

Characterization of an Additively Manufactured CoCrMo Advanced Porous Structure

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Disclosures: Ghayoor, Zang, and Morrison (3A, 4 – Smith & Nephew, Inc.)

INTRODUCTION: In addition to titanium-based alloys, cobalt-chromium-molybdenum alloy (CoCrMo) is one of the most important materials used in orthopedic applications, e.g., total hip replacement and total knee replacement. The wide application of CoCrMo alloy in the medical industry is due to excellent mechanical properties, biocompatibility, corrosion resistance, and wear performance [1]. Traditionally, CoCrMo medical devices have been fabricated via casting, forging, and machining. More recently, additive manufacturing (AM) has experienced rapid development because it offers more design freedom in producing integrated, complex components compared with traditional manufacturing methods [2]. Laser powder bed fusion (LPBF) is one of the most widely used AM techniques in the medical industry. About a decade ago, Smith & Nephew launched the clinically successful REDAPT[®] Revision Acetabular System, which is fabricated by LPBF and incorporates the Ti-6Al-4V CONCELOC[®] Advanced Porous Structure for bone ingrowth. The purpose of this study was to additively manufacture the same CONCELOC Advanced Porous Structure with CoCrMo alloy using LPBF technology and characterize some of the key metrics.

METHODS: In phase 1, a set of porous coupons with various process parameters was printed, and the physical outputs were compared to commercially available CONCELOC Advanced Porous Titanium (Ti-6Al-4V). To achieve this, the coupons were evaluated in terms of the gravimetric porosity, pore morphology analysis (ASTM F1854), and strut diameter, and were observed under the SEM to subjectively evaluate the appearance of the CoCrMo porous structure (Figure 1). In phase 2, after selecting the optimum CoCrMo process parameters that achieved a physical output that matched the Ti-6Al-4V CONCELOC porous structure, the mechanical properties of the CoCrMo porous structure were evaluated. Various coupons were printed to evaluate the compressive yield strength (YS), tensile attachment strength (TAS), static shear strength, and shear fatigue strength of CoCrMo porous coupons, and the results were compared with the metrics in the FDA guidance document on coatings [3]. The bone cement shear attachment strength of the CoCrMo porous structure was also evaluated.

RESULTS: A low magnification, SEM image of the porous structure (Figure 1(b)) illustrated the randomness and interconnected porosity of the structure and the similar appearance to cancellous bone. The gravimetric porosity of the CoCrMo porous structure was $64.8 \pm 1.1\%$, which was similar to Ti-6Al-4V CONCELOC ($65.1 \pm 0.1\%$). The pore size of the CoCrMo porous structure was $324\text{--}521\ \mu\text{m}$, which met the minimum and maximum requirements of the FDA guidance document ($100\text{--}1000\ \mu\text{m}$). The compressive YS and Young's modulus of the CoCrMo porous structure were $55.7 \pm 4.7\ \text{MPa}$ and $3.7 \pm 1.3\ \text{GPa}$, respectively. The bone cement shear strength of the CoCrMo porous structure was $31\ \text{MPa}$, about 150% higher than grit-blasted cast CoCrMo samples ($12.3\ \text{MPa}$) that were representative of cemented knee femorals. Some of the other metrics that were tested in this study are summarized in Table 1. All the tested metrics of the CoCrMo porous structure met the recommendations outlined in the FDA guidance document on coatings.

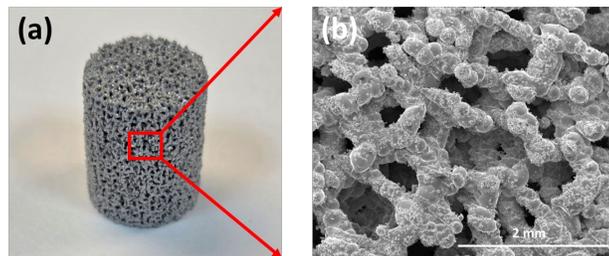


Figure 1. (a) Compression coupon of a fully CoCrMo porous structure produced by additive manufacturing, and (b) SEM image of the surface of the CoCrMo porous structure

DISCUSSION: This study shows that the CoCrMo porous structure matched the appearance and physical characteristics of the Ti-6Al-4V CONCELOC porous structure. Furthermore, the pore-morphology metrics and mechanical properties of the CoCrMo porous structure met the recommendations of a metallic coating on orthopedic devices specified by the FDA guidance document on coatings, suggesting that a medical device manufactured with this porous structure could promote bone ingrowth. A previously published animal study of Ti-6Al-4V CONCELOC in a load-bearing animal model showed that the combination of high porosity and roughness of the bone-interfacing surfaces of the additively manufactured porous structure improved the osseointegration, as evidenced by the significantly higher push-out loads after 12 weeks [4]. Considering the long history of CoCrMo alloy in cementless total hip and knee replacements in orthopedic applications, combined with the results from this study, which showed that the physical structure of the CoCrMo porous structure was similar to Ti-6Al-4V CONCELOC and that the properties meet FDA recommendations, it is expected that the CoCrMo porous structure will also promote bone ingrowth.

SIGNIFICANCE: This study demonstrates that the CoCrMo porous structure produced via an additive-manufacturing process had the physical characteristics and mechanical performance of an effective porous structure for use on the surface of cementless orthopedic implants that are in contact with tissue or bone cement.

REFERENCES: [1] G. Mani *et al.* JBMR-B 112, no. 6 (2024): e35431. [2] C. Yap *et al.* Applied physics reviews 2, no. 4 (2015). [3] FDA, Characterization of Metallic Coatings and/or Calcium Phosphate Coatings on Orthopedic Devices (Draft), 2024. [4] M. Williams *et al.* ORS, 2005 (2016).

Table 1. Mean (\pm standard deviation) results from testing of CoCrMo porous structure. For comparison, the FDA guidance specified recommendations are also provided [3].

Property	Output Metrics	FDA Recommendation
Gravimetric Porosity (%)	64.8 ± 1.1	30-70
Pore Size (μm)	392 ± 48	100-1000
Strut Size (μm)	319 ± 57	—
Compressive YS (MPa)	55.7 ± 4.7	—
Compressive Young's Modulus (GPa)	3.7 ± 1.3	—
Tensile Attachment Strength (MPa)	73.5 ± 1.3	22
Static Shear Strength (MPa)	62.2 ± 3.0	20
Shear Fatigue Strength (MPa)	10	10