

# Fully Porous 3D Printed Titanium Femoral Stem to Reduce Stress-Shielding Following Total Hip Arthroplasty

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Received 4 June 2016; accepted 15 September 2016

Published online 4 October 2016 in Wiley Online Library (wileyonlinelibrary.com). DOI 10.1002/jor.23445

**ABSTRACT:** Current hip replacement femoral implants are made of fully solid materials which all have stiffness considerably higher than that of bone. This mechanical mismatch can cause significant bone resorption secondary to stress shielding, which can lead to serious complications such as peri-prosthetic fracture during or after revision surgery. In this work, a high strength fully porous material with tunable mechanical properties is introduced for use in hip replacement design. The implant macro geometry is based off of a short stem taper-wedge implant compatible with minimally invasive hip replacement surgery. The implant micro-architecture is fine-tuned to locally mimic bone tissue properties which results in minimum bone resorption secondary to stress shielding. We present a systematic approach for the design of a 3D printed fully porous hip implant that encompasses the whole activity spectrum of implant development, from concept generation, multiscale mechanics of porous materials, material architecture tailoring, to additive manufacturing, and performance assessment via in vitro experiments in composite femurs. We show that the fully porous implant with an optimized material micro-structure can reduce the amount of bone loss secondary to stress shielding by 75% compared to a fully solid implant. This result also agrees with those of the in vitro quasi-physiological experimental model and the corresponding finite element model for both the optimized fully porous and fully solid implant. These studies demonstrate the merit and the potential of tuning material architecture to achieve a substantial reduction of bone resorption secondary to stress shielding. © 2016 Orthopaedic Research Society. Published by Wiley Periodicals, Inc. *J Orthop Res* 35:1774–1783, 2017.

**Keywords:** porous biomaterial; total hip arthroplasty; stress shielding; digital image correlation; additive manufacturing

Total hip arthroplasty (THA) is commonly used to relieve pain, restore function, and improve the quality of life for patients with compromised hip joints when conservative treatments have failed. Despite the success of THA, some of the main complications of THA, such as aseptic loosening, stress shielding, and peri-prosthetic fracture, remain a concern. Bone resorption secondary to stress shielding can be significant and arises from the mismatch of the mechanical properties between the implant and the surrounding native femoral bone.<sup>1,2</sup> Materials currently used in hip implants, such as titanium-based alloys, cobalt chromium alloys, and 316L stainless steel, all have stiffness considerably higher than that of bone. Once a metal implant is implanted into the femur, most of the physiological loading is transferred to the implant, away from the comparatively more compliant surrounding bone. The altered load transfer in the implanted femur leads to the bone being under-loaded compared to its natural state. As a result bone, a living tissue that is sensitive to mechanotransduction, resorbs and loses mass by an adaptive process known as bone remodeling.<sup>3</sup> This phenomenon is termed bone loss secondary to stress shielding.<sup>1,4</sup> The reduction in bone stock can lead to serious complications, including peri-prosthetic fracture, while the mismatch

in modulus between the implant and the bone can result in thigh pain.<sup>5–7</sup> Stress shielding also reduces the quality of the remaining bone stock leading to a significantly increased risk of fracture and aseptic loosening with revision surgery, should one be required. This is particularly concerning for the future, as the number of revision THAs is projected to rise, with younger patients now undergoing THA and life expectancy also increasing.

Several attempts have been made to modify femoral stems with the goal of reducing stress shielding and its adverse complications. Approaches to reduce stress shielding are mainly based on reducing the femoral stem stiffness. Methods to achieve this aim include: modification of the geometric profile of the implant, modification of its material properties, or a combination of both material and geometrical modifications. Geometric modifications include geometric variation of the stem cross section,<sup>8–10</sup> stem length reduction,<sup>5,11,12</sup> taper and/or curvature along the femoral stem,<sup>10,13</sup> attachment of a collar or anchor at the proximal portion of the stem,<sup>14,15</sup> and adoption of a hollow stem profile and internal grooves.<sup>1,13,16</sup> Modifications of material properties include stem concepts with graded cellular materials from both cobalt chrome alloys as well as titanium alloys.<sup>17–22</sup> Some existing works on porous materials focus on their use as surface coating on the implant to allow bone in-growth to achieve biologic fixation.<sup>23,24</sup> Other works attempt to use porous materials for bone replacement, but they are mainly limited to computational modeling,<sup>25,26</sup> manufacturing and testing of small samples,<sup>19,27,28</sup> morphological characterization,<sup>29–31</sup> and proof-of-concept implants with uniform porosity.<sup>19,20,32</sup> So

Conflicts of interest: None.

Grant sponsor: Natural Sciences and Engineering Research Council of Canada (NSERC); Grant sponsor: Canadian Institutes of Health Research (CIHR).

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far, no work has successfully tackled the challenge of using a fully porous material for femoral stems. Furthermore, there is no work that has experimentally proved the merit of tuned porous architecture to reduce stress-shielding in an implanted femur. Herein, we present a systematic approach for the design of a fully porous hip implant that encompasses the whole activity spectrum of implant development, from concept generation, multiscale mechanics of porous materials, material architecture tailoring, to 3D implant manufacturing, and performance assessment via in vitro experiments.

