

Analysis of Adverse Events Associated with Total Knee Arthroplasty Using the FDA MAUDE Database

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AUTHOR BIO

Alison Chi-Yan Fung is a student at the Illinois Mathematics and Science Academy with research interests in mechanical engineering, medical devices, and prosthetic technology. She is particularly interested in designing affordable assistive technologies that improve patient mobility and quality of life. Outside of the classroom, Alison conducts engineering research focused on computer vision and machine learning applications for prosthetic hand control. She also serves as Operations Captain for her FIRST Robotics Competition team and enjoys mentoring younger students through STEM outreach and leadership programs. She hopes to pursue a career in mechanical engineering while continuing research in prosthetics and rehabilitation technologies.

ABSTRACT

Total knee arthroplasty (TKA) is one of the most commonly performed orthopedic procedures for treating end-stage osteoarthritis. Although the procedure generally improves pain and mobility, adverse events may occur and can negatively affect patient outcomes while increasing healthcare costs. This study investigated adverse events associated with TKA prosthetic devices using data from the U.S. Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database. Reports associated with FDA product code OOG were collected for the years 2016 through 2025 and analyzed to identify trends in overall adverse events, injury reports, and malfunction reports. Annual case counts were compiled and visualized using line graphs. Results showed that reported adverse events generally increased over the study period, with total reports peaking in 2024. Injury reports demonstrated the largest increase, rising from 11 cases in 2023 to 64 cases in 2024, while malfunction reports fluctuated throughout the study period and remained comparatively lower. Although the MAUDE database cannot be used to determine true complication rates because of limitations such as underreporting and incomplete reports, it provides valuable information for identifying trends in post-market device performance. Continued surveillance of TKA adverse events may help improve prosthetic design, guide regulatory oversight, and ultimately enhance patient safety and clinical outcomes.

Keywords: *Arthroplasty, Total Knee Arthroplasty, Adverse Events, FDA MAUDE, Medical Device Reporting, Osteoarthritis, Device Malfunction, Injury Reports, Post-Market Surveillance, Medical device complications*

INTRODUCTION

Total knee arthroplasty (TKA), also known as total knee replacement, is a surgical procedure used to treat severe knee osteoarthritis and other degenerative joint diseases. Osteoarthritis gradually wears away cartilage in the knee joint, leading to chronic pain, stiffness, swelling, and reduced mobility. When non-surgical treatments such as medication, physical therapy, or lifestyle changes are no longer effective, TKA may be recommended as a long-term solution. During the procedure, damaged cartilage and bone are replaced with artificial prosthetic components that are designed to restore movement and reduce pain. TKA is considered one of the most successful orthopedic surgeries because many patients experience significant improvements in mobility and quality of life after recovery (Gemayal & Varacallo, 2023, para. 1). However, despite advances in surgical techniques and implant technology, approximately one out of five patients remain dissatisfied following surgery (Gemayal & Varacallo, 2023, para. 36).

TKA is also one of the most commonly performed orthopedic procedures in the United States. Ward and Dasgupta (2020) found that the rate of arthroplasty among white Medicare beneficiaries was 9.3 procedures per 1000 people, although rates varied significantly by region (para. 8). This regional variation suggests that TKA may be overperformed in certain areas while underutilised in others. The number of procedures performed annually is also expected to continue increasing as the population ages and osteoarthritis becomes more common. Recent estimates project that by 2030, approximately 3.48 millions TKAs will be performed annually in the United States (Gemayal & Varacallo, 2023, para. 3). Since the procedure is performed so frequently, TKA places a substantial financial burden on the healthcare system. During fiscal year 2011, Medicare reimbursed hospitals approximately \$3.5 billion for TKA procedures, making it the largest CMS expenditure for a single procedure type (Culler et al., 2015, para. 2).

Although TKA is generally effective, it remains a highly invasive surgical procedure that carries significant risks for adverse events. Since patients often experience reduced mobility and extended hospitalisation during the recovery period, they are at increased risk for short-term complications such as thromboembolism, pneumonia, infection, hemorrhage, and postoperative shock. Huddleston et al. (2009) found that 6.5% of patients undergoing TKA experienced at least one adverse event during their hospitalisation (para. 16). The study also found that patients with preexisting conditions such as congestive heart failure or chronic obstructive pulmonary disease were significantly more likely to experience complications. In addition, adverse events after TKA were associated with increased 30-day mortality rates among Medicare patients (Huddleston et al., 2009, para. 1). Bohl et al. (2018) found that longer operative times were independently associated with an increased risk of postoperative complications following primary total joint arthroplasty (para. 4).

