Litigations following spinal neurosurgery in France: “out-of-court system,” therapeutic hazard, and welfare state

Bertrand Debono, MD,^{1,2} Carole Gerson, MD,³ Thierry Houselstein, MD,³ Lynda Lettat-Ouatah,⁴ Renaud Bougeard, MD,⁵ and Nicolas Lonjon, MD, PhD⁶

¹Centre Francilien du Dos, Neurosurgery Department, Paris; ²Neurosurgery Department, Private Hospital of Versailles–Ramsay Santé, Versailles; ³Compensation and Medical Communication Department, Mutuelle d'Assurances du Corps de Santé Français (MACSF), Paris; ⁴Cabinet Clapot-Lettat, Lyon; ⁵Department of Neurosurgery, Clinique du Val d'Ouest, Ecully; and ⁶Department of Neurosurgery, Hôpital Gui de Chauliac, Montpellier University Medical Center, Montpellier, France

OBJECTIVE Spinal surgeries carry risks of malpractice litigation due to the random nature of their functional results, which may not meet patient expectations, and the hazards associated with these complex procedures. Claims are frequent and costly. In France, since 2002, a new law, the Patients' Rights Law of March 4, 2002, has created an alternative, out-of-court scheme, which established a simplified, rapid, free-of-charge procedure (Commission for Conciliation and Compensation [CCI]). Moreover, this law has optimized the compensation provided to patients for therapeutic hazards by use of a national solidarity fund. The authors analyzed the consequences of this alternative route in the case of claims against private neurosurgeons in France.

METHODS From the data bank of the insurer Mutuelle d'Assurances du Corps de Santé Français (MACSF), the main insurance company for private neurosurgeons in France, the authors retrospectively analyzed 193 files covering the period 2015–2019. These computerized files comprised the anonymized medical records of the patients, the reports of the independent experts, and the final judgments of the CCI and the entities supporting the compensation, if any.

RESULTS During the 5-year study period (2015–2019), the insurance company recorded 494 complaints involving private neurosurgeons for spinal surgery procedures, of which 126 (25.5%) were in civil court, 123 (24.9%) were under amicable procedure, and 245 (49.6%) were in the out-of-court scheme administered by the CCI. Out of these 245 cases, only 193 were closed due to delays. The conclusions of the commission were rejection/incompetence decisions in 47.2% of the cases, therapeutic hazards in 21.2%, nosocomial infections in 17.6%, and practitioner fault in 13.5%. National solidarity compensated for 48 complaints (24.8%). The final decision of the CCI is not always consistent with the conclusions of the experts mandated by it, illustrating the difficulty in defining the concept of hazards. The authors found that the therapeutic hazards retained and compensated by the national solidarity included decompensated spondylotic myelopathies (15% of the 40 cases) and cauda equina syndromes (30%). As allowed by law, 11.5% of the patients who were not satisfied triggered a classical procedure in a court.

CONCLUSIONS In the French out-of-court system, trial decisions resulting in rulings of proven medical malpractice are rare, but patients can start a new procedure in the classical courts. The therapeutic hazard remains a subtle definition, which may be problematic and require further discussion between experts and magistrates. In spite of the imperfections, this out-of-court system proposes a major evolution to move patients and medical providers from legal battles to reconciliations.

<https://thejns.org/doi/abs/10.3171/2020.8.FOCUS20582>

KEYWORDS malpractice; litigation; no-fault system; out-of-court system; therapeutic hazard; spine surgery

SPINE surgery, particularly for procedures involving degenerative conditions, has the dual characteristic of experiencing quasi-exponential development in its indications,¹ particularly for fusions,² and representing a major source of litigation between patients and sur-

geons.³ The functional context of the conditions treated, the impact of complications in one's personal and professional life, and the potential severity of the associated neurological lesions explain why complaints are frequent and compensation is potentially high.^{4,5}

ABBREVIATIONS ACDF = anterior cervical discectomy and fusion; ALIF = anterior lumbar interbody fusion; CCI = Commission for Conciliation and Compensation; MACSF = Mutuelle d'Assurances du Corps de Santé Français; NI = nosocomial infection; ONIAM = National Compensation Office for Medical Accidents; PDR = permanent disability rate; PRL = Patients' Rights Law.

ACCOMPANYING EDITORIAL DOI: 10.3171/2020.8.FOCUS20764.

SUBMITTED June 29, 2020. **ACCEPTED** August 13, 2020.

INCLUDE WHEN CITING DOI: 10.3171/2020.8.FOCUS20582.

