An Analysis of a Decade of Lumbar Interbody Cage Failures in the United States

Amit Satish Piple, Victor Ungurean, Oluwatodimu Richard Raji, Andrea Rowland, Adam Schlauch[1], Dimitriy G Kondrashov[2], Ken Y Hsu, James F Zucherman[2]
[1]Saint MaryS Medical Center, [2]San Francisco Spine Surgeons

INTRODUCTION:
While lumbar interbody cage material and production methods have evolved to withstand the physiological loads they experience following lumbar interbody fusion, implant failures remain prevalent. Although the Food and Drug Administration (FDA) ensures the safety of these devices postoperatively, rates of intraoperative failure due to transient loading conditions may be overlooked. These failures are of particular concern as any undetected damage to the implant components during implantation may lead to subpar postoperative outcomes. Therefore, this study aims to assess rates of lumbar interbody cage failures based on their production material and manufacturer.

METHODS: The FDA's Manufacturer and User Facility Device Experience (MAUDE) database was queried for all reports of lumbar interbody cage device failures from 2012 to 2021. Each report was manually analyzed and categorized on the basis of failure type (i.e. cage breakage, cage migration, screw failure, instrumentation failure, collapse, and assembly failure). The implants were then categorized by its core and surface material (i.e. poly-ether-ether-ketone [PEEK], titanium, and silicon nitride), which was obtained from 510(k) premarket notifications. Rates of failures were compared based on core and surface material type. A market analysis was performed by dividing the total number of failures per year for each manufacturer by their approximate yearly revenue from spinal implants in the U.S. (in hundreds of millions of dollars), generating "failure to revenue indices". Outlier analysis was performed to generate a threshold value above which failure rates were defined as greater than the normal index.

RESULTS: In total, 1,620 total entries were identified from the MAUDE database. After removing duplicates, entries with incomplete data, non-lumbar cage failures, and non-implant related failures, 1,520 failures were available for assessment. Of these, 934 (61.4%) were cage breakages, 216 (14.2%) were instrumentation-related failures, 41 (2.7%) were cage migrations, 42 (4.5%) were screw-related failures, and 14 (0.9%) were due to cage collapse. Of the cage breakages, 878 (94.0%) had a core composed of PEEK while 49 (5.2%) were titanium. Of the cage migration failures, 83 (52.9%) had a surface material composed of PEEK while 62 (39.5%) were titanium and 2 (1.3%) were silicon nitride. Upon manufacturer market analysis, Zimmer-Biomet was found to have failure to revenue indices exceeding the calculated threshold (11.6 failures/100 million dollars yearly revenue). (Figure 1)

DISCUSSION AND CONCLUSION: Lumbar interbodies manufactured using PEEK were more likely to fail by breakage than by migration whereas titanium cages were more likely to fail by migration than by breakage. Market analysis of manufacturers demonstrated that Zimmer-Biomet implants exceeded the failure to yearly revenue index threshold in the most recent fiscal years. Interestingly, the second most common failure was instrumentation breakage whereby the inserter fractured intraoperatively, which can result in the introduction of metal debris into the wound. Similarly, the majority of the cage breakages identified in the present study occurred intraoperatively. These findings call for more detailed FDA evaluation of these intraoperative failures prior to commercial approval. Further studies regarding the influence of patient and operative factors on lumbar interbody failures are warranted as the MAUDE database does not contain clinical data. The true incidence of intraoperative cage failure is unknown since there is no universal reporting standard between different manufacturers and facilities. It is possible that the manufactures with greater reported failures have more stringent reporting guidelines.