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# Allegations of Failure to Obtain Informed Consent in Spinal Surgery Medical Malpractice Claims

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**IMPORTANCE** Predictive factors associated with increased risk of medical malpractice litigation have been identified, including severity of injury, physician sex, and error in diagnosis. However, there is a paucity of literature investigating informed consent in spinal surgery malpractice.

**OBJECTIVE** To investigate the failure to obtain informed consent as an allegation in medical malpractice claims for patients undergoing a spinal procedure.

**DESIGN, SETTING, AND PARTICIPANTS** In this retrospective cohort study, a national medicolegal database was searched for malpractice claim cases related to spinal surgery for all years available (ie, January 1, 1980, through December 31, 2015).

MAIN OUTCOMES AND MEASURES Failure to obtain informed consent and associated medical malpractice case verdict.

**RESULTS** A total of 233 patients (117 [50.4%] male and 116 [49.8%] female; 80 with no informed consent allegation and 153 who cited lack of informed consent) who underwent spinal surgery and filed a malpractice claim were studied (mean [SD] age, 47.1 [13.1] years in the total group, 45.8 [12.9] years in the control group, and 47.9 [13.3] years in the informed consent group). Median interval between year of surgery and year of verdict was 5.4 years (interquartile range, 4-7 years). The most common informed consent allegations were failure to explain risks and adverse effects of surgery (52 [30.4%]) and failure to explain alternative treatment options (17 [9.9%]). In bivariate analysis, patients in the control group were more likely to require additional surgery (45 [56.3%] vs 53 [34.6%], P = .002) and have more permanent injuries compared with the informed consent group (46 [57.5%] vs 63 [42.0%], P = .03). On multivariable regression analysis, permanent injuries were more often associated with indemnity payment after a plaintiff verdict (odds ratio [OR], 3.12; 95% CI, 1.46-6.65; P = .003) or a settlement (OR, 6.26; 95% CI, 1.06-36.70; P = .04). Informed consent allegations were significantly associated with less severe (temporary or emotional) injury (OR, 0.52; 95% CI, 0.28-0.97; P = .04). In addition, allegations of informed consent were found to be predictive of a defense verdict vs a plaintiff ruling (OR, 0.41; 95% CI, 0.17-0.98; P = .046) or settlement (OR, 0.01; 95% CI, 0.001-0.15; P < .001).

**CONCLUSIONS AND RELEVANCE** Lack of informed consent is an important cause of medical malpractice litigation. Although associated with a lower rate of indemnity payments, malpractice lawsuits, including informed consent allegations, still present a time, money, and reputation toll for physicians. The findings of this study can therefore help to improve preoperative discussions to protect spinal surgeons from malpractice claims and ensure that patients are better informed.

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Corresponding Author: Mohamad Bydon, MD, Department of Neurologic Surgery, Mayo Clinic, 200 First St SW, Rochester, MN 55902 (bydon.mohamad@mayo .edu). edical malpractice litigation is a known financial, emotional, and time drain for American physicians, leading to anxiety and burnout. <sup>1,2</sup> It continues to be shrouded in controversy by health care professionals who deem this a malpractice crisis that requires defensive medicine and contrasting attorneys who argue that it protects patients from negligence in a system resistant to regulations. <sup>3</sup> Because of this controversy, there has been a push for research to elucidate the prognostic factors for malpractice claims.

A large portion of alleged malpractice and patient injury claims involve factors before the patient enters the operating room, including diagnosis, treatment selection, and communication. Communication is a broad category, including not only how a surgeon speaks to a patient but also the content of that preoperative discussion to obtain informed consent for risks and complications of a procedure and explain alternative treatment options.

