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Non-Destructive quality assessment of bio-engineering parts using Industrial Micro X-ray Computed Tomography: A Review

Jitendra Singh Rathore[a], Prateek Saxena[b,c]

[a] *CEA-LIST, Département d'Imagerie, Simulation et Contrôle, 91191 Gif-sur-Yvette, France*
[b] *Sustainable Manufacturing Systems Centre, School of Aerospace, Transport and Manufacturing, Cranfield University, Bedfordshire, UK*
[c] *School of Engineering, Indian Institute of Technology Mandi, Mandi, Himachal Pradesh, 175005 India*

Abstract

Bio-engineering parts are widely used in hearing aid applications, dental applications, inhalation therapy blends, etc. Conventional tactile measurement techniques offer a limitation in the quality assessment of such parts due to the complex shape of the part and also due to their inability to measure internal features in a three-dimensional space. Industrial micro X-ray computed tomography (μXCT) is a robust characterization technique designed to maintain part quality, facilitate precision manufacturing, and reduce material waste due to part rejection. This work highlights the limitations and challenges of conventional measurement techniques in the assessment of the quality of bio-engineering components. Capabilities of μXCT are presented and its application in the bio-engineering sector is discussed in this work.

Keywords: Micro X-ray Computed Tomography, Bio-engineering, Quality control, Non Destructive Technique, Precision manufacturing

1. Introduction

Bio-engineering components are conventionally manufactured with micro injection molding e.g. micro filters for acoustics, hearing aids, implantable clips,

Email addresses: jitendra-singh.rathore@hotmail.com (Jitendra Singh Rathore), pra.9000@gmail.com (Prateek Saxena)

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etc. In recent times, additive manufacturing is also being utilized especially for the manufacturing of metallic parts such as implant solutions and scaffolds. Bio-engineering parts are characterized by small and complex features often with dimensions in the order of microns which also require very high precision to ensure effective usage. For example, accurate volume measurement of cavities is required for predicting the maximum dosage that can be loaded on a drug-eluting stent [1]. Depending on the quality criteria, several techniques are being used conventionally, such as optical and/or probe-based instruments are utilized for dimensional measurements, the Archimedes method for total porosity, and the gravimetric method for volume/wear measurements. However, they pose specific limitations for parts with intrinsic features and complex shapes. Hansen et al. [2] showed a classification of instruments with respect to the aspect ratio of the measuring parts, which is a crucial criterion to define the complexity of the features to be measured. In addition, there are several challenges and/or limitations associated with most measuring instruments, which further justify the need for new technologies. For examples, probe-based systems could not access the complex features and optical instrument are not fully three-dimensional (3D) as well as probe-based machines could induce unwanted damages and/or deformations (in polymeric components) due to clamping and probing forces leading to a large measurement uncertainty [3]. Industrial Micro X-ray Computed Tomography (μXCT) could provide a solution for such complex bio-engineering parts for their holistic measurements both internally and externally. The unique feature of this measurement technique is that it is entirely three-dimensional, which enables holistic data acquisition.

2. Industrial X-ray CT

μXCT is an X-ray 3D imaging technology which is based on the same principle as in the medical CT systems but could utilize high power and achieve very high resolution for industrial use [6, 7]. Over the years, it has become an established technique for non-destructive quality control in industrial environments across various domains [8, 9, 10, 11]. This Non-Destructive Technique (NDT) offers great advantages such as, in particular, no sampling preparation, complete 3D information, no sectioning, etc. In contrast to the tactile coordinate measuring machines (CMMs), a CT scan of an object acquires all surface points of the part including all hidden features which otherwise remain inaccessible non-destructively with other methods. **Fig. 1a** shows the working principle of μXCT systems, the X-ray projections are acquired for a complete rotation cycle. The acquired projec-

