Introduction: Interbody fusion devices (IFDs) have been in widespread clinical use for a number of years. While early outcome reports contained high clinical and fusion success rates, complications, such as cage migration, subsidence and loosening have been described. We hypothesize that a loss of mechanical integrity results from trabecular damage accumulation occurring adjacent to an IFD subjected to load. The aims of this study are 1) To determine the quantity and distribution of acute, local in-vitro trabecular damage resulting from the presence of IFDs when subjected to load and 2) to determine the change in mechanical properties due to trabecular damage accumulation surrounding an IFD relative to analytical results.

Materials and Methods: Four treatment groups each consisting of six specimens were evaluated. Generic IFDs of two cross-sectional shapes (square [S] and round [R]) and two damaging structural strains (1% and 2.5%) defined the four treatments. Twenty four vertebral pairs were randomly assigned to treatment groups and implanted with bilateral IFDs. A trapezoidal, three-cycle mechanical testing sequence was applied that included non-damaging diagnostic cycles before and after the damaging cycle. The ratio of the post- to pre-damage diagnostic cycle was determined for loading and secant stiffnesses for each specimen. Stiffness means and measures of permanent deformation (PD) were compared across treatment groups within a strain level using the Mann-Whitney U test.

Before and after mechanical testing, vertebræ were labeled with the fluorescents alizarin complexone and calcein, respectively. Following mechanical testing, vertebral halves were embedded in polymethylmethacrylate, sectioned, glued to acrylic slides, ground and polished to 150-200μm thickness. Histologic images were obtained from one longitudinal and two transverse histologic sections from each vertebra under ultraviolet light. Images were stitched to form a composite image of the region adjacent to the IFD. An image processing scheme was used to segment and measure trabecular bone area (BAr) and diffuse damage area (DxAr) in each composite image [1]. Mean damage area fraction (DxAr/BAr) was compared across groups within a strain level using the Mann-Whitney U test. The spatial distribution of damage was determined from the transverse histologic sections for each specimen and evaluated by two methods. Spatial histograms were generated by stratifying the absolute values of the transverse centroid (XC) of an area of damage into 1mm clusters relative to the center of the IFD (e.g., 0-1mm, 1-2mm, etc.). These linear distributions (XCd) were compared between treatment groups within a strain level using the Kolmogorov-Smirnov test.

Results: At 1% strain, mechanical damage in the IFD-R group was significantly greater than that of the IFD-S specimens; significant differences were not found at 2.5% strain. Similarly, the predicted force-displacement curves derived from the analytical model showed little difference between IFDs. PD was significantly greater for the IFD-S group at 1% strain and for the IFD-R group at 2.5% strain. Physical damage included linear and cross-hatched microcracks and regions of diffuse damage. Histologic analysis revealed diffuse damage to be the most common form of damage, which occurred within 2mm of the bone-implant interface in all specimens. Although a statistical difference for DxAr/BAr was not found between IFD groups, difference in the distribution of damage was found. The XCd were significantly different between treatment groups at both strain levels. The box plots illustrate that the damage associated with the IFD-R specimens was found at all regions adjacent to the device whereas for the IFD-S group, damage areas were skewed to the device corners regardless of applied strain level. This is in excellent agreement with the analytically predicted damage patterns [2].

Discussion: At the lowest strain level, significantly more mechanical damage occurred in the IFDs with round versus square cross-sections, although this difference may be due to the methods used for endplate preparation (tap versus broach). Differences in mechanical damage were not found at the higher strain. Histologic damage was found in close proximity to the bone-implant interface and in all specimens, including those that did not demonstrate mechanical damage. Localized damage at the bone-implant interface is not detected using gross structural mechanics measures. At both strain levels, the spatial patterns of histologic damage were different for the two IFDs.


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