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Study of Legal Cases Involving Refractive Surgery in Japan and the United States by Using Court Case Databases

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In Japan, refractive surgery began to spread and was advertised widely from around 1995. In the United States, it became popular from around 1985. In this study, the court cases involving refractive surgery were compiled in Japan and the United States to analyze and compare the characteristics of the cases from each country. "Lexis" was used to refer to those in the United States and "Hanrei Master" to the Japanese cases. From those related to the sequelae of surgery, nine points were investigated—the year of decision, period of deliberation, victim's condition caused by the surgery, the point of illegality, the issue of the suit, among others. All plaintiffs examined in this study won their cases and large sums of money were awarded by the Japanese courts. By contrast, the majority of the plaintiffs lost their suits in the United States. This comparison revealed the differences that exist between the two countries in their laws, judicial systems, guidelines, related to the practice of refractive surgery, and the attitudes of ophthalmologists and reactions to medical mistakes.

The biggest dispute issue in the court cases of both countries is the question as to whether informed consent was enough or not. It was found that prior to surgery, the Japanese patients had anticipated marked improvement in their visual acuity and therefore felt betrayed when the results did not measure up to their expectations. Ophthalmologists should try to make patients decide as to whether they undergo surgery. It is essential that patients be informed of both good effects and bad effects of the surgery. In both countries, non-ophthalmologists operate refractive surgery, take precedence of profits and compete in gaining patients who cannot afford to undergo refractive surgery economically. It is necessary to establish requirements of this surgery and of physicians selection and impose these requirements on them under strong leadership so that this surgery can advance toward to a right direction for patients. Further, information should be made public thoroughly to avoid medical mistakes and recurrence prevention system and funds for relieving medical victims in case should also be established.

Key words: refractive surgery, medical suits, informed consent, Japan, The United States

Introduction

In our country, the number of refractive surgeries has been rising rapidly for the past two or three years. This prevalence was further en-

Table 1 Indication for excimer laser refractive surgery (Japanese Ophthalmological Society, 2000: Refference No 6)

● Guidelines for excimer laser refractive surgery

A person who is older than 20 years and cannot wear eyeglasses or contact lenses. A person must be informed of the following explanation. A person comes under any of the following:

1) Anisometropia exceeding 2D
2) Astigmatism of the cornea exceeding 2D
3) Stable myopia with a refractive angle exceeding 3D

The amount of corrected refraction is less than 6D. It is intended that the refractive angle after surgery will be such that hyperopia does not occur in future. Doctors must perform refractive surgery in not more than 10D under enough informed consent.

● Interval which both eyes are to be operated on

① More than a month (PRK)
② More than seven days (LASIK)

hanced by mass communications media that touted the benefits of the procedure enjoyed by a well known professional golfer and a baseball player and the active advertising campaigns conducted by the physicians themselves. The history of this surgical procedure started in the 1940s in Japan[1]. RK (Radial keratotomy) is a surgical procedure in which incisions are made in the front surface of a patient's cornea to decrease its mid section by cutting on a pupil radially and correct myopia. Regrettably, RK did not progress in Japan because many of grave side effects occurred. This surgery was improved in the USSR in the 1970s and spread in the United States in the 1980s. RK was supplanted by PRK (photorefractive keratectomy) from 1990 when PRK was used extensively thanks to excimer laser authorization obtained. PRK involves removing the outer protective layer of the cornea by the excimer laser to change the refractive force of a patient's cornea and correct refractive error. In addition, LASIK (laser-assisted in situ keratomileusis) quickly spread from around 1995[2]. This surgical technique is the way to remove the superficial cornea and turn it to the original position after treating corneal stroma with the PRK technique. Refractive surgery began to be recognized from around 1995 in Japan where the excimer laser was authorized to be used in 2000[3].

The purpose of this surgery is to improve the quality of one's vision (QOV). It is conducted on a cornea that is anatomically and optically normal. Thus the basic idea behind this procedure[4] differs radically from other ophthalmological procedures that are applied to treat ocular lesions. This procedure, a revolutionary one, was initially applied to a special segment of the population (e.g., professional athletes, airline pilots, and entertainers) who found the use of eyeglasses and contact lenses disadvantageous. The success witnessed by these individuals led to popularity among general public. The procedure is closely related to medical economics in the following manner: its cost is high in comparison with other ophthalmological surgeries (¥400,000 to ¥700,000 vs. ¥300,000 for cataract or glaucoma); the upkeep of the machines and other systems needed for surgery is costly; extensive advertising campaigns are necessary to cultivate new markets and recruit patients; and business managers (other than medical personnel) must be in control of the organizational management and vision-care companies finance the operation[5]. The Japanese Ophthalmological Society has shown (Table 1) the summary of indications for refractive surgery[6].

Table 2 Number of cases related to medical department newly accepted at the district court in Japan from 1998 to 2001 (formal announcement by the Supreme Court)

Year	1998	1999	2000	2001
Number of new acceptances	622	643	775	805
Medical department				
Internal medicine・Pediatrics	157	169	202	234
Surgery・Orthopedics	217	202	286	286
Obstetrics and gynecology	89	109	114	108
Psychiatry (neurology)	14	11	29	28
Dermatology・Urology	18	22	21	25
Ophthalmology	**18**	**22**	**27**	**29**
Otolaryngology	15	19	20	22
Dentistry	50	43	39	48
Others	44	45	50	65
Total	622	642	788	845

