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Medical Litigations Associated with Cataract Surgery in Korea

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ABSTRACT

Background: To analyze the results of court rulings about medical litigations related to cataract surgery in Korea.

Methods: We collected 50 anonymized judgements regarding cataract surgery between 2000 and 2016 and analyzed the reasons for the medical litigations, the court rulings, the reasons for compensation, and the amount claimed and finally awarded.

Results: Forty-eight litigations (96%) resulted from errors in treatment, and the reasons were as follows: endophthalmitis, dissatisfaction of visual outcome or ocular discomfort, bullous keratopathy or corneal opacity, retinal detachment, glaucoma or vitreous hemorrhage due to the progression of an underlying diabetic retinopathy, and others in order. Two litigations (4%) arose due to errors in diagnosis. Among the 50 final cases, 21 litigations (42%) were decided in favor of the plaintiff, and 29 litigations (58%) were decided against the plaintiff and dismissed. Ten cases awarded damages to the plaintiffs because of a violation of duty of care, and 11 cases awarded damages due to a violation of informed consent. When comparing cases with errors in diagnosis to cases with errors in treatment, there was no significant difference in the relative risk of a defendant's verdict ($P = 0.503$). The total amount of awarded damages was KRW 439,124,496 (USD 399,204), and the average amount was KRW 20,910,690 (USD 19,010).

Conclusion: Nearly half of the cases were decided in favor of the plaintiff due to the violation of informed consent. This study's results will be helpful in understanding the results of medical litigations regarding cataract surgery and reducing future lawsuits.

Keywords: Cataract Surgery; Medical Disputes; Medical Litigations; Ophthalmology; Violation of Duty of Care; Violation of Informed Consent

INTRODUCTION

Cataract surgery is the most commonly performed surgery in the field of ophthalmology, with more than 3 million operations per year in the United States¹ and over 200,000 operations per year in United Kingdom.^{2,3} According to a survey conducted by the Korean National Health Insurance Review and Assessment Service in 2015, 346,000 cataract surgeries are performed out of 1,490,000 domestic operations per year, which means that cataract surgery is the most frequent operation undertaken in Korea not only in the ophthalmic field but also

Disclosure

The authors have no potential conflicts of interest to disclose.

Author Contributions

Conceptualization: Kwak JY, Han KE.
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in all surgical fields. Due to the improvements in surgical techniques and devices and the growing popularity of cataract surgery using high-cost, premium intraocular lens (IOLs), such as presbyopia-correcting and/or astigmatism-correcting IOLs,^{4,7} cataract surgery is considered not only for the removal of cataract but also as a refractive surgery to achieve high visual quality.

Medical disputes are likely to occur from cataract surgery due to the high number of surgeries and high-sometimes even unrealistic-expectations for postoperative visual outcomes. In the United Kingdom, the National Health Service Litigation Authority reported that medical malpractice claims associated with cataract surgery accounted for 31% (357/963) of all cases in ophthalmology-related medical malpractice litigations between 1995 and 2009.⁸ Similarly, in the United States, the Physicians Insurance Association of America reported that about 47% of 324 ophthalmic litigations between 1985 and 2005 were associated with cataract surgery.⁹ In Korea, there is only one report regarding medical litigations in the field of ophthalmology, and among the 42 concluded judgements of ophthalmology-related medical litigations, only 7 claims were related to cataract diseases.¹⁰ The reasons for and results of the cataract surgery-related litigations were not analyzed in their study; in addition, there are litigations that are not disclosed.

We performed this study to analyze the closed medical litigations related to cataract surgeries and investigate the reasons for litigations, court ruling results, types of errors made by ophthalmologists and recognized in court, and the amounts of damages.

METHODS

We visited the Supreme Court of Korea and browsed domestic cataract surgery-related medical litigations in the section of the court's records related to civil lawsuits. We searched 410 closed (i.e., concluded) cases of precedents from January 2000 to December 2016 by key words of cataract, ophthalmology, and surgery. Afterwards, we obtained copies of the cases after filing an application form on legal portal sites to the Supreme Court and each lower court.¹¹ The courts had anonymized each copy of the case documents, concealing the personal information of plaintiffs and defendants. We analyzed the results of the cases, and if a case had an appeal hearing or appellate trial, we considered the related trials as one case and recorded the final court ruling.

