

# Reported Adverse Events for Hip Prostheses and Knee Prostheses Before, During, and After the COVID-19 Pandemic

Zehui Yi<sup>1</sup>, Sujata K. Bhatia<sup>2</sup>

<sup>1</sup>University of California, Santa Barbara  
6522 Sabado Tarde Isla Vista, CA 93117  
Zehui65@ucsb.edu

<sup>2</sup>Department of Continuing Education, Harvard University  
51 Brattle St, Cambridge, MA 02138  
sbhatia@g.harvard.edu

**Abstract** – The SARS-CoV-2 (COVID-19) pandemic had a profound impact on surgical practices in the United States due to the limited medical resources and cancellation of inpatient treatments, including elective surgeries. As two of the most frequently performed surgical procedures, total knee arthroplasty (TKA) and total hip arthroplasty (THA) can provide insights into the impact of the COVID-19 pandemic on healthcare outcomes. This study investigates the number of reported adverse events for TKA and THA based on United States Food and Drug Administration (FDA) data in the Manufacturer and User Facility Device Experience (MAUDE) database. The MAUDE database was searched using the NJL product code for TKA devices, and the NXT product code for THA devices, and the study compares the number of reported adverse events before, during, and after the COVID-19 pandemic. The findings indicate that knee prostheses and hip prostheses exhibited distinct trends for reported adverse events from 2018 to 2023. Reported injuries for knee prostheses peaked during the pandemic period, as the number of reported injuries increased significantly by 43% from 1709 to 2443 cases ( $p < 0.003$ ) from 2020 to 2021. However, reported injuries for hip prostheses peaked before the pandemic, with a significant 77% decrease in reported injuries, from 573 to 133 ( $p < 0.0007$ ) from 2018 to 2023. Possible explanations for the differences in reported injury trends between TKA and THA include differences in the patient population receiving knee prostheses compared to those receiving hip prostheses, for instance, differences in the underlying health status of patients. Also, differences in the level of difficulty between the two types of prostheses can be a possible explanation. Future research should investigate the underlying causes for trends in reported adverse events, and expand the investigation to include other orthopaedic devices such as ankle-foot prostheses and spinal implants.

**Keywords:** arthroplasty, knee prostheses, hip prostheses, COVID-19, adverse events, orthopedic surgery

## 1. Introduction

The SARS-CoV-2 (COVID-19) pandemic had a significant effect on US surgical operations. Hospital arthroplasty treatments were delayed or canceled due to a lack of medical resources and time, which increased the number of patients who had to return home. Total knee arthroplasty (TKA) and total hip arthroplasty (THA) are two of the most popular surgical procedures performed both domestically and internationally. These operations are normally regarded as elective surgeries, which means that they can be canceled or postponed because they usually do not involve an emergency.

TKA is one of the surgeries with the highest success rate among orthopedic surgeries, and can greatly relieve patients' pain, restore function, and improve quality of life, especially for patients with end-stage, tri-compartmental, degenerative osteoarthritis (OA) [1]. Among these, OA in particular affects millions of Americans. Every year, 400,000 TKA surgeries are performed in the United States due to OA [1]. Moreover, TKA is no longer a procedure just performed on the elderly; younger patients are having TKA procedures more frequently [1]. Between 1991 and 2010, the amount of TKA operations performed on U.S. Medicare beneficiaries increased by 161.5%, from over 93,000 cases to over 226,000 cases [1].

THA, like TKA, is one of the most cost-effective and consistently successful surgeries in orthopedics and can relieve pain, restore function, and improve quality of life [1]. THA mainly serves people with end-stage degenerative hip osteoarthritis (OA), who are also no longer restricted to the elderly, and there are more frequent cases of young people [1]. Millions of Americans suffer from OA, and each year 88 symptomatic instances occur for every 100,000 patients [1]. THA is more dependable and predictable than TKA, and the prostheses made with THA last for 15 to 20 years [1].