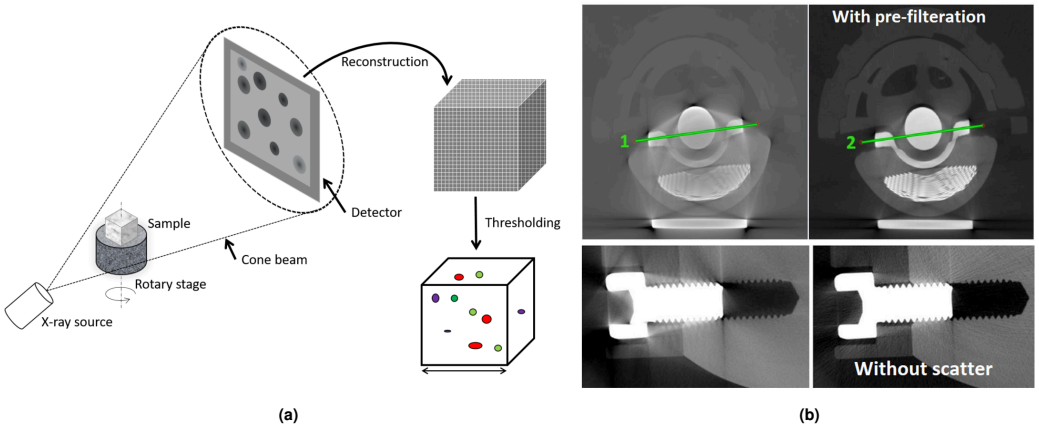


Figure 1: (a) Working principle of μXCT and (b) typical beam hardening artifact (top) and corresponding minimization with pre-filteration adopted from [4] and typical scattering artifacts adopted from [5]

tions are post-processed and a volumetric dataset is obtained, which is composed of gray-level-based voxels (three-dimensional pixels); smaller voxel size represents a higher resolution of the CT data. Then, a thresholding step is required which defines the boundary between the material and the background; an accurate threshold ensures precise quantitative analyses.

Although, μXCT has no limitations related to the probe access, because of the high penetration power of X-rays. However, there exist several limitations that affect the quality of the acquired data. According to the German guideline, VDI/VDE $2630-1.2$ [12], the influencing factors can be categorized into five groups of parameters: system, workpiece, data processing, environment, and operator. It is out of the scope of this review to discuss the influencing factors in detail, nevertheless, it is recommended to refer [4, 5] for further details. The quality of acquisition is affected in form of one or more artifacts, most common are the beam hardening and scattering artifacts which arise due to the polychromatic nature of X-ray beam and scattering of the X-ray photons after interaction with material respectively. Some of the artifacts can be avoided to some extent with pre-scanning strategies, moreover, the development of software based corrections is a major interest of researchers. An example of typical beam hardening and scattering artifacts is presented in **Fig. 1b**

μXCT can be utilized for various metrological tasks ranging from evaluating the global deviations against the nominal geometry to quantifying the local internal defects [23, 24] as well as fiber orientation in composites [7, 10, 25]. Numer-

Table 1: Common bio-engineering applications where μXCT is utilized for quality assessment

Application	Material	Quality criterion	Reference
Acetabular cup (metallic)	—	Surface texture	[13]
Artificial Urinary Sphincter	AMS 800 (Boston Scientific, Boston, USA)	Wall thickness and Model Validation	[14]
Microfludics	Cyclic Olefin Copolymers (COC)	Shrinkage and warpage	[15]
Dental file	Ti-Ni alloy	Dimensional	[16]
Drug-eluting stent	—	Volume measurement	[1]
Hearing aid toggle	Liquid crystal polymer (LCP)	Dimensional	[17]
Hip joint prostheses	Polyethylene	Wear	[3, 18]
Inhalation therapy blends	α -lactose monohydrate powders Polycarbonate (PC)	Powder characterization	[19]
Biomaterials	—	Morphological characterization	[20, 21]
Scaffolds	—	Micro-architecture	[20, 21, 22]

ous studies have reported the use of μXCT for quality inspection in the context of the bio-engineering components. **Table 1** discusses some common applications highlighting the quality criteria. It shows that μXCT can be used for a wide range of materials and qualitative and quantitative analyses based on several quality aspects related to the functional performance of the part; which makes μXCT a very versatile technique for quality assessment. We have broadly categorized the various measurement tasks among external and internal quality assessments.