## MATERIALS AND METHODS

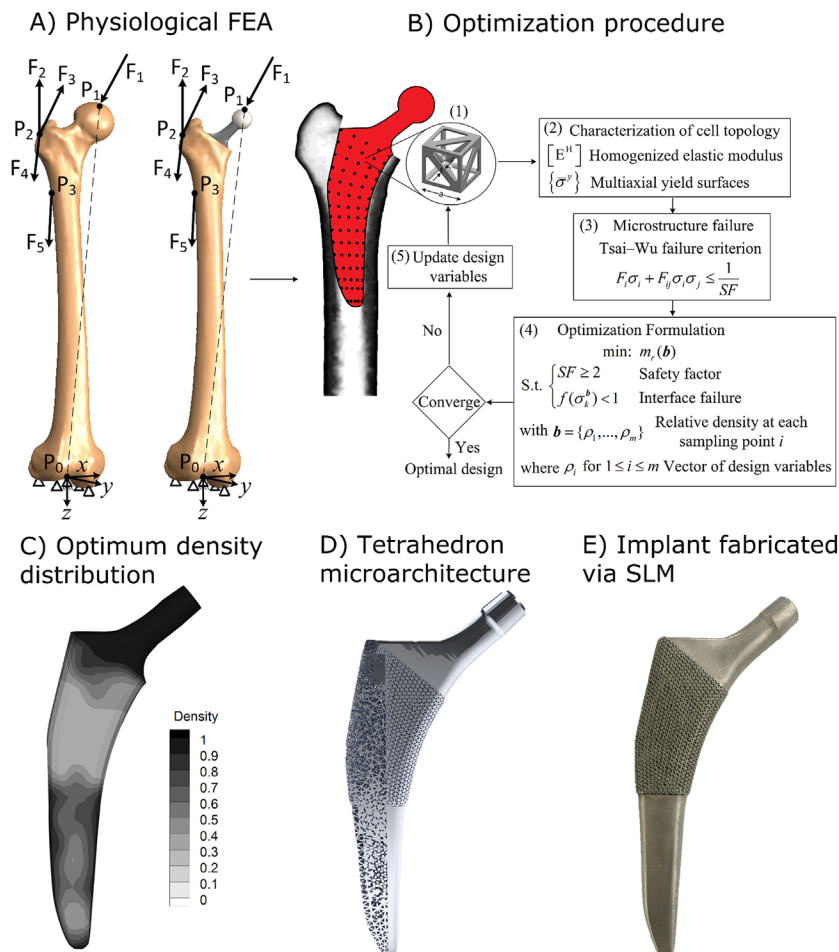
### Methodology of the Implant Design

Figure 1 summarizes the methodology that led to the development of the first fully porous femoral stem with tunable properties that minimize bone resorption as a result of stress shielding. A multiscale computational scheme dealing with the scale-dependent material architecture is integrated within a material tailoring scheme (Fig. 1B) to locally tune the stiffness distribution of the implant to those of the bone. Once an optimum relative density distribution solution is obtained (Fig. 1C), the result is mapped into an architected lattice ready for manufacturing (Fig. 1D). Selective Laser Melting (SLM) is used to build the implant (Fig. 1E), and micro-CT analysis of the manufactured

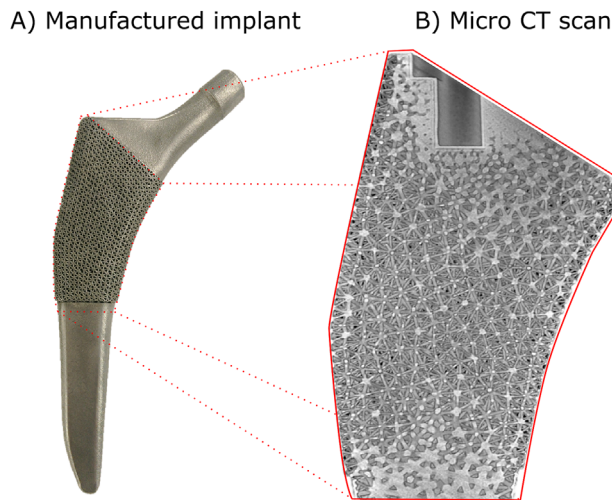
implant is performed to assess the fidelity of the implant micro-structure as well as to detect any entrapment of semi- or non-melted powder within the pores (Fig. 2). Finally, Digital Image Correlation (DIC) test is used to assess bone resorption performance relative to a commercially available fully solid implant of identical geometry, here used as a benchmark; a complementary Finite Element (FE) model of the experiment is also created to provide volumetric context of bone loss to the experimental results (Fig. 3). The multi-scale design and material tailoring scheme for the design of a tuned fully porous hip implant is described in the section below.