In 2020, about 30,000 main TKA and THA procedures and 3,000 revision surgeries per week were canceled after necessary surgeries were taken out [2]. Surgery postponements and cancellations had a detrimental effect on the economy and hospital revenues, with an 85% loss in surgeon fees and an 87% drop in Medicare revenues for US hospitals involved in arthroplasty [3]. In the United States, TKA volumes decreased by 94% and THA volumes decreased by 92% in mid-March 2020[3]. Failure of patients to receive timely care may result in the deterioration of the patient's condition.

Patients undergoing outpatient TKA and THA surgeries during the pandemic were more likely to be older and have more pre-existing medical issues than they were before the outbreak [4].

Utilizing information from the Manufacturer and User Facility Device Experience (MAUDE) database maintained by the U.S. Food and Drug Administration (FDA), we examined patterns in reported adverse events concerning artificial hips (hip prostheses) and knees (knee prostheses) during the pre-pandemic, pandemic, and post-pandemic periods.

## 2. Methods

This research uses the Manufacturer and User Facility Device Experience (MAUDE) database [5], a publicly available repository of adverse events and safety issues related to medical devices maintained by the U.S. Food and Drug Administration (FDA). The FDA requires that manufacturers, importers, and device user facilities enter the device model number, date of the event, date of return, operator, and a description of the adverse event into the MAUDE database following an adverse event or device malfunction, in order to minimize needless harm to patients [6]. Reports can be voluntarily added to the database by healthcare providers, patients, carers, and consumers [6]. Over 4 million occurrences have been recorded in the MAUDE database as of 2017; approximately 2,000 new reports are added every day [6]. The database contains four different categories of events: malfunction, injury, death, and others. It is important to note that although the MAUDE database has useful information regarding the safety of medical devices, there are some analytical problems with the data, such as underreporting, biased and imprecise reporting, duplicate reporting, and a lack of thorough analysis [6].

Adverse events are listed in the MAUDE database along with the date and type of the event and are classified by the product category, which is identified by a three-letter code. We selected NJL and NXT as our two product codes for analysis since they comprise the majority of the data on knee and hip prostheses in the MAUDE database. The official interpretation of these two codes by MAUDE is as follows:

NJL (Knee prostheses) - "It is intended to replace a knee joint to relieve pain and restore knee function, for indications such as osteoarthritis, inflammatory arthritis, traumatic arthritis, and revision of failed knee prostheses" [5].

NXT (Hip prostheses) - "This device is indicated for patients with degenerative joint diseases including osteoarthritis, rheumatoid arthritis, traumatic arthritis, dysplasia, or avascular necrosis, and for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip replacement due to an increased possibility of requiring future hip joint revision" [5].

Based on these two product codes, we collected data from 2018-2023, spanning the pre-pandemic, pandemic, and post-pandemic periods, and analyzed monthly data for injuries and malfunctions associated with the NJL and NXT product codes. The data were examined using a student t-test to compare the difference in the number of adverse events from year to year. The student t-test is a statistical analysis in which two lists of numbers are compared to determine whether they are significantly different. The t-test returns a p-value. The p-value is a measure of the probability that the results are due to chance. A p-value less than 0.05 is considered statistically significant. This means that there is less than a 5% chance that any differences seen are due purely to random chance. Thus, we used the cutoff of  $p < 0.05$  to determine whether to reject the null hypothesis that there is no difference in the number of adverse events from year to year. The formula for calculating the t-value in the student t-test is as follows:

$$t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{\frac{s_1^2}{N_1} + \frac{s_2^2}{N_2}}}$$

$\bar{X}_1$  = observed mean of 1st sample  
 $\bar{X}_2$  = observed mean of 2nd sample  
 $s_1^2$  = standard deviation of 1st sample  
 $s_2^2$  = standard deviation of 2nd sample  
 $N_1$  = sample size of 1st sample  
 $N_2$  = sample size of 2nd sample

