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The challenge of repeatable manufacturing and the influence on the anchoring strength at the example of press-fit acetabular cups

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Abstract: In the present study, the SLM process and Ti6Al4V were used to produce an acetabular cup design suitable for experimental purposes. The acetabular cups with load-bearing, open-pored structures on the acetabular surface were evaluated experimentally to evaluate the anchoring strength. A microscopic measurement was performed to evaluate the manufacturing accuracy and the press fit. The characterization of the global and local geometric conditions was performed using Micro-CT. While the press-fit determined by microscopic evaluation shows no correlation to the different anchorage strengths, the geometric deviation from the design specification in the press-fit area determined by micro-CT shows a significant correlation.

I. Introduction

The additive manufacture of components is fast becoming widespread [1]. The influence of the chosen process and the processing parameters on the mechanical, optical, thermal and functional properties is well known for many material types and systems. The influence of the process parameters on properties such as roughness, macro porosity and micro porosity as well as the resulting influences on the growth and supply of e.g. bone cells in medical applications is also already widely studied [2]. The development of optimized manufacturing parameters, controlled manufacturing and quality monitoring therefore play a special role [3]. In the context of this work, the influence of geometric changes on the anchoring strength is illustrated using the example of identical acetabular cups, which were manufactured at different production sites using identical manufacturing processes (the same model provided) and subsequently evaluated using Micro-CT and mechanical tests of anchoring strength.

II. Material and methods

In this work the cups built were designed hemispherically in a reduced variant using CAD software (PTC Creo, Version 2.0, Parametric Technology Corporation, Needham MA, USA) [4]. The press-fit cups were fabricated via selective laser melting using titanium powder (Ti6Al4V) under an ultra-pure argon atmosphere. The cup I was fabricated with the SLM 280 by C.F.K CNC–Fertigungstechnik (Kriftel GmbH, Kriftel, Germany) and the cup II by SLM solutions GmbH (Lübeck, Germany) using a continuous-wave Ytterbium fiber laser and an identical energy density E (J/mm³). The cups were built with a laser power P (275 W), a scan speed v (805 mm/s), a hatch spacing d (120 µm) and a layer thickness t (50 µm). For the anchoring test, synthetic bone was emulated by the application of Sika Block M 330 (Sika GmbH, Germany). This material, a thermosetting polyurethane with closed cells, is ideally suited for a comparative evaluation of the relevant acetabular cups.

II.I Anchoring strength

In order to characterize the anchoring strength of the acetabular cups, pull-out and lever-out tests were carried out [6]. The pull-out tests were performed on an INSTRON E 10,000 materials testing machine (Instron GmbH, Darmstadt, Germany) and the lever-out tests on a Zwick Z50 (Zwick GmbH & Co. KG, Ulm, Germany). In both test procedures, the acetabular cups were inserted into the prepared synthetic bone blocks using a specially prepared adapter, fixed with clamping devices and then released. The insertion and release was performed at a speed of 5 mm/min in both test variants.

II.II Measurements

The dimensions of the acetabular cups and the artificial bone bearings were checked using a non-contact measuring microscope (Mitutoyo - QVE-200 Pro; Mitutoyo Corporation; Japan). The measuring points were recorded in a circle and corrected using the least squares method. Outliers from the measurement data, which are due to light reflections and loose PUR particles, were made using a box plot (according to John W. Tukey) in a Matlab script. Quality control was performed using the resulting replacement diameters to verify the resulting press fits.

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II.III X-ray computed tomography

X-ray micro computed tomography (micro-CT) was used for inspection of both parts prior to mechanical tests. Each part was individually scanned using system and parameters optimized according to guidelines in [5,6]. Important parameters were the voltage 180 kV, current 180 µA and voxel size 32.5 µm. The resulting data was analyzed in VGSTUDIO MAX 3.2. For quantitative assessment in this work, a best-fit cone geometry was fit to the outer edge of the top and bottom of the lattice regions. The parts of lattice exterior to this best-fit cone was segmented and its volume reported.

II.IV Statistical analysis

All data are expressed as mean values ± standard deviation (SD). All statistical analyses were conducted using GraphPad Prism 7.02 (GraphPad Software, La Jolla, USA). A two-sample t-test with a with Welch's correction was performed to statistically examine significant differences between the means of the pull-out forces or the lever-out moment and the volume deviation.

III. Results and discussion

The results of the tests to determine the anchorage strength and the measurements in Table 1 show that the anchorage strength is influenced as a function of the volumes determined, which go beyond the area of construction (see Figure 1).

Table 1: Results of the anchoring strength (N=5) and the measurements as well as indication of the static evaluation, p-values <0.5 are statistically significant.

	Cup I	**Cup II**	**P-value**
Press-fit dimension – Mitutoyo [mm]	2.124	2.129	
Volume above the best-fit cone – CT [mm³]	112	226	
Pull-out force [N]	318 ± 16.6	525 ± 20.5	< 0.0001
Lever-out moment [kN]	3.1 ± 0.3	7.9 ± 1.1	0.0004

While the determination of the press fit using a microscope shows no significant differences, the determination of the volume fractions deviating from the constructive design shows significant differences.

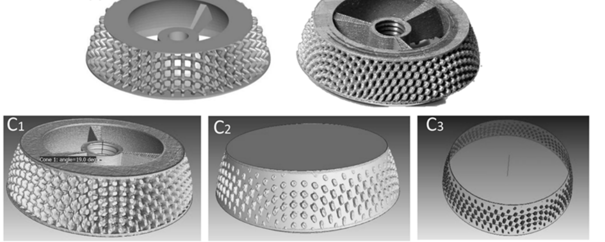

Figure 1: Presentation of the designed cup (A), the fabricated cup (B) and the results from the CT images - scanned cup (C1), cup with best-fit cone (C2) and only the volume above best fit (C3).

The experimentally determined pull-out forces ($p < 0.0001$) and the lever-out moments ($p = 0.0004$) differ significantly between cup I and II. The deviations of the manufactured volumes, which are responsible for the press-fit, result in different anchorage strengths. The volume built up beyond the design volume causes areas in the artificial bone bed that make subsequent detachment more difficult. On the one hand, a larger volume must be moved out of the bone bed. This requires more force. On the other hand, the larger volume also increases the resistance to movement and thus makes it more difficult to remove the cup from the bearing. Although the same procedures, materials and parameters were used for the production of the models, differences can be detected in the generated model. In addition to the parameters relevant for such applications, which influence the anchoring strength, there are obviously other influencing factors in the context of additive fabrication [7].

IV. Conclusions

It was shown that small differences in the produced model significantly affect the press-fit pull-out test strengths. The larger the area of lattice outside the design region into the attachment area, the stronger the attachment. The use of micro-CT for the verification and control of manufacturing geometries is excellently suited for the evaluation and validation of experimentally determined characteristic values. With this method it is possible to recognize qualitative and quantitative influences, to evaluate them and to transfer them into solution strategies in the context of the respective application.

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AUTHOR'S STATEMENT

Authors state no conflict of interest.

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