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1 The design of additively manufactured lattices to increase the
2 functionality of medical implants

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21

1 **Abstract**

2 The rise of antibiotic resistant bacterial species is driving the requirement for medical
3 devices that minimise infection risks. Antimicrobial functionality may be achieved by
4 modifying the implant design to incorporate a reservoir that locally releases a
5 therapeutic. For this approach to be successful it is critical that mechanical
6 functionality of the implant is maintained. This study explores the opportunity to
7 exploit the design flexibilities possible using additive manufacturing to develop
8 porous lattices that maximise the volume available for drug loading while maintaining
9 load-bearing capacity of a hip implant.

10 Eight unit cell types were initially investigated and a volume fraction of 30% was
11 identified as the lowest level at which all lattices met the design criteria in ISO 13314.
12 Finite element analysis (FEA) identified three lattice types that exhibited significantly
13 lower displacement (10-fold) compared with other designs; Schwartz primitive,
14 Schwartz primitive pinched and cylinder grid. These lattices were additively
15 manufactured in Ti-6Al-4V using selective laser melting. Each design exceeded the
16 minimum strength requirements for orthopaedic hip implants according to ISO 7206-
17 4. The Schwartz primitive (Pinched) lattice geometry, with 10% volume fill and a
18 cubic unit cell period of 10, allowed the greatest void volume of all lattice designs
19 whilst meeting the fatigue requirements for use in an orthopaedic implant (ISO 7206-
20 4). This paper demonstrates an example of how additive manufacture may be
21 exploited to add additional functionality to medical implants.

22

23 **Keywords:** additive manufacture; drug delivery; finite element analysis; lattice;
24 mechanical testing; therapeutics

1 Introduction

2 Additive manufacture (AM) is the process of creating a three-dimensional object
3 through layer-by-layer deposition of material. Commonly used AM techniques to melt
4 powdered metal material to create near net shape parts are selective laser melting
5 (SLM) and electron beam melting (EBM). Both of these approaches allow a greater
6 design flexibility than traditional manufacturing methods to produce metallic parts (1);
7 however, this advantage is not currently exploited to its full potential in medical
8 applications. The possibility of new implant designs produced via AM routinely
9 investigate osseointegration (2). However, increased functionality of implants can
10 also be created through incorporation and controlled local release of therapeutics
11 (3), or matching the mechanical properties of implants to the surrounding bone and
12 tissue, for example through graded structures (4). This improvement in implant
13 design has been possible due to the advances in additive manufacturing, where
14 conventional subtractive methods are not capable of achieving such complex
15 features.

16 Infection control of implants is a major concern in medicine, due to the increase in
17 antibiotic resistant species. Recently, Lenguerrand et al. (5) used the National Joint
18 Registry (NJR) for England, Wales, Northern Ireland and the Isle of Man to
19 investigate revision surgery due to prosthetic hip joint infection. Between 2005 and
20 2013, the prevalence of revision surgery due to prosthetic joint infection, within three
21 months of primary hip arthroplasty, increased 2.3-fold (5). Further, over 1000
22 procedures are performed due to prosthetic joint infection annually in this NJR region
23 (5). Incorporating a therapeutic agent into a temporary cement spacer is a common
24 solution to treat infection as it allows targeted local drug delivery with a controlled
25 release. When revision surgery is required due to infection of a primary hip

1 replacement, 2-stage hip revision is chosen to treat most cases (6, 7). However, a
2 cement hip spacer can result in poor patient quality of life during its implantation, due
3 to its limited strength resulting in restricted mobility (8). Thus, an implant that can
4 withstand normal loading conditions whilst eluting a desired therapeutic would be
5 advantageous. This may be realised by using AM technologies to create an internal
6 porous lattice structure to an implant that creates a void volume. A secondary
7 material loaded with an antibiotic could be incorporated into this void volume, such
8 as an antibiotic-loaded cement (9), and therapeutics released into the infected
9 surrounding tissue. It is important to consider the mechanical effect on an implant
10 when incorporating a lattice into a design, and ensure that fatigue and strength
11 criteria associated with the implant are still met.