2.1. External quality assessment

There could be several external quality criteria which are defined for efficient functional performance of a specific part. Some of the important criteria have been highlighted and discussed in detail.

2.1.1. Dimensional measurements

For a manufacturer, dimensional accuracy is the primary objective, which becomes extremely important when the part is characterized by strict tolerances. As mentioned, bio-engineering parts usually consist of miniature functional features with strict tolerances. Some typical measurands are height/depth in microfluidics, internal/external diameters in hearing aid toggles, etc. **Fig. 2a** shows an example of a hearing aid toggle as produced and the measurands defining the functional performance of such toggles are outer diameter (D), inner diameter (d) and pillar height (H) (**Fig. 2b**) [17]. The results obtained from μXCT for three such toggles are compared against the reference measurements taken with an optical coordinate measuring machine (OCMM) and the deviations are plotted in **Fig. 2c**. In general,

the deviations are as low as $0\ \mu m$ but always $\leq 10\ \mu m$, which depicts the ability of the μXCT to make measurements comparable to the conventional OCMM.

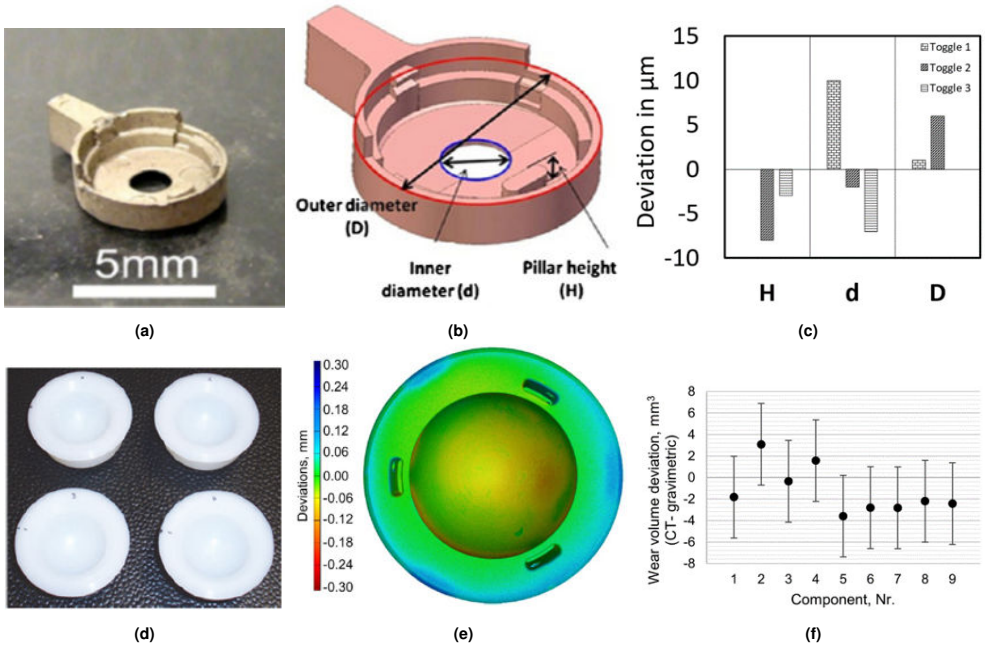


Figure 2: Examples of dimensional and wear measurements by μXCT: (a) Hearing aid toggle as produced, (b) Defined quality measurands, (c) Obtained CT measurements (deviations from reference values) [16], (d) Polyethylene acetabular cups with 30 mm diameter of spherical bearing surface [26], (e) Wear/deformation map of acetabular components and (f) Deviations between volumetric wear measurements obtained by CT and gravimetric method [3].