Long-term complications following TKA may also occur, even when the surgery itself is technically successful. Some patients experience chronic pain, stiffness, implant loosening, instability, or the need for revision surgery years after the original procedure. Researchers have also identified adverse local tissue reactions caused by metal debris released from implant components through wear and corrosion. In rare cases, patients have developed large soft-tissue masses and inflammatory reactions

surrounding the prosthesis following revision TKA procedures (Bellova et al., 2021, para. 1). Additionally, studies investigating proprioception and reaction time after TKA suggest that some patients continue to experience reduced balance and slower movement responses even after recovery, which may affect long-term mobility and overall satisfaction (Özden et al., 2024, para. 9).

Adverse events following TKA also contribute significantly to healthcare costs. Complications often increase hospital length of stay, require additional medical treatment, and may result in hospital readmission or revision surgery. Culler et al. (2015) found that the additional cost of treating adverse events ranged from \$2,167 for hemorrhage or postoperative shock requiring transfusion to \$30,902 for pneumonia (para. 1). Because TKA is already one of the most expensive and commonly performed procedures covered by Medicare, reducing complication rates could substantially lower healthcare expenditures while improving patient outcomes.

The U.S. Food and Drug Administration maintains the Manufacturer and User Facility Device Experience (MAUDE) database, a publicly accessible database that contains reports of adverse events involving medical devices. Reports are submitted by mandatory reporters like manufacturers, importers, and device user facilities, as well as voluntary reporters such as healthcare professionals, patients, and consumers. The combination of mandatory and voluntary reporting in the MAUDE database allows both healthcare professionals and members of the public to participate in monitoring medical devices safely, increasing the likelihood that a wider range of adverse events and patient experiences will be documented. The MAUDE database is commonly used for post-market surveillance because it helps identify potential safety concerns and device related complications after products have been approved for public use (U.S. Food and Drug Administration, 2025). By analysing adverse event reports associated with total knee arthroplasty prostheses, the goal of this study is to investigate reported adverse events associated with total knee arthroplasty and examine how these complications affect patient outcomes.

METHODS

Adverse event reports associated with total knee arthroplasty (TKA) prosthetic devices were identified using the FDA product code “OOG.” Reports were collected by searching the MAUDE database for cases associated with this product code between 2016, the earliest reported data, to 2025, the most recently completed year of data (U.S. Food and Drug Administration, 2026). The total number of reported cases per year was recorded and organised into a spreadsheet for analysis.

The data were analysed to observe trends in the frequency of reported adverse events over time. Annual case counts were compared across years to identify increases, decreases, and overall patterns in reporting frequency. A line graph was created to visualise the number of adverse events per year for product code OOG.

Since the MAUDE database is a passive surveillance system, duplicate reports, incomplete reports, and underreporting may be present within the dataset. Therefore, the results of this study are

intended to identify reporting trends and commonly documented adverse events rather than determine the true incidence rate of complications associated with TKA devices.

RESULTS

Figure 1 shows the total number of adverse event cases reported each year for FDA MAUDE product code OOG between 2016 and 2025. The number of reported cases generally increased over time, although some fluctuations were observed between years. From 2016 to 2021, annual case counts remained relatively low, with fewer than 20 reported cases each year. Beginning in 2022, the number of reports increased more rapidly, rising from 18 cases in 2022 to 26 cases in 2023, representing a 44.4% increase. The largest increase occurred between 2023 and 2024, where reported cases increased from 26 to 73, an increase of approximately 180.8%. Following this peak, the number of reports declined to 34 cases in 2025, representing a 53.4% decrease. Overall, the data demonstrates a substantial rise in reported adverse events associated with product code OOG in recent years, increasing by approximately 1,725% between 2021 and the peak observed in 2024.



Figure 1

Total number of cases of adverse events per year of product code OOG from the FDA MAUDE database

Figure 2 shows the annual number of injury-related adverse event reports associated with FDA product code OOG from 2016 to 2025. Injury reports remained relatively low throughout most of the study period. Between 2016 and 2021, annual injury reports never exceeded 14 cases and were recorded as zero in both 2017 and 2018. A moderate increase occurred in 2022, when injury reports rose from 1 case in 2021 to 18 cases in 2022. Reports then decreased slightly to 11 cases in 2023 before a dramatic

increase to 64 case in 2024, representing a 481.18% increase from the previous year. This was the highest number of injury reports observed during the study period. In 2025, injury reports declined to 30 cases, a decrease of 53.1% from the peak in the previous year. Overall, injury-related adverse event reports demonstrated a substantial upward trend over time, with injuries accounting for the majority of reported events during the later years of the study period.