France has not escaped this phenomenon, which impacts not only patients but also surgeons.⁶ In accordance with the history of France and its tradition as a welfare state, there is free universal health coverage, supplemented by an optional system of private insurance coverage of medical costs, which is relatively inexpensive compared with systems used in other countries.⁷

Historically, French patients had to sue their healthcare providers for compensation for complications related to treatment. Proof of fault was essential to win the case, as well as recourse to the court, a lawyer, advance payment of expert fees, and so forth.⁸ Delays were very long, disparities in the processing of similar requests were common, and dissatisfaction was frequent for all parties, leading to a need for reform that crystallized in 2002 with a new health act, the Patients' Rights Law (PRL) of March 4, 2002.⁹

Faithful to the principle of national solidarity, this law created a complementary “out-of-court” scheme based on a “no-fault” concept. The scheme allowed the possibility of a national compensation office taking charge of a therapeutic hazard, with the aim of offering the patient free, simple, and rapid treatment of his claim.¹⁰

The objective of the work reported here was to study the impact of this out-of-court scheme for litigations concerning spinal neurosurgery in France over a 5-year period (2015–2019). In addition, the work exposes the consequences for the patients and surgeons involved, particularly in the no-fault context of therapeutic hazards.

Methods

Study Settings

We retrospectively analyzed data provided by a major French medical liability–specialized insurance company for private practitioners (Mutuelle d'Assurances du Corps de Santé Français [MACSF]). The company provides legal assistance to its members.¹¹ We reviewed all of the closed cases of complaints filed for spinal neurosurgical procedures between 2015 and 2019, a period during which the MACSF insured almost all French private neurosurgeons through an agreement with their scientific society (Société Française des Neurochirurgiens Libéraux).¹² These computerized files comprised the anonymized medical records of the patients, the reports of the independent experts nominated by the legal authorities, the correspondence between lawyers, the final judgments, and the entities supporting the compensation, if any.

Private Neurosurgical Practice and Rules of Medical Liability in France

Our investigation concerned French private neurosurgeons, almost all of whom were insured by MACSF. These neurosurgeons almost exclusively treated spinal conditions and were subject to the civil law system.^{8,13,14}

In 2002, the PRL established a complementary “no-fault, out-of-court” scheme to obtain compensation “quickly” and more easily.^{9,15} Table 1 presents an overview of the French regulations for medical liability applicable to private neurosurgical practice. According to these regulations, any patient can initiate a claim free

of charge under the admissibility criteria defined by the Commission for Conciliation and Compensation (CCI) (Fig. 1). An independent expert reviews the case, and the CCI shall reach one of the following conclusions within 6 months of the referral: strict liability (medical hazard or severe nosocomial infection [NI]), no fault, or negligence proven.^{10,16} In a no-fault case (therapeutic hazards or severe NI), compensation is paid by the National Compensation Office for Medical Accidents (ONIAM), supported by the national solidarity fund.^{17–19} The 2002 PRL proposes, as a condition for compensation by national solidarity, that the therapeutic hazard has had “abnormal consequences for the patient with regard to his state of health and the foreseeable evolution of his health.”¹⁵

Data Collection

The following data were retrospectively recorded in the computerized files: characteristics of the patient (name, age, sex, medical history, and profession), index spinal surgery, reasons for claims, delay between index surgery and claims, outcomes of expert review (no fault, NI, strict liability, or proven negligence), and outcomes of CCI decision (proven negligence, strict liability, or moderate or severe NI). The CCI is expected to rule on liability only for serious medical accidents causing damage above a threshold defined by law, as follows: 1) If the imputable injuries are found to be below this threshold after the expertise, the CCI is obliged to declare itself incompetent to rule and does not have to rule on liability—in other words, the CCI pronounces a decision of incompetence even in the case of culpable medical accidents or therapeutic hazards. 2) The CCI may pronounce a rejection when the damage is linked to a previous condition (foreseeable evolution of the disease or comorbidities) or in the event of a medical accident that is not at fault but does not fall within the acceptance of the therapeutic risk (e.g., if the frequency of occurrence in the literature is too high to comply with the definition of therapeutic risk). According to case law, if the frequency of an event in the literature is higher than 5%, then this event is outside the framework according to the 2002 PRL and does not justify compensation by national solidarity (ONIAM). We also looked at which entity took charge of the financial compensation at the end of the procedure, and whether the claimant started a new procedure in another jurisdiction (civil court).

Results

Case Characteristics

During the 5-year study period (2015–2019), MACSF recorded 494 complaints involving private neurosurgeons for spinal surgery procedures, of which 126 (25.5%) were in civil court, 123 (24.9%) were under amicable procedure, and 245 (49.6%) were in the out-of-court scheme administered by the CCI. Due to delays—in particular, due to the recent COVID-19 pandemic—of these 245 cases, only 193 were closed, and these cases were the focus of our study (Table 2).