The causes of the legal allegations presented in the judgements were classified into errors in treatment and errors in diagnosis. Errors in treatment included medical negligence related to examinations, treatments, anesthesia, and follow-ups. The reasons for the plaintiffs' compensation were divided into a violation of duty of care and a violation of informed consent.¹² The duty of care is "the obligation to take the best care of patients and to prevent risks in accordance with the specific symptoms or circumstances of the patients while performing medical treatment."¹³ The duty of informed consent means that: "Doctors are obliged to explain about the symptoms of the illness and the details and necessity of the treatment methods that are considered to be significant in the level of medical care. Doctors have to explain details to the patients or their family as the premise for obtaining a consent to do things such as surgery, that could harm the patients, and to allow the patient to make a choice, so-called self-determination to receive the medical treatment or not by fully comparing the necessity and the risk."^{14,15}

Cases that were paid by the doctors for the damage, regardless of the amount, are considered to have been in favor of the plaintiff. Cases that were dismissed or overruled are considered to have been in favor of the defense. We analyzed the causes of cataract surgery-related medical lawsuits, the number of lawsuits each year, the court ruling results, the types of doctors' medical malpractice recognized by the courts, the amounts claimed by plaintiffs, and the amounts of damages paid by doctors. Since most judgements did not contain the patients' visual acuity, it was impossible to analyze the relation between the corrected visual acuity and the outcome of the lawsuit. If court rulings compensated for both a violation of duty of care and a violation of informed consent in one case, the result of the case was considered to be a violation of duty of care. In cases with multiple plaintiffs, the final amount of damage was defined as the sum of the amount of damages that the doctor would pay.

Statistical analyses

We used the Fisher's exact test to calculate the relative risk of getting a defendant's verdict based on the type of errors and the Mann-Whitney U test to compare the awarded damages based on the reasons of the final decision. *P* values less than 0.05 were considered statistically significant using SPSS software (Version 19.0, SPSS, Inc., Chicago, IL, USA).

Ethics statement

This study adheres to the Helsinki Declaration and reviewed by the Institutional Review Board of Ewha Womans University Mokdong Hospital (No. 2017-10-034). Informed consent was waived by Institutional Review Board.

RESULTS

Among the 410 concluded cases of precedents from January 2000 to December 2016, we excluded duplicated cases or cases unrelated to cataract surgery and, as a result, collected 50 relevant cases. The number of ophthalmology-related closed cases during the study period was 314.

Of the closed cases related to cataract surgery, 14 were from 2000 to 2004 (28%), 13 cases from 2005 to 2009 (26%), 21 cases from 2010 to 2014 (42%), and 2 cases (4%) during the last two years (2015 to 2016). **Table 1** shows the detailed numbers of annual judicial cases. Thirty-five cases were concluded at the first trial, 14 cases were filed at the appellate court (9 cases were filed by the plaintiff [patient], 3 cases were appealed by the defendant [doctor], and 2 cases were filed by both sides), and 1 case proceeded to a trial at the Supreme Court. Twenty-one cases (42%) were decided in favor of the plaintiff and 29 cases were decided in favor of the defendant.

Table 2 shows the amount of damages claimed by plaintiffs and the awarded amount. In most of the cases that were decided in favor of the plaintiffs (20/21), the amount of compensation was partially reduced, and in four of these cases, the amount was reduced because the patient's negligence or a force majeure was recognized. When analyzing the 21 cases decided in favor of the plaintiff, the total claimed amount by the plaintiffs was KRW 2,662,374,800

Table 1. Numbers of annual closed cases related to cataract surgery from 2000 to 2016

Year	2000'	2001'	2002'	2003'	2004'	2005'	2006'	2007'	2008'	2009'	2010'	2011'	2012'	2013'	2014'	2015'	2016'
No. of cases	3	2	2	3	4	5	0	3	2	3	2	4	4	7	4	1	1