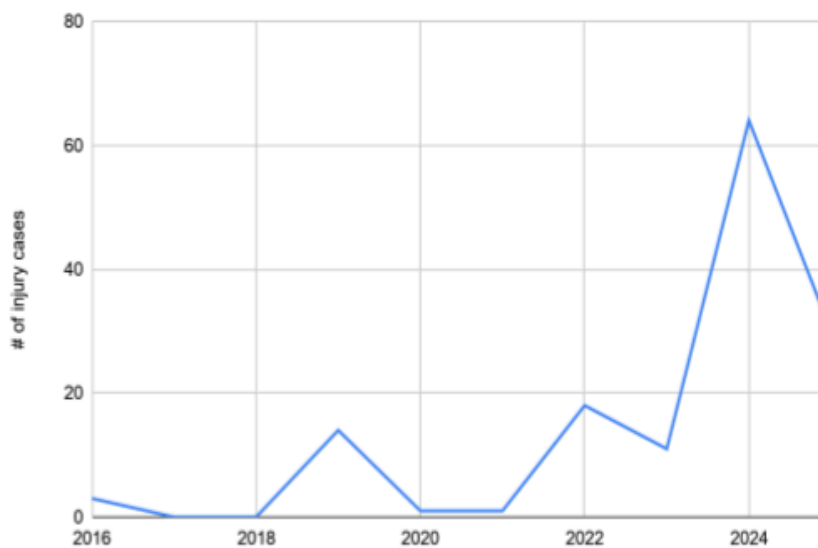


Figure 2

Total number of reported injury cases per year associated with product code OOG from the FDA MAUDE database

Figure 3 shows the annual number of malfunction-related adverse event reports associated with FDA products code OOG from 2016 to 2025. Malfunction reports fluctuated considerably from year to year without exhibiting the sustained increase observed for injury reports. Reports increased from 1 case in 2016 to 10 cases in 2017 before declining to 2 cases in 2018 and 1 case in 2019. A second increase occurred in 2020, when malfunction reports rose to 7 cases, followed by a decline to 3 cases in 2021 and 0 cases in 2022. The highest number of malfunction reports was observed in 2023, with 15 reported cases



Figure 3

Total number of reported malfunction cases per year associated with product code OOG from the FDA MAUDE database

DISCUSSION

The results of this study show that the number of adverse event reports associated with total knee arthroplasty (TKA) devices in the FDA MAUDE database generally increased between 2016 and 2026. While annual case counts remained relatively low through 2021, reports increased substantially beginning in 2022 and reached a peak of approximately 73 cases in 2024 before declining in 2025. This trend may reflect increased use of TKA procedures, greater awareness of adverse event reporting, or changes in device utilization over time. Because millions of TKA procedures are performed annually in the United States, monitoring adverse events remains important for identifying potential safety concerns and improving patient outcomes. The findings support previous research demonstrating that adverse events following TKA are associated with increased patient morbidity, longer hospital stays, and greater healthcare costs (Culler et al., 2015, para. 1; Huddleston et al., 2009, para. 1).

Several limitations of the MAUDE database should be considered when interpreting these results. One limitation of the FDA Manufacturer and User Facility Device Experience (MAUDE) database is that it operates as a passive surveillance system, meaning that it depends on healthcare providers, manufacturers, and patients to voluntarily or mandatorily submit reports of adverse events. Since reporting is not always complete or timely, the database may contain underreported, inaccurate, incomplete, unverified, or biased data. The FDA also states that MAUDE data cannot be used to determine the true incidence or prevalence of adverse events because the total number of devices in use is unknown and not all complications are reported. Additionally, duplicate reports may occur when both healthcare facilities and manufacturers report the same event, making interpretation more difficult. Some reports also lack detailed clinical information, preventing researchers from establishing a direct

cause-and-effect relationship between a device and the reported complication. Due to these limitations, MAUDE data should be interpreted cautiously and used alongside other clinical studies and surveillance systems when evaluating medical device safety (U.S. Food and Drug Administration, 2025).

Future research should examine the specific types of adverse events reported for TKA devices and identify which complications occur most frequently. Additional analysis could investigate trends among different manufacturers, implant designs, or patient populations to determine whether certain factors are associated with higher numbers of reported events. Future studies may also compare MAUDE data with findings from clinical registries or peer-reviewed studies to provide a more comprehensive understanding of TKA safety. As the number of TKA procedures continues to increase, ongoing surveillance and research will be essential for improving prosthetic design, reducing complications, and enhancing long-term patient outcomes.

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