### Multiscale Design, Material Architecture Tailoring, and Physiological FEA of Bone Remodeling

The procedure used to develop the porous hip implant starts from the generation of a finite element model of the femoral bone which is created by processing CT-scan data of a 38-year-old patient bone. To achieve this goal, we use radiographic density of CT images, quantified as Hounsfield Unit (HU), to represent the local material properties of the human femur. The apparent density  $\rho$  for each finite element of the femur model is then determined from the Hounsfield value (HU) measured from CT data ranging from 0 to 1,567 HU. The maximum value of HU corresponds to the densest region of the cortical bone with apparent density of  $2,000 \text{ kg/m}^3$ . From the apparent density distribution, the effective elastic moduli of bone are



**Figure 1.** (A) Physiological FEA of the implanted femur. Forces  $F_1$ -5, acting forces points  $P_0$ -3, and boundary conditions applied to the intact and implanted femur are during the gait cycle and are taken from.<sup>39,40</sup> (B) Computational scheme for multiscale mechanics and material property optimization of a minimally invasive 3D hip implant with minimum bone resorption. (C) Optimum relative density distribution of the fully porous implant. (D) Generation of lattice micro-architecture from optimal relative density distribution using a high strength tetrahedron topology. (E) Implant manufacturing via Selective Laser Melting.



**Figure 2.** (A) Implant manufacturing via Selective Laser Melting. (B) Micro CT assessment of the implant lattice in the proximal region. The hole at the top left of the implant is an M6 thread which was necessary to interface with the Depuy Synthes inserter instrumentation. The inserter is identical to that of the commercial fully solid implant, and it allows to precisely control both varus-valgus as well as anteversion-retroversion positioning of the implant using the identical instrumentation that is used intraoperatively.

obtained through the relation<sup>33–35</sup>:

$$\begin{cases} E = 1,904\rho^{1.64} & \rho < 0.95 \\ E = 2,065\rho^{3.09} & 0.95 < \rho \end{cases}, v = 0.3 \quad (1)$$

where  $E$  is the elastic modulus of the bone, and  $v$  is the Poisson's ratio. Bone is treated here as isotropic material, as this simplification does not lead to a noticeable difference from those results obtained by considering orthotropic properties.<sup>34,35</sup> More details on how to assign material properties to bone for finite element simulations are described in the Supporting Information (S1).

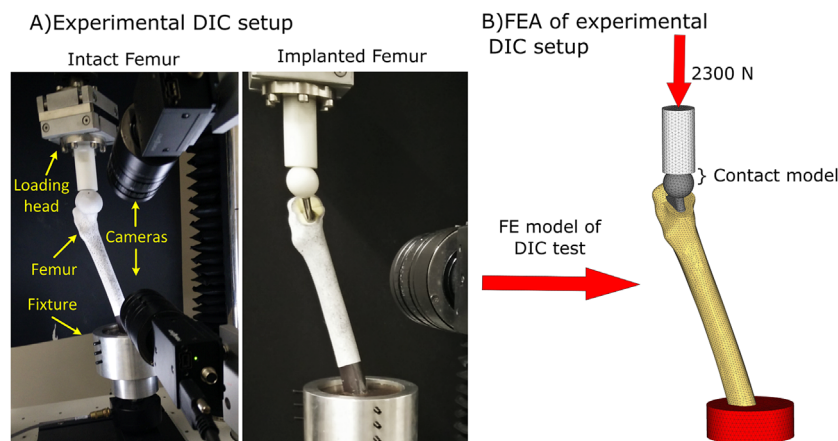
The macro geometry of the hip implant has a tapered-wedge shape. The design domain of the prosthesis is assumed to possess a 3D lattice micro-architecture, obtained through an aperiodic tessellation of a tetrahedron based unit cell, which has been shown appropriate for both load bearing orthopaedic applications and bone ingrowth.<sup>36</sup> Mechanical properties, in particular the homogenized stiffness tensor

$[E^H]$  and the multi-axial yield surface  $\{\sigma^y\}$ , are calculated via Asymptotic Homogenization (AH) theory.<sup>26,37,38</sup> We have shown that AH theory can capture stress distribution within the micro-structure with a considerably higher accuracy compared to other homogenization approaches.<sup>26,38</sup> The effective elastic properties and yield strength as determined by AH are detailed in the Supporting Information (S2).

To obtain the optimum relative density distribution throughout the implant to minimize bone resorption secondary to stress shielding, we discretize the 3D implant domain with 75 sampling points on the medial-lateral plane of the implant, as shown in Fig. 1B and S3. The relative density at each sampling point forms the vector  $b$  of the design variables. To obtain the relative density distribution throughout the implant, we considered four sampling points as a 4-node bilinear quadrilateral element. The relative density of each element of the implant FE model is then obtained from the linear interpolation between the relative densities of the nodes of the 4-node bilinear element. Details on how to assign relative density distribution throughout the implant are given in Supporting Information S3.

The interior micro-architecture of the implant (Fig. 1D) is obtained for a femur loaded under the physiological loading and boundary conditions,<sup>39,40</sup> as shown in Table 1 reporting force location and their values.

