Recalls of Arthroscopic Equipment After FDA 510(k) Approval: A Twenty-Year Analysis of Causes, Trends, and Time To Recall (2004 to 2024)

Thriaksh Rajan, Christian Joseph Hecht, Comron Saifi, Prem N Ramkumar, R. Justin Mistovich

INTRODUCTION: Current reliance on the expedited 510(k) approval pathway has driven rapid commercial availability of novel arthroscopic devices. Despite the low complication rates of arthroscopic procedures, products from this pathway are suspected to increase the rate of recalls and device malfunctions. This study aimed to characterize arthroscopic device recalls, analyze trends in recall incidence, and identify predictors of time-to-recall.

METHODS: A 20-year retrospective cross-sectional study was conducted using the FDA Recalls database. Recalled devices approved under the FDA 510(k) pathway were identified and categorized by type, manufacturer, recall class, and cause. Statistical analyses included Poisson regression for trends and Cox proportional hazards modeling for predictors of time-to-recall.

RESULTS:

A total of 124 recalls were initiated during the study period (average 6.2 recalls/year), with packaging and process control issues accounting for 50.7% of recalls. Recall incidence remained stable over time, though nearly half occurred in 2008, 2010, 2012, and 2019. Mean recall time was 491 days (95% CI: 444-539). Devices recalled due to material/component contamination had significantly shorter times (HR: 3.73 [95% CI: 1.78-7.82]), whereas process control issues prolonged recall times (HR: 0.56 [95% CI: 0.31-1.00]). Manufacturer was another predictor of time to recall, with one manufacturer exhibiting substantially extended recall times (HR: 0.45 [95% CI: 0.22-0.92]).

DISCUSSION AND CONCLUSION:

Arthroscopic device recalls are largely caused by packaging and process control issues, emphasizing the need for stricter quality assurance during manufacturing. While recall incidence remained stable over the past two decades, variability in recall times highlights opportunities for improved manufacturer accountability and FDA oversight. Increasing procurement scrutiny, enhancing FDA audit practices, and integrating recall data with clinical outcomes can minimize disruptions in arthroscopic surgery.