Adverse Events Associated with Robotic-Assisted Arthroplasty: An Analysis of the US Food and Drug Administration Manufacturer and User Facility Device Experience Database

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INTRODUCTION:
The use of robotic assistance in lower extremity arthroplasty is increasing; however, the spectrum of adverse events potentially associated with this technology is unclear. Improved understanding of the nature and causes of adverse events in robotic-assisted arthroplasty can prevent future incidents and enhance patient outcomes.

METHODS:
Adverse event reports to the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database from January 1, 2020 to July 1, 2021 involving robotic-assisted total hip arthroplasty (THA), total knee arthroplasty (TKA), and partial knee arthroplasty (PKA) were reviewed to determine causes of malfunction and related patient impact.

RESULTS:
Overall, 263 adverse event reports were included. The most frequently reported adverse events were unexpected robotic arm movement for TKA (59/204, 28.9%) and retained registration checkpoint for THA (19/44, 43.2%). There were 99 reports of surgical delay with an average delay of 20 minutes (range 1-120). Thirty-one cases reported conversion to manual surgery. In total, 68 patient injuries were reported, 7 of which required surgical re-intervention. Femoral notching (12/36, 33.3%) was the most common for TKA and retained registration checkpoint (19/28, 67.9%) was the most common for THA. Although rare, additional reported injuries included femoral, tibial, and acetabular fractures, MCL laceration, additional retained foreign bodies, and an electrical burn.

DISCUSSION AND CONCLUSION:
Despite the increasing utilization of robotic-assisted arthroplasty in the U.S., numerous adverse events are possible and technical difficulties experienced intra-operatively can result in prolonged surgical delays. While reported patient injuries are relatively infrequent and generally clinically insignificant, more serious complications can occur. Improved surgeon awareness of the potential pitfalls of robotic-assisted arthroplasty is critical as this technology gains popularity.