Material architecture tailoring is achieved by minimizing bone resorption,  $m_r(b)$ , subjected to a set of inequality constraints, including the fatigue safety factor,  $SF \geq 2$ , and the interface failure,  $f(\sigma_k^b) < 1$ . We use the Tsai–Wu failure criterion for the failure analysis of the tetrahedron lattice under multiaxial and fatigue conditions. To design against fatigue failure, we assume the lattice micro-structure to be free of defects, such as scratches, notches, and nicks. As a result, the constant life diagram can be constructed to verify and design the lattice against fatigue failure.<sup>41</sup> Detailed formulations for multiscale and fatigue design of porous microstructure are provided in the Supporting Information S4. The amount of bone loss around the stem is determined by assessing the amount of bone that is under loaded post implantation relative to the intact femur. Bone can be considered locally under loaded when its local strain energy ( $U$ ) per unit of bone mass ( $\rho$ ) ( $S = \frac{U}{\rho}$ ), is beneath the local reference value  $S_{ref}$ , which is the value of  $S$  when no prosthesis is present. Bone resorption starts when the local value of  $S$  is beneath the value of  $(1-s) S_{ref}$ .<sup>42,43</sup>  $s$  is the threshold level or dead zone. In this study, the value of dead zone is set to be 0.75.<sup>43</sup> The interface failure  $f(\sigma_k^b)$  is



**Figure 3.** (A) In vitro assessment of stress shielding using Digital Image Correlation (DIC) and (B) FE model of DIC test.

**Table 1.** Forces, Acting Forces Points, and Boundary Conditions Applied to the Intact and Implanted Femur During the Gait Cycle (Taken From<sup>33,34</sup>)

Force (N)				Location (m)			
Load cases	X	Y	Z	Points	X	Y	Z
$F_1$	-486	-295.2	2062.8	$P_0$	0	0	0
$F_2$	64.8	104.4	-118.8	$P_1$	0.035	0.009	-0.449
$F_3$	522	38.7	-778.5	$P_2$	-0.039	-0.018	-0.41
$F_4$	-4.5	-6.3	171	$P_3$	-0.022	-0.01	-0.375
$F_5$	-8.1	-166.5	836.1				

expressed by  $f(\sigma_k^b) = \frac{\tau}{S_s} < 1$ , where  $\tau$  is the local shear stress at the bone-implant interface, and  $S_s$  is the bone shear strength. The interface failure  $f(\sigma_k^b)$  is constrained to be lower than one to ensure the bone-implant interface failure will not occur. Detailed formulation for bone loss measurement and interface failure are presented in the Supporting Information S5. Through this process of material property tailoring, an implant with tuned high strength porous architecture that realizes minimum bone resorption is obtained. The implant is then manufactured with SLM technique, as described in the following section.

#### Manufacturing

The internal micro-architecture of the implant is generated from the relative density distribution determined from the optimization process previously described. The relative density of each tetrahedron lattice is obtained by calculating the average relative density over the lattice using a Gauss quadrature integration technique with one Gauss point. SLM constraints and bone in-growth requirements, including minimum manufacturable strut thickness, porosity, and pore size, are also considered during the development of the micro-architecture. In particular, the proximal portion of the hip replacement stem is constrained for optimum pore size and porosity to allow for early and extensive bone in-growth.<sup>36</sup> Pore size of 500  $\mu\text{m}$  and porosity of 70% are designed on the surface of the proximal bone apposing section of the hip implant. The minimum strut thickness is constrained to 200 microns throughout the implant to ensure manufacturability. The architected fully porous implant is manufactured with Selective Laser Melting (SLM) by Renishaw AM250 (Renishaw Limited, Mississauga, ON) with a power of 200 W and energy density of 60 J/mm<sup>3</sup> (Fig. 1E). The laser spot diameter is 70  $\mu\text{m}$ . The powder size is between 15 and 50  $\mu\text{m}$ , and the powder layer of 30  $\mu\text{m}$  is used. The part is processed at 720° Celsius under argon for 2 h, and is removed from the build plate post treatment using EDM wire cutting.

To assess the quality of the manufactured internal architecture, the implant is scanned using a Nikon Xt H225 ST (Nikon Canada, Mississauga, ON) (high-resolution micro-CT) (Fig. 2B). Detailed inspection of CT-scan images confirms mechanical integrity of each cell strut with complete formation of all the struts with neither break nor discontinuity among the elements and absence of loose powder particles within the cell pores. To assess bone resorption performance for the manufactured implant, a benchtop biomechanical test and a complementary FE model of the experiment are conducted to provide volumetric context of stress and strain variation in composite femora subjected to quasi-physiologic loading conditions.

#### Experimental Evaluation: DIC Evaluation With Complementary FEA

To demonstrate the methodological approach followed in this work, a set of complementary in vitro DIC test and computational investigations are conducted on a simplified model. The simplified model utilizes artificial composite femurs (Sawbones<sup>®</sup>, Vashon, WA) under quasi-physiological loading conditions in order to minimize the variability between samples. This allows a clearly controlled experimental set up that demonstrates the experimentally measured performance of a graded fully porous implant compared to an identical clinically available fully solid titanium alloy implant of equal geometry (Trilock BPS, DePuy, Warsaw, IN), our benchmark. A total of six femurs are used, with three femurs randomly allocated to each treatment to receive either the fully porous or the solid control stem. The fourth generation femurs from Sawbones<sup>®</sup> are selected for their claimed ability to reproduce a biomechanical behavior similar to that of fresh cadaver specimens as well as low inter-specimen variability.<sup>44</sup> Sawbones<sup>®</sup> femurs are made of a solid material representing the cortical bone, and a foam representing the trabecular bone. Although Sawbones<sup>®</sup> femurs provide a basic tissue differentiation between the cortical and trabecular bone, we emphasize their material properties are still isotropic ( $E = 16.7$  GPa for the solid material, and  $E = 0.155$  GPa for the foam); the foam, in particular, has uniform relative density, that cannot represent the actual femoral anisotropy of native trabecular bone.