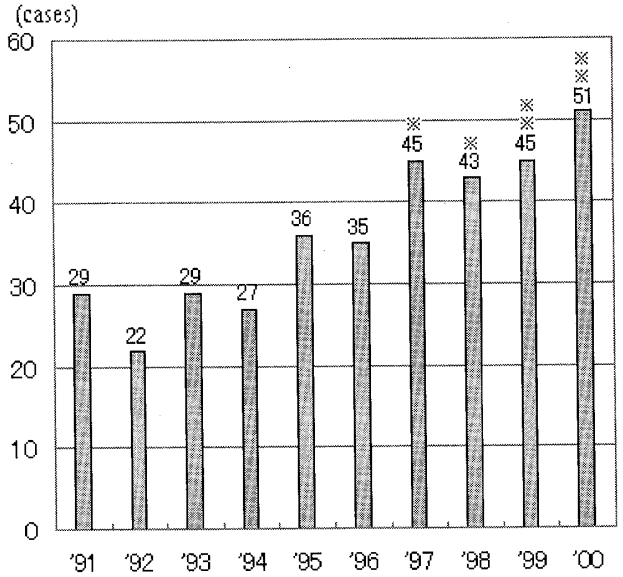

Fig. 1 Number of medical dispute cases of ophthalmology in Japan[8]
※: one refractive surgery, ※※: two refractive surgeries.

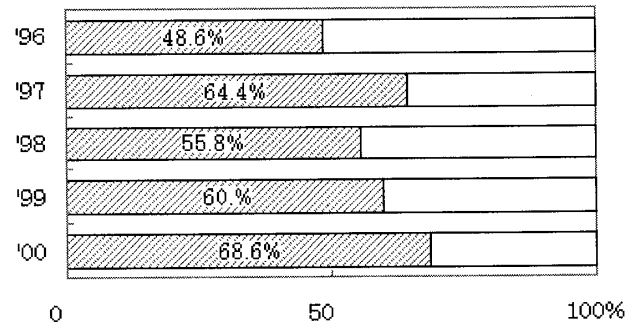

Fig. 2 Breakdown of surgeries of medical dispute of ophthalmology (Japan Ophthalmologists Association)

From a survey conducted by the Japan Medical Jurisprudence Subject Examination Committee between 1981 and 1991 on individuals who succumbed to medical accidents, medical specialties were ranked as follows in descending order of the frequency of medical incidents: surgery, internal medicine, obstetrics and gynecology, orthopedics, dentistry, and otolaryngology. Ophthalmology is not included at all[7], because this specialty is concerned with only a small part of the body and any treatment is not likely to result in a fatal outcome. The suits related to ophthalmology are brought to the court not because of a loss of life but as complaints related to a deterioration in one's visual acuity. The number of new cases accepted by district courts and their distribution among various medical departments between 1998 and 2001 are shown in Table 2 [statistics compiled by the Civil Affairs Bureau of the General Secretary of the Supreme Court]. The number of new cases increased remarkably, among which the number of ophthalmology cases has accounted for from 2.9% to 3.6% of the total cases, a slight increase. According to the 1991～2000 survey conducted by the Japan Ophthalmologists Association on medical disputes, they increased 1.76 times for ten years (Fig. 1). All cases came before the court, among which more than 50% were related to surgical procedures (Fig. 2). Since the report made in 1997 for the first time, refractive surgery cases have occurred for four consecutive years (Fig. 1)[8].

Up to the present, there have been no reports on the trends or status of court cases related to refractive surgery in Japan. The current study was conducted to analyze and evaluate court

cases related to refractive surgery in both the United States and Japan.

Object and Method

To examine Japanese court cases, "Hanrei Master", a database on Japanese legal cases, was used, while "Lexis", a database on foreign legal cases, was the sources of information for those reported overseas. The former carries the information on and summary of court cases that were published in private magazines; and a summary, major passages, and explanations of important precedents in its entirety since 1947, the inceptive year of the current court system. As of the first half of 2002, there were 110,513 cases. The data are updated twice a year. The search parameters include the date of decision, referenced provision, key words, and the names of the courts. "Lexis" is a database on foreign legal cases that are cited most frequently (classified by area and field) and it carries the whole citation of the law, court cases and literature from the EU and each country (the United States of America, the United Kingdom, New Zealand, France, China, and Canada), as well as international law. Much data have been added since 1950. It also carries data related to the United States, including the precedents of the Federal Government from 1789, regulations and laws of the Union, the official gazette of the State Department, minutes on assembly bills and deliberations by the Federal Government, official documents issued by the President, administrative directives of the Federal Government, and precedents and laws of all States. The searchable parameters include persons concerned with the suits, the case numbers, names of courts, dates of decision, names of attorneys and judges, and key words.

Court cases were searched by using the key words, "myopia" and "refractive surgery." From the cases retrieved in this manner, those related to postoperative sequelae were extracted and the whole passage for these were obtained to examine the following nine parameters:

① The content of the case
② Provisions referred
③ Name of the matter
④ Year of decision, year when the suit was initially brought to court, and the duration of deliberation
⑤ Conclusion of the suit (outcome of the trial)
⑥ Final court (with or without subsequent appeal)
⑦ Alleged victim's age, gender and condition caused by the surgery
⑧ Amounts claimed and approved
⑨ Point of illegality and issue of the suit

Besides the period of deliberation, the amounts claimed and approved were compared with other court cases related to ophthalmology in Japan. These were retrieved by using the key words, "ophthalmology", "glaucoma", "cataract" and "retinopathy of prematurity (ROP)".

Results

1. Court cases that were retrieved and court cases analyzed

A search by using the key words, "myopia" and "refractive surgery" yielded 12 cases from Hanrei Mater and 64 cases from Lexis. The entire passage was analyzed in these 64 cases, which are in English. The postoperative sequelae were the central theme of three of 12 cases from the Hanrei Master and five of the 64 extracted from Lexis. In addition, 61 ophthalmology-related cases in Japan were extracted. Main results are shown in Table 3.

