MEDICAL MALPRACTICE PREDICTORS AND RISK FACTORS FOR OPHTHALMOLOGISTS PERFORMING LASIK AND PRK SURGERY

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ABSTRACT

Purpose: To identify physician predictors in laser-assisted in-situ keratomileusis (LASIK) and photorefractive keratectomy (PRK) surgery that correlate with a higher risk for malpractice liability claims and lawsuits.

Methodology: A retrospective, longitudinal, cohort study comparing physician characteristics of 100 consecutive Ophthalmic Mutual Insurance Company (OMIC) LASIK and PRK claims and suits to demographic and practice pattern data for all active refractive surgeons insured by OMIC between 1996 and 2002. Background information and data were obtained from OMIC underwriting applications, a physician practice pattern survey, and claims file records. Using an outcome of whether or not a physician had a prior history of a claim or suit, logistic regression analyses were used separately for each predictor as well as controlling for refractive surgery volume.

Results: Logistic regression analysis demonstrated that the most important predictor of filing a claim was surgical volume, with those performing more surgery having a greater risk of incurring a claim (odds ratio [OR], 31.4 for >1,000/year versus 0 to 20/year; 95% confidence interval [CI], 7.9 –125; $P = .0001$). Having one or more prior claims was the only other predictor examined that remained statistically significant after controlling for patient volume (OR, 6.4; 95% CI, 2.5 – 16.4; $P = .0001$). Physician gender, advertising, preoperative time spent with patient, and comanagement appeared to be strong predictors in multivariate analyses when surgical volume was greater than 100 cases per year.

Conclusion: The chances of incurring a malpractice claim or suit for PRK or LASIK correlates significantly with higher surgical volume and a history of a prior claim or suit. Additional risk factors that increase in importance with higher surgical volume include gender, advertising, preoperative time spent with patient, and comanagement with optometrists. These findings may be used in the future to help improve the quality of care for patients undergoing refractive surgery and provide data for underwriting criteria and risk management protocols to proactively manage and reduce the risk of claims and lawsuits against refractive surgeons.

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INTRODUCTION

We live in a culture in which displeased patients have increasingly turned to litigation as a means of obtaining redress from perceived deficiencies in the quality of care received from their physicians. Diminishing trust in physicians, exaggerated claims of miracle cures, and widespread media publicity hinting at the wonders of newly developed medical technology have resulted in unrealistic patient expectations and have fueled the development of our litigious society.

The incidence and prevalence of medical errors,[1] combined with the upward spiraling of court monetary awards, have created a system that is both enticing and financially rewarding for attorneys.[2] Some lawyers have rationalized medical malpractice litigation as a tool for error reduction and as a means of spurring physicians to improve the quality of medical care rendered to their patients.[3] Those in the management field strongly disagree and view medical malpractice litigation as a form of retrospective punishment for the individual physician that contributes little to system-wide quality improvement.[3]

The incidence of malpractice claims is particularly high for elective surgical procedures, especially those in which the cost of the procedure is borne by the patient rather than by third-party payers.[4] The advent and growing popularity of refractive surgery is a case in point. Over the past several years, consistent with its growing popularity, the incidence of malpractice cases related to laser-assisted in-situ keratomileusis (LASIK) and photorefractive keratectomy (PRK) has risen steeply. Data from the Ophthalmic Mutual Insurance Company (OMIC) have shown a threefold increase in LASIK claims and suits

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between 1998 and 2001.[5]

The present study has utilized data from OMIC files and from responses of OMIC-insured refractive surgeons to a detailed questionnaire in order to identify and analyze factors that correlate with a higher risk of malpractice liability claims and lawsuits. Additional analyses of procedure and patient data that might identify other risk factors in these cases have also been performed. The findings should assist the development of guidelines for improved quality of care for surgery patients. They may also provide useful information for underwriting criteria and risk management protocols to enable proactive reduction of future claims and lawsuits against refractive surgeons.

