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A novel approach to determine primary stability of acetabular press-fit cups

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ABSTRACT

Today hip cups are used in a large variety of design variants and in increasing numbers of units. Their development is steadily progressing. In addition to conventional manufacturing methods for hip cups, additive methods, in particular, play an increasingly important role as development progresses.

The present paper describes a modified cup model developed based on a commercially available press-fit cup (Allofit 54/JJ). The press-fit cup was designed in two variants and manufactured using selective laser melting (SLM). Variant 1 (Ti) was modeled on the Allofit cup using an adapted process technology. Variant 2 (Ti-S) was provided with a porous load bearing structure on its surface. In addition to the typical (complete) geometry, both variants were also manufactured and tested in a reduced shape where only the press-fit area was formed. To assess the primary stability of the press-fit cups in the artificial bone cavity, pull-out and lever-out tests were carried out. Exact fit conditions and two-millimeter press-fit were investigated. The closed-cell PU foam used as an artificial bone cavity was mechanically characterized to exclude any influence on the results of the investigation.

The pull-out forces of the Ti-variant (complete-526 N, reduced-468 N) and the Ti-S variant (complete-548 N, reduced-526 N) as well as the lever-out moments of the Ti-variant (complete-10 Nm, reduced–9.8 Nm) and the Ti-S variant (complete-9 Nm, reduced–7.9 N) show no significant differences in the results between complete and reduced cups. The results show that the use of reduced cups in a press-fit design is possible within the scope of development work.

1. Introduction

Through the integration of modern, generative or additive manufacturing (AM) processes, more and more activities in the field of implant development are becoming apparent. The manufacture of implants for the spinal, head and maxillofacial regions or of bone reinforcing plates has become an interesting and widespread field of research and application in both veterinary and human medicine (Harrison et al., 2014; Levine, 2008; Murr, 2017; Simoneau et al., 2017; Sing et al., 2016). In the field of human orthopedic care such as implantation of cement-free acetabular cups in a press-fit or screw-type cup design (Gollwitzer and Gradinger, 2006), the use of generative manufacturing methods offers new possibilities but also new constructive and process engineering challenges for development engineers. All the design factors which influence the function of the cup are to be considered with special attention. The design of the region between the cup and the human bone or the transition from the cup to the human bone is essential for the desired success of the implant as a bone replacement.

A number of the design variants are therefore provided with biocompatible or bioactive surfaces to ensure improved ingrowth of the bone trabeculae (Le Guéhennec et al., 2007). The implant surfaces are partially micro- or macro-structured to achieve improved secondary stiffness (Benazzo et al., 2010; Bertollo et al., 2011; Emmelmann et al., 2011; Harrison et al., 2013). The structure is achieved either by applying metal fiber braids made of titanium (pore size 400 µm) or by coarse blasting the surface with corundum. The application of tetrapods makes it possible, e.g., to achieve macro-porous surfaces which have been shown to be beneficial for bone growth (Effenberger, 2007).

The use of open-pore structures on orthopedic implants or in other biomedical problem situations is known, although the mechanical properties are initially only designed for cancellous bones and affect the secondary stability particularly positively (Ahmadi et al., 2014; Marin et al., 2010). In addition to the now established use of geometrically defined scaffold or lattice structures (scaffolds) as an implant component, promising efforts are being made to develop metallic

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interconnecting cell systems or meshes for applications in the biomedical field (Li et al., 2015; Murr et al., 2010).

The aim is to provide structural elements, which, in addition to selected biological properties, also meet the mechanical property requirements by exploiting the immense advantages of the AM technologies. This purpose should be achieved through the application of material and surfaces modifications, as already applied in multiple forms, as well as through the use of material combinations (Fernandez-Yague et al., 2015; Issa et al., 2014).

The construction and design of orthopedic implants such as acetabular cups in the standard design are state of the art (Effenberger, 2007). The development of new cup designs by applying additive manufacturing technologies and using titanium and titanium alloys as well as the integration of property improving design features also requires the proof of their suitability for the intended purpose (Hazlehurst et al., 2017; Müller et al., 2006; Parthasarathy et al., 2010; Schwerdtfeger et al., 2010; Vasconcellos et al., 2008; Yan and Yu, 2015). In addition to the properties determined substantially by the materials used, such as corrosion resistance, mechanical strength and cell biological compatibility, or by surface texture, the functional qualities are also to be proved (Le Cann et al., 2014; Long and Rack, 1998; Olivares et al., 2009; Swarts et al., 2015; Takemoto et al., 2005; Vannoort, 1987). In addition to the initial stability during insertion of the cup into the bone cavity, this primarily includes primary stability, which decisively influences the success of an implantation (Chang et al., 2011; Chanlalit et al., 2011; Small et al., 2013).

Of particular interest in pre-clinical investigations for the assessment of the primary stability of press-fit acetabular cups is experimental work to evaluate the pull-out and lever-out behavior of acetabular cups (Macdonald et al., 1999; Morlock et al., 2002). The stability of the acetabular components is also of particular importance in post-clinical investigations. Toossi et al. (2013) completed a meta-analysis to compare the survivorship and revision rate of cemented and cementless acetabular components utilized in total hip arthroplasty. Roth et al. (2006) investigated the influence of an additional screw fixation for a better primary and secondary fixation from press-fit cups. Tabata et al. (2015) evaluated the mutual influence between press-fit and screw fixation on initial cup stability.