2. The current status of court cases related to refractive surgery in Japan

1) Content of court cases

Only 3 were related to refractive surgery and all were concerned with sequelae after surgery. These victims had undergone RK or LASIK.

2) Reference provisions

Table 3 The results of the suits

	Cases	Year when the suit was first brought to court	Year of decision	Duration of deliber-ation	Result	Appeal	Kind of surgery	Plaintiff's gender (the number of plaintiff's)	Post-operative condition	Defendant	Key points of the suits
Japan	1	1994	1998	4y	won	+	RK	M(1)	OV, A, NVA, G, CS Vd 0.06→0.7 Vs 0.07→0.9	Doctor Hospital	The obligation to provide an explanation
	2	1993	1998	5y	won	+	RK	M(32) F(15)	OV, A, G, CS, NVA	Doctor Hospital	A violation of the duty of the procedure beforehand
	3	1999	2000	1y	won	+	LASIK	F(1)	NVA Vd 1.0→0.6 Vs 1.0→0.8	Doctor	The obligation to provide an explanation
USA	4	1995	1999	3y6m	lost	+	PRK	F(1)	Vd 0.1→0.5	Doctor Hospital Laser conpany	A lack of informed consent Professional negligence
	5	1997	2002	4y8m	lost	+	PRK	F(2)	G, H	Doctor Hospital	A medical mistake
	6	1995	2000	4y10m	lost	+	RK	F(2)	G, H, F Vd=Vs=1.0	Administ-ration	A dispute concerning compensation from Social Security benefits
	7	1989	1991	2y8m	lost	+	RK	M(1)	Vs→0.05, RD	Doctor Hospital	A lack of informed consent Neglect in postoperative care
	8	1996	2002	6y	lost in part	+	RK	M(1)	VA no change, G	Doctor	A lack of informed consent A medical mistake Neglect in postoperative care

OV: overcorrected, A: astigmatism, G: glare, CS: decline of night contrast sensitivity, NVA: decline of near visual acuity, H: hazy vision, F: fluctuaring vision.

For these three, the reference provisions were cited as follows: The reference provision cited in all three is Article 709 of the Civil Law (general condition and effect of an illegal act); "When a man infringes on another's rights intentionally or accidentally, he must assume responsibility for compensation for damages." The reference cited in two cases Case 2[9] and Case 3[10] is Article 415 of the Civil Law (precondition for compensation for damages by default on an obligation): "When the debtor fails to carry out his obligation, the creditor may claim compensation for damage. When the debtor cannot carry out his responsibility, the creditor may still claim the same." Article 715 of

the Civil Law (user's responsibility) is referred to in one case Case 2: "A party employing others to conduct its business must assume responsibility for compensation for damage when its employee causes a loss to unrelated others through performing such business."

3) Name of the matter

All three cases were involved in compensation for damage. One case Case 2 was brought to the court by a group of 47 plaintiffs, while Case 1[11] and Case 3 were brought by individual plaintiffs. The court ordered the defendant to pay in all cases.

4) Year of decision, year when the suit was first brought to court, and duration of deliberation.

Case 1: decision in 1998, initiated in 1994, lasted for four years. Case 2: decision in 1998, initiated in 1993, lasted for five years. Case 3: decision in 2000, initiated in 1999, lasted for within one year.

The average duration for the three cases was 3.3 years. However, all cases have appealed to higher courts and the time required to reach a final decision is still unknown. In our country, the average deliberative time by the court for cases related to ophthalmology is 9.3 years for ROP, five years for glaucoma, and 4.5 years for cataract.

5) Court decision (outcome of the suits)

The plaintiffs won in all cases. For the group action Case 2, the postoperative ocular condition was judged to be normal in 31 of 47 plaintiffs.

6) Names of the courts where the appeals were last made and whether further appeals were made.

The last court was the Okayama District Court for Case 1 and Osaka District Court for Case 2 and Case 3. All three cases are currently being appealed to higher courts.

7) Plaintiff's age, gender and condition caused by surgery.

The victims were a man Case 1 and a woman Case 3. The group action Case 2 was brought by 32 men and 15 women. There were no mentions of age in any of the cases.

The surgical procedure was held responsible for the following conditions: for Case 1, surgery improved the preoperative vision without glasses of 0.06—refractive power 4.75D cyl-0.5 Ax105° (right eye) and 0.07—refractive power 2.5D cyl-1.5 Ax80° (left eye) to 0.7 (right) and 0.9 (left). But the far refractive angle was overcorrected from myopia to hyperopia. In addition, astigmatism was aggravated. Near vision deteriorated. The patient became aware of glare (glaring as if ice appeared to be scattering around an image) and decline of night contrast sensitivity.

For Case 3, the preoperative vision was 0.02 (corrected vision 1.0) for the right and 0.03 (corrected vision 1.0) for the left eye. After surgery, the vision was 0.05 (corrected vision 0.6) for the right and 0.06 (corrected vision 0.8) for the left. The corrected near vision after surgery was 0.3 for both eyes, which was considered to be a very poor surgical outcome.

For Case 2, the details were unavailable from the database except for one person, who represented a difficult case (the so-called "one eye" because the vision of the left eye was not available due to keratoconus). The surgical procedure conducted on right eye resulted in overcorrecting myopia to hyperopia and irregular astigmatism. The right near vision was reduced from 0.8 to 0.4. The patient experienced glare and a decline in contrast sensitivity both night and day.

8) Monetary sums claimed and acknowledged.

