Micro-CT Based Post-Market Imaging of 3D Printed Implants

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INTRODUCTION:

3D printing (additive manufacturing) has rapidly been adopted in the manufacture of orthopaedic implants and North America remains the leading market for their use, which is projected to grow 16% annually to 2029.

This technology brings with it a completely new way of producing implants, which enables greater customisation and promises enhanced short and long-term bony fixation. However, all new methods have risks, which are high for 3D printed orthopaedic implants particularly because over a short time there has been rapid adoption of this technology, which previously was mainly used for 'rapid prototyping'

There is a known risk in 3D printing of structural cavities forming within dense regions of printed parts, which may increase the risk of fracture of the component. The prevalence of these cavities and their differences between custom-made and off-the-shelf designs is not understood. Furthermore, the assessment of these cavities in orthopaedic implants is currently not defined in post-market surveillance strategies.

In this study, we used micro-CT imaging to compare the characteristics of structural cavities between large, custom-made 3D printed cups for hip replacement surgery and off-the-shelf 3D printed cups.

METHODS:

This study investigated a total of 25 3D printed cups produced by 8 different manufacturers, Figure 1. These consisted of 10 cups which had been custom-made for patients with large acetabular defects but for whom these specific implants were no longer required. The remaining 15 cups were 'off-the-shelf' designs, of which 7 had been retrieved from patients following revision surgery. The retrieved implants were from 2 male and 5 female patients with a median (range) age at implantation of 61 (48-71) years and a median time to revision of 25 (21-46) months. All cups had been printed from a starting titanium powder.

We performed high resolution micro-CT scans of each cup in order to interrogate their internal structure and identify the presence of any cavities within the dense regions of the implants. Once a 3D model was segmented from the micro-CT images through an automated thresholding process, the dimensions of these cavities were measured where appropriate.

RESULTS:

Micro-CT imaging revealed evidence of internal cavities in all the 3D printed cups examined in this study; these were all localised to the dense regions of the implants. There was a wide variability in the number of identified cavities present in the different implant designs, with a median of 485, ranging from 1 to 3,115 structural cavities.

The median diameter of the cavities of the custom-made implants was 260 μm (130 to 700 μm). The median volume fraction (representing how much of the component volume was dense material) was 99.958% (99.876 to 100%). Comparatively, the off-the-shelf cups had a median cavity diameter of 22 μm (10 to 137 μm) and a median volume fraction of 99.989% (99.881 to 99.997%). The custom-made implants had a maximum of 1.2 cavities/mm^3, compared with 23.1 cavities/mm^3 in off-the-shelf cups.

There was no difference in cavity characteristics between unused and retrieved off-the-shelf cups.

DISCUSSION AND CONCLUSION:

The presence of internal cavities within 3D printed cups is an undesirable consequence of the manufacturing process. We found that cavities were present to some extent in all cups that we examined. The custom-made cups had a comparable number of cavities to the off-the-shelf cups however the cavities were approximately 10-fold larger in size. This may be due to the greater complexity of the shapes printed or the irregular nature of how often they are printed, compared to the repeatable nature of printing off-the-shelf designs.

There does not currently appear to be a clinical concern of fracture of these devices however surgeons and regulators should be aware of the potential for crack propagation initiating from these cavities. The use of appropriate post-market surveillance of these devices will be important as more designs are introduced to the market.

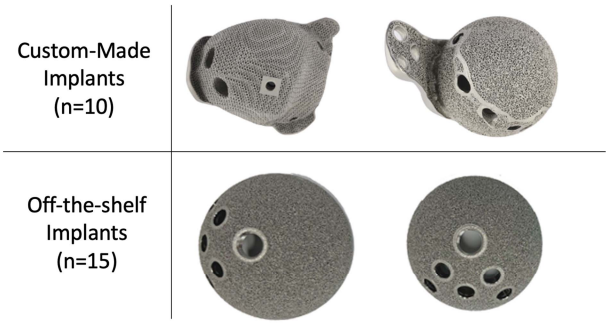

Figure 1: Examples of the custom-made and off-the-shelf 3D printed hip implants that were examined in this study

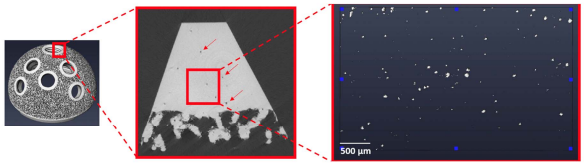

Figure 2: Example of the structural cavities that were observed within the dense regions of the 3D printed cups. These are represented by the white regions within the image on the right