### 3. Results

Results regarding knee joint prostheses (NJL) injuries showed that from 2018 to 2020, the number of reported injuries increased significantly by 45% from 1180 to 1709 cases ( $p < 0.02$ ). There was no significant difference in the number of reported injuries between 2019 and 2020 ( $p > 0.05$ ). From 2020 to 2021, the number of reported injuries increased significantly by 43% from 1709 to 2443 cases ( $p < 0.003$ ) (Figures 1 and 2). From 2021 to 2022, there was no significant change in the number of reported injuries ( $p > 0.05$ ). In general, there was an increase in injuries from 2018 to 2020, and then again from 2020 to 2021, i.e., the year after the outbreak. From 2021 to 2023, there was a significant decline in the number of reported injuries, from 2443 to 1478 ( $p < 0.000003$ ). In summary, the number of reported injuries for NJL knee prostheses peaked in 2021. The malfunction rates for NJL devices were not analyzed, as there was an insufficient number of malfunction reports to draw reliable conclusions.

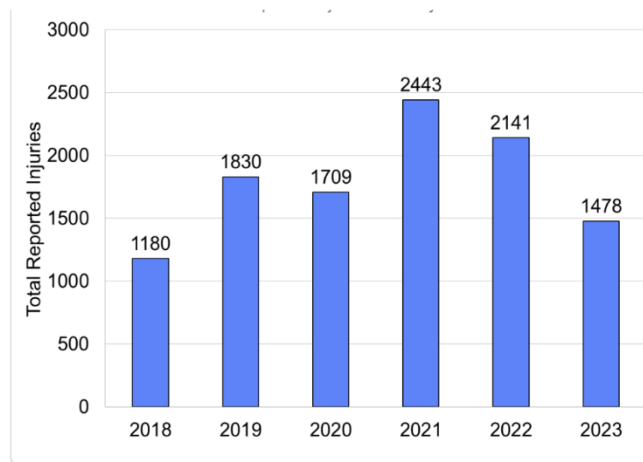


Figure 1. Annual reported injuries for NJL devices.

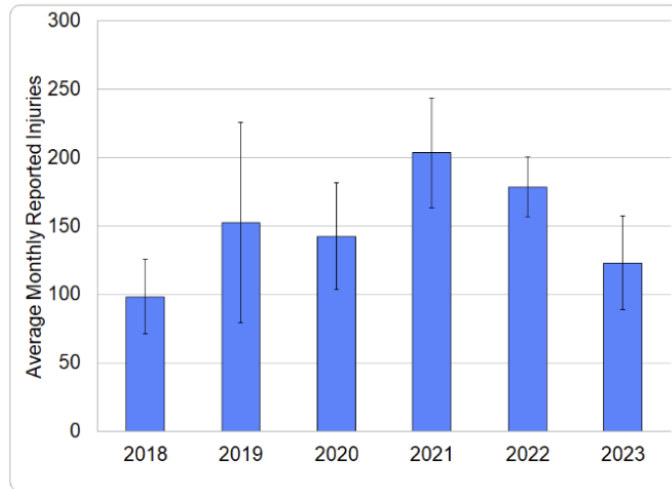


Figure 2. Average monthly injuries for NJL devices per year. Error bars represent standard deviation of monthly injuries for the year.

For NXT hip prostheses, the number of malfunction reports was sufficient to allow analysis.

Between 2018 and 2023, hip joint prostheses (NXT) experienced a significant 77% decrease in reported injuries, from 573 to 133 ( $p < 0.0007$ ). From 2018 to 2019, there was no significant decrease ( $p > 0.05$ ). Then, from 2019 to 2020, the number of injuries rose from 463 to 503 ( $p > 0.05$ ). Injury numbers declined steadily from 503 in 2020 to 482 in 2021 ( $p > 0.05$ ), 482 in 2022 ( $p > 0.05$ ), and declined dramatically to 133 in 2023 ( $p < 0.00008$ ) (Figures 3 and 4).

