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Medical malpractice in robotic surgery: a Westlaw database analysis

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Abstract

Malpractice claims involving robot-assisted surgical procedures have increased more than 250% in the past 7 years compared to the seven years prior. We examined robotic surgery malpractice claims to identify trends in claimed liabilities, describe legal outcomes, and determine strategies to minimize future litigation. The Westlaw legal database was queried retrospectively for U.S. state and federal trials regarding robot-assisted surgical procedures from 2006 to 2013 and 2014 to 2021. Data abstracted from verdict reports included year, state, court type, defendant specialty, procedure performed, claimed injuries and liabilities, verdict, and damage amount awarded. Sixty-one cases across 25 states were identified, 16 cases between 2006 and 2013, and 45 from 2014 to 2021. Among those 45 cases, defendant verdicts predominated (n = 35, 77.8%), with only four plaintiff verdicts (8.9%) and six settlements (13.3%). Overall, 169 liabilities were claimed, most commonly negligent surgery (82.2%), misdiagnosis/failure to diagnose (46.7%), delayed treatment (35.6%), and lack of informed consent (31.1%). Thirteen cases resulted in indemnity payments (mean = \$1,251,274), with damages ranging from \$10,087 (infection and retained foreign body) to \$5,008,922 (patient death). Hysterectomy (n = 19, 42.2%) was the most commonly litigated surgery, followed by prostatectomy (n=5) and hernia repair (n=4). The most litigated specialties were obstetrics/gynecology (48.9%), general surgery (28.9%), and urology (15.6%). Malpractice litigation in robot-assisted surgery is infrequent. As robotic procedures become more commonplace, surgeons must keep common liabilities in mind, as there are valuable and actionable lessons to be learned from these cases. Malpractice reform, continuing medical education activities, and improved informed consent protocols may help minimize future litigation.

Keywords Malpractice · Litigation · Robotic surgery · Westlaw database

Introduction

Since 2001, there has been a steady decline in the number of paid medical malpractice cases against U.S. physicians: the number of paid claims dropped nearly 50% (from 16,000 to 8500) between 2001 and 2016. The payout for each of these claims also decreased significantly, approximately 23%, in that same period [1].

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that physicians take by overusing tests and procedures to avoid malpractice liability, generates a significant economic burden, estimated to cost \$46 billion annually in the US alone [2]. Painting the landscape of litigation in a given specialty can highlight lessons to be learned and indicate which issues are addressable and thus avoidable in the future. As such, litigation analysis and physician education are imperative to further reduce the number of malpractice claims and annual fiscal burden of these claims [2–7]. Additionally, the analysis of malpractice claims can help improve patientcentered care and guide healthcare providers in the creation of risk management protocols.

Even so, defensive medicine, the self-protective measures

Over the last two decades, the use of robotic technology during surgery has rapidly expanded as an alternative minimally invasive operative approach [8]. One of the most widely adopted surgical platforms, da Vinci (Intuitive Surgical, CA), was approved by the US Food and Drug Administration (FDA) in 2000 [9], and has now been accepted

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across many surgical specialties, including urology [10], gynecology [11], neurosurgery [12], and otolaryngology [13]. Due to its fairly recent addition to the surgeon's armamentarium, robotic surgery and its associated malpractice litigation trends have not been fully explored. In this study, we aimed to: (1) provide a summary of robot-assisted surgery malpractice litigation from 2006 to 2021, (2) compare robot-assisted surgery malpractice cases in the former half of that period (2006–2013) to similar malpractice suits in the latter half (2014–2021) of that period, and (3) examine the impact of increasing robot implementation on trends in malpractice litigation.