Table 2. Amount claimed of damages by plaintiffs and awarded amount by doctors

Currency	Amount claimed of damages by plaintiff (n = 50)				Awarded amount by doctors (n = 21)			
	Total	Average	Min	Max	Total	Average	Min	Max
KRW, ₩	4,933,245,353	98,664,907	7,412,668	839,228,288	439,124,496	20,910,690	2,600,000	81,071,928
USD, \$	4,484,769	89,695	6,739	762,935	399,204	19,010	2,364	73,702

Table 3. Reasons and types of legal allegations, court rulings, and the amount of awarded damages

Types of legal allegations	No.	Plaintiff verdict, No. (%)	Defendant verdict, No. (%)	Amount of awarded damages, KRW(USD)	
				Total	Average
Errors in treatment					
Endophthalmitis	13	5 (39)	8 (61)	105,071,646 (95,520)	21,014,329 (19,104)
Subjective dissatisfaction of visual outcome or ocular discomfort	8	2 (33)	6 (67)	31,127,927 (28,298)	15,563,964 (14,149)
Bullous keratopathy or corneal opacity	7	4 (57)	3 (43)	46,432,087 (42,211)	11,608,022 (10,553)
Retinal detachment	6	2 (33)	4 (67)	70,323,830 (63,931)	35,161,915 (31,965)
Glaucoma or vitreous hemorrhage due to progression of underlying diabetic retinopathy	5	1 (20)	4 (80)	3,000,000 (2,727)	-
Macular degeneration	2	2 (100)	0 (0)	12,600,000 (11,455)	6,300,000 (5,727)
Intraocular lens related complications	2	1 (50)	1 (50)	5,901,628 (5,365)	-
Death due to hypoxic brain damage or Steven-Johnson syndrome	2	2 (100)	0 (0)	92,571,928 (84,156)	46,285,964 (42,078)
Central retinal artery occlusion	1	1 (100)	0 (0)	22,095,450 (20,087)	-
Suprachoroidal hemorrhage	1	1 (100)	0 (0)	50,000,000 (45,455)	-
Transient choroidal detachment	1	0 (0)	1 (100)	-	-
Errors in diagnosis					
Optic nerve atrophy	1	0 (0)	1 (100)	-	-
Macular hole	1	0 (0)	1 (100)	-	-
Total	50	21 (42)	29 (58)	439,124,496 (399,204)	20,910,690 (19,010)

(USD 2,420,341) and the average amount was KRW 126,779,752 (USD 115,254), ranging from KRW 11,768,120–839,228,288 (USD 10,698–762,935).

Table 3 shows the reasons for and numbers of legal allegations, court rulings, and the amount of awarded damages. Cases related to endophthalmitis featured the most common cause as well as the highest total awarded damages of medical litigations. We found that in eight cases including immediate diagnosis and treatment, or referral or transfer to higher-level hospital was done, the doctors did not pay damages. Among the five cases in which doctors paid damages, doctors paid damages due to a violation of duty of care in three cases. In the other two cases, doctors paid damages despite prompt treatment for endophthalmitis due to a failure to provide adequate information regarding surgical procedure and postoperative complications or a lack of preoperative laboratory testing for a diabetic patient.

Litigations related to the subjective dissatisfaction of visual outcome or ocular discomfort included eight cases, and subjective dissatisfaction of visual outcome or ocular discomfort was the second most common reasons for medical litigations. Subjective complaints included: floaters or visual discomfort (5), diplopia and halo after multifocal IOL insertion (1), not being informed about wearing glasses after surgery (1), and discomfort after surgery due to permanent mydriasis induced by iridectomy during surgery (1). In the two cases of not being informed about glasses wearing and discomfort after surgery due to iridectomy during surgery, doctors paid the damages due to infringement of self-determination. However, the six other cases were not recognized as the doctor's fault because either there was no structural abnormality in the eye or the corrected visual acuity was not abnormally poor.