2.1.2. Wear measurements

Measurement of wear volumes and geometric characterization are of primary importance for understanding wear mechanisms and improving technological solutions provided by prosthetic joint components manufacturers. The laboratory determination of wear rate is an important part of the pre-clinical validation of prostheses [26]. The most commonly applied method for wear evaluation of prosthetic joint components is the gravimetric method. It is generally accurate and reliable but has got certain limitations. In particular, gravimetric measurements cannot provide information about the localization of wear damage and deformation over the component's surface. As an alternative, tactile coordinate measuring machines are used to evaluate both volumetric wears and wear damage distribution over the worn surface. However, considering polymeric prosthetic compo-

nents, these machines could induce unwanted damages and/or deformations due to clamping and probing forces leading to a large measurement uncertainty [3]. In such a case, μXCT can be used for the measurement of volumetric wear as well as for the determination of the local distribution of wear and deformation without any risk of further damaging or deforming polymer components.

An example of a hip prosthesis with ultra-high molecular weight polyethylene (UHMWPE) cups is shown in **Fig. 2d**. Geometrical measurements were conducted before and after the wear test using μXCT to be able to evaluate the volumetric wear. A deviation map obtained from the CT data showing local wear and deformations as distributed over the worn surfaces is shown in **Fig. 2e**. The difference between CT volumetric wear measurements and the conventional gravimetric method is reported in **Fig. 2f**. The results indicate that there is not a clear systematic trend of differences between CT and gravimetric results. However, the majority of the measured deviations are negative and this might be caused by the presence of systematic errors [3]. Nevertheless, this study further exploited CT capabilities.

2.1.3. Nominal-actual comparison

One of the most important applications of micro injection molding is microfluidics, which demands holistic quality control for mass replication. μXCT as an emerging technology provides a significant improvement in quality control and reverse engineering due to its non-destructive nature. Rathore et al. [15] showcased the use of μXCT for such applications, the authors used a specific microfluidic system which was manufactured in two different materials: Cyclic Olefin Copolymers (COC) and Polycarbonate (PC). μXCT provided significantly important results as far as the part quality is concerned. The μXCT based measurement of the overall linear shrinkage of part revealed that the shrinkage is x and y directions are lower than 0.5% for COC and slightly higher than 0.5% for PC. In z direction, the COC part exhibits 3% shrinkage whereas PC exhibits 3.5%. Therefore, it can also be concluded that the part with PC witnesses more shrinkage compared to the COC. The non-uniform shrinkage resulted in warpage of the part, which was also possible to quantify from the CT results using the nominal-actual comparison.

2.1.4. Wall-thickness analysis

Wall-thickness analysis is also one of the important quality parameters, which needs to be quantified in a number of bio-engineering applications. An important example is the Artificial Urinary Sphincter (AUS) device used for surgical treatment of urinary incontinence as demonstrated in [14]. An AUS cuff is a fun-

damental component of the device, providing the mechanical action addressed to urethral occlusion and therefore, it needs to be investigated by computational approach. μXCT is used to acquire the cuff conformation both in deflated and inflated conditions, for an accurate definition of the geometrical characteristics. An accurate 3D geometrical model of the cuff in the deflated configuration is obtained using μXCT (**Fig. 3a**) and the wall-thickness and internal distance between surfaces (**Fig. 3b**). Furthermore, model validation is achieved by comparing the measurements provided by the tomography of the AUS cuff inflated at selected pressure levels and the corresponding numerical results. The relative error was reported to be below 2.5%. Thanks to μXCT, this study is the first step in the understanding of AUS mechanical behavior and enables the development of computational tools for the analysis of the lumen occlusion process.

