

Increased Resistance to Subsidence in Standalone Anterior Lumbar Interbody Fusion Through Endplate Tailored Implants

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INTRODUCTION: Disc degeneration is caused by many biochemical processes that occur with aging such as changes in permeability and water content. Anterior lumbar interbody fusion (ALIF) is used to relieve pain caused by degeneration of the intervertebral disc that is not amenable to conservative non-operative treatment. Among the potential complications of the ALIF procedure is progressive implant subsidence. Moderate implant subsidence is classified as ≥ 2 mm with substantial subsidence being ≥ 4 mm or 50% of total implant height. In a systematic review, Parisien et al. identified subsidence rates of anterior lumbar interbody fusion (ALIF) as between 6-24%. Another prospective study by Prasanth et al. of 147 post-operative ALIF patients saw a subsidence rate of 10.7% with a mean distance of 4.7 mm and reported no significant impact of subsidence on clinical outcomes or fusion rate. The cage sizing criteria are dependent on the surgical approach and the patient's anatomic considerations such as lordosis angle, size of the vertebral body, and adjacent intervertebral disk status. Proper size choice is important to limit damage to surrounding structures while still maintaining stability. According to the current surgical technique, the surgeon's goal is to achieve the widest surface area contact possible without posing a risk to surrounding neurovascular structures or compromising the intervertebral foramina. Biomechanical studies have shown that 30% of endplate coverage is optimal for proper interbody fusion and improved load capacity. This decision is also supplemented with pre-operative radiographic imaging to assess the width and height of the cage needed. The current study aims to identify how the tailoring of the cage footprint to the endplate influences the subsidence load. We hypothesize that endplate tailored ALIF implants will withstand higher loads with decreased subsidence as compared to regular implants.

METHODS: After obtaining IRB approval, CT scans of L5 vertebrae harvested from a total of 15 cadaveric spines with an age of $80\text{years} \pm 7$ (40% males, 60% females) were performed using a GE LightSpeed VCT scanner at a slice thickness of 0.625mm. The vertebrae were reconstructed in a 3D slicer isolating endplates and cortical shells from the inner trabecular core. The obtained surfaces were imported in Fusion 360 (Autodesk, Mill Valley, California) and sectioned in correspondence with the superior endplate at 2 mm below the endplate to extract profiles of the outer cortex and inner trabecular core. The profiles of the surrogates were obtained through the linear extrusion of 20 mm in length and CNC machined using bone surrogate foam manufactured in accordance with the ASTM F1839 standard. More specifically, the foam blocks were machined in PCF 40 and PCF 15 as performed in previous biomechanical studies, to obtain cortical shell and trabecular core surrogates, respectively. Following a previously used methodology the novel implant was positioned on the bone surrogates and compressed at a rate of 5mm/min using an Instron 8874 (Instron, Norwood, MA). Each of the bone surrogates was tested with the implant in two configurations: unexpanded having a width of 37mm (regular) and expanded to maximize coverage (tailored). Data was acquired at 100Hz and 1N increment from a reference preload of 5N. Mechanical characterization of the constructs was performed identifying the peak load within the 2mm displacement used as reference for subsidence, while stiffness was evaluated as the angular coefficient of the linear regression describing the obtained load-displacement curve. Normality of the data was evaluated for the regular group using the Shapiro-Wilk test and differences between the two implant configurations were evaluated using paired T-test or Wilcoxon signed-rank test for non-parametric data. A p value of 0.05 was used for these comparisons. Peak subsidence load and stiffness relationships were analyzed using Pearson Correlation Coefficient. All analyses were performed in R.

RESULTS SECTION: Tailored implants did not result in a significant improvement in stiffness ($3165\text{N/mm} \pm 572$, $p=0.083$). However, the subsidence load of $3478\text{N} \pm 588$ measured for the Tailored implants was significantly higher than the load found for regular implants ($p=0.002$, see Figure 2b). The coefficient of determinations of the linear regressions used to calculate the construct stiffness were no different between the two groups (regular, $r=0.96 \pm 0.28$, tailored $r=0.97 \pm 0.17$, $p=0.489$). The subsidence load was not correlated to the surface of the cortical bone in the regular implants ($r=0.260$, $p=0.350$) while was found to be correlated in the group with the tailored implants ($r=0.796$, $p<0.001$). Construct stiffness was found not correlated to the surface of cortical bone in both groups ($r<0.411$).

DISCUSSION: The results of the current study provide evidence that the use of an implant tailored to maximize surface coverage has the potential to increase the resistance to subsidence. Furthermore, the instrumentation with the tailored implant resulted in a load proportional to the cross-section of cortical bone. The extension of this finding is limited by the use of bone surrogates and needs to be corroborated with experiments on real vertebrae.

SIGNIFICANCE/CLINICAL RELEVANCE: Increasing resistance to subsidence is paramount in lumbar interbody fusion. This study has shown the potential of tailored implants to improve this resistance. Furthermore, the potential relationship between cortical bone cross-section and subsidence load warrants exploration of predictive models that could be used in surgical planning.

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IMAGES AND TABLES:



Figure 1: Experimental setup

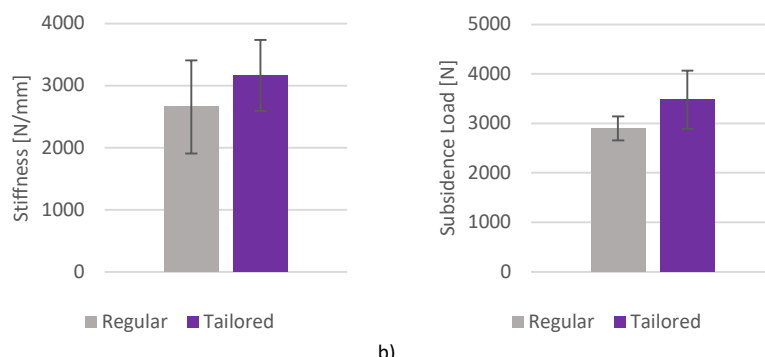


Figure 2: Experimentally obtained results in terms of Construct Stiffness (a) and Subsidence load (b).