Neurosurgery and orthopedic surgery are 2 high-risk specialties associated with some of the highest number of medical malpractice lawsuits. <sup>5-7</sup> In both these fields, spinal surgery, most commonly at the lumbar level, has the highest rates of malpractice suits. <sup>8-10</sup> Informed consent is a significant allegation in malpractice lawsuits after spinal surgery. In 2 separate studies <sup>11,12</sup> of malpractice cases that involved cervical spinal surgery, more than 50% of suits cited informed consent as the basis for lawsuits. Despite the high annual rates of claims, there is a paucity of literature specifically on the role of informed consent allegation in lawsuits after spinal surgery. We sought to fill this gap by using a national medicolegal database.

## Methods

#### **Data Source**

We searched the Westlaw legal database<sup>13</sup> (Thomson Reuters) for malpractice claim cases related to spinal surgery for all years available (ie, January 1, 1980, through December 31, 2015). Westlaw is a major legal database used for the retrieval of court records and case descriptions across the United States. <sup>14</sup> It is an online legal research tool that contains more than 40 000 databases of statutes, case law, and public records from both US federal and state courts. <sup>15</sup> These cases include those that are reported

## **Key Points**

**Question** What is the role of informed consent allegations in medical malpractice litigation in the high-risk surgical specialty of spinal surgery?

**Findings** In this cohort study of 233 patients who underwent spinal surgery and filed a malpractice claim, the most common specific informed consent allegations were failure to explain the risks and adverse effects of surgery followed by failure to explain alternative treatment options. In addition, allegations of failing to obtain informed consent were found to be predictive of a defense verdict compared with a plaintiff ruling or settlement.

**Meaning** Informed consent allegations are less likely to result in an unfavorable case verdict outcome for surgeons but still present an important aspect of medical liability.

voluntarily by attorneys and involuntarily, identified with labels such as anonymous or confidential. Keywords used to query the database for eligible cases included general search terms, such as medical malpractice and informed consent, and filtered search terms for spinal procedures. Exclusion criteria included age younger than 18 years, surgical intervention other than spinal, primary surgeon other than orthopedic or neurosurgeon, and cases in which spinal surgery was not the main reason for the claim. Only cases that included failure to obtain informed consent as a primary or secondary allegation were included in the informed consent group.

## **Primary Outcome of Interest**

The primary outcome of interest was the outcome of the verdict (ie, in favor of the plaintiff, the defendant, or a settlement between the surgeon and the patient).

#### **Covariates of Interest**

Covariates of interest included the following: year of the procedure, year of the final verdict, age of patient at the time of surgery, patient sex, surgeon's specialty, type of surgical practice (academic vs private), state where the procedure was performed, severity of injury (death, permanent, temporary, or emotional only), need for additional surgery, primary allegation for malpractice claim, and malpractice payment amount.

Control		Informed Consent Malpractice		Total	
State	No. (%)	State	No. (%)	State	No. (%)
California	16 (20.0)	California	29 (19.0)	California	45 (19.3)
Texas	11 (13.8)	Pennsylvania	20 (13.1)	New York	29 (12.4)
New York	9 (11.3)	New York	20 (13.1)	Pennsylvania	27 (11.6)
Pennsylvania	7 (8.8)	Washington	11 (7.2)	Texas	16 (6.9)
Illinois	6 (7.5)	Missouri	7 (4.6)	Washington	15 (6.4)
Washington	4 (5.0)	Florida	6 (3.9)	Missouri	10 (4.3)
Florida	4 (5.0)	Texas	5 (3.3)	Florida	10 (4.3)
Missouri	3 (3.8)	New Jersey	5 (3.3)	Massachusetts	8 (3.4)
Massachusetts	3 (3.8)	Michigan	5 (3.3)	New Jersey	7 (3.0)
New Jersey	2 (2.5)	Massachusetts	5 (3.3)	Illinois	6 (2.6)

Table 2. Bivariate Analysis of Temporal, Geographic, and Patient Demographic Characteristics of Malpractice Cases, Including Informed Consent Malpractice<sup>a</sup>