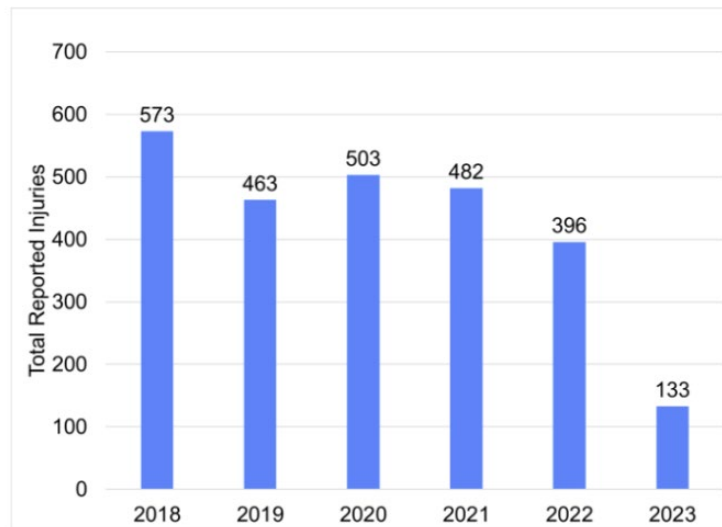


Figure 3. Annual reported injuries for NXT devices.

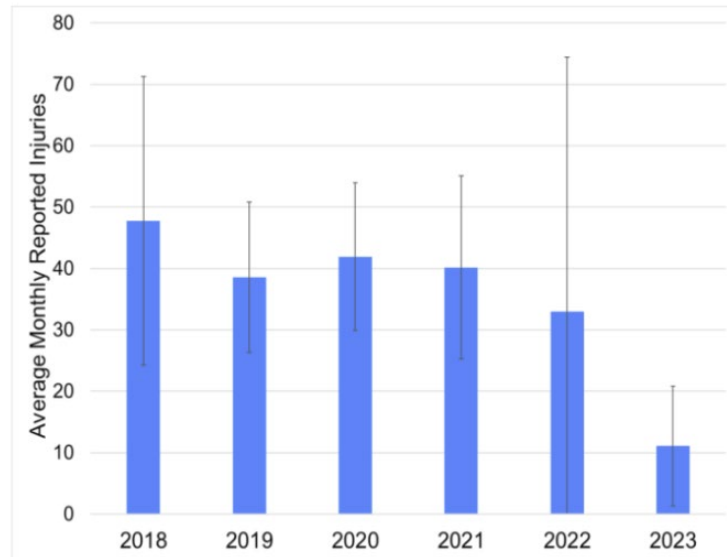


Figure 4. Average monthly injuries for NXT devices per year. Error bars represent standard deviation of monthly injuries for the year.

Compared to injuries, the total number of malfunction reports varied between 2018 and 2023, but there was no clear trend; some years had a higher number of malfunction reports, such as 27 in 2021, while others had a lower number, such as 4 in 2019 (Figures 5 and 6).

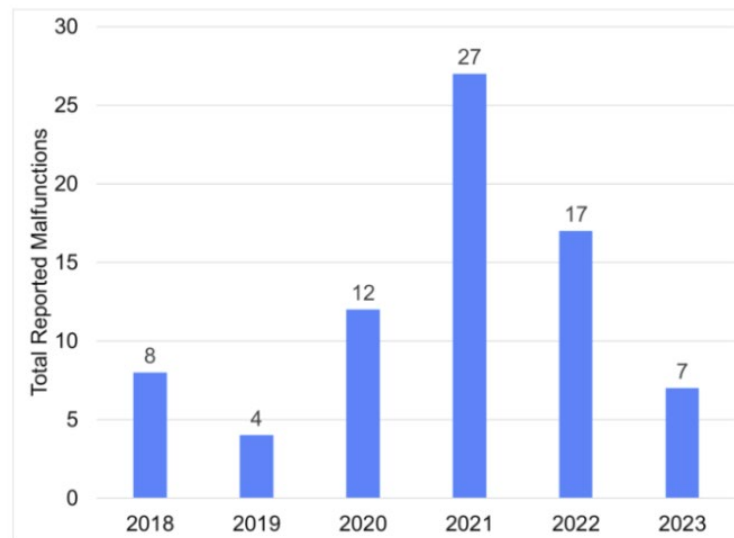


Figure 5. Annual reported malfunctions for NXT devices.