12 To demonstrate the potential of AM in medical implants, optimisation of an alternate
13 2-stage hip revision spacer with internal lattice structuring was investigated in this
14 study, with an example design shown in Figure 1. Titanium alloy (Ti-6Al-4V) was
15 chosen as the implant material due to its biocompatibility and suitability for
16 orthopaedic applications (10). SLM was chosen to manufacture lattices due to the
17 technologies capability to produce small strut diameters of 0.2 mm. It is critical for a
18 correctly designed implant to withstand deformation, due to induced stress from the
19 applied physiological loads, and also have a satisfactory fatigue strength. The aim of
20 this study was to develop and additively manufacture a lattice structure that could be
21 used in the design of a therapeutically loaded orthopaedic hip implant as an
22 alternative to a partial-load bearing traditional cement spacer. Ultimately this
23 approach has the potential to improve patient mobility and as such quality of life, as
24 well as decrease the need for secondary stage surgery associated with hip revision
25 due to infection.

1

2 **Figure 1 – Computer Aided Design (CAD) of a hip implant: a) traditional implant; b) increased**
3 **functionality due to integration of lattice design, providing a void space to load a therapeutic agent.**

4

5 **Materials and Methods**

6 *Lattice design*

7 Lattices were designed according to ISO 13314 (11), the international standard for
8 mechanical compression testing of porous metals, briefly explained here. A
9 cylindrical design with diameter (D_o) of 15 mm, and height (H_o) of 15 mm was chosen
10 for compression lattices, observing the relationship in equation 1 (11). The
11 association between average pore size (d_a) and diameter of cylindrical specimen is
12 specified by equation 2 (11). Notably, the resolution of the M2 Cusing® SLM system
13 (Concept Laser, Germany) requires a minimum strut diameter of approximately
14 0.2 mm to achieve an acceptable part quality. Therefore, designs of lattices were
15 kept within these parameters.

Equation 1 – Specimen height

$$H_o = D_o \sim 2D_o$$

Equation 2 – Specimen diameter

$$D_o \geq 10 d_a$$

16

17 Compression lattice geometries were created using Simpleware ScanIP software
18 (Synopsys, Mountain View, USA), for each appropriate unit cell type available
19 (Figure 2). 2.5D lattices were not considered in this study due to their
20 inappropriateness for design of AM medical implants. Resampling was set at 0.1 mm
21 as standard, but was adjusted to 0.2 mm when the number of elements of a
22 compression lattice exceeded 1 million. Using the Simpleware FE module

1 (Synopsys, Mountain View, USA), a coarse mesh was applied to the lattice
2 geometries and these were exported for finite element analysis (FEA).
3 To enable incorporation of the largest volume of therapeutic agent, the target volume
4 fraction (ratio of solid to void) of each cell type was decreased in increments of 10,
5 until the lowest possible volume fraction was identified whilst maintaining all design
6 parameters. The unit cell period (the number of cells that fill the image domain along
7 an axis) was varied in steps of 5. To maintain a cubic structure, the unit cell period
8 was identical in the X , Y , and Z directions.

9 As the volume fraction was decreased the strut diameter decreased also,
10 compensating for the reduction in volume by removing material from the unit cell
11 shape. Increasing the unit cell period also resulted in a decrease in strut diameter, as
12 more unit cells were fitted along each axis length of the image domain. Thus, after
13 determining the lowest volume fraction possible, the highest unit cell period was
14 designed for each compression lattice. This would present the smallest strut
15 diameter for each cell type that was within the limits of the SLM machine.

16

17 **Figure 2 – CAD compression lattice cylinders (green) at 30% volume fraction, and a cubic unit cell period**
18 **of 10 in the X , Y and Z axis. Individual unit cells (blue) with 30% volume fraction. Unit cell type below**
19 **each image. Minimum strut and average pore diameters of CAD compression lattices shown for each cell**
20 **type, evaluated by Simpleware software.**

21

22 *Finite element analysis*

23 FEA uses computational methods to simulate applied physical conditions to a
24 structure, and analyses the theoretical behaviour. In this study, Comsol
25 Multiphysics® v5.2 (Comsol AB, Stockholm, Sweden) was used to perform FEA. A

1 tetrahedral mesh was applied to each lattice geometry (Figure 3). To simulate a
2 comparable force across all lattices, 2300 N was applied axially, and a fixed restraint
3 in all directions was applied to the bottom face. The 2300 N relates to the maximum
4 force applied during fatigue testing of orthopaedic hip implants, as described in ISO
5 7206-4, the international standard of implants for surgery – partial and total joint
6 prostheses (12). A stationary study was performed, using material properties for Ti-
7 6Al-4V: Young's modulus of 113.8 GPa; Poisson's ratio of 0.342; and density of
8 4430 kg/m³ (13). The maximum displacement and von Mises stress were used to
9 evaluate the performance of each design.