There were 93 male patients (48.2% of all cases) and 100 female patients (51.8%) included in this study. The

TABLE 1. Focuses on private neurosurgical practice and rules of medical liability in France

Focus	Details
Characteristics of private neurosurgery in France^{12–14}	
French neurosurgery landscape	The French health system combines public and private hospitals. Due to historical organization, neurosurgery activity has long been concentrated in the regional university hospitals, which are public entities subject to administrative law. These centers (tertiary referral hospitals) perform cranial, functional, and spinal surgery.
Private practice	The private system (subject to civil law) brought together 121 neurosurgeons in 2019 who, because of an authorization obligation, essentially performed only spine surgery. These neurosurgeons represented 27.4% of the 442 French spine surgeons, combining neurosurgeons and orthopedists. According to 2019 official health ministry data, private neurosurgeons perform 36.0% of the national spinal surgery activity, covering all degenerative, traumatic, and oncological disorders, regardless of the severity of the cases.
Focus on medical malpractice and compensation in France^{8,9,16,17}	
Classical scheme with civil court	In the civil legal system, the private practitioner is liable in the event of a complaint, whereas for a public practitioner, only the liability of the public hospital service can be invoked for the failure of a public service and not the actions of a particular individual, which is very protective. To practice medicine, the physician has the obligation to take out professional liability insurance.
Out-of-court scheme criteria (2002 PRL)	In 2002, a complementary legal route to obtain compensation quickly and more easily was established with a new act. This new law established the current French no-fault, out-of-court scheme concerning acts of prevention, diagnosis, or care. Any patient can start this process free of charge under the admissibility criteria based on the severity of the sequelae (PDR >24%; temporary sick leave >6 consecutive mos, or 6 nonconsecutive mos over a period of 1 yr; disability considered to be particularly severe for activities of daily living; definitive incapacity to exercise one's previous profession; temporary functional deficiency ≥50% for 6 consecutive mos, or 6 nonconsecutive mos over a period of 1 yr).
CCI	Where the prejudice suffered meets these criteria, the CCI, chaired by independent judges, appoints an independent expert and shall then give its conclusions within 6 mos of the referral: strict liability (medical hazard or severe NI), no fault, or negligence proven. The contradictory expert review is an important stage of the procedure. The patient does not have to be assisted by a lawyer throughout the procedure.
Compensation for medical accidents	<ul style="list-style-type: none"> If there is negligence, it is the insurer of the liable party who is called upon and who must make an offer, which can be either accepted by the plaintiff, who is then compensated within 4 mos, or rejected by the plaintiff. A dispute is then decided by court proceedings. In the case of a medical accident that is not at fault, therapeutic hazards, or severe NI, compensation is paid by the ONIAM, which is supported by the national solidarity.
Focus on "strict liability" in France (therapeutic hazards and NIs)^{9,10,15,16,18,21}	
What the 2002 PRL says	The 2002 PRL proposes, as a condition for the compensation by national solidarity, that the therapeutic hazard has had "abnormal consequences for the patient with regard to his state of health and the foreseeable evolution of his health."
What is abnormality?	<p>The concept of abnormality is uncertain as to its characteristics and is widely debated in case law, which has developed these criteria for assessment:</p> <ul style="list-style-type: none"> An abnormal act is an act that has significantly more serious consequences than those to which the patient was exposed. Damage that occurs in <5% of cases is abnormal (as no threshold is set by the texts, this criterion is purely jurisprudential).
The primordial role of expertise	The problem is that setting the rate at 5% is particularly low and severely limits the recognition of therapeutic hazards. There is a challenge in setting this percentage, which must be justified by medical literature. These elements underscore the importance of expert board reviews (supported by literature analysis) for all parties involved in this out-of-court scheme and explain that CCI decisions can seem radically different for similar clinical histories.
The special case of NIs	In the case of an NI, in the no-fault scenario, the patient is always compensated, either by the healthcare establishment's insurance company, when the degree of disability is <24%, or by national solidarity (ONIAM), when the compensation rate is >24%.

FIG. 1. Synoptic description of the French medicojudicial complaint system. The ONIAM (*) compensates for severe NIs, but in the case of a moderate infection (patient's degree of disability < 24%), the insurer of the care establishment in question pays the compensation. The claimant, ONIAM, and insurers can terminate an out-of-court procedure at any time and bring the case before the court(s) (dashed line).

mean $\pm$ SD patient age was 51.1 ± 11.9 years, and 54 patients (28.0%) had a history of spine surgery.

Emergency procedures accounted for 16 cases (8.3%). The series included 64 lumbar discectomies (33.2%), 24 anterior cervical discectomies and fusions (ACDFs; 12.4%), 28 lumbar decompressions (14.5%), and 59 fusions (30.6%; short and long constructs, anterior lumbar interbody fusion [ALIF]), among others. The lumbar level was involved in 144 cases (74.6%). The series included 4 deaths (2.1%) because of the medical procedure involved, and 60 newly acquired neurological deficits (31.1%), i.e., cauda equina syndrome, spinal cord, or radicular injury. The most common cause of claims alleged by plaintiffs was surgical negligence (29.5%), followed by a delay in diagnosis and/or treatment (18.7%), infection (16.6%), and unsatisfactory outcome (16.6%). These data are detailed in Table 2.

