Interbody Implant Initial Micromotion as a Function of Surface Architecture and Simulated Anatomical Spondylolisthesis Conditions

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Introduction: Spondylolisthesis is a debilitating, degenerative condition of the spine in which the superior lumbar vertebra translates anteriorly with respect to the inferior vertebra. While several fusion devices are currently available, severe cases often require 360° surgery, i.e., a combined anterior/posterior approach, to restore anatomic alignment and alleviate pain. This procedure is both invasive and expensive. The present study is part of a series of ongoing in vitro evaluations of surface architecture for a novel standalone 3D-printed interbody device. In this study, we examined the effects of surface architecture on interface micromotion under simulated physiological loading.

Methods: Three implant surface architectures were evaluated under simulated spondylolisthesis loading conditions using composite model bone blocks (10 PCF solid rigid polyurethane foam, 0.16g/ cm 3). The 3 architectures were 1mm, 45° serration, 2mm, 45° serration, and 2mm, 60° serration, (N=6 each, total N=18). Spondylolisthesis loading was simulated using an MTS 858 mini-bionix servo-hydraulic load frame equipped with a custom apparatus to simulate 30° and 45° of lumbar spondylolisthesis. A cyclic load profile with an amplitude of 100N, increasing the maximum force in increments of 100N after every 10 cycles was applied at a rate of 0.5 Hz in a step-wise fashion until failure. Shear micromotion of the implant relative to the bone was measured using an LVDT. Interfacial motions were examined and compared at 800-900N loading, representing physiological loading conditions. All three implant designs were evaluated at a 30° test angle (N=3 each, total N=9) and then at a 45° test angle. We performed a univariate ANOVA to examine the overall dataset (N=18) as well as a separate ANOVA for the 30° and 45° test angles respectively (N=9).

Results: **C**yclic displacement at 800 to 900 N at a 30° test angle was statistically lowest in the 1mm height 45° implant serrations. The average cyclic displacement was 8.4 µm for 1mm serrations, 10.7µm for the 2mm, 45° serrations, and 13.7 µm for the 2mm, 60° serrations. In the overall dataset, there was a significant difference between the 1mm serrations and both the 2mm serrations ($p<0.001$), and the p-value comparing the 2mm 45° and 60° serrations was higher at $p=0.05$. At a 30° test angle, when comparing the cyclic displacement of the 2mm height 45° and 60° serrations, the 45° serrations had lower micromotions at 10.7 µm compared to 13.7 µm on average for the 60° serrations ($p=0.02$); however, when the test angle was increased to 45°, there was no longer a significant difference between the 2mm, 45° and 2mm, 60° serrations at 24.3 µm and 24.9 µm respectively. ($p=0.7$) The 1mm serrations exhibited significantly less micromotions at 14.9µm compared to both 2mm height serrations at the 45° test angle ($p<0.001$), but at the 30° test angle the 1mm, 45° serrations at 8.4 µm was relatively closer to the 2mm, 45° serrations at 10.7 µm.

Discussion: At physiological loading levels of 800 N to 900 N when examining the overall dataset, smaller height serrations resulted in less cyclic micromotion. One explanation for this observation is that the larger surface area for the 2-mm height serration device resulted in greater integration with the bone analog, which under cyclic motion, resulted in more damage to the bony interface. At the 30° angle, the 2mm, 45° serrations outperformed the 2mm, 60° serrations, but this did not remain consistent when the deformity angle was increased to 45°. This could be due to the tip of the 60° serration being oriented closer to the direction of shear force and causing the 60° design to cut into the bone analog more than the 45° serrations. The potential advantage of the 45° serrations over the 60° serrations appeared to be less relevant at higher angles of deformity. At lower angles of deformity, the difference between the 2mm, 45° serrations and 1mm, 45° serrations was less than it was at higher angles of deformity. This indicates that the benefits of smaller serration height is less at lower angles of deformity.

Clinical Relevance: The results of this study indicate that the 2mm height implant serrations exhibit higher levels of micromotion than the 1mm height device. The results will direct future studies to determine the optimal design for interbody fusion implants, particularly for suboptimal bony conditions.