10 *Manufacture of parts*

11 Lattice cylinders were fabricated from Ti-6Al-4V gas atomised powder (TLS Technik,
12 Germany) sized 20-50 µm, with a M2 Cusing® SLM system (Concept Laser,
13 Germany). Recycled powder was sieved to ensure a powder size <60 µm.
14 Processing took place under an Argon atmosphere to limit oxygen pickup; the
15 atmosphere was controlled to <0.1% oxygen. An Nd:YAG laser was used, with a
16 maximum output power of 400 W, spot size of 60 µm, and wavelength of 1075 nm.
17 The same optimised process parameters, designed to reduce residual porosity, were
18 utilised from the authors' previous study (3). These parameters used an island
19 scanning strategy with a scanning speed of 1750 mm/s, hatch spacing of 75 µm, 150
20 W laser power, and 20 µm slice thickness. To improve stability during manufacture,
21 sacrificial support structures were built between the base substrate and each
22 individual lattice cylinder, which were removed after manufacture.

23 *Micro-computed tomography*

1 Lattice cylinders were scanned using a Skyscan1172 micro-computed tomography
2 (micro-CT) system (Bruker, Belgium) with 80 kV maximum X-ray energy, 8 W beam
3 power, 1750 ms exposure per projection, aluminium and copper filter, and 3.38 μm
4 pixel size. MicroCT was only employed on the Schwartz primitive (Pinched) 10%
5 lattices since reliable results on higher volume fraction lattices was unachievable due
6 to beam hardening and poor penetration of titanium. Reconstructed data were
7 visualised in 3D using CTVox software (version 3.0, Bruker). A porosity analysis was
8 performed using CTAn software (version 1.15.4.0, Bruker). Briefly, a region of
9 interest was created within the strut material of each lattice, and this was interpolated
10 across slices of the strut, to create a volume of interest (VOI) of approximately 0.015
11 mm^3 . Global thresholding was applied to create a binary image, and a 3D analysis
12 used to determine the total porosity within the VOI. The mean of 3 values taken from
13 separate struts was calculated for each sample ($n = 5$).

14 *Porosity determination using an Archimedes balance*

15 Using an Archimedes balance, the mass of the lattice cylinders was taken in both air
16 and ethanol, and additionally the height and diameter of each sample was measured
17 using a Vernier calliper. The density of the lattice material was calculated from
18 equation 3, where A is the mass of sample in air, B is the mass of sample in ethanol,
19 ρ_0 is the density of ethanol (0.79 g/cm^3), and ρ_L is the density of air (0.0012 g/cm^3).
20 The apparent solid density (ρ_C) of the cylinder was calculated from equation 4, where
21 the volume of the cylinder (V) was calculated from its height and diameter and ρ_T is
22 the theoretical density of Ti-6Al-4V (4.43 g/cm^3).

Equation 3 – Material density

$$\rho = \frac{A}{A - B} (\rho_0 - \rho_L) + \rho_L$$

Equation 4 – Apparent density

$$\rho_c = \frac{A/V}{\rho_T} \times 100$$

1

2 *Strut and pore dimensions*

3 The strut and pore dimensions could not be measured with Vernier callipers due to
4 their geometry within the lattice. Therefore, to validate the manufactured part versus
5 the stereolithography file (STL) sent for printing, images were taken of the
6 specimens and the minimum strut and average pore diameters were measured using
7 ImageJ (National Institutes of Health, Bethesda, MD, USA) (Figure 4). The
8 photographic images allowed external features to be measured. Three repeat
9 measurements were taken, and the mean calculated for external minimum strut and
10 average pore diameters of manufactured lattices, with $n = 5$ for each lattice unit cell
11 type. In addition, ImageJ was used to measure average internal strut and pore
12 diameters for specimens scanned by micro-CT. Five repeat measurements were
13 taken for strut and pore diameters and the mean calculated, with $n = 5$ for sample
14 number.