Conclusions of the Medical Expert Reviews

The conclusions of the medicolegal expert reviews prior to the CCI's decisions were as follows: proven negligence in 66 cases (34.2%), strict liability in 36 cases (18.7%), NI in 29 cases (15.0%), and no fault in 62 cases (32.1%).

Final Decision of the CCI

The CCI, after juridical analysis of the medical experts' reports, concluded that there was proven negligence in 26 cases (13.5%), strict liability in 41 cases (21.2%), and NI in 34 cases (17.6%), including moderate NI in 26 cases (13.5%) and severe NI in 8 cases (4.1%). The CCI reported on 1 procedure that was aborted because of the patient's

intercurrent suicide. The CCI declared itself incompetent to rule in 26 cases (13.5%), alleging that the threshold of prejudice had not been reached, regardless of the conclusion of the expert review (Fig. 2). The CCI rejected the claim in 65 cases (33.7%), arguing that there was no fault or that the frequency of the alleged complication exceeded the exceptional occurrence of 5% in the literature (taking this case outside the framework of the 2002 Act and, therefore, outside the scope of national solidarity).

Apart from the cases in which the CCI declared itself incompetent to rule or rejected the complaint, the CCI confirmed the experts' conclusions in all but 21 cases (10.9%). In particular, there were 7 cases in which the expert concluded that the accident was at fault (CCI conclusions: 3 CCI incompetent-to-rule declarations, 2 rejections, 1 strict liability, and 1 NI) and 12 cases in which the expert had concluded strict liability (no fault, with the following CCI conclusions: 1 CCI incompetent-to-rule declaration, 6 rejections, 4 proven negligence, and 1 procedure aborted due to patient suicide). The conclusions of the expert reviews and of the CCI are illustrated in Fig. 3.

Case Examples of CCI Decision Discrepancies

The following 2 cases illustrate discrepancies in CCI decisions:

- Case 1: A 49-year-old male patient with a previous C5–6 ACDF with progressive myelopathy, including deteriorating symptoms and a T2 MRI hypersignal, underwent a new ACDF (C4–5) in 2016. He was tetraplegic in the immediate postoperative period, with poor delayed recovery. The expert concluded that there was

a therapeutic hazard (theoretically opening up the possibility of compensation by the ONIAM), but the CCI concluded that, considering the surgical history and the known and evolving myelopathy, the risks of spontaneous evolution and procedural complications could amount to more than 20%. Therefore, the conditions laid down by the law were not met to enable the patient to obtain compensation under the national solidarity scheme.

- Case 2: A 58-year-old female patient with no surgical history and with progressive myelopathy, including deteriorating symptoms and a T2 MRI hypersignal, underwent an ACDF (C5–6) in 2016. She was tetraplegic in the immediate postoperative period, with poor delayed recovery. The expert review concluded that there was a therapeutic hazard frequency of 8%, which is higher than the jurisprudential threshold of the established definition. The CCI confirmed this conclusion by ordering the compensation of the patient through national solidarity.

Compensation by Insurers and Cases Covered by National Solidarity (strict liability and severe NI)

According to the conclusions of the CCI, 92 claims (47.7%) were not compensated, 26 (13.5%) were compensated by the physician's insurer for a proven fault, and 27 (14.0%) were compensated by the insurer of the health-care facility for a moderate NI with a permanent disability rate (PDR) < 24%. The ONIAM compensated 48 claims (24.8%), including 8 cases (4.1%) of severe NI (PDR > 24%) and 40 cases (20.7%) of therapeutic hazards. These hazards are detailed in Table 3.

New Claim Before the Court Instituted by Patients or Their Relatives After Completion of the Procedure by CCI

After the conclusions of the CCI, with or without a proposal for compensation by ONIAM or the care provider's insurer, the claimants brought 22 lawsuits (11.4%) before the civil court, as permitted by the 2002 Act.

Discussion

Overview of Our Study

Over the period under review, CCI claims accounted for half of the files received by MACSF for neurosurgeons (i.e., 193 complaints studied), resulting in 47.2% for rejection/incompetence decisions, 21.2% for therapeutic hazards, 17.6% for NI, and 13.5% for practitioner fault. National solidarity compensated for 48 complaints (24.8%). The final decision of the CCI was not always consistent with the conclusions of the experts mandated by it, illustrating the difficulty in defining the concept of hazards. Among the therapeutic hazards retained and compensated by the national solidarity, we pointed out decompensated spondylotic myelopathies (15% of the 40 cases) and cauda equina syndromes (30%). As allowed by law, 11.5% of the patients who were not satisfied triggered a classical procedure in a court.