METHODS

The study was designed to identify physician predictors and overall potential risk factors for incurring a claim or suit for LASIK or PRK. A "predictor" is defined as a statistically significant ($P<.05$) characteristic in a physician's professional profile (ie, demographics or practice patterns) that indicates the likelihood that an event (claim or suit) will occur. A "risk factor" is defined as an important, but not necessarily significant, characteristic in a physician's, patient's, or case profile that indicates the likelihood that an event (claim or suit) will occur.

An analysis of physician, patient, and case characteristics from 100 consecutive OMIC LASIK and PRK claims and suits was undertaken and compared to demographic and practice pattern data for all active OMIC-insured refractive surgeons between 1996 and 2002. Data were derived from a detailed review of physician underwriting applications, a physician refractive surgery practice pattern survey, and both open and closed claim files.

PHYSICIAN UNDERWRITING APPLICATIONS

The standard OMIC insurance application form includes demographic and professional background information for the physician (Appendix 1). The standard policy excludes coverage for refractive surgery. A physician applying for malpractice liability coverage for these operations must complete both the standard underwriting application and a supplemental application for each refractive procedure. The supplemental application includes multiple questions specific to the refractive procedure (Appendix 2) and must be approved by the underwriting staff or physician committee before coverage is granted.

In addition, as a condition of coverage, insured physicians must agree to comply with OMIC's standard refractive surgery guidelines and recommendations specific to a particular procedure (Appendices 3 and 4). The responses to the questionnaire must fall within these guidelines for coverage to be approved. Pertinent information from these applications and questionnaires was entered into the physician database.

PHYSICIAN REFRACTIVE SURGERY PRACTICE PATTERN SURVEY

Between January 2000 and December 2001, 750 refractive surgery surveys were sent out with renewal applications to all OMIC insured who had applied for LASIK or PRK coverage during this period. Seven hundred and eight completed surveys were returned, for a response rate of 94.4%. The surveys requested updated information on the insured physician's practice patterns and specifically requested the information listed in Table I.

The data from these surveys were analyzed, and surgeons with active refractive surgery practices, including those with and without claims or suits, were identified. A comparison with statistical analysis was performed between those physicians who were active refractive surgeons with a claim or suit and the entire survey group. For the purposes of this study, a claim was defined as a written demand by the patient (plaintiff) for compensation from a medical incident. A claim may be denied or settled and, if denied, the plaintiff may file a suit. A suit was defined as a formal legal action initiated in the courts and requiring a formal response from the physician (defendant). There typically is a period of discovery and then either a settlement or a jury trial.

CLAIMS FILES

The first OMIC claim or lawsuit for PRK or LASIK was filed in August 1997 following PRK surgery performed in April 1996. Beginning with this case, 99 additional consecutive claims or suits filed against individuals or entities between 1996 and 2002 were then reviewed, and pertinent information was entered into the database. For the purposes of this study, "individuals" were defined as specific ophthalmologists, whereas "entities" were defined as a form of business organization, such as a partnership, professional association, or corporation that may need its own separate liability coverage.

DATA ENTRY

All data entries from the claim and suit files were divided into three categories: physician (defendant) data, case-specific information, and patient (plaintiff) background. The data collected included detailed information believed to be relevant as potential risk factors for medical malpractice litigation. There were a total of 47 separate data entries for each claim or lawsuit (4,700 total entries) with only 729 missing data entries (15.5%) for the entire study. Information within 43 of these categories (Table II) was then collated and compared to the data that were available for statistical analysis from the survey of the physician group. Missing data were requested from the physician (defendant) or defense attorney by mail (Appendix 5).

TABLE I: REFRACTIVE SURGEON PRACTICE PATTERN SURVEY

1. Name and practice location?
2. Approximately how many refractive surgery procedures do you perform annually?
3. What percentage of your total practice does refractive surgery represent?
4. Do you advertise specifically for refractive surgery?
5. How much time, on average, do you (personally) spend with each patient prior to surgery (including time during preoperative visits, informed consent discussions, and other meetings leading up to the decision to have surgery)?
6. Do you comanage your refractive patients?
7. On what percentage of your patients do you perform bilateral simultaneous surgery?