Variable	Control (n = 80)	Informed Consent Malpractice (n = 153)	Total (N = 233)	P Value	
Time between surgery and verdict, mean (SD), y	5.3 (2.5)	5.1 (2.6)	5.4 (2.5)	.97	
Region					
Northeast	24 (30.0)	53 (34.6)	77 (33.0)		
Midwest	13 (16.3)	31 (20.3)	44 (18.9)	- 20	
South	20 (25.0)	23 (15.0)	43 (18.5)	30 	
West	23 (28.8)	46 (30.1)	69 (29.6)		
Demographic characteristic					
Female sex	38 (47.5)	78 (50.9)	116 (49.8)	.61	
Age, mean (SD), y	45.8 (12.9)	47.9 (13.3)	47.1 (13.1)	.83	

<sup>a</sup> Data are presented as number (percentage) of patients unless otherwise indicated.

Cases of discrepancies in interpretation of allegations were discussed between the 2 primary reviewers and the senior author. Last, we examined whether the nature of cases, the case outcome, and the median payment amount were different in those states that had significant tort reform (eTable in the Supplement) before and after the tort legislation changes. When more than one reform occurred in the same state, we took into account the most recent year.

#### **Statistical Analysis**

We grouped the different states into 4 main regions: Northeast, South, Midwest, and West. Because of the low number of emotional injuries and deaths, we grouped emotional with temporary injuries and deaths with permanent injuries. Age was analyzed as a continuous variable and in a binary fashion, using the cutoff of 50 years (third quartile). Continuous variables were compared using the 2-tailed, unpaired t test and Mann-Whitney test. Categorical variables were compared using the  $\chi^2$  and Fisher exact tests. Statistical significance was established at P = .05. To account for missing variables, multiple imputation was conducted. Afterward, multinomial regression analysis was performed in the imputed data sets and fitted for the outcome of the verdict, controlling for available covariates. The results reported here represent the pooled coefficients and 95% CIs. Statistical analysis was performed using commercially available (JMP, version 10; SAS Institute Inc) and open-source software (R software, R Development Core Team). The study was exempt from review by the Mayo Clinic Institutional Review Board; therefore, no informed consent was required.

## Results

#### **Case Characteristics**

A total of 233 medical malpractice cases from the Westlaw Next database from January 1, 1984, through December 31, 2015 (verdict year), were analyzed in this study (117 [50.4%] male and 116 [49.8%] female; mean [SD] age, 47.1 [13.1] years in the total group, 45.8 [12.9] years in the control group, and 47.9 [13.3] years in the informed consent group). Median interval between year of surgery and year of verdict was 5.4 years (inter-

quartile range, 4-7 years). Of the 233 cases, 80 were included in the control group, in which no allegation concerning informed consent was made, and the remaining 153 malpractice cases listed failure to obtain informed consent as a primary or secondary allegation. The 10 American states with the highest number of malpractice claims for the control group, informed consent malpractice group, and all cases are summarized in Table 1. For all 3 groups, the highest number of malpractice claims occurred in California, comprising approximately 20% of cases in each. Texas was the second state for number of claims in the control group (11 [13.8%]) vs seventh in the group in which failure to obtain informed consent was alleged (5 [3.3%]). Pennsylvania had a higher rate of informed consent malpractice allegations (20 [13.1%]) compared with the control group (7 [8.8%]), whereas Illinois comprised 6 malpractice claims (7.5%) in the control group but is not one of the top 10 states in which informed consent malpractice played a role.

## **Bivariate Analysis**

Table 2 summarizes the temporal, geographic, and demographic characteristics of patients with informed consent malpractice allegations. The mean (SD) time between the spinal surgery and verdict was 5.3 (2.5) years in the control group, 5.1 (2.6) years in the informed consent malpractice group, and 5.4 (2.5) years in the total group. Each group had an approximately equal division of male and female patients. No statistically significant difference was found between the control and informed consent malpractice groups for time between surgery and verdict, geographic region of cases, or patient demographic characteristics.

