Influence of Process Conditions on the Fatigue Performance of an Additively Manufactured Stemless Shoulder Implant

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INTRODUCTION: Recent advances in the additive manufacturing (AM) field have revolutionized the field of orthopedic implants. Advanced AM techniques like Direct Metal Laser Sintering (DMLS), Selective Laser Sintering (SLS) and others are overtaking traditional implant manufacturing methods like casting and machining as they allow creation of highly customized complex structures with better specifications quickly and at a lower cost [1]. Understanding the role of AM process parameters is vital, as these conditions significantly impact the device's performance and strength. Properly optimizing these parameters helps to minimize defects such as porosity, surface roughness, residual stress and ultimately device performance. FDA guidelines [2] require the orthopedic implant industry to test device fatigue in worst-case material and testing condition. The objective of this study was to develop a test method to determine the worst-case process conditions of DMLS additive manufacturing.

METHODS: Three key process parameters were identified as critical to the microstructure and mechanical properties of printed device: Laser power, solution anneal soak temperature and solution anneal soak time. Stemless humeral anchors were manufactured from five unique AM process condition groups encompassing both nominal and extreme process combinations of laser power, annealing temperature, and time to study the impact on fatigue performance (Figure 1). In an initial study, a Wöhler S-N curve was developed by evaluating stemless anchors from the High/High group under various load magnitudes to determine the load magnitude for the main Weibull study where a single load magnitude was applied to all test samples. The initial study demonstrated consistent fracture locations in the humeral implant at a load magnitude of 8000N, where high cycle fractures occurred (100k-2.5 Mc). Thus, a minimum of 8 samples from each group were tested at 8000N (R=0.1) in the main study. For each test group, the fatigue cycles were analyzed using Weibull analysis. A comparison of the scale factor or Mean Time To Failure (MTTF) of the fatigue cycles was conducted to determine if there was a statistically significant difference among the five test groups. Utilizing the MTTF data from the test groups, an S-N curve for each group was also estimated by adjusting it based on the MTTF difference relative to the High-High group from the initial Wöhler S-N curve study, maintaining a constant slope as suggested by Murakami et al [3]. This methodology was employed to approximate the S-N curves for each group and to ascertain the 5-million-cycle fatigue limit for each group.

RESULTS: Weibull analyses demonstrated low laser power, low anneal temperature and short anneal soak time (Low/Low) resulted in the lowest fatigue performance of the implants ($p<0.001$). Figure 2 displays the Weibull probability plot. The estimated 5 million cycle fatigue strength of the High/High group was 15% higher compared to the Low/Low process condition. Fracture locations were consistently observed at the same location of the implant in samples across different groups.

DISCUSSION: The process parameters in this study were set intentionally outside the nominal range to create extreme conditions. Weibull analyses showed that low laser power and anneal temperature, combined with a shorter soak time, significantly reduced fatigue strength, with the Low/Low process condition demonstrating the lowest MTTF. Low laser power can increase internal voids and pores, affecting fatigue performance. For example, laser powder bed fusion of 316 stainless steel showed a seven-fold increase in porosity when laser power was halved [4]. The low MTTF in the Low/Low condition likely results from increased defect and pore density, greater brittleness, and insufficient removal of thermal residual stresses. While our study was limited due to the sample size, future studies with larger sample size along with non-destructive test data such as CT-scan and SEM analysis from all five test groups could provide more insight into the effect of these process parameters on part defects and mechanical properties.

SIGNIFICANCE/CLINICAL RELEVANCE: To our knowledge, this is the first study to evaluate the worst-case additive manufacturing process conditions and device fatigue performance of stemless shoulder implants. Currently, there are no technical standards to provide guidelines on either the shoulder implant fatigue performance or worst-case AM process condition determination. This study highlights the importance of understanding AM process conditions, as evidenced by the observed 15% variation in fatigue strength. Additionally, these results may provide useful information for development of future standardized test methods to be used in additively manufactured orthopedic implants.

REFERENCES:

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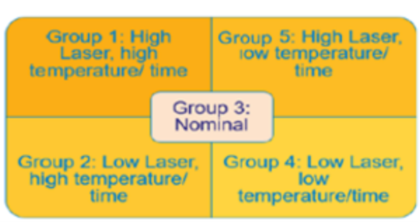

Figure 1.Process map of parameter combinations

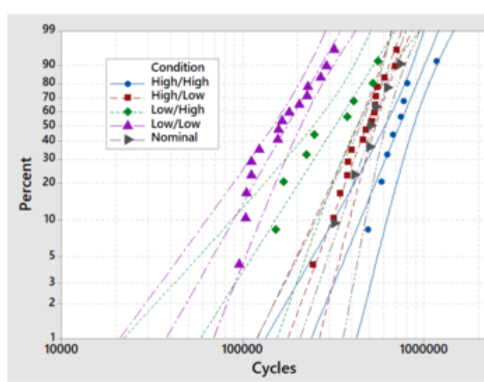

Figure 2. Weibull Probability Plot (90% CI)