TABLE II: POTENTIAL RISK FACTORS FOR MALPRACTICE LITIGATION

DEFENDANT INFORMATION	PLAINTIFF INFORMATION	CASE INFORMATION
Age	Gender	Suit versus claim
Group vs solo practice	Age	Time: incident to open date
Location state	Occupation	Time: open to close date
Prior suits and claims	Marital status	Negligent issue
Use of marketing	Health	Actual injury
Fellowship	Habits	Prior ocular surgery
Refractive surgery experience	Prior disability	Preop refraction
Type of laser	Lawsuits prior	Dominant eye
Type of microkeratome	Location state	Outcome refraction
Location of laser		Enhancements
Fee for surgery		Disposition of case
Comanagement		Expense paid
Was consent form used		Indemnity paid
Consent process		Indemnity reserve
Note in chart by surgeon		Expense reserve
Frequency of visits presurgery		Bilateral versus unilateral surgery
Frequency of visits postsurgery		
Consultation		

STATISTICAL ANALYSIS

Using an outcome of whether or not a physician had a prior history of a claim or suit, logistic regression analyses were used separately for each predictor while controlling for refractive surgery volume. Controlling for volume was done in order to eliminate a possible confounding effect and more accurately determine if the risk of incurring a claim or suit occurred more frequently in this group. The predictors analyzed were taken from the OMIC survey of 708 refractive surgeons and were as follows: surgeon gender, use of advertising, time (minutes) spent with patient prior to surgery, region of the country (Eastern, Central, Mountain, or Pacific time zone), comanagement with optometry, and prior OMIC claims. Volume was categorized as 5 to 20 refractive surgeries per year, 21 to 100 surgeries per year, 101 to 300 surgeries per year, 301 to 1,000 surgeries per year, and greater than 1,000 surgeries per year. Odds ratios (ORs) with 95% confidence intervals (CIs) and *P* values were determined for all relationships. All analyses were done using SAS, version 8.0.

RESULTS

OVERALL DEMOGRAPHICS

As of October 31, 2002, there were a total of 2,933 OMIC insured: 2,500 (85.2%) were male and 433 (14.8%) were female; 2,274 (77.5%) were age 40 or older and 659 (22.5%) were younger than age 40. The average age was 48.9 years, and the median age was 48 years (Figure 1). Using the standard time zone boundaries, 1,186_(40.7%) practiced in the Eastern, 975 (33.5%) in the Central, 253 (8.7%) in the Mountain, and 499 (17.1%) in the Pacific time zone.

Almost one third (971) of 2,933 insured on October 31, 2002, indicated that they performed LASIK or PRK surgery. Of the 971 refractive insured, 334 (34%) practiced in the Eastern, 290 (30%) in the Central, 99 (10%) in the Mountain, and 248 (26%) in the Pacific time zone (Figure 2). Eight hundred fifty-one had approved coverage for PRK and 850 for LASIK, with overlap between the two groups.

PRACTICE PATTERN SURVEY DEMOGRAPHICS

Of the total 750 refractive surgeons who were insured by

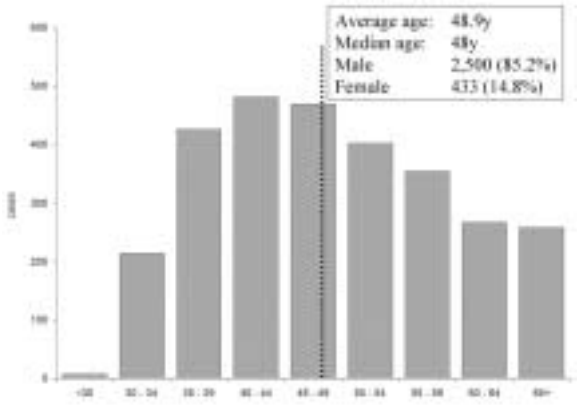

FIGURE 1
Age distribution of all OMIC-insured physicians (October 2002).