It should be noted that between 2015 and 2019, the CCI received an average of 4500 claims per year, all specialties combined, with 31% of the decisions for compensation.²⁰

TABLE 2. Case characteristics for 193 spine surgery malpractice claims, 2015–2019

Variable	Value
Mean age in yrs $\pm$ SD	51.1 $\pm$ 11.9
Sex	
Male	93 (48.2%)
Female	100 (51.8%)
Employment data	
Unemployed	27 (14.0%)
Disabled	7 (3.6%)
Retired	40 (20.7%)
White collar	50 (25.9%)
Blue collar	69 (35.8%)
Previous spinal surgery	54 (28.0%)
Spinal surgery procedure	
Lumbar discectomy	64 (33.2%)
Fusion: short construct	41 (21.2%)
Decompression	28 (14.5%)
ACDF	24 (12.4%)
Fusion: long construct	11 (5.7%)
Other surgical procedure	10 (5.2%)
ALIF	7 (3.6%)
Thoracic discectomy	5 (2.6%)
Cervical posterior decompression	3 (1.6%)
Emergency cases	16 (8.3%)
Spine region	
Cervical	27 (14.0%)
Thoracic	11 (5.7%)
Lumbar	144 (74.6%)
Multiple	11 (5.7%)
New neurological deficit	
Tetraplegia/-paresis	9 (4.7%)
Paraplegia/-paresis	11 (5.7%)
Cauda equina syndrome	21 (10.9%)
Radicular deficit	19 (9.8%)
Death	4 (2.1%)
Purported and/or alleged "malpractice" events	
Surgical negligence	57 (29.5%)
Delay in diagnosis	36 (18.7%)
Surgical site infection	32 (16.6%)
Unsatisfactory surgical outcome	32 (16.6%)
Inadequate implant positioning	20 (10.4%)
Inadequate follow-up	5 (2.6%)
Misdiagnosis	5 (2.6%)
Lack of communication/informed consent	3 (1.6%)
Lack of organization/supervision	3 (1.6%)
Claim's delay from index surgery in mos $\pm$ SD	35 $\pm$ 30.9

Values are presented as the number (%) of patients unless otherwise indicated.

FIG. 2. Pie chart showing conclusions of the CCI concerning 193 litigation cases (2015–2019).

These results must be put into context with the claims rate (frequency of the number of declarations per 100 members of the insurer): that of French neurosurgeons was 78% in 2018, the highest of all the private specialties insured by the MACSF.¹¹

National Solidarity and the Welfare State

The idea of national compensation in the absence of any fault is part of the historical evolution of a welfare state whose roots can be found in the motto “Liberty, Equality, Fraternity”—chosen following the French Revolution. The concept of “fraternity” is politically similar to that of “solidarity” and has enabled the development of the welfare state and social legislation, as well as public service.¹⁷

It is not surprising, in this context of social security, that concerns leading to reflection were raised regarding the compensation of no-fault cases, within the broader framework of the 2002 PRL.²¹ A fascinating reflection, but beyond the scope of this article, is to define what needs to be compensated, within a general trend that has always been to extend risk coverage, in a society that refuses fatality and is characterized by an “ideology of compensation.”¹⁸ However, within the group of accidents linked to an act of care, there is a continuum between previous status, thera-

peutic hazard, negligence, and proven fault, which places a rather heavy assessment task on the medical experts and magistrates who will settle the case. Even via ONIAM, the funds are not unlimited and several corrective orientations have already taken place to adapt reality to theory.^{8,18,20,22}

The Out-of-Court System After the 2002 PRL: A One-Stop Shop and a Mixed Bag?

This alternative system offers a free, simple, out-of-court, and fast procedure. It is not a simple amicable settlement; there are significant criteria to trigger the procedure, there is independent contradictory expertise, and the final decision is given by a commission chaired by a magistrate.⁹ Specifically aimed at the management of no-fault accidents, this alternative scheme’s goals were a simplification of the system and decongestion of the courts.²¹ Finally, the CCI rejected or declared itself incompetent to rule in 47.2% of the cases in 5 years, proving that it does not systematically compensate. Subsequently, 11.5% of the patients who were not satisfied triggered a classical procedure in a court. This alternative scheme tends to become a one-stop shop rather than a preferred route for hazards, even if it means taking a traditional secondary action before a court.

FIG. 3. Discrepancies between the conclusions of the expert reports (**left**) and those of the CCI (**right**) concerning 193 litigation cases (2015–2019).

The other interests of this alternative route are to counteract defensive practices by trying to reduce and control insurance and legal costs for the parties (in fact, lawyers are not necessarily involved in CCI procedures).^{3,23,24} In addition, no-fault schemes make it easier to communicate and think about the identification and prevention of adverse events.^{25,26}

Therapeutic Hazards and the Paramount Role of the Medical Expert

The term “hazard” has many meanings, far beyond the limited scope of “therapeutic hazard,” to extend to the hazards of disease and life. Compensation for national solidarity is not an abstract consideration. It meets precise legal conditions, compliance with which guarantees the sustainability of the system.

