Adverse Events Associated With Robotic-Assisted Spine Surgery: An Analysis of the U.S. Food and Drug Administration MAUDE Database

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INTRODUCTION:
Despite the purported benefits of robotic assistance in spine surgery, there remains a risk of associated adverse events leading to patient morbidity and surgical delay. The aim of this study was to determine the nature and frequency of adverse events associated with robotic-assisted spine surgery.
METHODS:
All adverse event reports to the FDA MAUDE database involving robotic-assisted spine surgery were reviewed from January 2018 to December 2021.
RESULTS:
A total of 236 adverse event reports were included. The most frequently reported type of adverse event was unexpected robotic arm movement (11/236, 4.7%). There were 161 reports of surgical delay with delays ranging from less than an hour up to over three hours. There were 108 cases that required conversion to manual surgery. A total of 52 patient injuries were reported, 22 of which required surgical re-intervention. Of these, spinal canal breech (18/236, 7.6%) was the most common. Additional injuries reported included nerve injury with possible associated pain, muscle weakness and sensory changes, infection, tissue damage, implant failure and cyst formation.
DISCUSSION AND CONCLUSION:
As the adoption of robotic technology in spine surgery continues to expand in the United States, improved understanding of associated adverse events can help inform both patients and surgeons. Increased awareness of the potential limitations of this technology may help prevent future adverse events with the goal of improving patient outcomes.

Table 1 Adverse Events Reported to the FDA Maude Database

Total Adverse Events		236
Component Type Involved, n (%)		
	Software	116 (49.2)
	Mechanical	61 (25.8)
	Both	18 (7.6)
	Other	41 (17.4)
Surgical Delay Reported, n (%)		162 (68.6)
	1-59 minutes	136 (57.6)
	>60 minutes	23 (9.7)
	Not Specified	3 (1.3)
Conversion to Manual, n (%)		97 (41.1)
Case Aborted, n (%)		8 (3.4)
Patient Injury, n (%)		51 (21.6)
Surgical Re-Intervention due to Injury, n (%)		22 (9.3)
Total Surgical Re-Intervention, n (%)		37 (15.7)

MAUDE, Manufacturer and User Facility Device Experience; FDA, US Food and Drug Administration;
a Percentage based on total adverse events

Table 2 Frequency of All Reported Adverse Events Components

	Total n	Percentage
	254*	
Inaccurate Guidance Causing Deviated Trajectory	101	39.8%
Inaccurate Instrument Tracking	18	7.1%
Soft Tissue Pressure Causing Deviated Trajectory	10	3.9%
Failed Surgical Arm Accuracy Test	9	3.5%
Registration Difficulty	8	3.1%
Software Crash	7	2.8%
Anatomy Shift	6	2.4%
Unprompted Surgical Arm Movement	6	2.4%
Surgical Arm Component Loose	5	2.0%
Camera Connection Failure	4	1.6%
Surgical Arm Joint Malfunction	4	1.6%
Other Surgical Arm Malfunction	4	1.6%
Incorrect Surgical Arm Movement	4	1.6%
3Define scan Issue	3	1.2%
Controller Communication Error	2	0.8%
Surgical Arm Vibration	2	0.8%
Instrument Stuck in Place	2	0.8%
Drill Vibrations	2	0.8%
3D Marker Crossthreading	1	0.4%
Accuracy Pointer Bent	1	0.4%
C Arm Calibration Issue	1	0.4%
Dilator Attachement Broken	1	0.4%
Display Screen	1	0.4%
Draping Issue	1	0.4%
Excessive Drilling Force	1	0.4%
Incorrect Screw Loaded	1	0.4%
O Arm Connection Failure	1	0.4%
Stealth Camera Failure	1	0.4%
Unprompted Emergency Stop	1	0.4%
Cable Connection Failure	1	0.4%
Dull Drill Bit	1	0.4%
Naviock Tracker Malfunction	1	0.4%
Instrument Verification Problem	1	0.4%
Segmentation Failure	1	0.4%
Unspecified	41	16.1%

a Percentage based on total adverse events for each surgery
*18 of the 236 reports had both a mechanical and software component

Table 3 Primary Types of Reported Patient Injuries

	Total n (%) a	Requiring Surgical Re-Intervention n (%) b
All	59*	
Spinal Canal Breech	18 (34.6)	8 (44.4)
Pain	13 (25)	10 (76.9)
Weakness	9 (17.3)	7 (77.8)
Infection	5 (9.6)	0 (0)
Unspecified Nerve Damage	5 (9.6)	0 (0)
Tissue Damage	2 (3.8)	0 (0)
Sensory Changes	1 (1.9)	1 (100)
Implant failure	1 (1.9)	1 (100)
Cyst Formation	1 (1.9)	1 (100)
Unknown	4 (7.7)	0 (0)

a Percentage based on total patients who were injured (52)
b Percentage based on individual patient injury
*Some injuries fell under multiple classifications