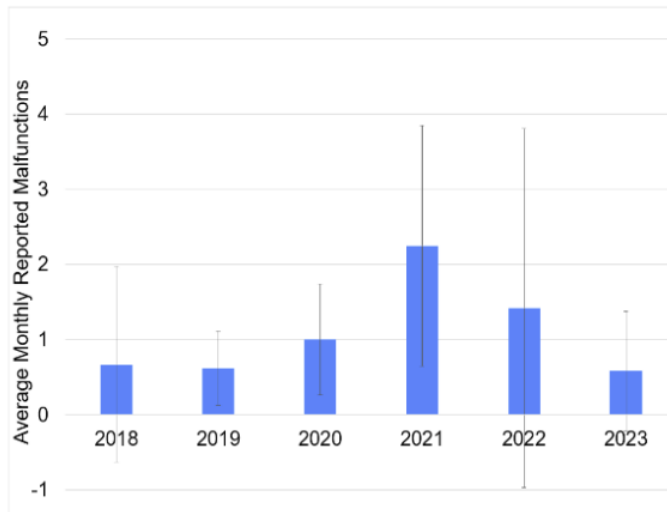


Figure 6. Average monthly malfunctions for NXT devices per year. Error bars represent standard deviation of monthly injuries for the year.

Overall, knee prostheses had the fewest adverse events in the pre-pandemic period (2018 and 2019), the most in the pandemic period (2020 and 2021), and a drop in the number in the post-pandemic period (2022 and 2023), but remained higher than in the pre-pandemic period. Hip prostheses, on the other hand, showed insignificant changes in reported injuries from 2018 through 2022 followed by a precipitous drop in 2023, with the maximum number in the pre-pandemic period, a moderate reduction during the pandemic period, and a 77% decrease after the pandemic in 2023.

#### 4. Discussion

The significant increase in adverse events for knee prostheses during the pandemic in 2021 could be caused by the overburdened healthcare system with delayed surgery, changes in surgical protocols, or reduced post-operative care, all of which may have increased the risk of knee prostheses complications during this period. The decline in adverse events in the post-pandemic period, although still higher than the adverse event numbers in the pre-pandemic period, may indicate that the healthcare system is gradually improving, but is still adapting to the negative influences brought by the pandemic.

On the other hand, there was a downward trend in adverse events for hip prostheses, with the highest number observed during the pre-pandemic period. The minor decline during the pandemic could be caused by fewer elective surgeries performed, due to limited vacant hospital beds and inadequate resources. The significant decrease following the pandemic may indicate that, as the pandemic ended, healthcare resources returned to normal levels, allowing for better preoperative evaluation, surgery, and care, lowering the chance of adverse events.

The difference in adverse event trends for knee prostheses versus hip prostheses requires further investigation. The distinct trends may result from differences in the patient populations receiving knee prostheses versus hip prostheses; for instance, the underlying health condition and age of the patients may be different for knee prostheses than for hip prostheses. For instance, it has been found that 21.1% of patients undergoing total hip arthroplasty have underlying osteoporosis, whereas 29.4% of patients undergoing total knee arthroplasty have underlying osteoporosis[7]. Thus, patients undergoing total knee arthroplasty generally have poorer bone health, and may be more prone to injuries, compared to patients undergoing total hip arthroplasty. This may offer a potential explanation for the differences in adverse event trends for knee prostheses versus hip prostheses, and the peak in knee prostheses injuries during the pandemic. The patient populations undergoing knee arthroplasty versus hip arthroplasty may also face different risk