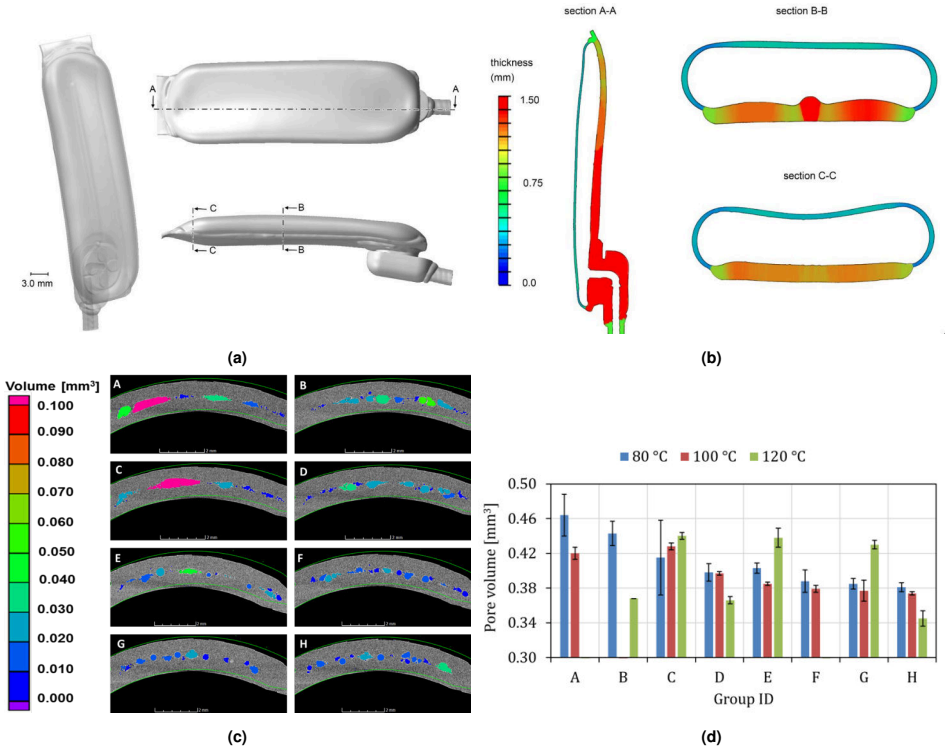


Figure 3: (a) Reconstructed CT volume of AUS device with different views of the geometrical model of the cuff with indicated sections *A*-*A*, B-B and *C*-*C*, (b) Contour of the material wall-thickness at the corresponding sections [14], (c) μXCT Measurement results of total pore volume and (d) Cross sectional view showing the pore morphology at different process conditions which are represented with letters *A* to *H* [24].

2.2. *Internal quality assessment*

Depending on the manufacturing process several parts are suffered from poor internal quality mainly with a presence of pore or inclusions. X-ray tomography can be used for inspection of internal flaws which is presented with some case studies.

2.2.1. *Porosity*

Internal porosity or defect is a very important issue in several manufacturing processes, particularly injection molding, where the molten polymer solidifies in the cavity, and therefore accurate detection of such porosity is of great importance for optimizing process settings. μXCT enables the user to obtain holistic information about the internal porosity including the 3D spatial distribution of the pores and the local and global pore volumes which otherwise may not be solely possible with other conventional methods. Rathore et al. [24] studied a micro-component with a V-shaped geometry which is present in several medical applications, especially where the hinging function is required e.g. ligating clips. They used a design-of-experiment approach concerning the process parameters (denoted with letter A to H) at three mold temperatures $80°C$, $100°C$ and $120°C$ and used CT based feedback for correlation. The cross-sections obtained from the CT reconstruction are shown in **Fig. 3c** at mold temperature $80°C$. The variation of pore sizes can be seen with varying process conditions. Furthermore, the quantified mean pore volumes with the standard deviation are plotted for all the process condition at different mold temperatures (see **Fig. 3d**). As it can be seen with color-coding, the process settings A at $80°C$ yields the maximum void volume while H at $120°C$ yields the minimum void volume. Moreover, the pores are distributed mainly along the central symmetrical plane (parting plane) of the part and individual pore volume ranges from 0.010 mm^3 to 0.10 mm^3. This pattern of pore distribution can be attributed to the fact that the material around the central plane is the last to solidify and, therefore, it is more prone to air/gas entrapment and/or differential shrinkage.