The first study considers a quasi-physiological loading pattern that can be precisely reproduced in vitro. The goal is to compare changes in surface strain relative to an intact composite femur as a bench top experimental estimate of the expected in vivo stress shielding. The experiment set up consists of a digital image calibration (DIC) system calibrated to measure the surface strain of both intact and implanted femurs during loading. The change of strain, measured on the medial aspect of the femur, is used as an experimental proxy for stress shielding. For the experimental preparation, all femoral condyles are resected at a distance of 22 cm measured from the tip of the greater trochanter. Using a customized fixture, the femurs are angled at 12° flexion, and 12° adduction, and potted into epoxy (detailed description provided in the Supporting Information S6). The femoral head is loaded up to 2300 N through a fixture that is free to translate within the transverse plane such that there is no un-physiological moment applied. A stereo mounted camera set up is used to acquire synchronized images of the medial calcar and medial aspect of the femur covering Gruen zones 4 through 7.<sup>45</sup> The surface of the composite femora are speckle painted to achieve a distribution of speckles ranging

from 500 to 1,000 microns (Fig. 3A), as described in detail in the Supporting Information S7. Images are taken at a frequency of 6 Hz starting from an unloaded state, up to the maximum load at 2300N using five MP CCD cameras (Point Grey Research Inc., Richmond, BC) with Fujinon 25 mm c-mount lenses (Fujifilm, Valhalla, NY). From the recorded image, digital calibration is performed using Vic-3D (Correlated Solutions, Irmo, SC). The stereoscopic camera system is attached directly to an electromechanical testing frame (Bose 3510 electroforce—Bose, Eden Prairie, MN) using a custom fixture to ensure consistent camera position. The femurs are then randomly allocated to receive either the fully porous or the control stem (Supporting Information S8). An Anterior-Posterior (AP) and Medial-Lateral (ML) radiograph are taken to ensure consistent implant position, as well as correct neck offset and length (Fig. S6, Supporting Information S9). The DIC data for each individual femur is exported and registered to an atlas femur using an iterative process involving closest point minimization (Figs. S7–8, Supporting Information S10). This ensures that each local strain measurement is reliably and anatomically located across all femurs.

To be consistent with strain energy measurements used in bone loss measurement during the design process, we considered as a metric for bone resorption, the ratio of post implantation surface strain to the pre-implantation surface strain squared. Using the principle compressive strain, we can roughly estimate the strain energy of each element as follows:

$$S_{\text{elm}} = \frac{1}{2} \varepsilon_{\text{pc}}^2 E V_{\text{elm}} \quad (2)$$

where  $S_{\text{elm}}$  is the strain energy of an element,  $\varepsilon_{\text{pc}}$  is the principle compressive strain,  $E$  is the Young's modulus of the element material, and  $V_{\text{elm}}$  is the element volume. If we consider  $S_{\text{ref}}$  as the local strain energy before implantation, the ratio of the strain energy of element material on the surface of the composite femur after and before implantation is as follows:

$$\frac{S_{\text{elm}}}{S_{\text{ref}}} = \left( \frac{\varepsilon_{\text{pc}}}{\varepsilon_{\text{pc(ref)}}} \right)^2 \quad (3)$$

Equation 3 shows that the strain energy before and after implantation can be related to the ratio of the post implantation surface strain and the pre-implantation surface strain squared. Therefore, in this work Equation 3 was adopted as metric for bone loss measurement on the surface of the composite femur. If the reduction of strain after implantation is greater than 50% relative to the intact femur, the bone surface region is deemed to be prone to bone resorption (Supporting Information S11). This value is chosen to coincide with the physiological FEA model value for the dead zone threshold (Supporting Information S5) used to design the architected stem (Fig. 1B). The percentage of surface susceptible to bone resorption is compared between the fully porous and solid control stem for Gruen Zones 5 through 7 using a two tailed student *t*-test with  $p < 0.05$ , which is considered statistically significant.

One limitation of the experimental technique described above is that only surface strain can be recorded. Bone resorption secondary to stress shielding, however, is a volumetric phenomenon. To address this issue, we conduct FE simulations replicating the experimental conditions of

the implanted femur (Fig. 3B) with the goal of obtaining volumetric measures of bone resorption that would supplement the surface strain measure obtained experimentally. For this purpose, a 3D model of the composite femur is created from an accurate reconstruction of CT-scan data, and FE simulations with loading and boundary conditions equivalent to those used in the experiments, are conducted in pre- and post-implantation conditions. The isotropic properties of the Sawbones<sup>®</sup> femur (Young's modulus: 16.7 GPa for cortical bone and 0.155 GPa for trabecular bone) are used for the computational model. The strain energy of the bone before and after implantation is measured to calculate bone loss via the criterion used during the material tailoring process. The percentage of bone loss on the bone surface is also measured and compared with the DIC results to bolster the experimental measures of bone loss in the fully porous titanium alloy stem and the fully solid titanium alloy control stem. The results are segregated into radiological Gruen zones that are commonly used to clinically assess the performance of THA.<sup>46,47</sup>

## RESULTS

### Material Tailoring and Physiological FEA

The material architecture tailoring described in the methodology section resulted in the optimum density distribution shown in Fig. 1C. The amount of bone resorption for the optimized implant is presented in Fig. 4 and compared with the amount of bone resorption of a fully solid implant. The physiological FEA model (Fig. 4) shows a total of 34% of bone resorption secondary to stress shielding for the fully solid implant, and 8% in the optimized fully porous implant. This indicates a greater than 75% reduction in bone loss secondary to stress shielding. The fully porous implant can realize 8% volumetric bone loss in Gruen zone 7, whereas the fully solid implant 27% in zone 7, followed by 5% and 2% bone loss in Gruen zones 6 and 2, respectively. This shows that the amount of bone resorption for the fully porous implant is mainly limited to the proximal region in Gruen zone 7, whereas for the fully solid implant the amount of bone resorption extends to the distal region zone 6.