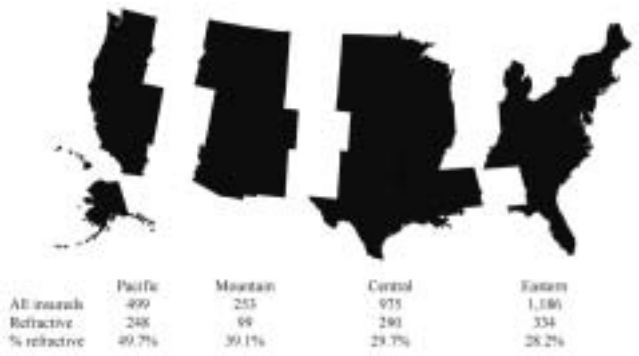

FIGURE 2
Distribution of OMIC insured physicians by region.

OMIC between January 2000 and December 2001, all were mailed surveys and 708 (94.4%) responded. Of these responses, 574 (81%) indicated that they were actively practicing refractive surgery (>5 cases per year). Five hundred and four (87.8%) were male and 70 (12.2%) were female (Figure 3).

One hundred eighty-five (32.2%) of the active refractive surgeons were located in the Eastern, 176 (30.5%) in the Central, 78 (13.6%) in the Mountain, and 135 (23.5%) in the Pacific time zone (Figure 3).

Within this survey group of active refractive surgeons, 58 (10.1%) indicated that they had experienced a claim or suit associated with PRK or LASIK surgery while insured with OMIC. These 58 physicians are included within the database from the 100 consecutive claims or suits studied. This incidence (10.1%) is slightly lower than the overall ratio for the entire OMIC cohort (124 claims or suits for PRK and LASIK among 971 refractive surgeons) (12.8%).

OVERALL REFRACTIVE SURGERY CLAIMS AND SUITS

In January 1989, the first OMIC refractive surgery claim was filed for a radial keratotomy performed in March 1987. The first PRK claim was filed in August 1997 for surgery performed in April 1996, and the first LASIK claim was filed in April 1998 for surgery performed that same month. A total of 146 refractive surgery claims and suits were filed between January 1989 and October 2002. Of this group, 116 (79.5%) have been for LASIK and 8 (5.5%) have been for PRK, for a total of 124 cases. The remaining 22 claims and suits (15.1%) were for radial keratotomy (RK) and automated lamellar keratectomy (ALK) (Figure 4). As the popularity of LASIK has increased, so, too, have the claims and suits (Figure 5).

Of the 146 total refractive surgery reported cases, 91 were suits and 55 were claims. These may be divided as follows: LASIK, 67 suits (57.3%) and 49 claims (42.2%); PRK, 6 suits and 2 claims; RK, 17 suits (81.8%) and 4 claims; and ALK, 1 suit (Figure 6). Of these cases, only 42 (35.9%) of the LASIK cases and 4 of the PRK cases are closed (Figure 6). The majority, 19 of 22 (86.4%), of the RK cases and ALK cases are now closed.

IN-DEPTH ANALYSIS OF CASES

An analysis of the first 100 consecutive PRK and LASIK claims and suits from the 124 (116 LASIK and 8 PRK) total OMIC cases was performed by examining data from several sources. These data reflect information collected from the physician underwriting applications, the refractive surgery practice survey, and open and closed claim and suit files. There were 58 physicians identified in the practice pattern survey that overlapped with this group of 100 cases. Follow-up letters were sent to physicians and attorneys requesting any missing information (Appendix 5). There were a total of 47 separate data entries for each claim or suit examined, with only 15.5% missing data entries for the entire study.

Of the 100 cases studied, 77 represented "unique" defendants (74 individuals and 3 entities). Unique defendants are defined as physicians or entities that are entered only one time in the database and that may have one, two, or more claims or suits filed against them. Within this group of 77, 62 had only one claim or suit, 9 had two claims or suits, and 6 had three or more claims or suits (Figure 7). An additional analysis of the group of physicians and entities with more than one claim or suit was performed (see discussion that follows).

