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Femoral stem incorporating a diamond cubic lattice structure: Design, manufacture and testing

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ABSTRACT

Background: The current total hip prostheses with dense femoral stems are considerably stiffer than the host bones, which leads to such long-term complications as aseptic loosening, and eventually, the need for a revision. Consequently, the lifetime of the implantation does not match the lifetime expectation of young patients.
Method: A femoral stem design featuring a porous structure is proposed to lower its stiffness and allow bone tissue ingrowth. The porous structure is based on a diamond cubic lattice in which the pore size and the strut thickness are selected to meet the biomechanical requirements of the strength and the bone ingrowth. A porous stem and its fully dense counterpart are produced by laser powder-bed fusion using Ti-6Al-4V alloy. To evaluate the stiffness reduction, static testing based on the ISO standard 7206-4 is performed. The experimental results recorded by digital image correlation are analyzed and compared to the numerical model.
Results & conclusions: The numerical and experimental force-displacement characteristics of the porous stem show a 31% lower stiffness as compared to that of its dense counterpart. Moreover, the correlation analysis of the total displacement and equivalent strain fields allows the preliminary validation of the numerical model of the porous stem. Finally, the analysis of the surface-to-volume and the strength-to-stiffness ratios of diamond lattice structures allow the assessment of their potential as biomimetic constructs for load-bearing orthopaedic implants.

1. Introduction

1.1. Biomimetic implants

The long-term life expectations of young patients subjected to total hip arthroplasty (THA) drive the need for the improvement of femoral components of commercially available hip prostheses (Pivec et al., 2012; Learmonth et al., 2007). One of the main concerns in this regard relates to the stiffness mismatch between the femoral stem and the host bony structure. This mismatch is known to lead to stress shielding in the femur, and to bone resorption and aseptic loosening of the implant (Gibson et al., 2010; Ridzwan et al., 2007). This loosening generally leads to the need for an arthroplasty revision after implantation (Sundfeldt et al., 2006; Huiskes et al., 1992). Consequently, the longevity of existing hip prostheses does not match the average expected lifetime of the host patients (Mirza et al., 2010). Indeed, Pennington et al. (2015) determined that the average duration of perfect health after THA for mainstream hip prostheses is about 9 quality-adjusted life years (QALY).

The stiffness of metallic femoral stems can be reduced by the use of porous structures (Gibson et al., 2010). Moreover, if these porous structures are open to the surrounding environment and interconnected, they can promote bone ingrowth inside a stem to obtain a long-term fixation and avoid problematic revisions (Fujibayashi et al., 2004). The integration of open porous structures can be interpreted as a paradigm shift from the conventional cementless femoral stems designed to allow bone on-growth via the use of porous coatings or grit-blasted surfaces (Glassman et al., 2006) to biomimetic femoral stems featuring an open pore architecture and designed for bone ingrowth and lifelong service (Murr, 2017). The biomimetic design should allow mechanical stimulation of the surrounding and ingrowing bone tissue (Simmons et al., 2001; Markaki and Clyne, 2004), and prevent excessive relative motion at the bone-implant interface (Pilliar et al., 1986).

The design of biomimetic porous orthopaedic implants calls for a compromise between service life exceeding the patient's expected lifetime and porosity features. These requirements guide the selection of the pore size and volumetric porosity of the porous structures. In this

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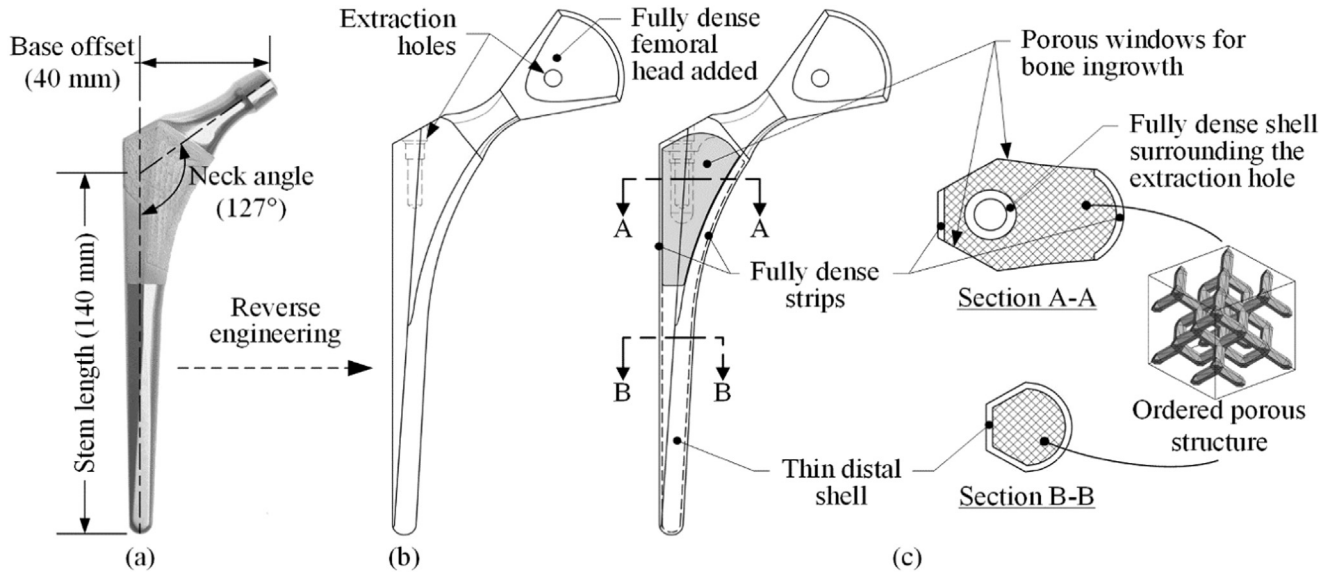

