

## Interdependence of Cross-Sectional Area and Exposed Perimeter on Spinal Cage Subsidence

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**INTRODUCTION:** Patients afflicted with degenerative disc disease can experience substantial pain due to nerve root impingement within the intervertebral foramen, which is a direct result from loss of disc height and concomitant closing of the foramen. Restoration of disc height is commonly achieved by surgical implantation of a spinal cage, which is designed to facilitate fusion between the superior and inferior vertebral bodies. However, contact stresses can result in post-surgical subsidence. It is usually assumed that devices with a lower cross-sectional area will result in greater subsidence, and thus worst-case. However, cages also produce endplate shear loads at their perimeter, so the variation in the total cage perimeter might be another important factor to consider. This study aims to investigate the correlation, if any, between cage subsidence and the total perimeter of two mock intervertebral body fusion device design. It was hypothesized that with a constant cross-sectional area, the cage with a larger exposed perimeter will experience greater subsidence.

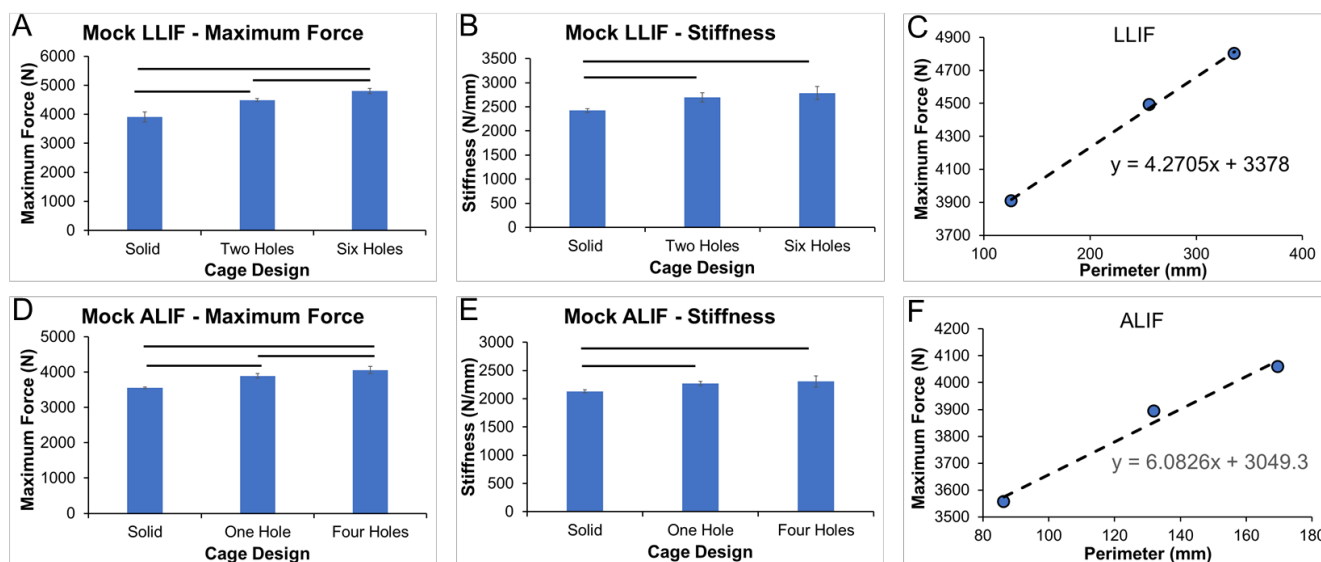
**METHODS:** Mock lateral (LLIF) and anterior (ALIF) lumbar intervertebral body fusion cages were designed in Solidworks (Dassault Systèmes, Waltham, MA). Three different designs were created for each cage type, each having a constant cross-sectional area, while the total perimeter value was varied by changing external dimensions and adding internal features. External dimensions were restricted to realistic cage sizes as reported by Peck et al. Mock cage designs were additively manufactured from nylon using an EOS powder bed fusion printer. ASTM F2267, which outlines a standard for measuring load-induced subsidence of intervertebral body fusion devices under static axial compression, was utilized to measure subsidence of the mock LLIF and ALIF cage designs. Each cage design (n = 4) was placed between PCF 15 foam blocks and 5mm of compression was applied at a rate of 0.1mm/s. Force (N) and displacement (mm) data were collected at 100Hz. Force-displacement data were used to obtain the system stiffness (N/mm) and maximum force during the test. All cages were also tested under axial compression per ASTM F2077 to obtain stiffness of the intervertebral body fusion device. Groups were compared with a one-way ANOVA followed by Tukey post-hoc tests. Significance was set at  $p < 0.05$ .

**RESULTS SECTION:** LLIF cages had a statistically significant higher maximum force at 5mm of subsidence with an increase in exposed perimeter. The solid LLIF cage had maximum force of  $39096 \pm 171N$ , the two-hole design had a maximum force of  $4491 \pm 53N$ , and the six-hole design had a maximum force of  $4801 \pm 85N$  (Figure 1A). Similarly, the solid ALIF cage had maximum force of  $3556 \pm 23N$ , the one-hole design had a maximum force of  $3893 \pm 69N$ , and the four-hole design had a maximum force of  $4058 \pm 103N$  (Figure 1D). For both LLIF and ALIF cages, the solid design had a significantly lower stiffness when compared with the one/two-hole designs and the four/six-hole designs (Figures 1B, 1E). No significant differences were observed in stiffness between the one/two-hole signs when compared with the four/six-hole designs, respectively. A clear linear correlation was observed between maximum force and total exposed perimeter (Figures 1C, 1F).

**DISCUSSION:** This study investigated the interdependence between cage subsidence and exposed perimeter of the mock intervertebral body devices. The results demonstrated a significant correlation between cage subsidence and the total perimeter of two mock intervertebral body fusion device types. Cages with a greater exposed perimeter are less prone to subsidence than cages with less exposed perimeter when cross-sectional area is held constant. When comparing two spinal cages with similar cross-sectional area, the total perimeter may be considered to determine potential for subsidence. Moving forward, medical devices manufacturers may be able to use this observed correlation during development and evaluation of novel intervertebral body fusion devices. The correlation may however breakdown when the cross-sectional area of a feature becomes very small.

**SIGNIFICANCE/CLINICAL RELEVANCE:** To reduce burden for conducting mechanical evaluation of spinal medical devices, manufacturers generally identify and then test the worst-case design within their product portfolio. Thus, identification of this worst-case device is critical. The findings from this study provide a new metric that can be used by medical device manufacturers to identify their worst-case device.

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**Figure 1:** ASTM F227 subsidence testing results for two mock designs of LLIF and ALIF cages showing interdependence of exposed perimeter on maximum force and stiffness at 5mm of subsidence. (A, D) Maximum force increased with increasing perimeter for both LLIF and ALIF cages (B, E) Solid designs had significantly lower construct stiffness when compared with the other designs (C, F) A linear correlation was observed between maximum subsidence force and total exposed perimeter for both LLIF and ALIF cages.