Mechanical Behavior of Additive Manufactured Proximal Humerus Fracture Fixation Plate: Experimental Study on Unstable 3-Part Fractures with Osteoporosis

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Introduction

Proximal humerus fractures are among the most frequent fractures within the osteoporotic patient population. If the fracture is displaced and surgical intervention is required, locking plates are often used to provide mechanical stability. It is thought that design features of these implants, such as fixed-angle screw trajectories and locking screw heads, improve the mechanical stability of the proximal humeral head. However, complications including varus collapse, loss of fixation, screw cutout, and impingement due to plate misalignment continue to be major challenges in this treatment approach with failure rates exceeding 10%. Additive manufacturing (AM) techniques, commonly referred to as 3-D printing, provide a unique opportunity to expand the design space for these plates besides offering personalized solutions for the most challenging cases in a quick and efficient manner. This study was designed to compare the initial fixation provided by a conventional locking plate and two AM implants including a novel design in which a strut provides medial support to the humeral head. It was hypothesized that the AM implants would have the capacity to recapitulate the fixation parameters provided by currently used implants, and that the addition of a strut will provided much-needed medial column support to the humeral head.

Methods

The experiment was designed to quantify the initial fixation properties of locking plates in the presence of an osteoporotic 3-part comminuted proximal humerus fracture. A total of 9 osteoporotic synthetic humeri (4^{th} Gen Composite Humerus, 10 pcf, Sawbones) were used in this study. Three types of implants were used: (i) conventional locking plates (3.5 mm LCP Proximal Humerus, DePuy Synthes) (CTRL, n=3); (ii) AM-made reversed engineered (to mimic CTRL) plates (RE, n=3); and (iii) novel design concept in which a solid medial strut is added to the conventional plate design (MS n=3) (Figure 1). RE and MS groups were fabricated via laser powder bed fusion technique using Stainless Steel 316L virgin powder with layer thickness of 60 μm and powder size distribution of 40-63 μm. Simulations of unstable 3-part fractures (AO 11-B3.2) were created with the aid of custom-built jig and reconstructions were performed by a senior surgeon (AA). Nondestructive quasi-static torsion and compression (-20°, 0°, 20° abduction) tests were performed in accordance with a previously established protocol. Fatigue tests were performed with monotonically increasing sinusoidal cyclic loads, where the peak load magnitude was increased by at every cycle. Relative displacement between bone fragments were recorded with 3D motion tracking techniques.

Results

There were no significant differences between groups with regard to quasi-static torsional and axial stiffness. The MS group significantly decreased the motion between the P1 and P3 fragments during quasi-static compression testing ($p < 0.05$, Figure 1A). The CTRL and RE groups exhibited similar stiffnesses and provided similar resistance to fragment

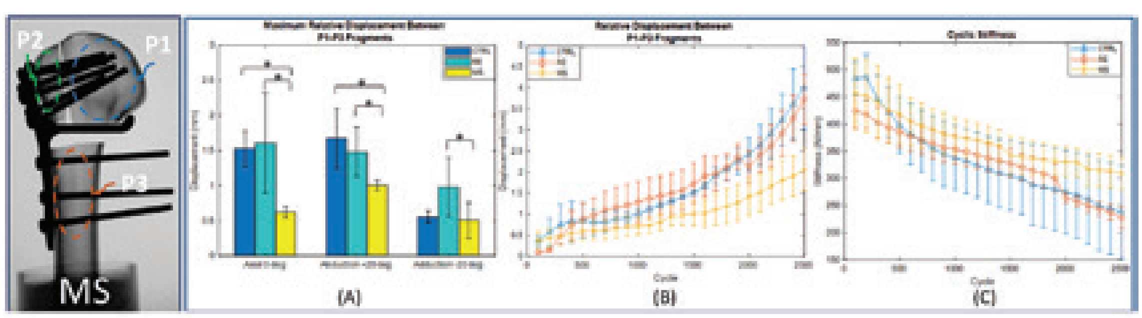

Figure 1. Example of the prepared construct; **(A)** Maximum relative displacement result for non-destructive testing (an asterisk (*) indicates p <0.05); **(B)** Relative displacement during fatigue testing; **(C)** Stiffness during the fatigue test. (Mean Standard Error)

migration throughout cyclic testing. In contrast, MS group with the novel medial support design showed significantly improved stiffness and more resistance to fragment migration throughout the fatigue test ($p<0.05$, Figure 1B-C).

Discussion

This study systematically evaluated the effectiveness of AM locking fracture fixation plates with respect to mechanical stability. Results suggest that reverse-engineered AM implants behaved similar to traditional forged locking plates with identical geometry. These outcomes may increase the confidence in AM locking plates and expand the design space for personalized implants in shorter manufacturing cycle. The addition of a medial strut in the AM design led to improved long-term stiffness of the construct and reduced the motion of the proximal head during fatigue testing. These findings may offer an alternative solution for medial support fixation in complex comminuted fractures. Additional design modifications, such as porous medial support in the place of conventional solid structures, can be readily made with AM processes, and would allow for bone ingrowth at the comminution site. This study was limited to 3-part comminuted fracture and conducted on synthetic bones. A cadaveric study will be conducted for additional validation.

Clinical Relevance

This study provided a new alternative design and fabrication technique for medial fixation of unstable comminuted proximal humerus fractures and showed significant reduction in the varus angulation by maintaining satisfactory mechanical stability.