Variable Stiffness Cervical Plates Affect Load Sharing in the Interbody Space In Vitro

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Introduction: Low back pain and neck pain are ubiquitous in all developed nations. Currently, the gold standard of treatment for patients who require surgery for low back and neck pain is a spinal fusion. However, time to fusion can be long, resulting in increased lost work time and lost wages. Previous work has shown that the design of the spinal fusion instrumentation has an effect on load transfer to the interbody graft [1]. Forces and deformation are known to affect bone remodeling, and while some studies have compared how implant design affects load transfer [2], the relationship between implant stiffness and load-sharing has not previously been quantified. We hypothesize that load-sharing can be controlled by modulating implant stiffness. The purpose of this work was to quantify the effects of implant stiffness on load-sharing between fusion instrumentation and interbody instrumentation.

Methods: Under simulated physiologic loading, we experimentally measured the amount of load-sharing allowed by plates of four different stiffnesses. To generate plates of different stiffnesses, we created a solid model of a clinically used anterior cervical fusion plate (Zephir, Medtronic), and evaluated its stiffness in extension using a simplified finite element model of the plate attached to two human vertebrae in ABAQUS 6.13. The stiffness was calculated under application of a 1.5 Nm load. We then modified the geometry of the solid model, to generate plates which were 75%, 50%, and 25% as stiff, as validated by our finite element model. Implants were fabricated using direct metal laser sintering of Ti-6Al-4V as shown in Figure 1A. We also developed an interbody fusion cage capable of housing a commercially available load cell (Figure 1B). Polymer blocks were used to simulate cervical vertebrae. Screw holes were pre-drilled to allow for an 8 mm gap between blocks when the plate was attached. Using low-melting temperature alloy, blocks were potted to our multi-degree of freedom spine testing machine. The plates were attached using cancellous screws using standard clinical technique. Stiffness was measured in extension at 0.2 degrees/second, up to a limit of 5° of extension, or 1.5 Nm under a 50 N axial preload. The stiffness of each plate design was calculated by using a regression model to calculate the slope of the applied moment vs. angular displacement. We tested load sharing under two conditions: (1) when the interbody implant was in contact with both blocks when the cervical plate was attached, and (2) when there was an imperfect fit of the interbody implant, modeled by creating a 1 mm gap between the interbody implant and the cranial block. The maximum increase in interbody force during extension measured by the interbody load cell was normalized by the applied axial load. Load sharing was tested under similar settings, with the applied moment increased to 2.5 Nm. We conducted these tests using 6 plates for each design and compared our results with an ANOVA and Fisher’s post hoc test (p<0.05).
Figure 1. The design process yielded plates which had 100%, 75%, 50%, and 25% relative stiffness (A). A custom designed interbody implant was used to house a subminiature button load cell which measured interbody forces (B).

Results: Experimental testing validated the results of the finite element model. The custom plates which we designed to have target stiffnesses of 75%, 50%, and 25%, had mean stinesses of 77%, 53%, and 26% respectively. When load-sharing was tested in blocks with no gap, there was a trend for an increase of interbody load when using a less stiff plate during extension motion. From the least stiff to most stiff plates, the increase in interbody load as a percentage of applied axial load was a mean 405%, 391%, 362%, and 354% as shown in Figure 2. However, we were not able to detect any statistically significant differences between designs. When load-sharing was tested in blocks with a 1 mm gap between the interbody implant and the cranial block, there was a statistically significant increase in interbody load when using a less stiff plate (p<0.05) (Figure 3).

Figure 2. Physical testing of cervical plates with varying stiffness showed similar amounts of load-sharing when there was no gap in the system.
Figure 3. Physical testing when the system had a 1 mm gap shows a statistically significant difference in load-sharing. Letters above a column indicate statistically distinct groups (p<0.05).

Discussion: These results show that the stiffness of cervical plates can be used to control the amount of load-sharing in the spine. This suggests that load-sharing can be optimized after fusion surgery through plate design. In vitro testing showed that plates of similar designs but with quantifiably different stiffness allowed for different amounts of load-sharing with the interbody space.

Significance: Our results show for the first time, a quantifiable relationship between plate stiffness and the extent of load-sharing in the interbody space; these data suggest that load-sharing can be controlled by modulating implant stiffness. In vivo, implants which balance stability and load-sharing through optimal stiffness can result in the ideal environment for fusion, and improve fusion outcomes.

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