2.2.2. *Characterization of scaffolds and biomaterials*

Biomaterials and scaffolds that are used as bone substitutes to repair critical defects serve mainly as a combined mechanical support and osteoregeneration functions and differ in their biological properties, such as osteoconduction, osteoinduction, and osteogenesis, as well as in their osteointegration and structural support [27, 28].

The use of additive manufacturing for scaffold application has become a preferred choice thanks to the NDT through μXCT. It can provide complete quality control of the AM scaffolds which allows producing scaffolds with desired microarchitecture, texture analysis, different porosities, strut sizes, and spacing [29]. The use of μXCT has been demonstrated for evaluating surface texture [13], dimensional accuracy of uniform and gradient scaffolds [22, 30] as well as scaffolds with intricate geometries (i.e. diamond lattice, triply periodic minimal surfaces) that enhance cell migration while retaining a high degree of mechanical and structural rigidity [31, 32]. Complex scaffold structures produced by electrospinning can be investigated using μXCT (see **Fig. 4a**), allowing for more complex measurements such as fiber distribution and orientation [33]. Furthermore, in-situ μXCT has also been used to characterize the compressive failure of 3D printed ceramic scaffolds for bone regeneration, enabling a deeper insight between the structural and failure behavior to further tailor the 3D printing process for ceramic biomaterials **Fig. 4b**.

In very recent work, Gajjar et al. [19] presented the use of μXCT for the characterization of dry powder inhalers (DPIs) which consist of a powder mixture of active pharmaceutical ingredients (API) and inert carriers (excipients) contained in a device that deagglomerates the particles upon inhalation to deliver a dose to the lung. Such DPI mixtures are required to be accurately characterized for their particle size distributions, surface roughness, fines' contents, and flow properties. Understanding the microstructure of the powder formulation is crucial, yet current characterization methods such as laser diffraction (LD) and optical microscopy (OM) are not sufficient. Therefore, μXCT was utilized for characterizing the DPI formulations and the numerical results were also compared with the laser diffraction. μXCT based 3D visualisations of Lactohale 100 (4894 particles) and Lactohale 200 (308554 particles) can be seen in **Fig. 4c** and **Fig. 4d** respectively. The difference between the sieving and milling processes is visible with Lactohale 200 showing a higher number of intrinsic lactose fines than Lactohale 100. The size distribution plot of the number of fines is shown in **Fig. 4e** in comparison with plot obtained from LD. Both Lactohale 100 and Lactohale 200 have main peaks around 100 μm corresponding to the coarse lactose, with Lactohale 200 showing a second smaller peak around 20 μm corresponding to lactose fines. Furthermore, the calculated mean densities of lactose fines as 9426 ± 559 particles per mm^3 and 66458 ± 6033 particles per mm^3 for Lactohale 100 and Lactohale 200 respectively.