Surgeon characteristics, including type of practice and surgical specialty, were also analyzed using bivariate analysis (**Table 3**). Approximately twice as many malpractice cases in the control group concerned an academic practice rather than a private practice (30 [62.5%] vs 18 [37.5%]). Approximately half of cases citing informed consent malpractice were academic and private, with no statistically significant difference (46 [47.4%] vs 51 [52.6%], P = .08). Neurosurgeons and orthopedic surgeons were similarly divided in the number of malpractice claims in which they were named for the control (33 [44.6%] for neurosurgery and 41 [55.4%] for

Table 3. Bivariate Analysis of Surgical Characteristics and Informed Consent Allegation

	No. (%)				
Variable	Control	Informed Consent Malpractice	Total	P Value	
Type of practice (n = 144)					
Academic	30 (62.5)	46 (47.4)	75 (52.1)	.08	
Private	18 (37.5)	51 (52.6)	69 (47.9)	.08	
Surgeon specialty (n = 218)					
Neurosurgery	33 (44.6)	75 (52.1)	108 (49.5)	.29	
Orthopedic surgery	41 (55.4)	69 (47.9)	110 (50.5)	.29	
Spinal region (n = 233)					
Lumbar	46 (57.5)	86 (56.2)	132 (56.7)		
Thoracic	2 (2.5)	6 (3.9)	8 (3.4)	.06	
Cervical	24 (30.0)	28 (18.3)	52 (22.3)		
Unspecified	8 (10.0)	33 (21.6)	41 (17.6)		
Surgical outcome of additional surgery required (n = 233)	45 (56.3)	53 (34.6)	98 (42.1)	.002	
Alleged severity of injury					
Emotional	1 (1.3)	12 (8.0)	13 (5.7)		
Temporary	28 (35.0)	64 (42.7)	92 (40.0)	.03	
Permanent	46 (57.5)	63 (42.0)	109 (47.4)	.03	
Death	5 (6.3)	11 (7.3)	16 (7.0)		
Mortality	5 (6.3)	11 (7.3)	16 (7.0)	.79	
Case outcome (n = 233)					
Defense	48 (60.0)	125 (81.7)	173 (74.2)		
Plaintiff	21 (26.3)	25 (16.3)	46 (19.7)	. 001	
Settlement	9 (11.3)	3 (2.0)	12 (5.2)	<.001	
Arbitration	2 (2.5)	0 (0.0)	2 (0.9)		

orthopedic surgery) and informed consent malpractice groups (75 [52.1%] for neurosurgery and 69 [47.9%] for orthopedic surgery), with no statistically significant difference (P = .30). Taking into consideration surgical outcomes, a significantly greater portion of patients required additional surgery in the control group (45 [56.3%]) vs the informed consent malpractice group (53 [34.6%], P = .002). The severity of alleged injury was found to be significantly different between the 2 malpractice groups. Malpractice cases alleging informed consent malpractice had a higher percentage of alleged temporary injury compared with the control group (64 [42.7%] vs 28 [35.0%], P = .03), whereas the controlgroup had a higher percentage of alleged permanent injury (46 [57.5%] vs 63 [42.0%], *P* = .03). Allegations of informed consent were more often associated with defense outcomes than allegations that did not include informed consent (125 [81.7%] vs 48 [60.0%], P < .001). To determine the effect of specifying informed consent allegations on case verdict, the control group, unspecified informed consent, and specified informed consent groups were compared. Both informed consent groups were more likely to result in defense verdicts compared with the control group (63 [86.3%]) in the unspecified informed consent group, 62 [77.5%] in the specified informed consent group, and 48 [60.0%] in the control group; specified informed consent vs control, P = .006 and unspecified informed consent vs control, P = .002), whereas no difference in case outcome was found between the specified and unspecified informed consent groups (8 [11.0%] plaintiff verdicts, 2 [2.7%] settlements, and 0 arbitrations in the unspecified informed consent group; 17 [21.3%] plaintiff verdicts, 1 [1.2%] settlements, and 0 arbitrations in the specified informed consent group; and 21 [26.3%] plaintiff verdicts, 9 [11.3%] settlements, and 2 [2.5%] arbitrations in the control group; unspecified informed consent vs specified informed consent P = .19). Other surgical analyses can be found in Table 3. Last, we did not find any statistically significant difference (after vs before) in number of informed consent cases (40 [59.7%] vs 43 [68.3%], P = .31), case outcome (defendant: 52 [77.6%] vs 50 [79.4%]; plaintiff: 8 [11.9%] vs 11 [17.5%]; settlement: 5 [7.5%] vs 2 [3.2%]; P = .30), and median payment amount (\$475 000 vs \$750 000, P = .44) in regard to the implementation of tort reform (eTable in the Supplement).