Fig. 1. (a) Commercial dense stem, (b) reverse-engineered dense stem, (c) stem filled with the ordered porous structure. Figure adapted from Simoneau et al. (2017).

regard, Bobyn et al. (1980) and Bragdon et al. (2004) found that an appropriate pore size for osseointegration ranges from 50 to 800 μm. Furthermore, the implant provides a firm bone fixation if the surface-to-volume ratio (STVR) of the porous structure approaches that of bone, which is in the range of 3–5 mm^{-1} (Beaupré et al., 1990; Coelho et al., 2009; Martin, 1984). On the other hand, the American Food and Drug Administration (FDA) specifies a porosity range of 30–70% for femoral components featuring fixation via bone ingrowth (FDA, 2016).

1.2. Additive manufacturing & porous femoral stems

The rapidly developing additive manufacturing (AM) technologies offer unprecedented capabilities to produce metallic implants with integrated engineered porous structures. Multiple publications feature porous femoral stems fabricated using different AM processes, such as electron beam melting (EBM) (Murr et al., 2010; Khanoki and Pasini, 2013), laser engineered net shaping (LENS) (Bandyopadhyay et al., 2008), and laser powder-bed fusion (L-PBF) (Harrysson et al., 2008; Hazlehurst et al., 2014; Harrison et al., 2013; Arabnejad et al., 2016; Simoneau et al., 2017; Limmahakhun et al., 2017). However, to the best of our knowledge, there are only few papers that present experimental assessments of the stress shielding-related improvements brought about by femoral stems incorporating such porous structures, and some of them will be briefly discussed hereinafter.

As examples of the above, Harrysson et al. (2008), Hazlehurst et al. (2014) and Limmahakhun et al. (2017) carried out mechanical testing to assess the compliance of their porous stems. However, to quantify the compliance of their stems, different testing conditions were used in each one of these studies, which do not allow their direct comparison. In effect, quasi-compressive testing was carried out in Harrysson et al. (2008), cantilever bending testing in Hazlehurst et al. (2014), and three-point bending testing in Limmahakhun et al. (2017). Arabnejad et al. (2016) described an attempt to locally decrease the stem stiffness by varying the porosity of the incorporated lattice structure. The mechanical testing and evaluations carried out on their stem rely on the implantation of the stem in a composite femur and on the original surface stress shielding model, without specifically testing the stem itself. Therefore, no validation of the mechanical behaviour, or stiffness reduction of the stem itself, were provided. Simoneau et al. (2017) developed and tested a stochastic porous structure, defined by an irregular pore distribution of random shapes and sizes (Tan et al. 2017), intended to reduce the stiffness of a commercial femoral stem. Nevertheless, the results they obtained must be compared to other designs for a comprehensive evaluation. Overall, to credibly establish the benefits of using porous structures in femoral stems for THA, more modeling and experimental work is needed, and this study intends to contribute to such efforts.

1.3. Scope of the study

This study describes the design, manufacturing and mechanical testing of a femoral stem incorporating an ordered porous structure with a twofold objective: a) to assess the overall stiffness reduction brought about by the design of the stem, b) to calculate the surface-to-volume (STVR) and the strength-to-stiffness (STSR) ratios of the stem's porous structure and their conformity with the same characteristics of the host bony structures. These metrics reflect the potential to reduce the stress-shielding phenomenon and mimic the corresponding structural characteristics of host bony structures. In this study, the porous structure of the stem contains diamond cubic lattice adapted for laser powder-bed additive manufacturing in Dumas et al. (2017). The approach used here for the experimental and numerical characterization of the porous stem is adopted from Simoneau et al. (2017), which consist in adopting the stem testing instruments and orientations suggested in the ISO 7206-4 standard for fatigue testing of femoral stems ISO 7206-4 (2010).

2. Materials and methods

2.1. Engineering workflow

The engineering workflow starts with the design of the porous and entirely dense stems, followed by the manufacture of the stems' prototypes, and ends with their ISO-based mechanical testing involving DIC measurements of the displacement and strain distributions. In parallel, numerical models of both stems undergo simulations, and the numerically calculated strain fields are compared to the experimental data.

2.2. Design of the porous stem

2.2.1. Determination of the porous design domain

Firstly, a reverse engineering method is used to obtain a CAD model of the Stryker "Secur-Fit™ MAX" 6052 0830A hip stem (Stryker Corporation, MI, USA) using the CATIA V5 R21 software package (Dassault Systèmes, Vélizy-Villacoublay, France), Fig. 1a. Then, a