Methods

All US trials with jury verdict reports involving medical malpractice in patients undergoing robot-assisted surgical procedures were searched retrospectively using an online legal research database (WESTLAW, West Publishing Co., St. Paul, MN). The database searches all federal and state court case verdicts submitted in all 50 states. All cases were reviewed for relevance and data were extracted from verdict reports including: year of verdict/settlement, case location (state) and court type, procedures, claimed injuries and liabilities, case outcome, damage amount awarded (if settlement), plaintiff and defendant demographics, and defendant specialty. Our search included all cases in circuit, district, and superior courts, as well as the court of common pleas, that reached a settlement or verdict between January 1st, 2006 and August 27th, 2021. Additional data collected included procedure performed and presence of cancer diagnosis. Of note, lawsuits settled prior to going to court are not captured via this search methodology, as the computerized database only compiles case information from court dockets.

Results

We searched the Westlaw database from 2006 to 2021 and identified 65 legal cases pertaining to robot-assisted surgeries. After duplicates were removed, we identified 61 unique lawsuits meeting inclusion criteria, with 16 cases filed between 2006 and 2013, and 45 cases occurring from 2014 to 2021 (Fig. 1).

Of the 45 cases from 2014 to 2021, 36 (80.0%) were concluded between 2016 and 2019. The 45 cases were filed in 23 different states, with the 3 most common states being Florida (n=6), Illinois (n=5), and New York (n=5). Most of the plaintiffs were female (n=33, 73.3%) and a minority were noted to have cancer diagnoses (n=4, 8.8%), although cancer diagnosis was not specified in over half of the cases (n=28, 62.2%). Hysterectomy (n=19, 42.2%) was the most commonly litigated surgery, followed by prostatectomy (n=5, 11.1%) and hernia repair (n=4, 8.8%). Accordingly, the most litigated specialties were obstetrics and gynecology (OB/GYN) (n=22, 48.8%), general surgery (n=13, 28.9%), and urology (n=7, 15.6%), with one case each in orthopedics and otolaryngology (Fig. 2).

Alternatively, between the years 2006 and 2013, most of the plaintiffs were male (n = 10; 62.5%). The most litigated specialties were urology (n = 9, 56.3%), general surgery (n = 5, 31.3%), then OB/GYN (n = 3, 18.8%)(Fig. 1). Robotic prostatectomy was by far the procedure most commonly associated with filed malpractice cases and accounted for 43.8% of all cases (n = 7), followed by splenectomy (n = 2, 12.5%). Hysterectomy, cardiac bypass,



Fig. 2 Percent of all cases filed in each specialty in 2006–2013 vs. 2014–2021



Table 1 Comparison of case characteristics by time period

	2006–2013	2014–2021
	(n=16)	(n = 45)
Plaintiff gender, n (%)		
Male	10 (62.5%)	12 (26.7%)
Female	6 (37.5%)	33 (73.3%)
Trial verdict, n (%)		
Defense	11 (68.8%)	35 (77.8%)
Plaintiff	5 (31.3%)	4 (8.9%)
Settlement	-	6 (13.3%)
Award amount		
Range	\$95,000-6,000,000	\$10,087-5,008,922
Mean	\$2,463,205	\$1,251,274
Defendant specialty, n (%))	
Urology	9 (56.3%)	7 (15.6%)
General surgery	5 (31.3%)	13 (28.9%)
OB/GYN	3 (18.8%)	22 (48.9%)
Orthopedic surgery	-	1 (2.2%)
Otolaryngology	-	1 (2.2%)
Not specified	_	1 (2.2%)

OB/GYN obstetrics and gynecology

cholecystectomy, dilation & curettage, pericardial mass removal, salpingo-oophorectomy plus appendectomy, and urethral reimplant were all only associated with one case each. Table 1 compares case characteristics between the two time periods.