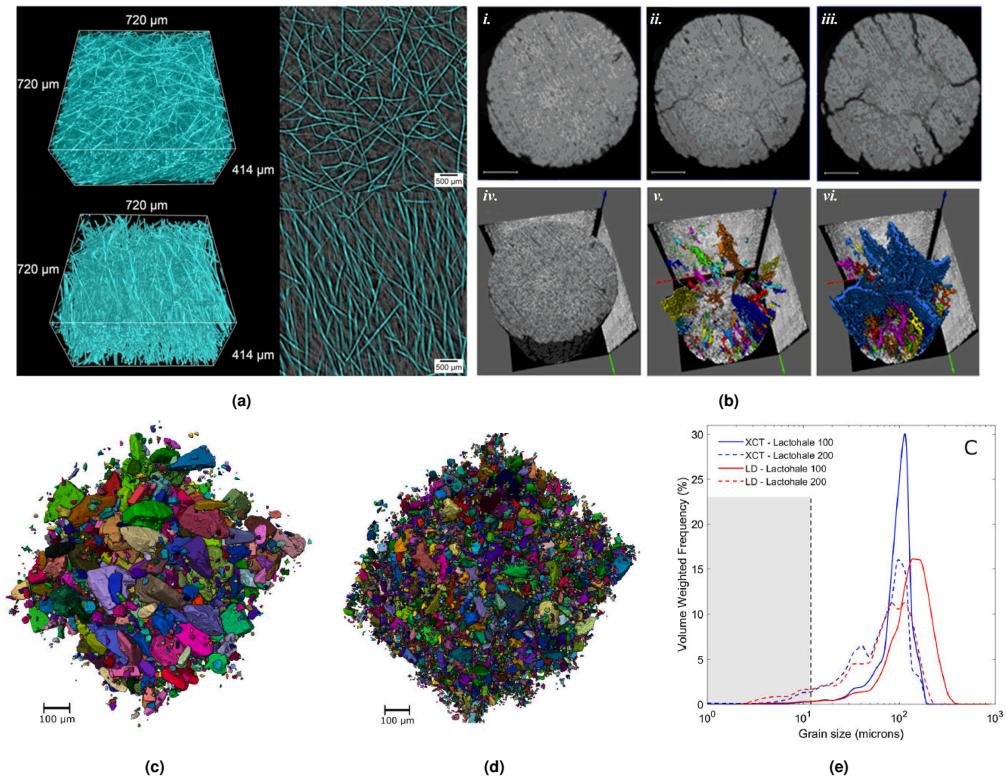


Figure 4: (a) Visualisation of polymer PCL scaffolds: randomly oriented *(top)* and well-aligned structures *(bottom)* manufactured using an electro-spinning process (3D view in left column and transverse section through sample height in right column) [33], (b) In-situ failure of a 3D powder printed ceramic scaffold under intermittent compression: representative CT cross-sections corresponding to the initial state *(i.)*, the progression of the crack generation *(ii.)* and the fractured state *(iii.)* and the corresponding reconstruction showing the mode of crack (coloured) generation and propagation in the bulk scaffold (*(iv)-(vi)*) [22], (c) CT visualisation of Lactohale 100, (d) Lactohale 200 (with one colour per particle) and (e) the size distributions for the two grades from CT and LD with fine lactose of size < 12 m highlighted in shaded grey region [19].

3. Limitations and outlook

As highlighted in section 2, μXCT does have some limitations. Some of the recent works have studied these limitations e.g. the influence of resolution on measurement results has been studied by Rathore et al. [34]. In addition, recent research has reported several solution for beam hardening correction [35] and scattering correction [36, 37]. Moreover, one of the most important limitations for μXCT based measurements is the lack of international standards to guide uncertainty estimation which is attributed to these numerous influencing factors and

their interactions [12]. Hence, there is an evident need for future research on various influences and their quantification which could eventually lead to standardization. Despite all these limitations, μXCT has a great potential to become the most preferred metrology solution in industrial environments especially with the increasing use of additive manufacturing parts.

4. Conclusions

Bio-engineering components typically require precision manufacturing and are primarily manufactured from injection molding or additive manufacturing techniques. The quality control of such parts is rather difficult with the use of tactile and optical measurement techniques due to the complex geometry of the parts and the internal micro-features. The utility and application of the industrial μXCT for the quality assessment of the bio-engineering components is presented in this work. This non-destructive quality tool can be used for precision manufacturing, wear measurement, wall thickness analysis, identification of internal porosity, deviation from the geometry of the intended part, and for the characterization of scaffolds and biomaterials. As a result, industrial μXCT scanners have the potential to reduce material waste due to part rejection, thus improving the production throughput of the manufacturing unit.

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