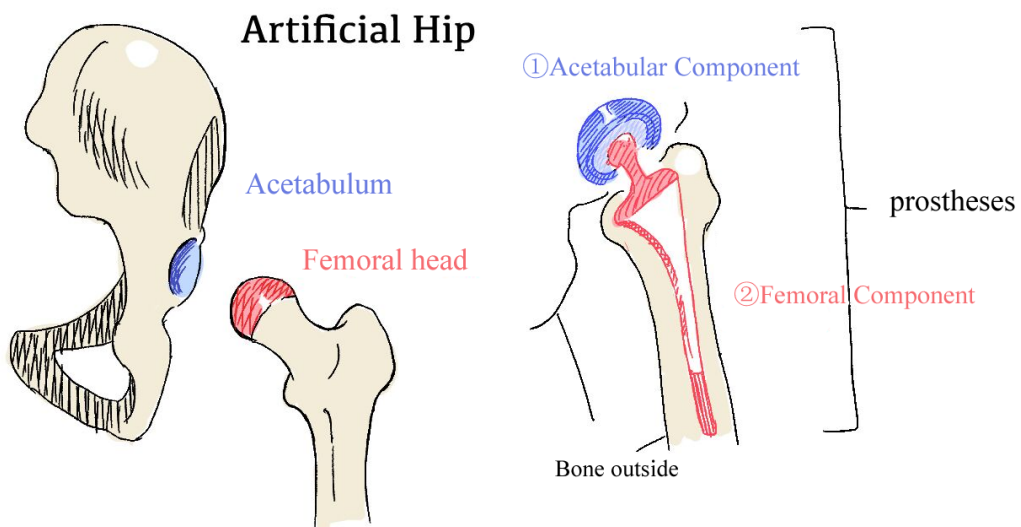
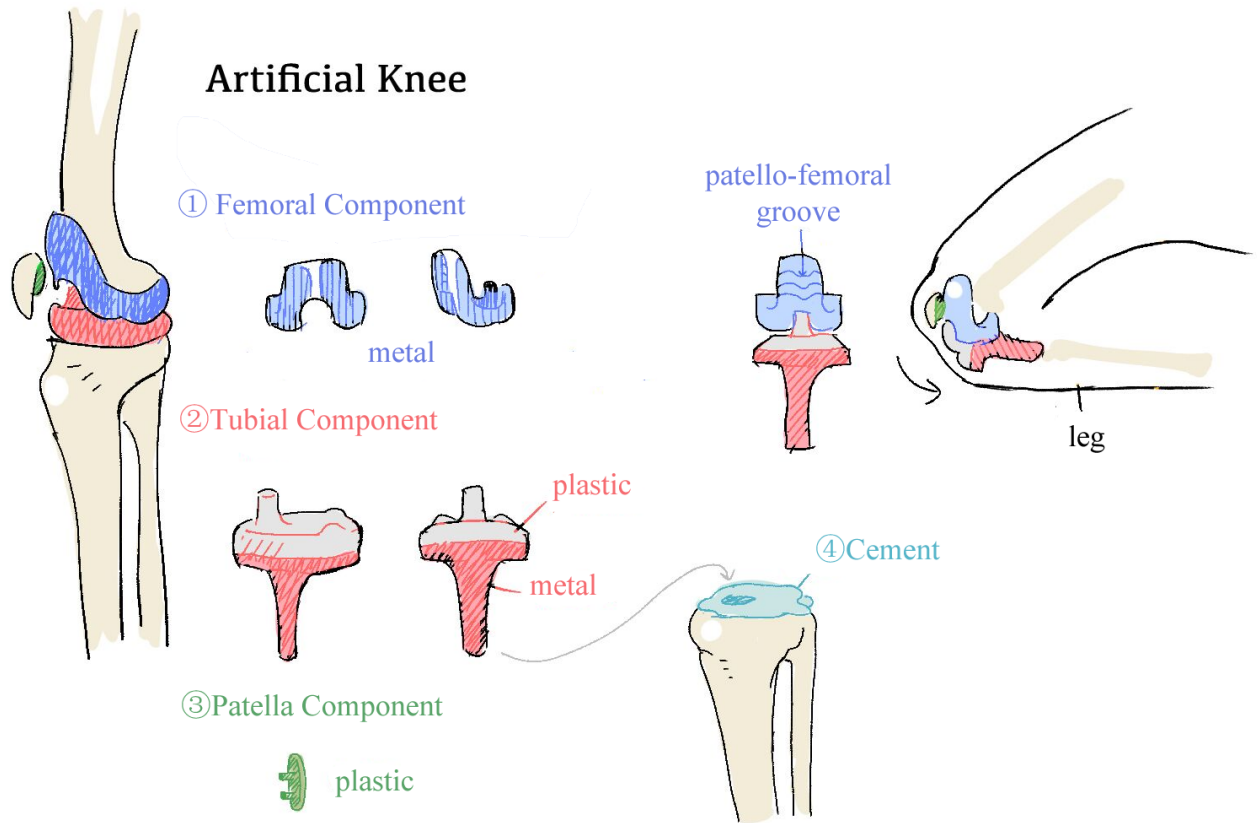