Case 1 claimed ¥17,270,000 for compensation but the court acknowledged ¥3,300,000 (of which ¥3,000,000 was for consolation). Case 3 claimed ¥28,160,000 and ¥15,000,000 was approved. For Case 2, the 47 plaintiffs claimed a combined sum of ¥470,000,000. The court deci-

sions for 16 plaintiffs was: ¥10,000,000 for five, ¥3,420,000 for three, ¥7,450,000 for two, and ¥7,730,000, ¥6,580,000, ¥3,800,000, ¥2,454,000, ¥2,216,000, ¥1,780,000 for one person each. The total sum acknowledged for these 16 plaintiffs was ¥99,720,000. The average amount of money approved per person was ¥6,230,000.

In one case cited above Case 2, the amount claimed (¥10,000,000) was also approved by the court for one plaintiff. Of this sum, the court specified ¥420,000 as the cost for the surgery, ¥4,100,000 as compensation for the after-effects, ¥14,910,000 for lost profit and ¥1,900,000 for the lawyer's fee, for a total of ¥21,330,000. The amount approved for Case 3 was larger than for the other cases involving RK because the court recognized both a violation of an obligation to explain and medical negligence.

The average amounts involving ophthalmology claimed in court in this country were: ¥50,260,000 for cases of ROP, ¥10,720,000 for glaucoma, and ¥14,150,000 for cataract, while the average claimed for surgical correction of refraction was ¥114,100,000. The average amount approved by court was: ¥ 24,710,000 for ROP, ¥6,290,000 for glaucoma, ¥8,360,000 for cataract, and ¥6,560,000 for ocular refractive surgery. The last is smaller when compared to the amounts set for ROP (the plaintiffs have nearly been blind from almost the time when they were born) but is comparable to those for other ophthalmic conditions.

9) Issues of illegality and key points of the suits

In Case 1, the doctor and the hospital were the defendants; in Case 2, the doctors and the hospital were named as defendants; and Case 3 brought the suit against the physician. The issue in the suit was a violation of the obligation to provide an explanation of the procedure for Case 1 and Case 3, while for Case 2, the issue was a violation of the duty of the doctor and the hospital to disclose the details of the procedure beforehand.

The defendants of Case 1 and Case 3 should have fully explained the risk of complications involved in LASIK and RK; and after the patients comprehended the procedures, they should have obtained the plaintiffs' consent to the operation. Instead, the physicians only gave vague assurances such as: "There is no possibility of failure; You will be able to see ten times better than you can now". For Case 2, the physicians even asserted that RK was absolutely safe refractive surgery, with no risk for developing hyperopia. It was revealed that about half of the patients were rushed into undergoing the operation on the day when the procedure was explained to them: the physicians told them that their service may not be available if they miss the opportunity then. In Case 3, an error in performing the surgical procedure was recognized (the corneal flap was not dehisced or affixed accurately during surgery); but no negligence was found in the way the patient was cared for after surgery (appropriate steps were taken to prevent a postoperative infection or corneal opacity).

In Case 2 and Case 1, both the physicians and the business organizations, which are the de facto managing bodies of the hospitals, were listed as co-defendants; but the user responsibility of the business organization was recognized for the former only, which was brought to court by 47 individuals. The advertising conducted by the company, methods to entice the public to undergo RK, details of the surgery, and the high cost of the procedure (¥700,000 for both eyes) are all indicative of a highly risky medical procedure that was intended to yield a high return.

Up to now, defects in one's far vision were evaluated on the basis of what a person might receive under workmen's compensation or as a consequence of injuries to be compensated by automobile insurance. For legal cases involving refractive surgery, however, disturbed near vi-

sion and a decline in contrast sensitivity are recognized on equal terms with defective far vision.

3. Current status of court cases involving refractive surgery in the United States

1) Content of the court cases

Of the 64 cases retrieved, 16 were related to refractive surgery. Among these, five were related to the sequelae of the surgical procedure. The remaining 11 cases were brought to court for the following reasons: United States Ophthalmological Society and the State Medical Society brought suit against optometrists who performed PRK. Optometrists are unlike ophthalmologists, licensed to give visual care but are not allowed to perform surgery. Some cases have issue of reimbursement by the medical insurance for the cost of the procedure although the surgery itself was a success and have the problems with employment after surgery in spite of a successful procedure. For the five individuals who suffered from sequelae, three had undergone RK and two, PRK.

2) Reference provisions

It is not customary in the United States to list legal references.

3) Name of the matter

Five were concerned with compensation for damages.

4) Year when judgment was rendered, suit first brought to court, and duration of deliberation.

Case 4: decision in 1999, initiated in 1995, lasted for 3.5 years. Case 5: decision in 2002, initiated in 1997, lasted for four years and eight months. Case 6: decision in 2000, initiated in 1995, lasted for four years and 10 months. Case 7: decision in 1991, initiated in 1989, lasted for two years and eight months. Case 8: decision in 2002, no mention of the year when initiated, lasted for about six years.

The average duration of the suits was 4.4 years.

5) Outcome of the suits (court decision for or against plaintiff)

Of the five suits, four plaintiffs lost their cases. In only one Case 8, the plaintiff won in part because of a medical mistake and failure on the part of the defendant to obtain informed consent in a complete form.

6) Name of the final court and appeals that were made.

All appealed. Only one Case 4 constituted one case with five trials, while each of the other four was a single case with two trials. The final appeal was made at the Federal Court of Appeals Case 4, Superior Court of Pennsylvania, Case 5, United States District Court Case 6, Court of Appeals of Tennessee Case 7, and Appellate Court of Connecticut Case 8.

7) Plaintiff's age, gender and outcome of surgery

The plaintiff's age and gender recorded in court were listed as follows:

Case 4, a woman, age unknown; Case 5, a woman, age unknown; Case 6, a 32-year-old woman; Case 7, a 42-year-old man; Case 8, a man, age unknown.