The therapeutic hazard is characterized by the following elements: 1) a medical accident (prevention, diagnosis, and care) causing damage directly attributable to this act; 2) does not involve human fault; 3) of a certain severity; and 4) with abnormal consequences, involving arbitration in relation to a standard norm.¹⁰ The first two elements (causation and fault) are familiar to lawyers, who gave them precise frameworks. The third, severity, corresponds to the concept of the threshold of severity, which presupposes an objective medical assessment of the damage. The

TABLE 3. Description of the 40 therapeutic hazards identified by the CCI and compensated by national solidarity (ONIAM)

Therapeutic Hazard Description	No. (%) of Cases
Related to ACDF	
Decompensation of a preexisting myelopathy	6 (15.0%)
Recurrent nerve paresis with dysphonia	1 (2.5%)
Related to an incidental durotomy	
Cauda equina syndrome	3 (7.5%)
Intracerebral hematoma	1 (2.5%)
Pseudomeningocele requiring revision surgery	1 (2.5%)
Related to a postoperative spinal epidural hematoma	
Cauda equina syndrome	3 (7.5%)
Radicular deficit	1 (2.5%)
Paraplegia/-paresis	2 (5.0%)
Related to an anatomical constraint (revision surgery, stenosis, medial discal herniation, etc.)	
Cauda equina syndrome	5 (12.5%)
Radicular injury	4 (10.0%)
Related to implants (positioning, breakage, migration, etc.)	
Cauda equina syndrome	1 (2.5%)
Convergent screw with radiculargia requiring revision surgery	3 (7.5%)
Mobilization	2 (5.0%)
Malposition of cages/prostheses with radiculargia requiring revision surgery	4 (10.0%)
Pseudarthrosis	1 (2.5%)
Related to neuropathic pain	
	2 (5.0%)
Total	40 (100%)

To be considered a therapeutic hazard, the incriminated event must cause abnormal consequences for the patient with regard to his state of health and the foreseeable evolution of his health and justify a frequency of occurrence of < 5% after analysis of the literature.

last of these conditions, abnormal consequences, sometimes leads to significant difficulties of interpretation and requires the use of the concepts of frequency and statistics.

Medical expertise is a key element in this process. The expert’s task is to shed light on the level of risks incurred and described in the medical literature and to make specific corrections to the case in question.¹⁶

Since the 2002 PRL, medical accidents that are not attributable to human fault have been increasingly accepted, but the criterion of abnormality remains key, which can be used when the act has consequences that are significantly more serious than those to which the patient was exposed or when the damage occurs in less than 5% of cases.^{9,16} By referring to medical literature, the analysis of a no-fault case can be carried out as close as possible to the data of the patient concerned. Literature data combined with the patient’s previous state can ultimately change the CCI’s decision (as in the 2 clinical cases included in our results) because the experts’ reference to “real-life data” cannot suffice to deprive their reasoning of the intellectual and scientific rigor required by their duties.¹⁰

Some International Aspects

In most European states, medical legislation is imposing new obligations for caregivers and recognizing new rights for patients, and specific compensation schemes are being set up to help victims of therapeutic risks. European institutions call for the harmonization of the principles of medical liability and compensation for personal injury following medical accidents.²⁷ The general principles of medical liability in Europe set two groups of countries against each other: the Scandinavian countries, which provide reparations through direct insurance systems and on the basis of a concept of objective liability based on the risk incurred, and the other European countries, for which the injury attributable to a fault remains the only one that can be compensated, with a certain number of variables.⁸ The out-of-court approach initiated by the Scandinavian countries is occasionally compared to the US workers' compensation system, in that it is less focused on finding fault than on compensating patients who have been harmed by inadequate care.

In the United States, Daniels et al. showed that 54.2% of spinal malpractice cases resulted in a defense verdict,⁴ a lower result than the 75% reported in favor of the surgeon by Makhni et al.²⁸ In his analysis of tetraplegia cases after cervical spine surgery, Epstein explained that one of the main drawbacks of the current tort malpractice system is its inability to compensate a large group of truly injured patients.²⁵ Another major disadvantage of the system is that large amounts are paid to lawyers and other third parties, rather than to injured plaintiffs. Nevertheless, we will not go so far as to agree with Chapman's Shakespearean suggestion in his provocative *BMJ* article, "The first thing we do, let's kill all the lawyers," which we think is highly inappropriate.²⁹ No-fault systems are less costly because, even if frivolous complaints cannot be eliminated, these systems remove the legal impediments to the filing and review of claims. Finally, the lack of a link between tort liability and the reduction of adverse events remains a major problem: defensive medicine—and its enormous costs—is still practiced, while medical errors remain underestimated or even undetected.^{24,30} Nevertheless, Makhni et al. concluded positively that the pursuit of tort reform in the United States may also have set a precedent for the protection of physicians, as well as an understanding that negative outcomes often result from factors other than the surgeon's gross negligence, which brings us closer to the concept of hazards.²⁸ Explorations are being conducted in the United States^{31,32} and in other countries^{33,34} to propose alternative routes, such as alternative dispute resolution, which has the potential to help reform the current liability system, reducing costs and increasing satisfaction for both parties.