Table 4. Awarded damages according to the type of violation by final decision, KRW (USD)

Types of violations	Median	25%	75%	P value
Violation of duty of care (n = 10)	27,149,015 (24,681)	7,475,407 (6,796)	49,404,277 (44,913)	0.061
Violation of informed consent (n = 11)	3,000,000 (2,727)	8,000,000 (7,273)	15,000,000 (13,636)	

Mann-Whitney U test.

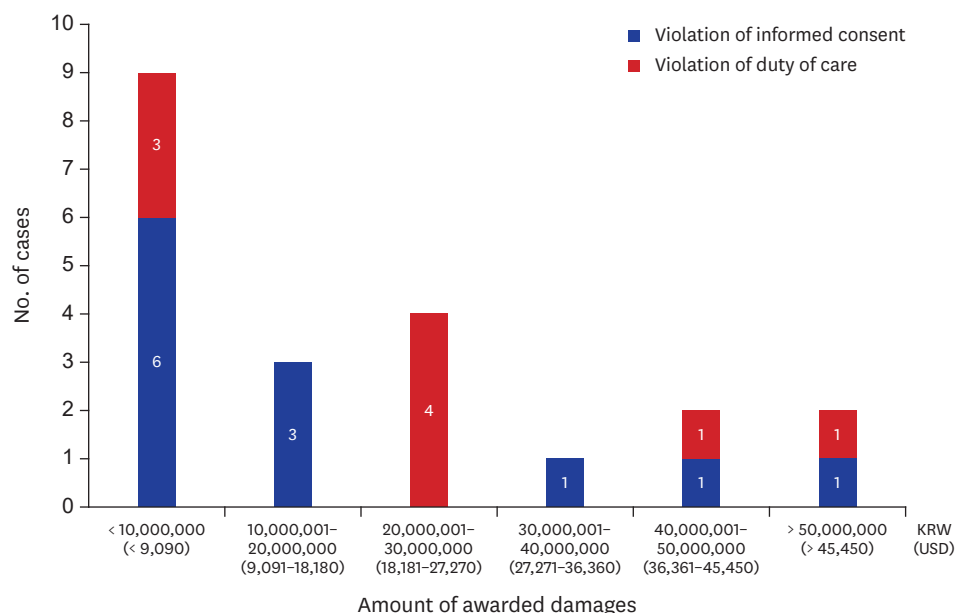


Fig. 1. Distribution of amount of damages according to the type of violation.

Seven of the cases included bullous keratopathy or corneal opacity. In the four cases ruled in favor of the plaintiff, three cases were due to a violation of informed consent and one case was due to a delayed in IOL insertion after posterior capsule rupture.

Among the total cases, when severe damages including death or blindness occurred after surgery, the court ruled in favor of the plaintiff. In the preoperative undiagnosed cases with optic nerve atrophy or macular hole, the court ruled in favor of the defendant because the doctors sufficiently explained the possibility of a lack of visual improvement due to a severely advanced cataract.

Among the 21 cases ruled in favor of the plaintiffs, 10 cases (47.6%, or 20% of total claims) were related to a violation of duty of care, and 11 cases (52.4%, or 22% of total claims) were related to a violation of informed consent. Among the awarded cases due to a violation of duty of care, medical negligence occurred during the surgical procedure (6 cases), during the preoperative examination (3 cases), and during follow-ups (1 case). **Fig. 1** shows the distribution of damages awarded according to the type of violation. There was no statistical difference in the amount of payments based on the type of violation ($P = 0.061$, Mann-Whitney U-test) (**Table 4**). There was also no difference in the relative risk of getting the defendant's verdict based on the type of error ($P = 0.503$) (**Table 5**).

Table 5. Types of errors determined within the lawsuits decisions

Types of errors	Plaintiff verdict	Defendant verdict	P value
Error in diagnosis	0	2	0.503
Error in treatment	21	27	

Relative risk of getting the defendant's verdict for error in treatment: 0.563 (95% confidential interval, 0.438–0.722).

