide information otherwise unreachable but new examination procedures need to be developed to ensure the quality of the results. The application of this technology for the investigation of AM products will allow their further development and utilisation in niche markets such as healthcare.

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