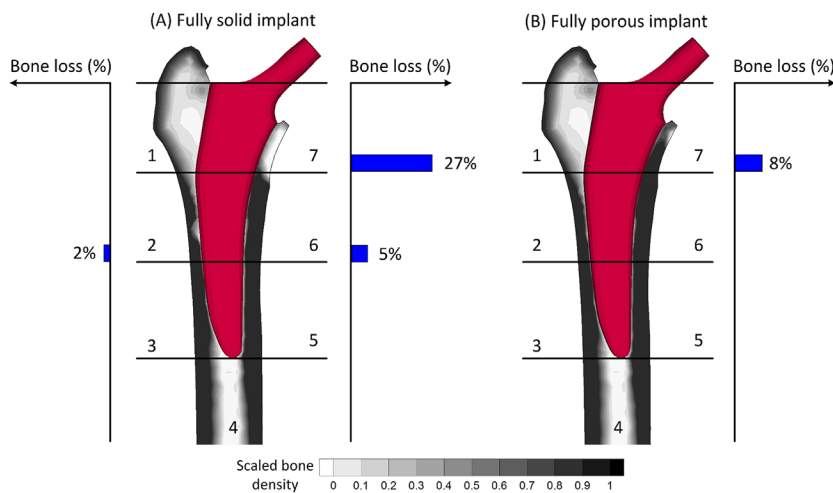
### Manufacturing

Figure 1D shows the mapping of the optimum material distribution into a tessellated tetrahedron micro-architecture. The reduced bone apposing pore size can clearly be seen, targeting an average of 500 microns for optimum bone in-growth. CT scanning inspection shows no gross malformations of struts or entrapped un-melted powder. Figure 2B shows the CT visualization of the internal micro-architecture of the manufactured implant.

### Experimental Evaluation: DIC With Complementary FEA

Figure 5 shows the results of the quasi-physiological DIC experimental model and the corresponding FEA model for both the optimized fully porous and fully solid implant. The DIC experiment shows the greatest change in strain in the proximal medial calcar in Gruen zone 7, with bone loss of  $70 \pm 24\%$  for the fully





**Figure 4.** Regions prone to bone resorption in Gruen zones 1–7 for (A) fully solid implant and for (B) fully porous implant with tailored relative density distribution. Values presented here are volume bone loss measured from the metric described in the Supporting Information S5. All zones with no reported bone resorption are 0%.

solid implant and  $71 \pm 14\%$  for the fully porous implant ( $p > 0.05$ ). Gruen zone 6 shows a statistically significant reduction in strain shielding for the fully porous implant as compared to the fully dense implant ( $25 \pm 5\%$  vs.  $7 \pm 7\%$   $p < 0.05$ ). Gruen zone 5 reports the least amount of strain shielding for both implants,  $7 \pm 10\%$  and  $2 \pm 3\%$ , respectively for the fully solid and fully porous implants ( $p > 0.05$ ). The medial diaphysis distal to the implant shows no variation in strain from the intact femur for both the optimum and fully solid prostheses. This indicates that the neck offset is appropriately established after implantation, thereby eliminating any systematic experimental bias of the stress shielding results. The corresponding FEA model provides both surface strain reduction as well as the volumetric change of strain for both implants. Gruen zone 7 shows the largest amount of stress shielding with a 27% and 16% volumetric reduction of bone for the fully solid and optimum porous implant, respectively. This shows 40% reduction of volume bone loss for the fully porous implant. In Gruen zone 6, the amount of volume bone loss for the fully solid implant is 14%; for the fully porous implant this value is equal to 2%, 78% lower than that for the baseline implant. Gruen zone 5 shows no variation between the implanted and intact femur for both implants.

At Gruen zone 7, the amount of surface bone loss for fully solid and fully porous implant is 86% and 71%, respectively. The extent of bone resorption at Gruen zone 6 for the fully dense implant is significantly higher compared to the fully porous implant. The amount of surface bone resorption for the fully porous implant is 8%, whereas for the fully solid implant this value is 36%. This shows 77% reduction of surface bone loss for the fully porous implant at Gruen zone 6 compared to fully solid implant. At Gruen zone 5, no surface bone resorption is observed for both fully porous and fully solid implant.

