# Ten-Year Risk of Recall of Novel Spine Devices

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INTRODUCTION:

Spinal implants represent the greatest contributor to orthopaedic device innovation growth over the last 20 years. Over 97% of devices enter the market without supporting clinical data. While the FDA's Premarket Approval (PMA) requires clinical trials to prove "safety and effectiveness," 510(k) relies on biomechanical testing to demonstrate "substantial equivalence" to an existing marketed device. Over 95% of recalls are for 510(k) devices.

The recall risk of a novel spine device over time has not been reported. We hypothesize spine devices pose higher risk of recall than other orthopaedic implants due to inherently higher risks of spine surgery. As a second primary outcome, interbody fusion devices were analyzed as a risk factor for recall. They add surgical complexity without proven clinical benefit, and in 2007 were granted permission to receive 510(k) certification after previously requiring PMA, leading us to hypothesize they possess an increased risk of recall.

Our Primary outcomes included: 1) 5 and 10-year hazard of recall for all spine devices and 2) recall hazard ratio of interbody fusion vs. all other, non-interbody spine devices. Secondary outcomes were the incidence of high-risk FDA recalls compared to independent spine surgeon categorization of the same recalls.

METHODS:

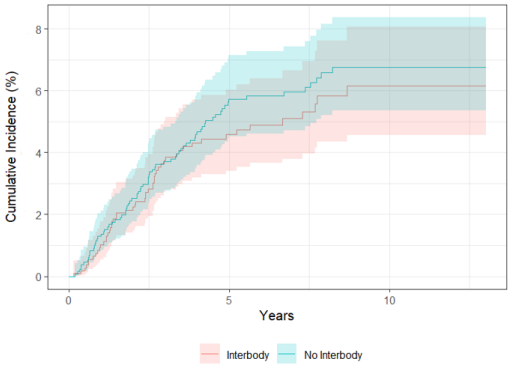
Spine devices cleared between January 01, 2008 and December 31, 2018 were identified from the FDA's 510(k) database. By individually querying the database for each device, relevant recall data, including whether it was recalled, reason, date, and recall class was obtained. Recall data was collected in January of 2021 to provide a 2-year minimum follow up for a recall to occur. Product labels were used to classify interbody fusion devices.

Cumulative incidence function was conducted to compare the overall risk of recall for FDA cleared spine devices, and the hazard ratio determined for interbody vs. non-interbody devices during the study period.

Recalls were grouped by their FDA Class. The highest risk recalls were designated Class 1 and defined by creating a "reasonable probability of serious adverse health consequences or death." Practicing spine surgeons were blinded to the FDA's ranking and asked to apply their own recall class on 2 separate occasions, 2 weeks apart for comparison.

RESULTS: A total of 2,394 spine devices were cleared via 510(k) in the study period. The hazard of recall at 5 years was 5.3% (95% CI: 4.4%-6.2%) and 6.5% (95% CI: 5.4-7.7%) at 10 years. No significant difference in recall risk was identified for interbody fusion devices compared to all other spine devices with a hazard ratio of 0.89 (95% CI: 0.63-1.26). The FDA determined 3 (1.82%) out of 165 recalls to be Class 1. Surgeon evaluators reported averages of 17.5 (10.61%), 11.5 (6.97%), and 28 (16.97%) Class 1 recalls between their two rankings.

DISCUSSION AND CONCLUSION: Contrary to our hypothesis, the risk of recall at 5 and 10 years of a novel spine device is about half that reported for orthopaedic devices in general. Despite lowered FDA regulations for interbody fusion devices, no increased risk of recall was detected. Lastly, practicing spine surgeons perceive recalls with greater severity than the FDA. Further research is necessary to explain the reason for the lower risk of recall with spine devices and better understand the discrepancy of opinions of practicing spine surgeons and the FDA.

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|---|---|---|---|
| **Interbody** | | | |
| At Risk | 1072 | 664 | 166 |
| Events | 0 | 46 | 53 |
| **No Interbody** | | | |
| At Risk | 1312 | 932 | 328 |
| Events | 0 | 70 | 77 |