Impacts for Litigating Parties

For patients in France, the free and rapid course of the compensation procedure has gradually led to more and more frequent recourse to the CCI, even though the motives for a complaint do not seem to give rise to a request for recognition of a hazard or an NI. In our study, the most common cause of claims alleged by plaintiffs was surgical negligence (29.5%), followed by delay in diagnosis and/or treatment (18.7%). The impact on the professional level

(prolonged work stoppages, loss of employment, or impossibility of resuming work) is also an explanation (35.8% of blue-collar workers). Therefore, well-advised patients tend to choose this fast-track procedure before another, even if it means taking the case to a civil court if their complaint is rejected by the CCI.

Practitioners and insurers feared an increase in procedures, which nevertheless remain moderate (on average, 1.5 complaints received per year),¹¹ and proven faults are rare (13.5% in our study). That said, the impact of this system on neurosurgeons in their daily practices has degraded the subjective vision that French private neurosurgeons have of their profession and of the doctor-patient relationship,^{6,35} which may even lead to litigaphobia.³⁶

Study Limitations

Our study was limited to a single insurer, but during the period 2015–2019, it covered almost all private French neurosurgeons performing a substantial part of the country's overall spinal surgical treatment.

The full picture of medicolegal complaints is complex to describe. Amicable complaints are difficult to collate because they are often settled at the level of healthcare institutions, and complaints before the courts follow extremely lengthy timeframes. Moreover, some cases use several paths (synchronous or successive). It seems that the number of cases reported gives a true picture of what the out-of-court system can represent at the country level, such as in France, in a specialty with a high claims rate.

Conclusions

The creation of the French out-of-court scheme provided the citizens a simple, quick, and efficient pathway to obtain compensation for a medical accident. This system exists alongside the classical courts and is now the preferred path. Therapeutic hazard management was conceptualized in line with the French philosophy of a collectivized approach to the sharing of risks within the community. Conclusions of proven medical malpractice are rare, but patients can start a new procedure in the classical courts. The definition of a therapeutic hazard remains subtle, and its progress between experts and magistrates is problematic and creates the potential for inconsistency in decision-making between cases of very similar appearances. In spite of these imperfections, however, the system proposes a major evolution to move patients and medical providers from legal battles to reconciliations.

References

1. Reid PC, Morr S, Kaiser MG. State of the union: a review of lumbar fusion indications and techniques for degenerative spine disease. *J Neurosurg Spine*. 2019;31(1):1–14.
2. Deyo RA, Gray DT, Kreuter W, et al. United States trends in lumbar fusion surgery for degenerative conditions. *Spine (Phila Pa 1976)*. 2005;30(12):1441–1447.
3. Din RS, Yan SC, Cote DJ, et al. Defensive medicine in U.S. spine neurosurgery. *Spine (Phila Pa 1976)*. 2017;42(3):177–185.
4. Daniels AH, Ruttiman R, Eltorai AEM, et al. Malpractice litigation following spine surgery. *J Neurosurg Spine*. 2017;27(4):470–475.