DISCUSSION

We found that doctors were deemed liable in nearly half of the total cases (42%) of medical litigations related to cataract surgery. Moreover, more than half of these cases resulted from a violation of informed consent, which means that perioperative explanations were not fully provided.

Until now, there was only one report regarding ophthalmology-related medical litigations in Korea. Yoo et al.¹⁰ analyzed 42 closed ophthalmology-related lawsuits between 1989 and 2014 and reported that out of the cases where doctors were found liable, 26 cases (62%) were related to a violation of informed consent, and 12 cases (29%) were related to a violation of duty of care. Eight cases were due to errors in diagnosis, and four cases were due to errors in treatment. However, they included litigations of all ophthalmic subspecialties and only included seven medical lawsuits regarding cataract disease. In our study, most of the violations of the duty of care were due to errors in treatment. The difference in the reasons for medical litigations may be because this study was limited to cataract surgery and data was collected in a different way.

Over 17 years, the number of judicial cases related to annual cataract surgeries increased from 14 cases from 2000–2004 to 21 cases from 2010–2014. There are only two cases in the last two years (2015–2016); this is probably because other lawsuits are likely ongoing. This trend is similarly found in other countries such as the United States, Australia, and New Zealand, all of which reported increases in medico-legal claims regarding ophthalmology practice increases.^{16,17}

The most common cause and the highest total awarded damages of medical litigations in this study was endophthalmitis. The Ophthalmic Mutual Insurance Company (OMIC) indemnified the largest amount of damages as a result of endophthalmitis-related cases in US reports as well.¹⁸ It is a serious complication that occurs with a 0.05% to 0.25% probability after cataract surgery, and even if treated properly and actively, visual acuity may be decreased or even lost.^{19,20} Because of its devastating prognosis, the affected patients are possibly motivated to feel the need for compensation and would like to sue the ophthalmologists.^{3,21} Ali and Little³ pointed out that even though nearly all of the informed consent forms describe the possibility of endophthalmitis, and even though doctors applied the proper preoperative disinfection and postoperative topical antibiotics, lawsuits related to endophthalmitis have been filed, especially in cases with delayed diagnosis, treatment, or transfer. Brick¹⁸ also suggested that even if little infection is suspected, a second opinion should be sought and transfer should be supplied immediately if there are abnormal findings. Similar to the previous studies, this study found that in cases where an immediate diagnosis and treatment, or referral or transfer to higher-level hospital was done, the doctors did not pay damages. Two cases in which doctors paid damages even with the prompt treatment were due to a violation of informed consent or a lack of preoperative laboratory tests. To prevent endophthalmitis-related lawsuits, preoperative explanation and perioperative disinfection should be performed, and if uncommon or severe inflammation is observed, patients should be examined more frequently and immediately referred or transferred for prompt treatment.

Complaints about visual outcome were the second most common reason for the plaintiffs' suits. The development of floaters and subjective visual discomfort were not recognized as the doctor's fault if there was no structural abnormality in the eye or if the corrected visual acuity was not

abnormally poor. However, when there was no preoperative explanation on the consent form regarding the possibility of postoperative spectacle usage, or when the patient complained of severe glare, and no pharmaceutical or surgical treatments were tried after iris sphincterotomy that was performed during surgery, doctors paid the damages. In previous studies, postoperative dissatisfaction with the visual outcome was also a major cause of compensation. Ali and Little³ reported that decreased visual acuity resulted in the greatest number of total damages and mean damages despite the patient signing the consent form, which indicated that visual acuity could be decreased. Interestingly, other studies reported that visual acuity did not affect the lawsuit results. Brick¹⁸ stated that doctors were found liable even though the patient's vision was 20/20, and Bhan et al.² also reported that good vision cannot protect doctors from litigations; therefore, doctors should continuously use risk-reducing activity. In this study, it was not possible to analyze the relationship between the correct visual acuity and the outcome of the lawsuit because most cases did not include the patient's visual acuity.

