Are All Cervical Cages Created Equal? An Analysis of a Decade of Adverse Event Reports in the United States

Victor Ungurean, Amit Satish Piple, 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:

As interbody cage usage during cervical interbody fusion grows in the United States (U.S.), there has been a concurrent rise in implant material, manufacturing and design options. The Food and Drug Administration (FDA) aims to ensure safety and efficacy of devices post-implantation, however, interbody systems may experience transient load conditions during implantation which may otherwise be overlooked. Despite its importance for preoperative planning before cervical spine fusion, there is a paucity of data in the literature characterizing perioperative failure rates among the commercially available implants in the U.S. Therefore, the goal of this study is to characterize failure rates of cervical interbody cages on the basis of their manufacturer and production material.

METHODS:

The FDA's Manufacturer and User Facility Device Experience (MAUDE) database was queried for all reports of cervical 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, 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. Two market analyses were performed. First, "failure to market share indices" were generated by dividing the number of failures per year for each implant material subtype by its yearly U.S. market share in cervical spine fusion. Second, "failure to revenue indices" were calculated 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). Outlier analysis was performed to generate a threshold value above which failure rates were defined as greater than the normal index.

RESULTS:

In total, 807 entries were identified from the MAUDE database. After excluding duplicates, entries with incomplete data, non-cervical implant failures, and non-implant related complications, 719 failures were available for assessment. Of these, 306 (42.6%) were cage breakages, 48 (6.7%) were cage migrations, 154 (21.4%) were instrumentation-related failures, 150 (20.9%) were assembly failures, and 71 (9.9%) were screw failures. Of the cage breakages, 291 (95.1%) were composed of a PEEK core while 8 (2.6%) were titanium. Of the cage migration failures, 21 (43.8%) were composed of a titanium surface and 24 (50.0%) were PEEK. PEEK implants had a higher failure by market share index for both migration and breakage compared to titanium. (Figures 1,2) Upon manufacturer market analysis, Zimmer-Biomet, K2M, and LDR Medical were found to have failure to revenue indices exceeding the calculated threshold (3.92 failures/100 million dollars yearly revenue). (Figure 3)

DISCUSSION AND CONCLUSION:

Cervical cages 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. However, PEEK implants had a higher failure to market share index for both failure types compared to titanium. A year-over-year reduction in failure to market share indices was observed for both PEEK and titanium. Market analysis of manufacturers demonstrated that Zimmer-Biomet implants exceeded the failure to yearly revenue index threshold in the most recent fiscal years. Importantly, many of these implant failures occurred intraoperatively during instrumentation, which underscores the need for FDA evaluation of these implants under these loading conditions prior to commercial approval. Further studies regarding the influence of patient and operative factors on cervical interbody failures are warranted as the MAUDE database does not contain clinical data.