The following were listed as the outcome of the surgical procedures: two cases, Case 4 and Case 7, postoperative reduction in visual acuity [Case 4, the corrected vision of the right eye was reduced from 0.5 to 0.1 after surgery and Case 7, the vision of the left eye was reduced to 0.05 due to retinal detachment after surgery]; Case 5, no mention of postoperative changes in visual acuity but a decline in peripheral vision, glare and hazy vision were reported; Case 6, her eyesight remained unchanged but glare was reported; and Case 8, glare, hazy vision, and fluctuating vision were experienced although vision was corrected to 1.0 for the right and left eyes after surgery.

8) Amounts claimed and recognized

No monetary amounts are listed in the records

in the United States.

9) Point of illegality and reasons for disputes

The plaintiff for Case 4 brought the suit against the physician, the hospital and the manufacturer of the laser system. For Case 5 and Case 7, the plaintiffs brought suit against the physician and the hospital. For Case 8, the plaintiff sued only the physician who performed the operation. For Case 6, the plaintiff sued the Commissioner of the Social Security Administration.

The issues at dispute were; Case 4, a lack of informed consent and professional negligence; Case 5, a medical mistake; Case 6, a dispute concerning compensation from Social Security benefits; Case 7, a lack of informed consent and neglect in postoperative care; Case 8, medical mistakes; a lack of informed consent, and a violation of contract.

For Case 4, the patient had been informed that the laser was still in the experimental stage. It was judged that the physician should not be held responsible for the postoperative decline in the patient's vision. Thus the case was dismissed.

For Case 5, no fault was found on the side of the medical staff and the case was dismissed.

For Case 6, the plaintiff brought the suit so that she might qualify for disability insurance and compensation for the income that she was unable to receive due to failure of the surgical procedure; however, her vision was 1.0 in both eyes and it was judged that she was able to work. Thus the case was dismissed.

For Case 7, the plaintiff complained that he was not informed of the possibility that he might die during surgery or about the risk of postoperative blindness. In addition, the plaintiff complained about myodesopsia after surgery but the physician was unavailable. Meanwhile the condition progressed to retinal detachment. The final postoperative vision was 0.05. However, the informed consent signed by the plaintiff also contained a detailed explanation by the physician; and RK was unlikely to cause retinal detachment. Thus all claims were dismissed.

For Case 8, the physician in charge clearly explained to the plaintiff that RK would correct the vision to 1.0 in his right eye but the vision on the left would be 0.5. The vision remained unchanged and the plaintiff noted glare. The suit, brought for negligence leading to these medical conditions and an incomplete informed consent, was rejected. Only a violation of the contract was recognized here. Based on the Law of Act of Unfair Trade, the case was considered to satisfy the following three conditions: ①There must be a representation, omission, or other practice likely to mislead the consumer; ②Consumers may interpret the contents of the message reasonably under certain circumstances; ③Misleading representation, omission, or practice may affect consumers' decisions or conduct.

Discussion

Among the court cases, RK was the predominant form (98%in Japan and 60%in the United States) of refractive surgery that the plaintiffs underwent. The application of RK had begun in the United States in the latter half of the 1970s. In 1981, a PERK study (Prospective Evaluation of Radial Keratotomy) was started to evaluate the effect and safety of RK. Since then, interim reports have been published in 1, 3, and 5 years after its inception, and in 1994 the results of the study for 10 years, which were made public, revealed specific postoperative problems[12]. The widespread use of the excimer laser since then has paralleled the reduced number of cases undergoing RK, which is hardly performed today. In the United States, the application of PRK was initiated in the 1990s. Since the FDA (Food and Drug Administration; a federal agency that is equivalent to the Ministry of Health and Welfare in Japan) permitted the use of excimer lasers for refractive surgery in 1995, the number of this

surgery increased rapidly[13]. After LASIK was developed, the number of these surgeries conducted grew at a dramatic rate while technological innovations such as PRK and LASIK followed.

According to the statistics in America, the number of refractive surgeries conducted there was 15,000 in 1995; but it increased in the range from 1.3 to 1.5 million in 2000[14], an increase of 100 times in five years. There is no field such as the refractive surgery among ophthalmological surgeries which has achieved technological innovations dynamically. With a dramatic gain in popularity overseas in the background, non-ophthalmologists (such as surgeons specializing in cosmetic surgery) played an active role in introducing refractive surgery to this country, while ophthalmologists remained hesitant in including refractive surgery in their practice due to the historical background and unsuccessful experiences.

In Japan, RK was initiated in the 1940s. Through bitter experience—frequent development of bullous keratopathy associated with the procedure—ophthalmologists learned to be very cautious and the surgical modality never became very popular. Unlike conventional ophthalmological surgery that is targeted to a diseased section of the eye or performed for some urgent purpose, this surgery is not urgent surgery. Understandably, it is not covered by health insurance. It is said that the average going rate for this surgery is between ¥400,000 to ¥700,000 for both eyes. The surgical fee for cataract or glaucoma, which is covered by health insurance, is ¥300,000, which shows how expensive refractive surgery is. Thus higher profits can be expected from this procedure; commercial concerns compete in attracting prospective patients and subsequent greater monetary gains through flamboyant, often inaccurate advertising campaigns.

The Japanese Ophthalmological Society, which had been taking a passive stance on this refractive surgery, finally came out with "Guidelines for Refractive Surgery" in 1993. In 2000, the Ministry of Health and Welfare approved corneal surgery by laser for correcting one's refraction.