In addition, there is an interest in investigations on possible impairments of primary stability using commercial implants with or without modifications (Adler et al., 1992; Ries et al., 1997). In addition to studies using bones (cadavers), closed cell foams are increasingly used to evaluate primary stability (Adler et al., 1992; Amirouche et al., 2014; Clarke et al., 1991; Klanke et al., 2002). Baleani et al. (2001) used two different PU foams to simulate two qualities of cancellous bone. In this study, the effects of fins on the initial stability of different acetabular cups were investigated. Olory et al. (2004) used EP-Dur polyurethane resin blocks to compare the primary stability of different press-fit cups. Fritsche et al. (2011) simulate osteoporotic bone and sclerotic bone to investigate the impaction and pull-out behavior of metal-backed acetabular cups. Polymethacrylamide (PMI) was used as an osteoporotic bone substitute, while a composite model made of a 4 mm thick (cortical) polyvinyl chloride (PVC) layer and a PMI block was deployed to simulate sclerotic bone.

At present, acetabular cups are characterized in terms of their suitability for achieving a high primary stability (anchoring strength) by means of test methods which require the use of a complete acetabular cup (Crosnier et al., 2014; Diehl et al., 2010; Souffrant et al., 2012; Wegrzyn et al., 2015; Zietz et al., 2015).

Within the scope of this work, a suitable test concept has now been developed to enable the evaluation of the primary stability (anchoring strength) by using press-fit cups based on practical test scenarios. The final application is aimed at the production of reduced cups by means of additive manufacturing principles. To achieve meaningful results, clearly different surface finishes of the cup were chosen.

The investigational focus was is on standard hip cups in the press-fit design which are designed with a porous layer on the surface. The porous layer is accomplished in such a way that the density of the implant can be significantly reduced, and the conditions for a successful osseointegration are provided by imparting load bearing properties to this layer. The design of the load bearing porous structure (micro- and macro-porosity) is based on bone-like stiffness, thus resulting in the actually occurring forces to be directly absorbed and transmitted in the implant cavity. The porous structure, which acts both osteoconductively and osteoinductively, can significantly improve the primary stability.

To simulate the human bone cavity, a PU foam was used in this work similar to other investigations in the field of press-fit cup evaluation (Adler et al., 1992; Macdonald et al., 1999; Ries et al., 1997). Although PU foam differs from the characteristics of acetabular bone, it is very well suited for assessing the issue due to its uniform cell structure and the accompanying mechanical properties. Besides animal bone, hard foam materials are used more and more often as bone substitutes. Reasons for this include, inter alia, better availability, the avoidance of ethical problems and above all the reproducibility of the results.

The application of a method for assessing primary stability (anchoring strength) which allows only the region relevant for the press fit of the acetabular cup to be evaluated represents an innovation in the development stage of acetabular cups. Within a development chain, the scope of variants can be increased and costs decreased. In addition, the process engineering simplification that comes along with this method offers the potential of accelerating the generative manufacture even further. With the geometrical tapering of the test specimen and the associated reduction of the material, generative manufacture can have a more gentle effect on the material (less heat input and thus less influence on the microstructure). Problems that can occur, e.g., due to mass accumulations in the manufacturing process are reduced.

2. Materials and methods

2.1. Cup design

Two modified cups (Fig. 1-Area A) were developed based on a commercially available press-fit cup (Allofit-IT 54/JJ; Zimmer GmbH; Winterthur; Switzerland). Here, the height profiles of the cup (Allofit-IT 54/JJ) were recorded (equatorial cup diameter 55.3 mm; pole flattening 1 mm) by means of a non-contact measuring microscope Mitutoyo - QVE-200 Pro (Mitutoyo Corporation; Japan), transferred to a CAD model (PTC Creo, Version 3.0, Parametric Technology Corporation, Needham MA, USA) and redesigned. Cup variant I (below named Ti) has a macro-structured surface resembling the Allofit-IT 54/JJ and with the individual teeth following the contour and coinciding with the Allofit cup in their height profile. Cup variant II (below named Ti-S) was also adapted in its outer dimensions to the height profile of the Allofit IT-54/JJ. The surface structure consists of repetitive open pore load bearing structural elements oriented orthogonally to the cup surface. A geometry having a depth **a** of 2.12 mm, a width **b** of 2.12 mm and a height **c** of 3 mm was selected as a load bearing structural element (unit cell) (Fig. 1 - Area B). The rod diameter **d** is 0.9 mm. The mechanical properties of the selected load bearing open-pore structure have been successfully described in preliminary investigations (Weißmann et al., 2016a, b). Based on the complete model of cups, reduced designs were developed constructively. The reduced variant is constructed in such a way that the press-fit region is retained, but the region close to the pole is removed. Cup regions from the press-fit regions protrude so far that a gap of 0.25 mm is created between the artificial bone stock and the cup (negative press-fit - Fig. 1- Area D).

2.2. Fabrication

(1) In this work, all cups were built using an SLM process. Based on