## **Allegation Classification**

Table 4 summarizes the top primary allegations in the control and informed consent medical malpractice cases. Surgical negligence was the most common allegation (74 [30.1%]) followed by failure to diagnose or treat (51 [20.7%]) and general malpractice (30 [12.2%]). Of note, the total number of primary allegations was 246 because of some cases citing more than 1 primary allegation. Almost half the informed consent cases did not specify an allegation beyond failure to obtain informed consent (75 [43.9%]). Therefore, the top specified allegation was failure to explain surgical risks or adverse effects (52 [30.4%]) and then failure to explain alternative treatment options (17 [9.9%]).

#### **Multivariable Analysis**

A multivariable analysis of verdict outcome is given in **Table 5**. Permanent injuries were significantly more likely to result in a verdict in favor of the plaintiff compared with temporary injuries (odds ratio [OR], 3.12; 95% CI, 1.46-6.65; P = .003) and an indemnity payment after settlement (OR, 6.26; 95% CI, 1.06-36.70; P = .04). Informed consent allegations were found to significantly result in fewer verdicts in favor of the plaintiff (OR, 0.41; 95% CI, 0.17-0.98; P = .046) or in settlement (OR, 0.01; 95% CI, 0.001-0.15; *P* < .001). In addition, informed consent allegations were significantly associated with less severe (emotional or temporary) injury compared with the control group, which was associated with more severe injury (OR, 0.52; 95% CI, 0.28-0.97; P = .04). Spinal fusion operations were found to be less likely to result in a settlement compared with nonfusion operations (OR, 0.09; 95% CI, 0.01-0.80; P = .03). Orthopedic surgery was less likely to be associated with settle-

Table 4. Top Allegations of the Control Group and Informed Consent Malpractice Cases

Allegation	No. (%) of Cases
Control allegation (n = 246)	
Surgical negligence	74 (30.1)
Failure to diagnose or treat	51 (20.7)
General malpractice	30 (12.2)
Unnecessary surgery	29 (11.8)
Hospital malpractice	24 (9.8)
Informed consent malpractice allegation (n = 171)	
Unspecified	75 (43.9)
Explanation of risks and adverse effects	52 (30.4)
Explanation of alternative treatment options	17 (9.9)
Surgeon's surgical experience	5 (2.9)
Use of a non-FDA-approved device	5 (2.9)

Abbreviation: FDA, US Food and Drug Administration.

ment case outcomes compared with neurosurgery (OR, 0.07; 95% CI, 0.009-0.68; P = .03).

#### Discussion

## **Study Findings and Implications**

In this study, 233 medical malpractice cases after spinal surgery were identified in the Westlaw Next database. Of these, approximately one-third (control group) did not include an allegation concerning failure to obtain informed consent compared with two-thirds (informed consent malpractice group) that listed it as a primary or secondary allegation. Spinal surgery has one of the highest rates of malpractice litigations among any surgical specialty. <sup>6,16</sup> When compared with medical subspecialties, however, surgical subspecialties, including neurologic and orthopedic surgery, have comparable malpractice rates. <sup>6,16</sup> In addition, previous studies <sup>11,14,17</sup> have found that lack of informed consent is an important issue in other surgical specialties. Therefore, although spinal surgery is not a perfect proxy for the overall surgical field, it may reflect the greater surgical malpractice environment.