15 *Mechanical testing*

16 Quasi-static compression tests were undertaken on $n = 5$ specimens per unit cell
17 type using a Z030 universal mechanical tester (Zwick/Roell, USA). Testing was
18 performed according to ISO 13314 (11). Each lattice was compressed at an initial
19 strain rate of 10^{-2} s^{-1} to failure (0.075 mm/s). Failure strain was set to 50% of the
20 specimen height. However, all specimens failed before the 50% maximum strain limit
21 or reached the maximum load cell limit of 25 kN. Force and displacement were
22 measured by the machine and from this, stress-strain curves were plotted for each

1 test, where stress and strain were calculated from equation 5 and equation 6,
 2 respectively. Following ISO 13314, results for quasi-elastic gradient (equation 7),
 3 plateau stress between 5-9% strain (Figure 5), first maximum compressive strength
 4 (Figure 5), energy absorption to 10% strain (equation 8) and energy absorption
 5 efficiency (equation 9) were reported (11). If specimens did not fail before the
 6 maximum load of 25 kN, the plateau stress could not be calculated. The plateau end
 7 strain could not be calculated for any of the specimens.

Equation 5 – Compressive stress (N/mm²)

$$\sigma = \frac{F}{A}$$

Equation 6 – Strain (%)

$$e = \frac{\Delta l}{l_0} \times 100$$

Equation 7 – Quasi elastic gradient (N/mm²)

$$E_{qe} = \frac{\sigma}{e}$$

Equation 8 – Energy absorption per unit volume (MJ/m³)

$$W = \frac{1}{100} \int_0^{e_0} \sigma de$$

Equation 9 – Energy absorption efficiency (%)

$$W_e = \frac{W}{\sigma_0 \times e_0} \times 10^4$$

8

9 F is the compressive force and A is the initial cross-sectional surface area
 10 perpendicular to the loading force, in accordance with ISO 13314. Δl is the overall
 11 compressive displacement, and l_0 is the initial gauge length. e_0 is the upper limit of
 12 compressive strain (%) and σ_0 is the compressive stress at the upper limit of
 13 compressive strain (N/mm²), and e_{cr} is the initial yield point corresponding to the start
 14 of the plateau regime.

15 Fatigue testing was performed to emulate the testing standard ISO 7206-4 (12),
 16 which determines the endurance properties of stemmed femoral components, on an
 17 ElectroForce 3300 (Bose Corporation, ElectroForce Systems Group, Minnesota,

1 USA). A sinusoidally varying compressive force between 300 and 2300 N was
2 applied at 5 Hz until failure or run-out of 5 million cycles (12). The displacement of
3 lattices was recorded at 300 cycles (f), and as specified in ISO 7206-4 the test was
4 programmed to end if the specimen displaced greater than either 5 mm or $1.25 \times f$,
5 whichever was the greater value. Specimen sample size for fatigue testing was $n =$
6 3.

7 All mechanical testing was performed at room temperature.

8 **Results**

9 Eight standard lattice types available in Simpleware ScanIP (Synopsis, Mountain
10 View, USA) were chosen for investigation. The lowest common target volume
11 fraction across all unit cell types, whilst maintaining design parameter requirements,
12 was 30% (Figure 2). Minimum strut diameter and average pore size were measured
13 for each CAD (computer aided design) lattice (Figure 2) at 30% target volume
14 fraction. The designed pore sizes varied from 0.55 mm (Neovius' surface) to 0.95
15 mm (Schwartz primitive (Pinched) and Schwartz diamond); and strut diameter varied
16 from 0.30 mm (Double Schoen gyroid) to 0.60 mm (Cylinder grid).

17 FEA was performed on the lattices listed in Figure 3 with the von Mises stress and
18 maximum displacement results displayed. Maximum stresses were noted at the
19 minimum strut diameters of all lattice designs, and specifically in the vertical struts
20 for the more cubic orientated lattices (Schwartz primitive, Schwartz primitive
21 (Pinched) and Cylinder grid). High stresses were also noted due to partially complete
22 unit cells at the edge of cylinder shapes. The original and displaced lattice cylinder
23 result from FEA is shown in Figure 3, with a colour map of von Mises stress. The
24 stiffest cell types identified were the Schwartz primitive, Schwartz primitive

1 (Pinched), and Cylinder grid, which all displaced ≤ 0.02 mm respectively (Figure 3;
2 identified by *). Therefore, these cell types were chosen for manufacture and
3 mechanical testing (Figure 4).

