# A Comprehensive Analysis of Complication Reports of Expandable Lumbar Interbody Cages

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INTRODUCTION:

Expandable lumbar interbody cages (ELIC) are commonly used for interbody fusion and provide lordotic correction by lengthening the anterior column of the vertebral spine. Some studies report increased segmental lordosis, disc height, and maintenance of lordotic correction, while others reported no greater benefit and increased rate of subsidence when compared to static cages. The Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database provides a unique opportunity to analyze reported complications for commonly used devices. To our knowledge, the complication profile of ELIC has not been previously investigated in the MAUDE database.

METHODS:

The FDA MAUDE database was analyzed for complication reports submitted for ELIC systems between November 2009 and October 2022. Complications for the most used ELIC were analyzed. Reports were categorized by manufacturer, brand name, device problem, and type of complication. Reports that were duplicated or had insufficient information were excluded from analysis.

RESULTS:

A total of 851 reports were analyzed. The top five types of complication reported across all manufacturers were migration of implant (167 reports; 20%), cage fracture (138 reports; 16%), insertion mechanism failure (112 reports; 13%), cage collapse (110 reports; 13%), and expansion problem (106 reports; 12%). These complications are presented in Table 1. A majority of the reports that detail the source of reporting were submitted by Healthcare Personnel (140 reports; 16%). The top five manufacturers with the most implant-related complications were independently analyzed as well. Manufacturer 1 (manufacturer with the most complications) had the highest number of implant-related complications with 190 reported cases. The most common complications were cage fracture (77 reports, 40.5%), followed by insertion problem (62 reports, 32.6%), migration of implant (14 reports, 7.4%), and expansion problem (11 reports, 5.8%). Manufacturer 2 (manufacturer with the second most complications) showed a high frequency of expansion problem (69 reports, 37.1%), Collapse (54 reports, 29.0%), insertion mechanism failure (27 reports, 14.5%), and device handling (23 reports, 12.4%). A total of 186 implant-related complications were identified for this manufacturer. This is detailed for all manufacturers in Figure 1.

DISCUSSION AND CONCLUSION:

The types of complications reported varied greatly between manufacturers. Manufacturer 1 presented a high frequency of cage fractures and insertion problems while Manufacturer 2 presented higher reports of expansion problems and cage collapse suggesting that more robust standardization between manufacturers is necessary. We found migration of implant and cage fracture to be the most common complications of ELICs, and even more common than reported in the literature. Lastly, our analysis uncovered other intraoperative complications such as insertion mechanism failures, expansion problems, and cage collapses that have not been previously reported. Such malfunctions may damage the vertebral endplate, potentially leading to increased risk of subsidence, migration, or additional postoperative complications. Further research is needed to determine the extent of the impact of cage fractures and other intraoperative malfunctions on the overall success and safety of ELICs.

Figure 1: Bar Chart of Complications Split by Manufacturer

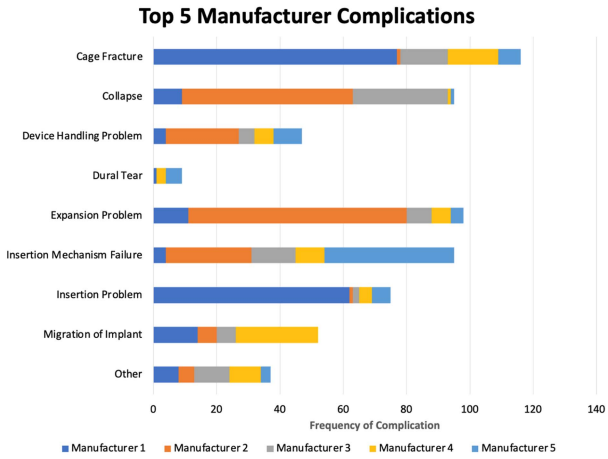


**Table 1.** Distribution of Complications as Classified from the MAUDE Database

| **Classifications** | **Frequency** | **Percentage** |
|---|---|---|
| Migration of Implant | 167 | 19.6% |
| Cage Fracture | 138 | 16.2% |
| Insertion Mechanism Failure | 112 | 13.2% |
| Collapse | 110 | 12.9% |
| Expansion Problem | 106 | 12.5% |
| Insertion Problem | 78 | 9.2% |
| Device Handling Problem | 54 | 6.3% |
| Dural Tear | 15 | 1.8% |
| Pain | 11 | 1.3% |
| Hardware Failure | 10 | 1.2% |
| Intraoperative Migration | 9 | 1.1% |
| Malpositioning | 8 | 0.9% |
| Subsidence of Implant | 5 | 0.6% |
| Infection | 4 | 0.5% |
| Screw Back Out | 4 | 0.5% |
| Cardiac Arrest | 2 | 0.2% |
| Expired Part | 2 | 0.2% |
| Hemorrhage | 2 | 0.2% |
| Malfunction | 2 | 0.2% |
| Manufacturing Problem | 2 | 0.2% |
| Non-union | 2 | 0.2% |
| ASD | 1 | 0.1% |
| Bone Fracture | 1 | 0.1% |
| Bone Fragment Stuck in Device | 1 | 0.1% |
| Bone Growth | 1 | 0.1% |
| Death | 1 | 0.1% |
| Overlabeled | 1 | 0.1% |
| Unspecific Failure* | 1 | 0.1% |
| Vessel Injury | 1 | 0.1% |

The total number of complications is 851. Each report was matched with one main complication, so the total number of complications is equal to the total number of reports.
*Unspecified Failure was explicitly stated in the complication report and thus was included.