When the Robot Fails in TKA: A United States Food and Drug Administration Database Analysis

Joseph Patrick Costello[1], David S Constantinescu, Nathan Cai, Justin Chen, Michele R D'Apuzzo[2], Victor H Hernandez
[1]University of Miami Miller School of Medicine, [2]University of Miami

INTRODUCTION: The integration of robotic-assisted total knee arthroplasty (RA-TKA) has emerged as a potential avenue to enhance surgical precision and optimize patient outcomes. The utilization of robotics in knee arthroplasty has increased dramatically within recent years due to its purported ability to provide real-time feedback, enhance surgical precision, and optimize patient outcomes. The increasing utilization of RA-TKA devices warrants an assessment of each device's unique preoperative and intraoperative events to identify and quantify common complications in an effort to continually improve patient safety. Thus, the objective of this study was to categorize adverse events associated with an RA-TKA device and calculate its annual incidence as reported to the United States Food and Drug Administration (FDA).

METHODS: The FDA's Manufacturer and User Facility Device Experience (MAUDE) database was queried to identify reports of all adverse events from January 1st, 2020 through December 31st, 2023 associated with a singular RA-TKA system. The chosen study period dates were selected based on the availability of national surgical number data. Adverse event reports were filtered for duplicates, incomplete reports, and reports unrelated to RA-TKA procedures, which were all excluded from analysis. The overall and annual rate of adverse events were computed using national surgical numbers specific to the system being analyzed.

RESULTS: A total of 79 events were analyzed. The overall rate of adverse events across the four years of analyzed data was 0.06%. The rate of adverse events fluctuated by year though generally trended downward. 2021 incurred the highest rate of adverse events (0.14%). A majority of the reported events were related to software issues (n=40). The most common adverse software event involved cut resections (n=24). The most common adverse mechanical event involved bone pins (n= 34). Three adverse events caused delays: two inaccurate bone cuts (mean delay: 20 min, range: 15-25 min) and one retained bone pin (45 min). Two adverse events prevented the cases from completing as planned via robotic assistance and required conversion to manual TKA. Three cases were ultimately canceled due to an unresolvable software error message. 50 adverse events led to patient injuries. The most common adverse event that led to patient injury was inaccurate bone over-resection (n=19), followed by foreign body (bone pin) left in the patient (n=17), and femoral notching (n=7). The most common patient injury related adverse event that required operative reintervention were femur fractures (n=3), one of which required intraoperative retrograde intramedullary nail.

DISCUSSION AND CONCLUSION: The incidence of adverse events associated with this RA-TKA system reported to the FDA is extremely low and continues to decline overall. Physicians and patients alike can be confident in the reliability of the technology.