Figure 7. Anatomical location and surgical technique for artificial knee prostheses and artificial hip prostheses.

factors following surgery. For instance, the risk of falls in the first 12 months following total knee arthroplasty is 6.2%-42.6%, whereas the risk of falls in the first 12 months following total hip arthroplasty is 25%-36% [8]. These risk factors may also influence the adverse event rate following surgery. The difference in adverse event trends could also result from differences in the surgical protocol, anatomical location, and complexity of a knee replacement surgery versus a hip replacement surgery (Figure 7).

The MAUDE database has limitations; it may not capture all adverse events because some reporting by healthcare providers, patients, carers, and consumers is voluntary [6]. Furthermore, duplicate reports in the database, as well as a lack of detailed information about patients' adverse event reports and follow-up care, make it difficult to determine causality or identify risk factors for specific adverse events, limiting the ability to determine the impact of COVID-19 in terms of the total amount of adverse event reports [6].

## 5. Conclusion

This study finds that knee prostheses and hip prostheses do not show the same trend in the number of reported adverse events from 2018 through 2023. While both categories of medical devices demonstrated the lowest numbers of reported adverse events during the post-pandemic period, their trends were distinct. Knee prostheses injuries peaked during the pandemic period and hip prostheses injuries peaked during the pre-pandemic period.

Future research could look into orthopedic devices other than knee and hip prostheses, such as ankle-foot prostheses, to determine their rates of adverse events and how they may be affected by pandemics or other external factors. Comparative studies across regions or healthcare systems, as well as the development of more in-depth research methodologies than the use of online repositories like MAUDE. Interviews or surveys of healthcare professionals and patients, may provide a more complete understanding of the underlying factors contributing to adverse event trends and potentially provide recommendations for best practices to reduce risks associated with orthopedic devices.

## References

- [1] Varacallo M, Luo TD, Johanson NA. "Total Knee Arthroplasty Techniques," In *StatPearls [Internet]*. Treasure Island (FL): StatPearls Publishing; 2024 Jan.
- [2] Bedard NA, Elkins JM, Brown TS. "Effect of COVID-19 on Hip and Knee Arthroplasty Surgical Volume in the United States," *The Journal of arthroplasty* vol. 35.
- [3] Barnes CL, Zhang X, Stronach BM, Haas DA. "The Initial Impact of COVID-19 on Total Hip and Knee Arthroplasty," *J Arthroplasty*.
- [4] Santoro AJ, Post ZD, Thalody HS, Czymek MM, Ong AC, Ponzio DY. "A Role for Outpatient Total Joint Arthroplasty During the COVID-19 Pandemic," *Orthopedics* vol. 46.
- [5] "Maude - Manufacturer and User Facility Device Experience." (2024, Jan 1). [Accessdata.Fda.Gov. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm)
- [6] Khalid N, Ahmad SA. "Use and application of MAUDE In patient safety," In *StatPearls [Internet]*. Treasure Island (FL): StatPearls Publishing, 2024 Jan.
- [7] Xiao PL, Hsu CJ, Ma YG, Liu D, Peng R, Xu XH, Lu HD. "Prevalence and treatment rate of osteoporosis in patients undergoing total knee and hip arthroplasty: a systematic review and meta-analysis," *Archives of osteoporosis* vol. 17.
- [8] Lo CWT, Tsang WWN, Yan CH, Lord SR, Hill KD, Wong AYL. "Risk factors for falls in patients with total hip arthroplasty and total knee arthroplasty: a systematic review and meta-analysis," *Osteoarthritis and cartilage* vol. 27.