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High-strength, porous additively manufactured implants with optimized mechanical osseointegration

Cambre N. Kelly [a], Tian Wang [b], James Crowley [b], Dan Wills [b], Matthew H. Pelletier [b], Edward R. Westrick [c], Samuel B. Adams [d], Ken Gall [a], William R. Walsh [b]

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Abstract

Optimization of porous titanium alloy scaffolds designed for orthopedic implants requires balancing mechanical properties and osseointegrative performance. The tradeoff between scaffold porosity and the stiffness/strength must be optimized towards the goal to improve long term load sharing while simultaneously promoting osseointegration. Osseointegration into porous titanium implants covering a wide range of porosity (0%–90%) and manufactured by laser powder bed fusion (LPBF) was evaluated with an established ovine cortical and cancellous defect model. Direct apposition and remodeling of woven bone was observed at the implant surface, as well as bone formation within the interstices of the pores. A linear relationship was observed between the porosity and benchtop mechanical properties of the scaffolds, while a non-linear relationship was observed between porosity and the ex vivo cortical bone-implant interfacial shear strength. Our study supports the hypothesis of porosity dependent performance tradeoffs, and establishes generalized relationships between porosity and performance for design of topological optimized implants for osseointegration. These results are widely applicable for orthopedic implant design for arthroplasty components, arthrodesis devices such as spinal interbody fusion implants, and patient matched implants for treatment of large bone defects.

Introduction

Accelerating and maximizing the osseointegration of an orthopedic implant through modulation of implant topology has garnered increasing interest in recent years. With the ability to fabricate porous metallic scaffolds with increasing complexity, laser powder bed fusion (LPBF) has enabled a paradigm shift in the topological design of biomedical implants [1]. The integration of advanced computational design tools with LBPF, has unlocked engineering of porous scaffolds with prescribed properties and patient matched geometries. In fact, recent investigations into characterization of mechanical properties of AM titanium scaffolds with varied topologies and porosities show a wide range of resulting strengths and stiffnesses within the range of bone [2,3]. Recent work has also demonstrated that triply periodic minimal surfaces (TPMS) sheet-based architectures, including the gyroid-sheet, exhibit favorable mechanical properties, by maintaining high strength and fatigue resistance relative to strut-based unit cell architectures of the same porosity [[3], [4], [5], [6]]. Additional topological design parameters such as the unit cell size, orientation, and even the ratio of the cell size to the overall porous volume impacts mechanical properties of porous scaffolds [2,4,7]. However, these topological design factors are all secondary to the dominating effect of scaffold porosity which drives the mechanical performance of the scaffold (strength and stiffness) and influences osseointegration [[2], [3], [4]].

By increasing the porosity of the titanium scaffold, the apparent modulus can be reduced to within the range of bone [2], however, there is also a correlated reduction in scaffold strength which must be balanced to support implantation and load bearing. Matching of implant stiffness to that of bone is considered favorable in maximizing load sharing between the two, and thus stimulating bone formation [[8], [9], [10]]. However simply achieving stiffness matching through material selection is not sufficient to ensure mechanical interlock and successful osseointegration, as polyetheretherketone (PEEK) spinal interbody cages have been shown to result in fibrous encapsulation despite their relatively low modulus within the range of bone [11]. Thus, it is believed that through a combination of stiffness matching, surface interaction, and three-dimensional porous networks that interfacial mechanical interlock between the implant and newly formed bone is achieved. Thus, optimization of the tradeoff between initial load bearing capacity of the implant, and long-term potential for osseointegration and load sharing must be considered.

A high strength bone-implant interface is critical to successful outcomes in many clinical applications including interbody fusion, arthroplasty fixation, and bridging of large bone defects. Clinical failure can be caused by lack of initial interlock, poor bone integration or subsequent resorption due to stress shielding, often resulting in revision surgery. This is especially challenging in treatment of segmental defects, such as those of the lower extremity, where a need for a high strength and fatigue resistant implant must be balanced with the need for bone ingrowth over a long distance [[12], [13], [14], [15]]. Currently, treatment of large bone defects is primarily achieved using fibular autograft or cadaver bone allografts, the latter of which have a 50% failure rate due to nonunion and collapse after at least 16 months [16,17]. Another challenge is lack of implant integration with the host bone in arthrodesis applications, leading to instability and micromotion caused by fibrous encapsulation of the implant [18,19]. Thus, achieving early osseointegration is critical in the success of fusion procedures. We recently reported the importance of topology on establishment of a stable bone-implant interface to achieve functional repair of critically sized defects of the rat femora using gyroid-sheet implants, where the amount of bone in the most proximal and distal interfaces dictated the torsional strength of the repair [12].

Better understanding of the mechanical and biomechanical tradeoffs dictated by the implant porosity must be achieved to optimize implant design. In this study, porous titanium implants with gyroid architecture were designed with porosity varied over a physiological relevant range and produced by LPBF of medical

grade titanium alloy (Ti6Al4V). Benchtop mechanical evaluation was conducted in parallel with an ovine osseointegration model to determine the tradeoff between the implant's load bearing capabilities and the biomechanics at the bone-implant interface after 4 and 12 weeks. Histological and histomorphometric evaluations were used to assess the volume and location of bone ingrowth into the porous implants in cortical and cancellous sites. The present results have implications for orthopedic implant design across numerous clinical applications.

Section snippets

Scaffold design, fabrication, and benchtop mechanical performance of titanium scaffolds

Titanium implants of varying porosity for mechanical evaluation and preclinical implantation were designed with a gyroid-sheet architecture and produced via LPBF of medical grade titanium alloy (Ti6Al4V) (Fig. 1 A, B). Porosity was systematically controlled by decreasing the wall thickness of the gyroid sheet. Porosity of the printed implants evaluated by μCT revealed a decrease in as-printed porosity from the idealized CAD model of up to 4% (Table S1). This is attributed to characteristic…

Discussion

The present mechanical, preclinical, and clinical results establish the use of porous titanium implants with gyroid-sheet architecture produced by AM for treatment of load-bearing bone defects and overall implant fixation. Driven by recent evidence that the role of substrate curvature is important in cuing tissue regeneration [23], gyroid and other TPMS-based architectures have received greatly increased interest for use as tissue engineering scaffolds as they have been shown to have local…

Conclusion

In this work, demonstration of a linear relationship between scaffold porosity and mechanical performance was observed, whereas a parabolic relationship with ex vivo pushout strength was seen. All porosities showed an increase in pushout shear strength from the 4 week–12 week timepoint. The highest pushout strength of the porous titanium gyroid implants at both the time points evaluated in a bicortical defect model was 60% porosity implants, which exceeded previously reported values for…

Study design

The objectives of the study were to establish a relationship between mechanical and biological performance of porous titanium scaffolds produced by AM for use in treatment of bone defects using patient-specific implants. Laser powder bed fusion (LPBF) of medical grade titanium alloy was used to manufacture implants with increasing porosity which were evaluated in a bicortical defect model in sheep. Bone-implant interface biomechanics were assessed, along with histological evaluation at 4 and 12 …

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Cambre Kelly reports a relationship with restor3d, Inc. that includes: equity or stocks. Ken Gall reports a relationship with restor3d, Inc. that includes: equity or stocks. Samuel B. Adams reports a relationship with restor3d, Inc. that includes: equity or stocks.…

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