This surgery is intended to improve one's QOV. QOV means the fact that it looks not only good but also comfortable. In fact, although visual acuity was recovered to nearly 1.0 after surgery, and because QOV was deteriorated due to symptoms such as glare and decrease in contrast sensitivity, patients both in Japan and the United States brought their cases to courts. Patients in the United States lost their cases. In Japanese cases, compensation was decided according to decline in contrast sensitivity, the extent of near vision disorder, but the condition and standard of assessment for glare in this cases were not decided then and it was not taken up as the basis of ill effects. Thus, if post-surgery visual acuity was recovered to over 0.7 even if glare emerged, patients lost their cases. Visual function after refractive surgery should be assessed by both visual acuity and functional sight.

To achieve this end, the establishment of a surgical indication is needed. For example, mid-level myopic is very favorable in near sight, but this favorable condition will become extinct if people undergo refractive surgery. In future, patients are sure to be grown farsighted even if they are free from glasses and contact lens thanks to refractive surgery. Because it is impossible for this surgery to respond to refraction which changes as patients become older. In our country, the Japanese Ophthalmological Society organized a committee to draft guidelines for this purpose. In 1993, the first guideline for the indication of refractive surgery using an excimer laser was introduced, followed by the second in 1995. Since then, further studies have been conducted, which resulted in the introduction of the third guideline in 2000, the contents of which are summarized in

Table 4 Difference in guidelines of Japan and the United States

	Japan	USA
Range of correction indicated	Anisometropia of 2.0D or more	Astigmatism of 0.5D ~ 6.0D
	Astigmatism of cornea ≧2.0D	0.5D≦ myopia ≦14D
	3.0D≦ myopia ≦10D	0.5D≦ hyperopia ≦6.0D
		There is a detailed regulation for each type of laser.
Schedule of surgery	PRK: an interval of a month or more LASIK: an interval of 7 days	Both eyes may be operated on the same day or on two consecutive days. The choice is set at the discretion of the patients.
Age when surgery may be indicated	≧20 years old	≧18 years old
Occupational restriction	No restrictions	Some restrictions
Reimbursement by health insurance	None (The patient pays the full amount)	Partial

Table 1. The doctor who performs the operation should be a specialist who is affiliated with the Japanese Ophthalmological Society and is well-acquainted with physiology and diseases of the cornea and ophthalmic optics. For the use of this device, it is mandatory that the physician who is to perform the procedure have attended seminars designated by the appropriate academic society and ones organized by the manufacturers of these devices so that he may become familiar with them.

In the United States, "Guidelines for the Indications for Refractive Surgery" is issued not by the American Ophthalmological Society but by the FDA. Under strict supervision by the FDA, a clinical trial was started in 1988; and based on the results of this trial, the use of the excimer laser was approved for the correction of myopia in 1995, for astigmatism in 1997, and for hyperopia in 1998. The FDA guidelines of 2002 are voluminous: the content is similar to that published in Japan but a few major differences are listed in Table 4: the FDA specifies in detail indications for refractive correction and the amount to be corrected for each type of laser used (12 types of laser for LASIK and 16 types for PRK have been approved), whereas in Japan, there are no specifications according to laser type.

In the United States where refractive surgery is advanced, many laser system companies strive to develop and further expand business market from myopia to hyperopia, and patients must be at least 18 years old, whereas in Japan, the minimum age is 20; this age is recognized to be stable refractive volume in Japan and the United States, but it is questionable for refractive volume to be stabilized in 18 years old and it seems to be difficult for refractive volume to be stabilized even in 20 years old. Some states prohibit this surgical procedure for those in certain occupations (e.g., pilots and members of the Armed Forces) and patients are encouraged to consult with their employers, trade unions, or the authorities in the Armed Forces prior to undergoing the procedure. Among the court cases retrieved from Lexis, there was an example related to a refusal of employment as a pilot after refractive surgery. There are neither regulations related to occupations in Japan, nor are any discussed in the Guidelines. Standards for visual acuity, contrast sensitivity, and glare inspection results should be defined clearly in traffic regulations as assessment of visual function after refractive surgery. It is required in Japan that the person who performs the

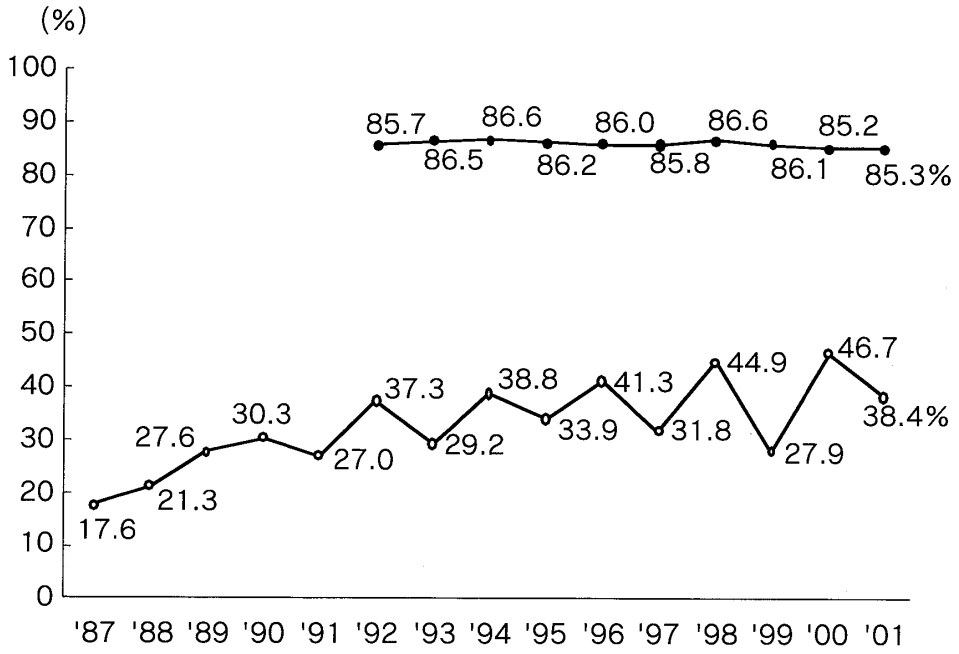

Fig. 3 The percentage of the plaintiffs who won by year in Japan (1987 to 2001)
○: medical suit, ●: general suit.