5. Gardner A, Gardner E, Morley T. Cauda equina syndrome: a review of the current clinical and medico-legal position. *Eur Spine J*. 2011;20(5):690–697.
6. Guillaumin A, Moncany A-H, Hamel O, et al. Spine neurosurgeons facing the judicialization of their profession: disenchantment and alteration of daily practice—a qualitative study. *Acta Neurochir (Wien)*. 2020;162(6):1379–1387.
7. Chevreul K, Durand-Zaleski I, Bahrami SB, et al. France: health system review. *Health Syst Transit*. 2010;12(6):1–291, xxi–xxii.
8. Watson K, Kottengen R. Patients' rights, medical error and harmonisation of compensation mechanisms in Europe. *Eur J Health Law*. 2017;25(1):1–23.
9. G'Sell-Macrez F. Medical malpractice and compensation in France. Part I: The French rules of medical liability since the patients' rights law of March 4, 2002. *Chic Kent Law Rev*. 2011;86(3):1093.
10. Trésallet C, Cardin JL, Belghiti J, et al. Medical expert witness testimony in France and in Europe. *J Visc Surg*. 2019;156(suppl 1):S3–S6.
11. Chirurgie du rachis—RA—MACSF. MACSF. Accessed September 10, 2020. <https://www.macsfr.fr/Rapport-annuel-sur-le-risque-medical/risque-profession-sante-cliniques/Cliniques-chirurgie-du-rachis-ra>
12. À propos de la société française des neurochirurgiens libéraux. SFNCL. Accessed September 10, 2020. <https://sfncf.fr/societe-francaise-des-neurochirurgiens-liberaux>
13. Conseil National de l'Ordre des Médecins. Trouver un Médecin. Accessed September 10, 2020. <https://www.conseil-national.medecin.fr/patient/cherche-medecin/trouver-medecin>
14. Activité établissement—casemix MCO | Stats ATIH. ScanSanté. Accessed September 10, 2020. https://www.scansante.fr/applications/casemix_ghm_cmd?secteur=MCO
15. Loi N° 2002-303 du 4 Mars 2002 Relative Aux Droits des Malades et à la Qualité du Système de Santé. Accessed September 10, 2020. <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000227015>
16. Legeais D. Medicolegal structure, consequences, and recommendations for daily practice: the example of surgical infection. *J Visc Surg*. 2019;156(suppl 1):S21–S32.
17. Thouvenin D. French medical malpractice compensation since the act of March 4, 2002: Liability rules combined with indemnification rules and correlated with several kinds of proceedings. *Drexel Law Review*. Accessed September 10, 2020. <https://drexel.edu/law/lawreview/issues/Archives/v4-1/thouvenin/>
18. Bright C, Hodges C. The Oniam scheme. Social Science Research Network; 2017. Accessed September 10, 2020. <https://papers.ssrn.com/abstract=3156212>
19. Barème indicatif d'évaluation des taux d'incapacité en droit commun. Accessed September 10, 2020. Unithèque. <https://www.unitheque.com/bareme-indicatif-evaluation-des-taux-incapacite-droit-commun/concours-medical/Livre/37877>
20. Rapport d'activité. ONIAM. Accessed September 10, 2020. <https://www.oniam.fr/indemnisation-accidents-medicaux/rapport-d-activite>
21. Taylor S. Clinical negligence reform: lessons from France? *Int Comp Law Q*. 2003;52(3):737–747.
22. Taylor S. *Medical Accident Liability and Redress in English and French Law*. Cambridge University Press; 2015.
23. Agarwal N, Gupta R, Agarwal P, et al. Descriptive analysis of state and federal spine surgery malpractice litigation in the United States. *Spine (Phila Pa 1976)*. 2018;43(14):984–990.
24. Nahed BV, Babu MA, Smith TR, Heary RF. Malpractice liability and defensive medicine: a national survey of neurosurgeons. *PLoS One*. 2012;7(6):e39237.
25. Epstein NE. A medico-legal review of cases involving quadriplegia following cervical spine surgery: Is there an argument for a no-fault compensation system? *Surg Neurol Int*. 2010;1:3.
26. Morris JA Jr, Carrillo Y, Jenkins JM, et al. Surgical adverse events, risk management, and malpractice outcome: morbidity and mortality review is not enough. *Ann Surg*. 2003;237(6):844–852.
27. Convention d'Oviedo et ses Protocoles. Bioéthique. Conseil de l'Europe. Accessed September 10, 2020. <https://www.coe.int/fr/web/bioethics/oviedo-convention>
28. Makhni MC, Park PJ, Jimenez J, et al. The medicolegal landscape of spine surgery: how do surgeons fare? *Spine J*. 2018;18(2):209–215.
29. Chapman S. The first thing we do, let's kill all the lawyers. *BMJ*. 1995;310(6987):1090.
30. Smith TR, Habib A, Rosenow JM, et al. Defensive medicine in neurosurgery: does state-level liability risk matter? *Neurosurgery*. 2015;76(2):105–114.
31. Sohn DH. Negligence, genuine error, and litigation. *Int J Gen Med*. 2013;6:49–56.
32. Sohn DH, Bal BS. Medical malpractice reform: the role of alternative dispute resolution. *Clin Orthop Relat Res*. 2012;470(5):1370–1378.
33. Amirthalingam K. Medical dispute resolution, patient safety and the doctor-patient relationship. *Singapore Med J*. 2017;58(12):681–684.
34. B-Lynch C, Coker A, Dua JA. A clinical analysis of 500 medico-legal claims evaluating the causes and assessing the potential benefit of alternative dispute resolution. *Br J Obstet Gynaecol*. 1996;103(12):1236–1242.
35. Debono B, Hamel O, Guillaumin A, et al. Impact of malpractice liability among spine surgeons: A national survey of French private neurosurgeons. *Neurochirurgie*. 2020;66(4):219–224.
36. Breslin FA, Taylor KR, Brodsky SL. Development of a litigation phobia scale: measurement of excessive fear of litigation. *Psychol Rep*. 1986;58(2):547–550.

Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Debono. Acquisition of data: Debono, Houselstein, Lonjon. Analysis and interpretation of data: Debono, Gerson, Houselstein, Bougeard, Lonjon. Drafting the article: Debono. Critically revising the article: Gerson, Houselstein, Lettat-Ouatah, Bougeard, Lonjon. Reviewed submitted version of manuscript: Gerson, Houselstein, Lettat-Ouatah, Bougeard, Lonjon. Approved the final version of the manuscript on behalf of all authors: Debono. Administrative/technical/material support: Lonjon. Study supervision: Debono, Lonjon.

Correspondence

Bertrand Debono: Private Hospital of Versailles–Ramsay Santé, Versailles, France. bdebono@gmail.com.