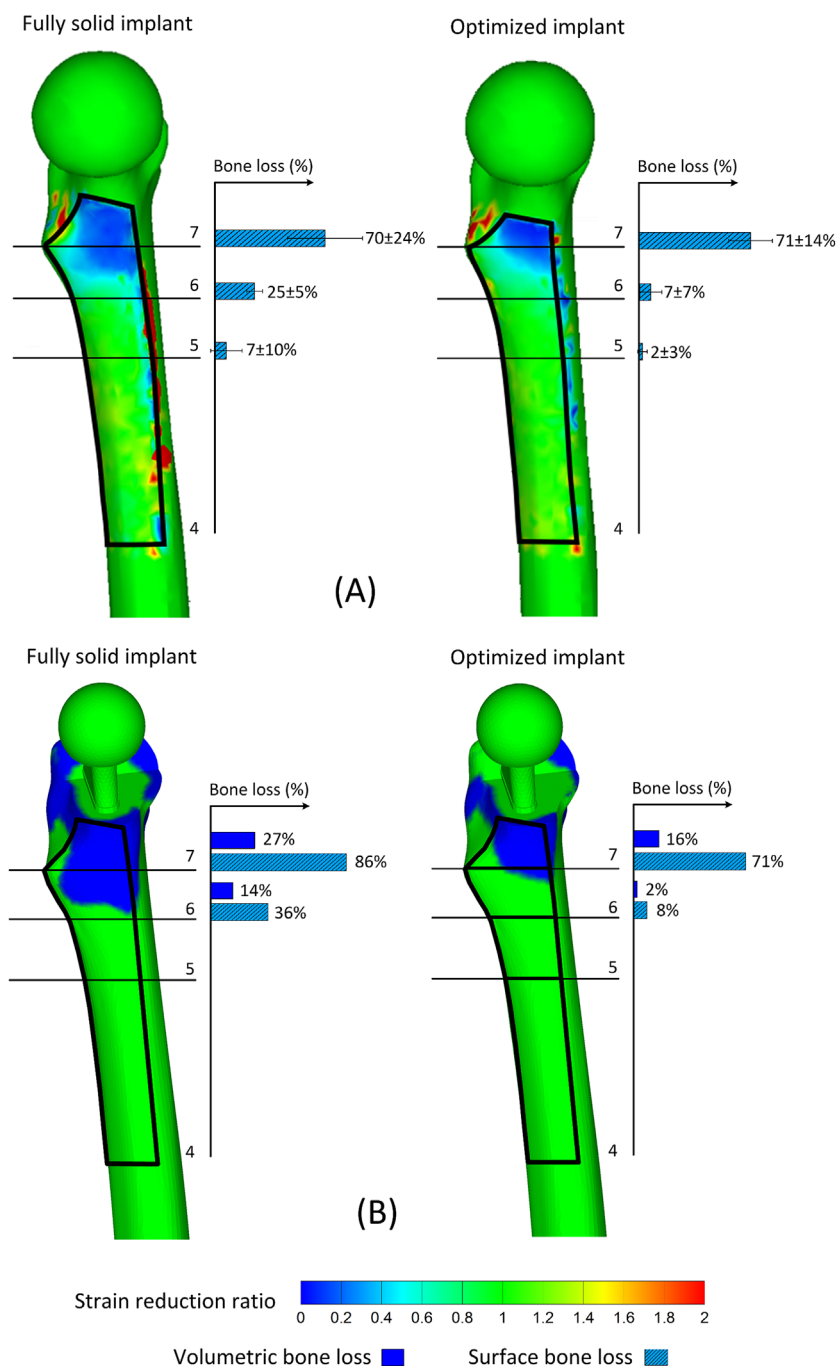
## DISCUSSION

The results from both the physiological finite element model and the DIC experiment of the current study

show a reduction in stress shielding of the porous implant as compared to a fully solid stem of identical geometry. Furthermore, CT analysis shows that the optimum relative density distribution could be mapped into an aperiodic lattice domain with no entrapped unmelted powder. This indicates that the hip implant is the first to be fully porous throughout, in contrast to existing stems with a porous coating on a solid part.

Previous designs relying on the modification of the material properties of femoral stems aimed at preserving bone stock have been used, with varying degrees of success. Isoelastic composite stems, introduced in the 1970s by Robert Mathys, were designed with a stainless steel core to improve the mechanical strength, and a polyacetal resin layer with elastic modulus similar to that of bone to avoid stress-shielding.<sup>48</sup> The results of 15 years follow-up revealed this prosthesis to perform extremely poorly.<sup>49</sup> Another composite implant is the EPOCH hip stem, which has a forged cobalt-chromium-molybdenum core section with an outer layer of pure titanium fiber metal mesh applied over a polyaryletherketone (PAEK) middle section.<sup>50</sup> While the data of 5 years follow-up suggest that this fully porous-coated implant design provides fixation and better maintained peri-prosthetic cortical thickness and density than conventional implants,<sup>51</sup> a recent study has demonstrated a 10–20% loss in peri-prosthetic bone at 7 years. This is very similar to that seen with a conventional stem.<sup>51,52</sup> The authors concluded that the merit of the Epoch stem in preserving bone mineral is only transient in nature. This can be likely attributed to the homogeneous and uniform material distribution of the stem no longer being truly isoeleastic. In contrast, the implant presented in this work has shown that optimal properties gradients enable the realization of a fully porous implant with properties that mirror the normally changing density of the surrounding proximal femoral bone.