The state with the highest number of cases, regardless of allegation type, was California, followed by New York, Pennsylvania, and Texas. These results are relatively consistent with statistics provided by the National Practitioner Data Bank on the number of total reports between 2004 and 2014, including medical malpractice payments, adverse action, and reinstatement restorations. <sup>17</sup> Of interest, according to the Dartmouth Atlas of Health Care, <sup>18</sup> the overall rates of spinal surgery in each region were not correlated with the per-capita number of orthopedic surgeons and neurosurgeons from 2002 to 2003. Therefore, there may be some other unknown cause for the increased rates of spinal surgery malpractice in these states. Choudhry and colleagues <sup>14</sup> investigated malpractice litigations in bariatric surgery and found moderate correlation between the number of malpractice cases reported in Westlaw

Table 5. Multinomial Regression	Analysis of Case	Verdict Outcome

	Verdict in Favor of Plain	itiff	Settlement	
Variable	Odds Ratio (95% CI)	P Value	Odds Ratio (95% CI)	P Value
Region				
Northeast vs Midwest	2.05 (0.74-5.64)	.16	2.62 (0.21-30.21)	.45
South vs Midwest	1.41 (0.44-4.53)	.56	1.03 (0.05-20.25)	.98
West vs Midwest	0.79 (0.24-2.54)	.69	4.10 (0.03-49.40)	.27
Age ≥50 vs <50 y	1.99 (0.79-5.01)	.14	2.88 (0.05-15.59)	.22
Male vs female	0.94 (0.46-1.92)	.88	1.40 (0.03-7.07)	.68
Fusion vs nonfusion procedure	0.86 (0.36-2.09)	.75	0.09 (0.01-0.80)	.03
Spinal region				
Lumbar vs cervical	0.93 (0.38-2.23)	.87	3.56 (0.05-26.80)	.22
Thoracic vs cervical	0.53 (0.04-5.90)	.61	NA	NA
Unspecified vs cervical	1.19 (0.39-3.60)	.76	7.66 (0.72-81.51)	.09
Orthopedic surgery vs neurosurgery	0.52 (0.24-1.13)	.10	0.07 (0.009-0.68)	.03
Permanent or death vs temporary or emotional injury	3.12 (1.46-6.65)	.003	6.26 (1.06-36.70)	.04
Additional surgery needed, yes vs no	0.94 (0.45-1.95)	.87	1.61 (0.04-7.14)	.52
Informed consent issue, yes vs no	0.41 (0.17-0.98)	.046	0.01 (0.001-0.15)	<.001

Abbreviation: NA, not available.

Next and the total number of active and resident lawyers per state where the claim was filed. This observation may be attributed to increased access to lawyers or to state tort laws that allow more malpractice claims to be filed, whereas more lawyers are present to take on the additional workload.

A significantly greater percentage of patients in the control group required additional surgery compared with the informed consent malpractice group. Although it is difficult to discern whether additional surgery was needed as a direct result of surgical error or because of a known complication or risk of surgery, a previous study<sup>19</sup> found that most subsequent operations after spinal fusions were for surgical complications rather than progression of a patient's underlying disease. In the present study, no difference was found in patient age or other patient or surgical characteristics. The higher rate of additional surgery in the control group of this study may therefore be a result of higher rates of surgical error when operating on patients with potentially complex preoperative injuries or disease states.