operation must be a physician, in particular a specialist who is skilled in handling the cornea and cornea-related diseases. In the United States, there is no mention of the qualification of the person who performs the surgery. The guidelines appear to circumvent the issue. In fact, there was a case in which an optometrist performed PRK, which resulted in a lawsuit brought by a professional organization[15]. It is preferable to observe Japanese guidelines to be able to respond to postoperative damage.

As noted above, only around ten years before have guidelines for the excimer laser refractive surgery been introduced in the United States and less than ten years before in Japan. PRK and LASIK have been conducted for less than 10 years so the results of a long-term observation are not yet available. Postoperative complications may be discovered in future: early display of information on these complications is important. The safety standard for refractive surgery (including the projection of its results) must be higher than surgical procedures that are performed for any other ophthalmologic diseases. Special attention should be paid to prevent all complications that may occur in association with this surgical procedure[16].

When a medical suit is brought to court specifying an illegal act in Japan, the patient must prove the shortcoming of the actions of the attending physicians, thus raising the possibility that the plaintiff may lose the case due to the expertise, confinement and exclusiveness involved. When a suit is instituted as a failure to carry out an obligation, the physician must prove that he has made every effort to discharge his responsibility. According to statistics of the Civil Affairs Bureau of the General Secretary of the Supreme Court of Japan, the rate at which plaintiffs win their suits about the conventional cases and medical mistakes is nearly 90% and between 30 and 35% respectively (Fig. 3).

Although the suits about medical mistakes are considerably less than those of the conventional cases, the former have increased gradually. In recent years, an illegal act and default on an obliga-

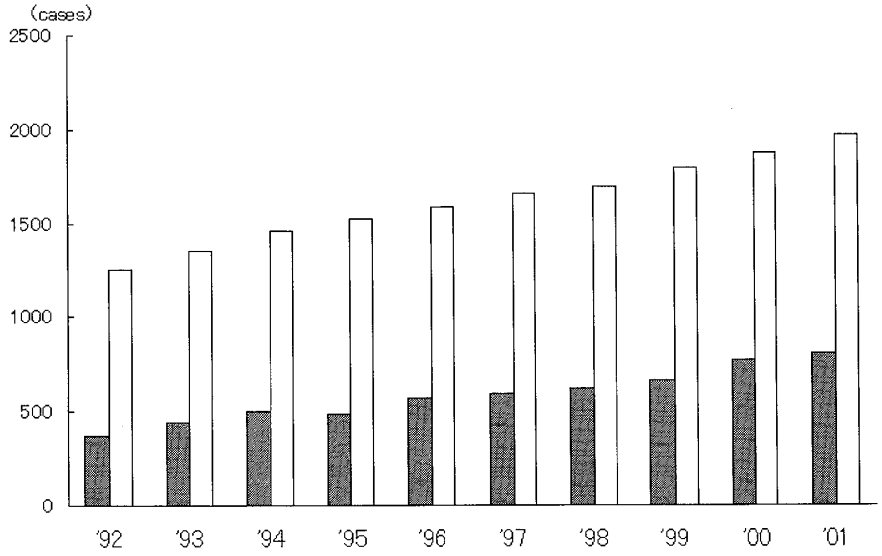

Fig. 4 Changes in the number of suits related to medical mistakes and the percentage of the plaintiffs' winning in Japan (Formal announcement by the Supreme Court)
▒ : new suits, □ : undecided matters.

tion have been considered to be the same. Although all the suits in this study were adduced as illegal acts, all plaintiffs won their cases. The main reason for this may be the inadequacy of the informed consents. Not having a complete form for the informed consent itself is a mistake, which is defined as an illegal act by Article 709 of the Civil Law. Refractive surgery is conducted on the eye that still retains a certain visual acuity; if a surgical procedure exacerbates the preoperative condition, the surgery itself is evidently the cause of the postoperative poor vision. Such a development can be easily proven by the patient. Recent reporting by the mass media of medical mistakes and iatrogenic accidents had the effect of pouring oil over a fire: it drove the public to distrust the medical profession in general. The number of lawsuits related to medical acts is rapidly increasing due to patients' rich knowledge and right consciousness (Fig. 4).

And many are being settled out of court, without ever being brought to court, nine times the number of lawsuits[17]. Therefore it is difficult to ascertain the exact number of legal actions related to medical care. Many cases related to compensation for damages from refractive surgery are also settled out of court. It is surmised that compared with other type of suits, the probability that the patient will gain a favorable result in a case of refractive surgery is much higher, whether settled out of court or not. Furthermore the Law of Consumers' Contract enacted in 2000 thoroughly applies to refractive surgery so the probability of plaintiffs winning their cases will further improve[18]. In the United States, where many of the suits were rejected by the courts, only a case that cited breach of contract prevailed. It was a case based on the Law of Unfair Trade, which is very similar in nature to our Law of Consumers' Contract.

In the United States, which is nicknamed a "lawsuit nation," physicians are thoroughly familiar with the practice of obtaining informed consent. For example, they organize seminars and distribute informative video tapes free of charge to educate patients. Physicians themselves attend informal courses to prepare a patient's agreement to surgery to avoid legal entanglements.

