

## **Risk of Recall for Musculoskeletal Oncology Implants: Time-to-Event Analysis over 15-Years**

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**INTRODUCTION:** Orthopedic oncology implants are complex devices used to treat often sick patients with challenging deformities, bone loss, and soft-tissue conditions. The physiologic forces endured by these implants can be vastly greater than those experienced by routine total joint arthroplasty utilized for primary osteoarthritis. These factors can lead to failure mechanisms that differ between these two types of implants. Previous literature has identified a 25% risk of recall for total joint arthroplasty devices ten years after Food and Drug Administration (FDA) authorization. Because of the complexities mentioned above, we hypothesized reconstruction devices designed for oncology care would experience greater risk of recall. In addition, to better understand real-world clinical impacts of complications with these devices, we sought to correlate adverse events (AEs) reported in the Manufacturer and User-Facility Device Experience (MAUDE) with the recalls. To our knowledge, no other study has investigated the risk of recall of orthopedic oncology implants or attempted to associate recalls with MAUDE reports.

### **METHODS:**

The publicly available FDA database was queried for orthopedic arthroplasty implants labeled for use in oncology. Results were limited to devices FDA authorized between January 01, 2008 and July 1, 2024. There were 79 musculoskeletal oncology devices identified, which were further divided into proximal femoral related devices (58 devices, 73%), distal femoral related devices (19 devices, 24%), and other (2 devices, 2.5%). Information regarding dates of recall, FDA classification of severity of recall, FDA Root Cause of recall, and manufacturer reason for recall were recorded.

To correlate AEs with recalls, the MAUDE database was queried for reports on each oncology device using the FDA's given 510(k) number. AEs were classified by the authors using the Henderson Classification for endoprosthesis failures. AEs that did not fit into a category, were considered "Other".

### **RESULTS:**

Of the 19 proximal femur devices, 5 (26%) were recalled compared to 17 (29%) of the distal femur devices. Of the 22 recalled devices, 9 were recalled multiple times (range 2- 9), leading to a total of 41 recalls. All recalls were Class 2 (moderate risk) recalls.

Cumulative incidence analysis showed the risk of recall of proximal femur devices to be 16.9% 10 years and 34.6% at 15 years compared to 29.2% at both time points for distal femur devices ( $p > .05$ ). There is no statistical difference in risk of recall between proximal and distal femur implants (figure 1).

In looking at MAUDE, recalled devices had more total AEs and AEs classified as Henderson 2 or 3 failures (table 1). This difference was statistically significant.

The FDA root cause of recall was most commonly related to processing/packaging (16 recalls, 39%) or labeling (12 recalls, 29%). There was also a weak correlation between number of adverse events and risk of recall. There were over 3700 adverse events recorded for these devices in that period through the MAUDE database.

### **DISCUSSION AND CONCLUSION:**

The findings of this investigation suggest that there is nearly a 30% risk of recall of orthopedic oncology devices at 15 years post-FDA authorization, with no difference between proximal and distal femur replacements. This approximates the reported 25% risk at 10 years for knee and hip arthroplasty devices used in osteoarthritis, but is much greater than the 12% reported for general orthopedic devices. While the most common FDA Root Cause of recall was related to processing/packaging or labeling, device design failures still made up a portion of the recalls.

Systematic device failures are frequently identified through adverse event (AE) reports submitted to MAUDE by manufacturers and health professionals. Oncologic recalled devices had over 16x as many AEs and 9x as many Henderson 2&3 AEs reported in MAUDE as compared to non-recalled oncologic devices.

In conclusion, orthopedic surgeons who utilize these devices in practice should be aware of the risk of these implants being recalled. They should also be aware of the crucial role they can play in identifying problematic devices by reporting issues they encounter in MAUDE. Further research into device regulation, recalls, and adverse events is necessary to better understand how to improve safety of novel devices after they enter market.