Of the 74 unique individual defendants, 51 (68.9%) were aged 40 and older and 23 (31.1%) were younger than 40. The average and median age for the entire physician group with a claim or suit was 46.0 years compared to 48.9 (average) and 48.0 (median) years for all OMIC insured. Seventy-one (96%) of 74 unique physician defendants were male, and 3 (4%) were female. Of 98 responses, for the entire cohort, 50 (51%) of the refractive surgeons were in a group practice, 45 (45.9%) were in solo practice, and 3 were employed full-time by a corporate entity. Of

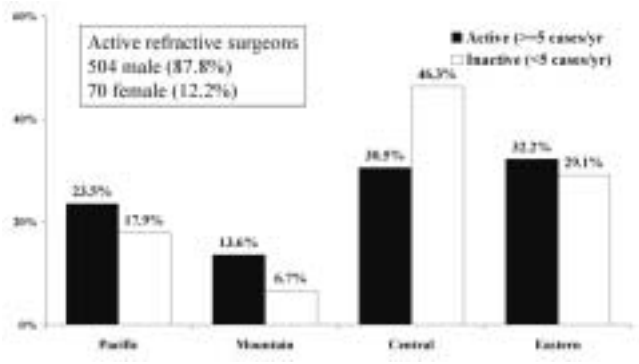

FIGURE 3
Distribution of active (574) and inactive (134) approved refractive surgeons.

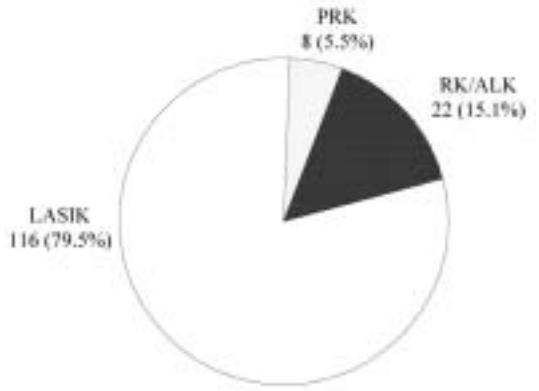

FIGURE 4
Refractive claim/suit case distribution (January 1989 – October 2002, n = 146).

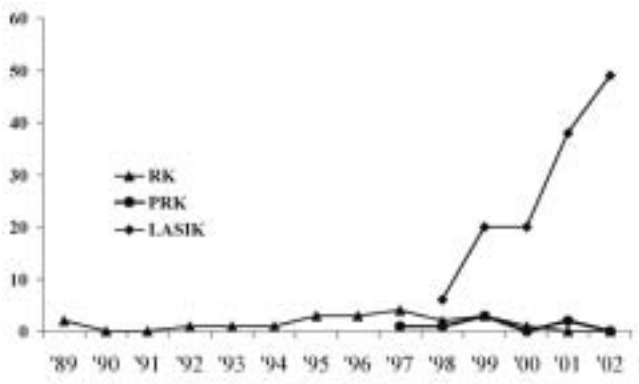

FIGURE 5
Annual incidence of OMIC refractive claim and suits.

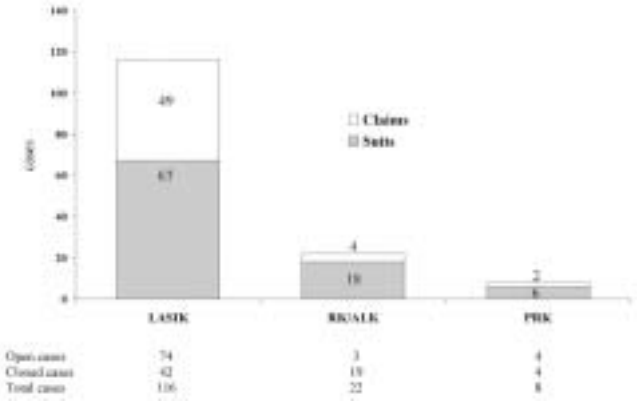

FIGURE 6
Total OMIC refractive claims and suits.

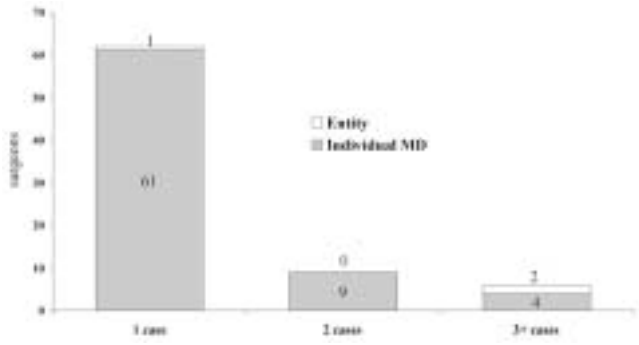

FIGURE 7
Number of cases against individual unique refractive surgeons or entities in the case study (n = 77).