Table 5 The main contents of the negative aspects to be explained before refractive surgery

1. Problems
   1) It is a new surgical procedure. A long-term prognosis has not been established.
   2) The procedure cannot be repeated on the same person.
   3) There may be a gap between the estimation and actual rate of reduction of the myopic state and astigmatism.
   4) A certain period is necessary to stabilize the refractive angle.
   5) The procedure makes it difficult to wear a contact lens.
   6) It may cause the eyeball to burst if an external force is applied (RK).
   7) Ocular function may be compromised.
      a. Decline in corrected vision
      b. Change in daytime vision (RK)
      c. Decline in contrast sensitivity
      d. Occurrence of glare
   8) When a person develops presbyopia, myopia is advantageous for near vision.
   9) The patient may experience throbbing pain after surgery.
   10) It may become necessary to wear eyeglasses or a contact lens after surgery for further correction.
2. Complications
   1) Infection
   2) Corneal turbidity under epithelium (RPK)
   3) Development of astigmatism
   4) Repeated inflammation of the cornea
   5) Rise in the intraocular pressure (RPK)
   6) Dry eye (LASIK)
   7) Posterior keratoconus (LASIK)

Nothing takes place until both the physician and patient come to a complete agreement. With such a background, it is difficult for the court to accept the possibility of a lack of informed consent. The plaintiff customarily loses his case when this is the issue. Among all Japan-US cases, all Japanese cases and three cases out of five cases (75% of all US cases) deal with a lack of informed consent. It shows numerically how important is a lack of informed consent to both patients and doctors. However, it should be noted that in the United States, compared to Japan, a tremendous number of cases are brought to court; a far greater number are settled out of court; and there are notable differences between the legal systems of the two countries. Therefore simple numerical comparisons are difficult vis-à-vis the rate at which plaintiffs win or lose their legal actions and the duration of deliberation.

It is necessary for ophthalmologists to observe the surgical indication of refractive surgery at their hospitals. This enables them to avoid the situation that practicing on eyes with slight refractive disorder regardless of an original surgical indication is made for economic reasons, massive funds required for investment in facilities and that flippant advertisement spreads. The present situation can be immediately recognized to be shameful. It is also necessary for the Ophthalmological Society and the FDA to determine requirements for the persons who conduct this type of surgery and the surgical indication and to guide right adherence to them. It is important to fully explain not only the good effects of refractive surgery but also negative aspects such as post surgery complications and side effects before the refractive surgery. Table 5 shows the main contents of the negative aspects to be explained to patients before refractive surgery. It is essential to explain the prospective outcome and inherent risks involved orally, concretely and easily prior to the operation[19]. Protection of patients

should be considered as the highest priority in emergency and tie-up with advanced medical institutions which can operate corneal transplant should be established.

What should be done in case of medical mistakes is to acquire facts and analyze causes at first. Next, in order to establish system for eliminating reoccurrence, medical institutions should make public surgery achievement, complications and side effects. Studies on how to prevent these complications will not only affect the results of future treatment; it will also offer very valuable information for the patient in selecting a treatment. In the United States, inspection systems of hospitals and doctors are established in each state to decrease medical suits and inspection results are required to be made public not for criticism but education of staff and promotion of better medical treatment for patients. Many doctors support peer review system of medical record, renewal system of doctors' certificates not available in Japan, introduction of training system and stricter punishment[20]. Successful methods in foreign countries should be introduced as means for preventing medical mistakes from happening as much as possible in Japan as well.

Finally, the system for the relieving victims must be established. There are systems which support them in case of medical mistakes medically and socially in the United Kingdom and New Zealand including North European countries[21]. These systems relieve patients' damages, regardless of mistakes on the part of medical institutions. The fund for the relief of the victims of vaccination and medicine-produced side effects was enacted in 1979 in Japan. Refractive surgery can be covered by this system.

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判例データベースを利用した日米の屈折矯正手術裁判例に関する考察

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1995年頃より，日本において屈折矯正手術（視力矯正手術）が普及しはじめ広く宣伝広告されている．アメリカでは，既に1985年頃より普及している．本考察においては，日米の屈折矯正手術裁判例を収集解析し，その特徴を明らかにすると共に双方を比較検討した．アメリカ裁判例の検索に『レクシス』を，日本裁判例の検索に『判例マスター』を使用した．抽出した両国の裁判例の中で，術後に後遺症の残ったものについて，判決年度，判決期間，被害者の転帰，違法点・論争の争点など，9項目について検討した．日本では，今回抽出された裁判例のすべてで原告が勝訴し，高額の損害賠償が認められている．一方，アメリカではそのほとんどが原告の敗訴であった．この背景には両国の法律・司法制度とそれをとりまく環境，医療指針，医師側の対応の違い，医療過誤に対する対処の違いがあると考えられる．

両国の裁判例における最大の争点はインフォームドコンセントが十分であったか否かである．患者は，屈折矯正手術によって現状よりもよく見えるようになることを期待し，信じて手術を受ける．それだけに結果が悪かった場合の患者の後悔の念は非常に強い．術者は患者が手術を受けるか否かを患者自身が判断できるように努めなければならない．そのためには，手術のプラス面，マイナス面の両方についてインフォームドコンセントを尽くすことが要求される．また，両国ともに眼科医以外のものの手術への関与，利潤追求を優先し手術適応外の患者の獲得などの問題点がある．

屈折矯正手術が患者にとって正しい方向に進むためには強力なリーダーシップのもとで手術適応基準，および術者選定基準を定め，それを順守させる必要がある．さらには医療過誤防止のための徹底した情報公開，再発防止システムの構築，万が一のための医療被害者救済基金の設置などの対策が進められなければならない．