From 2014 to 2021, 169 liabilities were claimed. In 37 of the 45 cases (82.2%), plaintiffs alleged that a negligent surgery was performed and in 14 cases (31.1%) plaintiffs contended that informed consent was not properly obtained

for the robotic surgery. Plaintiffs claimed in 20 cases (44.4%) that the surgeons misdiagnosed or failed to diagnose a clinical problem that negatively impacted the patient and in 16 cases (35.6%) argued that treatment for the patient was delayed. Regarding complications, seven cases (15.6%) noted intraoperative hemorrhage, 15 cases (33.3%) noted post-operative infection, and eight cases (17.8%) noted the need for additional surgery. Only six cases (13.3%) described a robotic surgery that was converted to an open surgery intraoperatively. Plaintiffs in five cases claimed failure of the surgeon and surgery team to calibrate/operate the robot, two cases alleged training deficiencies, two cases alleged manufacturing problems related to the robot, and one case alleged negligent credentialing related to the surgeon performing the robotic surgery. It is important to note that each suit had multiple allegations listed.

Among all cases filed between 2006 and 2013, 59 liabilities were claimed. Most commonly claimed liabilities included: negligent surgery (n=12, 75%), improper patient monitoring (n=6, 37.5%), training deficiencies (n=4, 25%), and misdiagnosis/failure to diagnose (n=4, 25%). Four cases (25%) cited post-operative infection, three cases (18.8%) were filed for retained foreign bodies, and seven cases (43.5%) cited a need for additional surgery. Table 2 summarizes all allegations claimed by time period.

In both time periods, verdicts for the defendants predominated (n = 11, 68.8% in 2006–2013; n = 35, 77.8% in 2014–2021). There were only four plaintiff verdicts (8.9%) and six settlements (13.3%) from 2014–2021, and five plaintiff verdicts (31.1%) and no settlements in 2006–2013. In all, from 2014 to 2021, 13 cases (28.3%) resulted in indemnity payments (mean = \$1,251,274), with damages ranging from \$10,087 (n = 1, for infection and retained foreign body) to

Table 2	Allegations	cited	by time	period
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Allegations, $n (\%)^a$	2006–2013	2014-2021
Negligent surgery	12 (75%)	37 (82.2%)
Misdiagnosis/failure to diagnose	4 (25%)	21 (46.7%)
Delayed treatment	3 (18.8%)	16 (35.6%)
Infection	4 (25%)	15 (33.3%)
Informed consent issue	3 (18.8%)	14 (31.1%)
Failure to monitor	6 (37.5%)	14 (31.1%)
Required additional surgery	7 (43.5%)	8 (17.8%)
Failure to refer	-	7 (15.6%)
Patient not candidate for surgery performed	2 (12.5%)	6 (13.3%)
Failure to calibrate/operate robot	-	5 (11.1%)
Improper positioning	-	3 (6.7%)
Failure to obtain complete pre-operative workup	2 (12.5%)	2 (4.4%)
Training deficiencies	4 (25%)	2 (4.4%)
Negligent credentialing	2 (12.5%)	1 (2.2%)
Manufacturing problem	2 (12.5%)	1 (2.2%)
Failure of perioperative VTE prophylaxis	3 (18.8%)	-
Total, <i>n</i>	59	169

VTE venous thromboembolism

 $^{\mathrm{a}}\mathrm{Cases}$ cited multiple reasons for allegations, so percentages do not add up to 100%

\$5,008,922 (n = 2, for patient death). In comparison, five cases (31.2%) resulted in indemnity payments in the former period (mean = \$2,463,205; range \$95,000–6,000,000).

Discussion

Medical malpractice occurs when a healthcare provider causes injury to a patient via negligence or omission in rendering care, and must fulfill four legal criteria: (1) professional duty owed to the patient, (2) breach of that duty via negligent violation of the standard of care, (3) negligence resulted in injury, and (4) injury resulted in damages [14]. Commonly cited allegations include misdiagnosis or delayed diagnosis, technical surgical/procedural errors, "unsatisfactory outcomes", and medication errors.