4

5 **Figure 3 – FEA performed on Schwartz primitive (Pinched) lattice, with 30% volume fraction and a cubic**
6 **cell period of 10. Deformation scale increased to 114 with original lattice ghosted, and von Mises stress**
7 **displayed as a colour map with scale bar shown. FEA displacement and von Mises stress results for CAD**
8 **compression lattices, with cubic unit cell structure of 10 in X, Y and Z axis. 30% volume fraction, except**
9 **Schwartz primitive (Pinched) 10%. Number of elements of coarse model mesh at 0.1 mm resampling. If**
10 **number of elements exceeded 1 million, models were resampled at 0.2 mm; where this is the case,**
11 **lattices are identified with †. The stiffest lattice types chosen for manufacture are highlighted by *.**

12

13 The Schwartz primitive (Pinched) lattice was capable of the lowest volume fraction
14 (10%) whilst maintaining design parameters: $D_o = 15$ mm; $H_o = 15$ mm; strut
15 diameter >0.2 mm. Using FEA, this lattice was identified as the strongest unit cell
16 type at 10% volume fraction, displacing 0.05 mm. Specimens were manufactured for
17 fatigue testing and porosity analysis with Schwartz primitive (Pinched) unit cell type,
18 10% volume fraction, and a cubic unit cell period of 10.

19

20 **Figure 4 – AM lattices with cubic unit cell period of 10; unit cell type, volume fraction, and designed and**
21 **manufactured pore and strut diameters, stated below each lattice. Height (top row) and diameter (bottom**
22 **row) of specimens shown (mean \pm standard deviation). Minimum strut and average pore diameters**
23 **shown below each lattice, analysed with ImageJ.**

24

25 *Fraction of volume and material*

26 The volume fraction and material density for specimens with the largest volume
27 available for incorporation of a therapeutic agent were evaluated. Of the
28 manufactured specimens, the Schwartz primitive (Pinched) lattices at 10% volume
29 fraction, with unit cell period of 10 in the X, Y and Z axes, contained the highest

1 designed porosity. The level of defects within the manufactured specimens (i.e.
2 porosity within the lattice struts) calculated by microCT was $99.0 \pm 0.7\%$. The density
3 of the lattice material was analysed using Archimedes balance measurements, as
4 $4.24 \pm 0.11 \text{ g/cm}^3$, comparable to the theoretical density of Ti-6Al-4V (4.43 g/cm^3).
5 The volume fraction of the cylinder (designed to be 10%), was calculated from the
6 Archimedes balance measurements, as $14.18 \pm 0.68\%$. For the Schwartz primitive
7 (Pinched) 10% lattices scanned by microCT and evaluated by ImageJ, no deviation
8 was found (variation of 3%) between the designed and manufactured internal strut
9 and pore diameters (Figure 4).

10 *Mechanical testing*

11 Schwartz primitive and Schwartz primitive (Pinched) 10% compression lattices failed
12 (reached their first maximum compressive strength) within the quasi-static
13 compression test limits. Two Schwartz primitive (Pinched) 30% compression lattices
14 also failed within these test parameters. The remaining ($n = 3$) Schwartz primitive
15 (Pinched) 30% lattices, and all the Cylinder grid compression lattices, did not fail
16 before 25 kN. The first maximum compressive strength could only be calculated for
17 specimens that failed within the test parameters. However, the stress-strain curves
18 for each lattice type indicate the Schwartz primitive (Pinched) 30% and Cylinder grid
19 lattices were plateauing towards the point of failure at 25 kN (Figure 5).