There were only two lawsuits related to IOLs in our study: one case was related to an implantation of the wrong IOL, and the other case was related to IOL dislocation. This characteristic is quite different when compared with previous studies, in which IOL problems were the first- or second-most common cause of the lawsuits.^{3,9,18} Brick¹⁸ reported that if the wrong IOL was implanted, or if IOL subluxation occurred, some doctors reimbursed the patients even though their visual acuities were good. In Ali and Little's study,³ the refractive power error of IOL was an important issue, and the paid-to-closed ratio was 62% even though the visual outcomes were good. In our study, it may be that IOL-related lawsuits were rare because of the development of various biometric machines and formulas.

When we compare lawsuits in other countries to those in Korea, some differences exist in reasons for lawsuits and the awarded damages. In this study, the reasons for lawsuits were: endophthalmitis, dissatisfaction regarding visual outcome, bullous keratopathy or corneal opacity, complications due to progression of underlying diabetes retinopathy, and others in order. In England, the reasons for lawsuits were: negligent surgery, errors in biometry or IOL power, reduced vision, postoperative endophthalmitis, and equipment failure, and others in order.³ In the United States, the reasons for lawsuits were: problems with IOL, retina, infection, cornea and others in order.¹⁸ These differences may result from the analyzed data: judgements of the court's rulings in this study; claim data from the insurer of ophthalmologists, the OMIC, in the United States,¹⁸ or claim data from National Health Service in England.^{3,9} In addition, the difference in the study period and the lower number of lawsuits in this study may also lead to the differences.

Considering the types of violations, the violation of informed consent was the main cause of the plaintiffs' compensation, which is in line with the results of previous research.^{2,10} The precedent of the Supreme Court states that patients have the right to decide for him/herself how to proceed based on what has already occurred with his/her body and mind and what will arise or may arise in the future.²² The preoperative explanation of possible complications cannot be exempted simply because the possibility of their occurrence is rare.²² The precedent suggested that complications should be explained in spite of their scarcity in cases where risks and side effects are typical or serious. Except for the extremely rare complication, in one case where the patient died due to Stevens-Johnson syndrome, the majority of cases in this study were related to well-recognized complications of cataract surgery that could happen to any surgeon. As shown in **Fig. 1** and **Table 4**, the amounts of damages due to a violation of informed consent was not inferior to those in the cases of a violation of duty

of care. This means that doctors have an opportunity to reduce a wide range of damages through proper perioperative explanation, except in some extremely rare cases.

Considering the types of errors, the relative risk of getting the defendant's verdict for errors in diagnosis did not differ from errors in treatment. This indicates that the type of errors did not affect the court's final decision. However, because of the limited number of cases with error in diagnosis in this study, additional research with more cases would be necessary to conclude this result.

To reduce medical litigations, any factor that may increase the risk of surgery for the patient should be noted.¹⁸ Some doctors try not to let the patient know when bad results occurred because of fear of medical litigation. However, as the disclosure-restitution program reduces the incidence of medical claims and reduces the compensation owed, it is necessary to communicate with the patients about complications or errors.^{23,24} Previous studies reported that some patients sued just to find out what complications or errors occurred.²⁵⁻²⁷ Considering that perioperative explanation and signed consent forms cannot prevent litigation when serious complications occurred,^{2,3} it is important to remember that when bad outcomes occur, sincere sympathy based on a strong rapport with patients and a precise explanation are of paramount importance in reducing medical litigations.¹

This study has some limitations, since only completed (closed) cases related to cataract surgery were analyzed, some cases were excluded: ongoing (opening) cases, cases that were settled out of court, or cases recommended for reconciliation even if a lawsuit was filed. Therefore, the number of included cases is significantly lower than the actual number of medical disputes. In addition, since the anonymized judgements were provided by the courts, it was impossible to analyze the type of institution, the defendant's age, the doctor's subspecialty, the existence of insurance, and the plaintiff's vision and age, all of which could have a significant impact on the amount of damages. However, since closed court cases that were the final results of a medical dispute were analyzed, this study was worthwhile as a basic data source to help doctors understand medical disputes and prevent lawsuits that may arise in the future with cataract surgery.

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