On the other hand, other fully porous materials that commercially available today are less stiff than the solid substrate materials, but do not provide a



**Figure 5.** (A) Surface bone loss measurement obtained from DIC experiment. (B) Surface and volume bone loss measurement from the FE model reproducing the condition of the experiment set-up. Surface bone loss is considered when the ratio of post implantation surface strain squared to the pre implantation surface strain squared decreases more than 75%. Volume bone loss is measured when the ratio of post implantation strain energy to the pre implantation strain energy decreases more than 75%.

viable option for creating an isoelastic femoral stem. An example is porous tantalum which is excellent for its biocompatibility, high volumetric porosity, and low modulus of elasticity, but its pore distribution is predominantly uniform. The reduced stiffness of tantalum foam, in fact, decreases bone resorption; yet, its homogenous distribution of pores has the undesirable effect of increasing interface stresses.<sup>43,53,54</sup> In addition, its use in femoral stems can only be as a porous coating on a stiffer solid titanium substrate, precluding a fully porous stem. As a result, most, if not virtually all of the advantages of its low modulus of elasticity, are lost when it is applied for use in a

femoral hip stem. The stem design in this study not only addresses the issue of stress shielding by its graded and fully porous design, but also allows the stem to have sufficient strength; its porous architecture is obtained from an aperiodic tessellation of a tetrahedron based unit cell, which has been shown appropriate for load bearing orthopaedic applications.<sup>36</sup>

The volumetric index of bone loss has significant clinical relevance since this corresponds to the bone stock available for revision surgeries. We found a reasonably good agreement between the amounts of surface bone loss from FEA and those from DIC

experiments. The figures show that FEA results are within statistic values obtained from DIC experiments. We can thus, assume the volumetric bone loss measured from simulations can reasonably assess the actual amount of stress shielding that might occur during the DIC experiment. This indicates the reduction of the surface strain is an appropriate proxy for stress shielding.

Although the reduced complexity of the experimental set up shows a promising reduction in stress shielding, cadaveric match pair femurs with physiological loading conditions should be used to reproduce the conditions for which the implant is designed. This is a part of future study. In addition, since the bone loss measured in this study do not account for the adaptive process of bone remodeling over time,<sup>55,56</sup> their values are still representative of the amount of bone resorption from 6 to 24 months post-operatively.<sup>57</sup> Although the majority of bone remodeling occurs within 2 years, Bone Mass Density can continue to decrease as a result of stress shielding even up to 14 years after implantation.<sup>57</sup> In this case, the amount of bone resorption can be detected with dual-energy X-ray absorptiometry (DEXA) with a precision of 1–4%.<sup>57</sup>

The implications of the work here undertaken are very promising, serving as a multidisciplinary bridge integrating biomechanics, material property tuning, additive manufacturing of 3D porous architecture, and clinically relevant experiments, all addressing shortcomings of existing materials for hip prostheses. We have demonstrated that three-dimensional material distributions with variable stiffness can be obtained to develop a hip stem, which is shaped into a minimally invasive geometry. The stem is a short and has a single tapered wedge design, which is the most common implant design type used in North America.<sup>58</sup> In this study, we also showed the effectiveness of using SLM technology to build Ti-6AL-4V controlled gradients of fully porous micro-architected stems.

Unsurprisingly, care must be taken also here with interpreting the results of this work and extrapolate a direct assessment of expected clinical outcomes. Bone resorption is a complex phenomenon involving a multitude of factors specific to the implant, the patient, the surgical procedure, and varying degrees of interaction between the aforementioned factors. It is important to underline that the values reported for stress shielding are percentages of bone that are susceptible to stress shielding immediately post operation, and not necessarily the bone tissue that will resorb in the long term. Although numerical techniques are available to represent this process that is time dependent, at the present time there are no widely-accepted in vitro biomechanical models available that can represent the phenomenon. As such, further experimental validation of the ability of a tuned fully porous implant to reduce stress shielding should rely upon long term in vivo models that can account for the biomechanical interaction complexity of a living system. Future work includes

replicating the current investigation in an animal model to examine the long-term bone remodeling of a fully porous implant.

## CONCLUSION

A high strength fully porous material with tunable mechanical properties is introduced for use in minimally invasive hip replacement. The implant micro-architecture is fine-tuned to locally mimic bone tissue properties, which results in minimum bone resorption secondary to stress shielding. This work demonstrates that a high strength fully porous femoral stem with tunable mechanical properties can be designed and manufactured to reduce stress-shielding. The proposed implant has been built successfully with SLM technique while respecting bone in-growth requirements at the implant interface. The in vitro test has proved substantial decrease of the femur surface strain, inferring substantial reduction in stress shielding. This development is promising and may possibly pave the way for tuned fully porous materials for bone interfacing implants of next generation use in orthopaedic arthroplasty surgery.

## AUTHORS' CONTRIBUTIONS

SA had substantial contributions to research design, finite element simulation, optimization of the hip implant, interpretation of data, and drafting the paper. BJ had substantial contributions to research design, design of experiment, the acquisition and interpretation of experimental data, and drafting the paper. MT had substantial contributions to research design, clinical evaluation, drafting the paper, and revising it critically. DP had substantial contributions to problem formulation and research design, computational mechanics and implant optimization, supervision, drafting, and revising the paper besides approval of the submitted and final versions. All authors have read and approved the final submitted manuscript.

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