20

21

22 **Figure 5 – Stress-strain curve for each AM lattice. a) Schwartz primitive 30%; b) Cylinder grid 30%; c)**
23 **Schwartz primitive (Pinched) 10%; d) Schwartz primitive (Pinched) 30%. Key: 1) quasi-elastic gradient; 2)**
24 **first maximum compressive strength; 3) plateau stress.**

25

1 **Table 1 – Mechanical testing results for AM lattices, with 30% volume fraction and cubic unit cell**
 2 **structure of 10. $n = 5$, except for † where $n = 2$. For ‡ energy absorption and efficiency calculated to 5%**
 3 **strain, otherwise calculated to 10% strain.**

Cell type	Schwartz primitive 30%	Schwartz primitive (Pinched) 30%	Cylinder grid 30%	Schwartz primitive (Pinched) 10%
Plateau stress (MPa)	---	---	---	27.8 ± 3.0
First maximum compressive strength (MPa)	126.8 ± 3.8	$138.1 \pm 0.1^\dagger$	>140.0	29.7 ± 7.7
Energy absorption (kJ/m^3)	5.11 ± 0.37	5.73 ± 0.54	6.43 ± 0.20	$0.31 \pm 0.04^\ddagger$
Energy absorption efficiency (%)	45.8 ± 2.6	43.0 ± 2.8	46.0 ± 1.4	$2.8 \pm 0.4^\ddagger$
Quasi-elastic gradient (GPa)	1.93 ± 0.05	2.31 ± 0.04	2.42 ± 0.09	0.92 ± 0.18

4

5 *Fatigue*

6 The Schwartz primitive (Pinched) unit cell with 10% volume fraction and a cubic unit
 7 cell function of 10 was chosen for fatigue testing, due to being the weakest
 8 mechanical structure of the 4 manufactured lattices (Table 1) and containing the
 9 greatest volume void space to incorporate a therapeutic agent. As the weakest
 10 mechanical structure but with the largest volume available for therapeutic
 11 incorporation, if the Schwartz primitive (Pinched) lattice with 10% volume fraction
 12 passed fatigue testing then the stronger lattice types should withstand with fatigue
 13 loading also in theory. Three samples completed 5 million cycles without failure
 14 (Supplementary Figure 1). The samples displaced 0.381 ± 0.115 mm after 300

1 cycles (f), and after 5 million cycles this had increased to 0.393 ± 0.113 mm, thus all
2 samples passed the fatigue criteria ($< 1.25 \times f$) set in ISO 7206-4.

3

4 **Discussion**

5 This paper describes a potential use of lattice design in orthopaedic implants, with
6 the 2-stage hip replacement spacer identified as a possible selection for redesign
7 due to its current limited life span and the inability for full patient load bearing. The
8 results of this study showed that the fatigue life of a Schwartz primitive (Pinched) unit
9 cell type, with 10% volume fraction and cubic cell function of 10, manufactured in Ti-
10 6Al-4V by SLM, was suitable for use in the design of an orthopaedic hip implant. Use
11 of such a lattice design would allow for the incorporation of a therapeutic agent, such
12 as a resorbable antibiotic-loaded cement, to allow the targeted release of a drug.
13 This could reduce the overall amount of antibiotics required, as the targeted delivery
14 would allow release of the antibiotics locally rather than if administered by alternative
15 methods. Whilst the Schwartz primitive (Pinched) 10% lattice design reduces the
16 mechanical strength of the implant, this study demonstrates that the structure was
17 capable of meeting the axial load requirements of an orthopaedic hip implant, as
18 described by ISO 7206-4. A major advantage of this design would be the increased
19 mobility of a patient during a 2-stage hip revision. There is even the potential to use
20 the implant as a permanent prosthesis, which is especially beneficial in cases where
21 further surgery is undesirable, for example in elderly patients (14) or high risk
22 surgical cases (15). Although this study assessed the capability of designed lattice
23 structures to meet the axial load conditions of an orthopaedic hip implant, further
24 work would study the associated torsion and bending forces.

1 A total of 8 reticulated lattice types were designed using CAD, with a possible
2 common minimum volume fraction of 30%. The Double Schoen gyroid, evaluated by
3 FEA, was the weakest lattice design (Figure 3; 1.23 GPa von Mises stress), with a
4 predicted displacement of 0.7 mm; this was approximately ten times weaker than
5 other lattice designs. Another notably weak lattice was the Neovius' surface, with von
6 Mises stress of 1.05 GPa. The common design feature of these cell types is their
7 organic shape structure, compared to the more cubic design of other cells (Figure 2).
8 As reported in other studies, stretch dominated structures are generally stiffer than
9 bending dominated structures, lending themselves as more suitable for weight
10 efficiency in structural applications (16). Since this study aimed to maximise the void
11 space available to determine the maximum volume of therapeutic agent that could
12 be incorporated, stretch dominated structures are an attractive solution to maintain
13 implant stiffness whilst removing material. This enables targeted drug delivery within
14 an orthopaedic implant and reduces the amount of antibiotics required to treat an
15 infection. Further, it provides a long-term implantable for when it is undesirable to
16 perform secondary surgery to remove a temporary cement spacer. The strongest
17 lattice types were the Schwartz primitive (Pinched) and Cylinder grid, with von Mises
18 stresses of 0.17 and 0.15 GPa, respectively (displacing 0.01 mm each). The FEA
19 results calculated in this study were used to inform the selection of lattice geometry
20 for AM and subsequently mechanical testing. Future work would involve validating
21 the FEA model to consider manufacturing defects and the influence of deviation from
22 the CAD model.

