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PII: S0021-9290(18)30532-3
DOI: https://doi.org/10.1016/j.jbiomech.2018.07.022
Reference: BM 8785

To appear in: *Journal of Biomechanics*

Received Date: 16 March 2018
Revised Date: 6 July 2018
Accepted Date: 9 July 2018

Please cite this article as: J.H. Peck, K.D. Kavlock, B.L. Showalter, B.M. Ferrell, D.G. Peck, A.E. Dmitriev, Mechanical performance of lumbar intervertebral body fusion devices: An analysis of data submitted to the Food and Drug Administration, *Journal of Biomechanics* (2018), doi: https://doi.org/10.1016/j.jbiomech.2018.07.022

Mechanical performance of lumbar intervertebral body fusion devices: An analysis of data submitted to the Food and Drug Administration

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Abstract

Lumbar intervertebral body fusion devices (L-IBFDs) are intended to provide stability to promote fusion in patients with a variety of lumbar pathologies. Different L-IBFD designs have been developed to accommodate various surgical approaches for lumbar interbody fusion procedures including anterior, lateral, posterior, and transforaminal lumbar interbody fusions (ALIF, LLIF, PLIF, and TLIF, respectively). Due to design differences, there is a potential for mechanical performance differences between ALIF, LLIF, PLIF, and TLIF devices. To evaluate this, mechanical performance and device dimension data were collected from 124 Traditional 510(k) submissions to the FDA for L-IBFDs cleared for marketing from 2007 through 2016. From these submissions, mechanical test results were aggregated for seven commonly performed tests: static and dynamic axial compression, compression-shear, and torsion testing per ASTM F2077, and subsidence testing per ASTM F2267. The Kruskal-Wallis test and Wilcoxon signed-rank test were used to determine if device type (ALIF, LLIF, PLIF, TLIF) had a significant effect on mechanical performance parameters (static testing: stiffness and yield strength; dynamic testing: runout load; subsidence testing: stiffness [Kp]). Generally, ALIFs and LLIFs were found to be stiffer, stronger, and had higher subsidence resistance than PLIF and TLIF designs. These results are