According to data collected from the American Medical Association's (AMA) 2016 Physician Practice Benchmark Survey, more than one third of doctors have had a lawsuit filed against them at some point in their careers [15]. Unsurprisingly, the probability of litigation increases with age and number of years practicing: almost half (49.2%) of doctors over the age of 55 have been sued, compared to only 8.2% of those under the age of 40 [15].

Rising medical malpractice costs have been implicated as a contributor to the dramatic increases in healthcare expenditures in the United States over the past several decades [2]. Further, the ever growing medical malpractice industry contributes to the practice of defensive medicine and overtreatment, including the over-prescription of medications and overuse of tests and procedures which carry additional risks for patients [2, 16]. It is imperative that physicians and other healthcare providers examine the causes of these malpractice claims and understand the legal landscape within their specialty. Though tort reform holds some promise for impeding malpractice litigation and its associated costs, litigation analysis and physician education improve patient-centered care and can mitigate the practice of defensive medicine.

Since the FDA approval of the da Vinci surgical platform 2000 [9], the number of robotic surgeries has increased dramatically [8]. Despite significant associated running costs, robot-assisted procedures have had a tremendous role in improving minimally invasive surgery. With decreased intraoperative blood loss and postoperative pain, and quicker recovery times, surgeon and patient demand for robotic surgery is at an all-time high and only continues to grow [17]. Now used in a wide variety of procedures, robotics has been integrated into general surgery [18], gastrointestinal surgery [19], urology [10], cardiovascular surgery, surgical oncology, pediatric surgery, gynecology [11], otolaryngology [13], neurosurgery [12] and more.

Only one outdated study has been published reviewing robot-assisted surgery malpractice cases, and only examined cases filed between 2005 and 2013 [20]. Although this period overlaps with the earlier period presented in our study, our paper notes a greater number of allegations and allegation types during this period than was previously presented. Further, as the present study is the only study to look at the entire time frame from 2006 to present, we are uniquely able to examine trends in malpractice cases associated with recent advancements and more widespread implementation of robotic surgery.

In our study, we found that malpractice claims involving robot-assisted surgical procedures have increased more than 250% in the past seven years (n = 45, 2014 - 2021) compared to the seven years prior (n = 16, 2006-2013) (Fig. 1). Of note, our study was concluded in August 2021, and thus likely underrepresents 2021 cases and the discrepancy in case incidence between the two periods. Although robotic surgery is utilized in many specialties, the only litigated specialties were OB/GYN, urology, general surgery, orthopedic surgery, and otolaryngology. As in 2006-2013, obstetricians/gynecologists, urologists, and general surgeons are still the three specialties most litigated for robot-assisted procedures, suggesting that the implementation of robotic surgery has had a relatively equal effect on medical malpractice claims across specialties (Table 1). Interestingly, between 2006 and 2013, prostatectomy (n = 7, 43.8%) was by far the most common procedure in filed malpractice cases, while in 2014–2021, these procedures accounted for only 11.1% of all cases. This decline in liability claims may result from an increase in systematic training for early adopters of robotic surgery, a cohort known to be at highest risk of litigation among surgeons performing robot-assisted urologic procedures [21]. Alternatively, hysterectomy (n = 19, 42.2%), which was the most commonly litigated surgery from 2014 to 2021, was only involved in one filed case in the 7 years prior.

Claims of negligent surgery and misdiagnosis/failure to diagnose were two of the most frequent allegations in both periods (Table 2). It is important to note that claims of delayed diagnosis and misdiagnosis/failure to diagnose are not directly tied to the robotic procedure itself but rather the medical management of the patient along the remainder of the perioperative continuum. Interestingly, training deficiencies were another commonly claimed liability (25%) between 2006 and 2013, but were noted in less than 5% of malpractice cases in the past seven years, indicating the more recent development of robotic surgery training programs and their adoption into surgical curricula. This further suggests that increased operating room time and hands-on experience with robotic technology improves outcomes and removes the learning curve initially faced with the introduction of innovative surgical techniques.