23 FEA was performed under identical conditions for all lattice types to provide a
24 comparison between designs. When evaluating lattice designs by FEA, stress
25 concentrations were noted at the edge of all specimens due to part cubic cells (cells

1 that were sectioned to fit within the cylindrical body). As noted in other studies, the
2 edge effect in FEA models of lattices makes it difficult to accurately model these
3 geometries (17). The displacement of Schwartz primitive (Pinched) manufactured
4 lattices (10% volume fraction) during fatigue testing was greater than predicted
5 during FEA (0.05 mm), due to specimens bedding in. Ultimately, although FEA
6 influenced the choice of which lattice geometries to manufacture, mechanical testing
7 of the lattices proved their validity as a choice for orthopaedic hip implants. The
8 compressive displacement of the Schwartz primitive (Pinched) lattices increased
9 during fatigue testing by 0.012 mm to 0.393 ± 0.113 mm, thus samples passed the
10 fatigue criteria ($1.25 \times f$) set in ISO 7206-4.

11 The density of the printed titanium alloy, calculated within struts as 4.24 ± 0.11
12 g/cm^3 , is similar to the theoretical density of Ti-6Al-4V (4.43 g/cm^3). This result,
13 accompanied by the low level of porosity ($1.0 \pm 0.7\%$) calculated from microCT data,
14 confirms minimum defects within the solid material of the structure, even with small
15 strut diameters of 0.37 mm.

16 Notably, the accuracy of the manufactured specimens was close to the designed
17 parts as evidenced by dimensional measurements. Specifically, the average pore
18 size for Schwartz primitive, Schwartz primitive (Pinched) and Cylinder grid for the
19 designed and manufactured parts were similar; 6%; -2%; -3%; variation from design
20 respectively. Furthermore, the minimum strut diameters for the same cell types
21 measured from the manufactured parts exhibited 29%, -4% and 6% variation from
22 design respectively. Similarly, the designed strut and pore diameters of Schwartz
23 primitive (Pinched) 10% lattices were designed as 0.29 mm and 1.18 mm. The
24 external strut and pore diameters measured by photography and ImageJ varied by

1 28% and -3%, while the internal diameters (0.30 ± 0.03 mm and 1.22 ± 0.03 mm)
2 measured by microCT and ImageJ varied by 3% and 3%. Although the greatest
3 variability of strut diameter may appear high at 29% (Schwartz primitive (Pinched)), it
4 is worth noting that the standard deviation of measurements for the minimum struts
5 manufactured diameter deviated a maximum of 0.17 mm from the designed
6 geometry, and the average pore size a maximum of 0.11 mm. These values are
7 beyond the resolution of the SLM machine used (0.2 mm), and therefore it can be
8 assumed that the predominant cause of measurement variation is most likely due to
9 the triangulation process when creating an STL file.

10 Traditionally, AM implants are finished through polishing techniques, therefore,
11 further investigation to assess the challenges associated with finishing lattice
12 structures would be beneficial. Although the example in this paper has investigated
13 the potential of lattices in the design of orthopaedic hip spacers, another use of
14 lattices is to mechanically match an implant to surrounding tissue (18). Titanium
15 alloys are the traditional material of choice for manufacture of implants due to their
16 biocompatibility, corrosion resistance and mechanical properties (10, 19, 20).
17 However, stress shielding is commonly cited as a barrier to titanium implants (19, 21,
18 22), since the material is significantly stiffer than that of the surrounding bone. The
19 elastic modulus of cortical and cancellous bone varies from 3 to 30 GPa and 0.02 to
20 0.3 GPa, respectively (23, 24), whereas the elastic modulus of Ti-6Al-4V is
21 significantly greater at 113 GPa (13). It is hypothesised that a lower Young's
22 modulus for the implant material results in more deformation of the implant and
23 therefore better bone ingrowth (25). A study by Schouman showed that by reducing
24 the overall stiffness of an implant through increased porosity, resulted in better bone
25 formation compared to a rigid design (21). By mechanically matching an implant to