This study is the first, to our knowledge, to identify the top specific informed consent allegations, which were failure to explain the risks and adverse effects of surgery and failure to explain alternative treatment options. Although informed consent conversations focus heavily on the risks and adverse effects of surgery, this study found that lack of discussion of alternative treatment options is a reason that patients file a malpractice claim against spinal surgeons. An additional consideration for medical malpractice concerning informed consent is the location in which it is obtained. In a small study of elective orthopedic operations, Bhattacharyya and colleagues<sup>20</sup> found a significantly decreased indemnity risk when obtaining a patient's informed consent in the office rather than in the hospital or preoperative holding area. Documentation of informed consent was also found to have a decreased risk compared with lack of a documented informed consent discussion. Studies 21-24 have also found that multimedia sources, including videos, reliable internet resources, and educational booklets, can help patients to better visualize and be informed about their treatment options. This option is an increasingly important consideration with the pervasive use of multimedia by the general public for medical knowledge. By openly communicating with the patient about complications, including those that may not be foreseen, and alternative treatment options, a surgeon may be able to reduce the risk of a malpractice lawsuit.

Informed consent was found to be a predictor of cases that ruled in favor of the defending surgeon. This is an important finding considering all the various factors that lead to a plaintiff verdict in a medical malpractice case. In addition, informed consent allegations were significantly associated with less severe injury. An allegation of failure to obtain informed consent, therefore, may have less merit compared with traditional allegations of physician error, including surgical negligence, failure to diagnose or treat, medication error, or wrongful death associated with more severe injury. This finding is consistent with the study by Studdert and colleagues, 25 who

found that medical malpractice cases that involve nonerror claims were less likely to result in a plaintiff verdict and indemnity payment compared with cases that claimed a physician error. Despite these findings, we cannot assume that cases that result in a defense verdict were without any lack of informed consent or error. Many factors may contribute to a defense verdict, such as unconscious bias on the part of a jury or judge or differences in opinion among various parties on what truly constitutes informed consent. In one study, <sup>26</sup> patients were tested on their 24-hour recall of the informed consent forms they had signed. Only 60% were found to understand the purpose of their treatment, and only 55% could list even one major complication. Factors, including educational level, medical status, and how carefully they read the form, contributed to this finding.

## **Strengths and Limitations**

To the best of our knowledge, this is the first study in the literature that specifically looked at the incidence of incomplete informed consent as an allegation for malpractice litigation by using a national medicolegal database. After identifying all patients who filed a malpractice lawsuit after a spinal procedure, we compared the characteristics between informed consent cases and the control group. In addition, we applied a robust statistical method to determine independent predictors of the case outcome.

This study has several inherent limitations. The Westlaw Next database does not include all cases; thus, we cannot make any claim of all-inclusiveness. Moreover, the database is populated by information based on lawsuits written by lawyers and court judges; therefore, not all filed cases included the clinical information of interest. In addition, this study included data from a relatively large period; differences in outcomes and number of cases might be influenced by enacted tort reform in several states, even though we did not find any such difference in our study, possibly because of limited sample size.

## Conclusions

In this study, we sought to determine the specific role that informed consent plays in medical malpractice in one of the highest-risk specialties: spinal surgery. Informed consent was found to be an independent predictor of defense verdicts and was associated with less severe injury. Although this study found that informed consent was not a strong allegation compared with traditional claims, such as surgical negligence, informed consent is still an important aspect of the preoperative discussion and medical malpractice litigation. The 2 most common informed consent allegations were failure to explain the risks and adverse effects of surgery and failure to explain alternative treatment options. The results of this study highlight the importance of preoperative discussions with patients when obtaining informed consent.

### ARTICLE INFORMATION

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**Author Contributions:** Dr Bydon had full access to all the data in the study and takes responsibility for

- the integrity of the data and the accuracy of the data analysis.
- *Study concept and design:* Grauberger, Kerezoudis, Choudhry, Bydon.
- Acquisition, analysis, or interpretation of data: All authors.
- Drafting of the manuscript: Grauberger, Kerezoudis, Alvi.
- Critical revision of the manuscript for important intellectual content: Grauberger, Kerezoudis, Choudhry, Nassr, Currier, Bydon.
- Statistical analysis: Grauberger, Kerezoudis, Choudhry, Alvi, Currier, Bydon. Study supervision: Nassr, Bydon.
- Conflict of Interest Disclosures: None reported.

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