As informed consent issues were cited in greater than 30% of cases, it is imperative that we revisit the surgical consent process and ensure that it is up to date and accurately reflects the surgery that is being performed. Further, as demonstrated by our findings regarding training deficiencies and negligent credentialing, the development of effective training programs and standard credentialing systems for robotic procedures would likely decrease incidence of litigation. More rigorous screening systems should be implemented to ensure that all surgeons remain current with their institution's credentialing requirements. Finally, operative complications and adverse events should be regularly presented at department-wide morbidity & mortality conferences to ensure that surgeons are learning from each other's mistakes, improving their own processes, and holding themselves accountable.

The observed trends in robotic litigation were subsequently compared with all non-robotic surgery medical malpractice cases with jury verdicts in the same time period. While robotic surgery malpractice cases increased between 2006 and 2021, cases involving open surgical procedures demonstrated a strong negative trend, decreasing more than 90% from 2006 to 2021 (Supplemental Fig. 1). Though national data are not available, this is consistent with the prior literature—in a state-wide analysis, Grogan et al. demonstrated a greater than eight-fold increase in general surgery procedures performed with robotic assistance between 2012 and 2018, with a concurrent decline in open surgical procedures [22]. In addition, while the three states with the most frequent robotic litigation were Florida, Illinois, and New York, conversely, open surgery litigation was found most commonly in California (19%), Florida (8%), and Texas (6%). Of note, California, Florida, and New York are the three most litigative states for medical malpractice [23], suggesting that the high case load in these states may be secondary to high case or high surgical volumes overall.

This study is not without its limitations. All cases were obtained from a single database, thus our study likely underestimates the incidence of litigation, as cases not included in the Westlaw database would have been missed by our systematic review. In addition, the Westlaw database only searches case summaries and jury verdict reports from federal or state courts, thus there is a risk of sampling bias as our study only captures cases that progress to that point in the legal pipeline. We have a limited study size of 61 cases, thus our sample may not be representative or generalizable to malpractice litigation as a whole. Further, as our search was completed in August, 2021, we may not have captured all cases conducted in 2021 and thus our data may underrepresent the existing trends: when 2021 data are excluded from analysis, the slope of linear fit increases and variance decreases. The COVID-19 pandemic may have also contributed to the apparent decline in cases from 2019 to 2020: during the pandemic, healthcare systems around the world diverted their resources to respond to increased COVID-19 patient burdens, which led to a significant decline in da Vinci system placements and procedure volumes [24, 25]. Entering 2021, however, da Vinci procedures recovered a significant portion of the pre-COVID-19 levels, which may be reflected in the uptick in litigation in 2021 [26]. This, however, does not account for delays between incident, filing, and trial/settlement that may obscure any temporal trends or relationships. Future studies with a greater number of cases would better enable the evaluation of litigation trends.

Conclusions

In this study, we provide an updated summary of robotassisted surgery malpractice litigation from 2014 to 2021 and analyze the trends in this period of increased robot implementation compared to similar malpractice suits from 2006 to 2013. Overall, the number of malpractice cases filed for robot-assisted procedures is not terribly alarming, and some frequently claimed liabilities are common to both robotic and open surgical procedures. However, lessons learned in studies such as this can help enact policies to reduce avoidable mistakes. Continued efforts to both reform and improve the medical malpractice system, and implement better informed consent, credentialing, and continuing medical education (CME) programs, are necessary to improve surgeons' confidence, minimize litigation, and ultimately provide safer and better care for patients.

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Declarations

Competing interests The authors have no relevant financial or non-financial interests to disclose.

Ethical approval This is a retrospective database study without human or animal participants, thus Institutional Review Board and ethics approval are not required.

Consent to participate Written informed consent was neither sought nor required as our study involved no human subjects.

Consent to publish Consent to publish was neither sought nor required as our study involved no human subjects.

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