1 surrounding bone, it is possible to prevent stress shielding and promote improved
2 osseointegration. The results of this study found that the quasi-elastic modulus of the
3 investigated lattices ranged from 0.92 ± 0.18 to 2.42 ± 0.09 MPa. These results are
4 within the range of those presented elsewhere: 2-6 GPa, with strut and pore
5 diameters of 400 μm and 650 μm , and relative density of 0.3 (26); and 0.5-1.5 GPa,
6 with 0.4 mm and 0.6 mm strut and pore diameter, and relative density 14% (27).
7 Notably, the results of this study are similar to the lower elastic modulus range of
8 cortical bone. Assuming a solid titanium structure would have an elastic modulus of
9 113 GPa, by varying the lattice geometry through an increase in volume fraction it is
10 predicted the modulus of the lattice structures could be designed to match the
11 variation in cortical bone. The manufactured specimens within this study failed at, or
12 around, a strain of 0.1 due to vertical struts within a layer fracturing. This strain range
13 is similar to that achieved in other studies (26). As vertical struts fractured at high
14 loads, the machine experienced rapid unloading (evident in Figure 5a), and therefore
15 tests were automatically stopped at this point due to the machine safety mechanism.
16 These lattices, therefore, did not reach the plateau stage. The exception to this is the
17 Schwartz primitive (Pinched) 10% lattice, which failed before a strain of 0.1 but at a
18 much lower load (Figure 5c), therefore plateau strength could be calculated for this
19 lattice type (Table 1).

20 Although this study demonstrates the suitability of lattice geometries for use in load
21 bearing orthopaedic applications, their design was limited to cylindrical geometry
22 with constant cross-sectional area to comply with ISO 13314. The final geometry of
23 lattices is still to be determined. Future work would involve further testing to evaluate
24 the effect of cross sectional area over which the lattice was applied. A similar
25 approach could be adopted to this study, which iterates between FEA and

1 experimental analysis, to assess the design envelope in which this lattice could be
2 employed.

3 The use of AM is not currently being exploited to its full potential in medical devices.
4 This study assesses the potential of a lattice design as an alternative for a cement
5 hip spacer, notably this approach could add value to other orthopaedic cases.
6 Implementation could decrease complications such as stress shielding by matching
7 implant strength to patient-specific bone properties, or to allow targeted delivery of
8 drugs by incorporating a chamber within an implant whilst maintaining associated
9 strength and fatigue requirements.

10 **Conclusions**

11 The design of implants can be redefined to increase functionality due to advances in
12 additive manufacture, with orthopaedic implants no longer restricted to simply
13 mechanically replacing or supporting damaged joints and bones. Here, we explore
14 the potential to exploit the void volume of porous lattice structures as a reservoir for
15 a secondary material containing a therapeutic agent. There is also the potential to
16 design implants containing lattice structures to mechanically match surrounding bone
17 and reduce stress shielding. This study assessed the suitability of additively
18 manufactured titanium lattices as an alternative design for hip cement spacers, to
19 decrease associated morbidity and further surgery. The weakest lattice design
20 (Schwartz primitive (Pinched) 10%), with the greatest volume void, withstood 5
21 million cycles of loading between 300 and 2300 N. In summary, this study confirms
22 that AM methods can produce a lattice design for use in a titanium implant that could
23 allow targeted drug delivery of a loaded therapeutic, without compromising the
24 fatigue life of a load bearing orthopaedic hip implant.

1

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11

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32

1 **Supplementary information**

2

3 **Supplementary Figure 1: Fatigue test data to 5 million cycles for Schwartz primitive (Pinched) unit cell**
4 **with 10% volume fraction and a cubic unit cell function of 10. Applied peak and trough load over 5 million**
5 **cycles (a). Strain (%) versus number of cycles for specimen 1 (b), specimen 2 (c), and specimen 3 (d).**

6