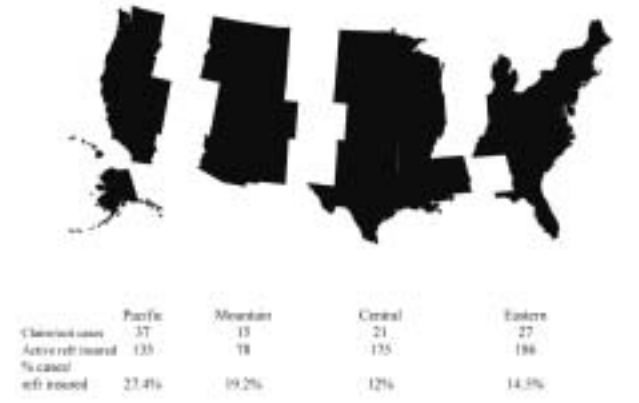

FIGURE 8
Case study distribution by US region (n = 100).

93 responses, 64 (68.8%) of the physicians had no formal Fellowship training in corneal or refractive surgery.

The regional distribution of the 100 claims and suits was as follows: 27 (27%) of the claims or suits occurred in the Eastern, 21 (21%) in the Central, 15 (15%) in the Mountain, and 37 (37%) in the Pacific time zone (Figure 8). The Pacific region had the highest incidence of claims or suits per refractive insured (27.4%) compared to the other regions (Figure 8).

PHYSICIAN PREDICTORS FOR A CLAIM OR SUIT

The predictors analyzed were taken from the OMIC survey of 708 refractive surgeons (Table I). A comparison was made between those physicians (58) who were active

refractive surgeons with a claim or suit and the total survey group. Using logistic regression analysis, each predictor was examined and statistical significance determined (Table III). High surgical volume and a history of a prior claim or suit were the most important predictors. Additional significant factors were also identified

High Volume

The most important predictor for a physician incurring a claim or suit was patient volume, with greater probability of a claim among those treating more patients (OR, 31.4 for > 1,000 procedures/year versus 5 to 20 procedures/year; 95% CI, 7.9-125; *P* =.0001).

Of the 574 active refractive surgeons from the OMIC survey, 516 were without a claim or suit. Of these 516, 373 (72.3%) performed 100 or fewer cases of PRK or LASIK per year, 61 surgeons (11.8%) performed over 300 cases per year, and 13 (2.5%) performed over 1,000 cases per year. The average number of cases for this group per year was 162.

In examining the database of 100 OMIC cases with a claim or suit, volume data were available for 85 cases. There appeared to be a substantial difference in increased volume for these cases compared to those without a claim or suit, with only 21 surgeons (24.7%) performing 100 cases or less per year, 41 surgeons (48.2%) performing over 300 cases per year, and 23 surgeons (27.1%) performing over 1,000 cases per year. The number of cases for this group averaged 491 per year, and this was significantly higher than the number of cases (162) in the group of refractive surgeons without a claim or suit (*P* = .001) (Figure 9).

Multiple Claims or Suits

Physicians having one or more prior claims or suits was the only other predictor examined that remained statistically significant when controlled for patient volume (OR, 6.4; 95% CI, 2.5-16.4; *P* = .0001).

Examination of the underwriting applications for the 74 unique physician defendants revealed that only 18 (24.3%) had no prior history of a claim or suit for their entire practice. In contrast, 25 (33.8%) had one or two prior claims or suits and 28 (37.8%) had three or more claims or suits. This differed significantly from the survey group of active refractive surgeons, in which only 58 of 574 (10.1%) indicated a prior claim or suit within their practice (*P* = .001).

Additional Risk Factors for Incurring a Claim or Suit

Additional predictors that increased in importance and became statistically significant with multivariate analysis as surgical volume increased were gender, advertising, preoperative time spent with patient, and comanagement with optometrists (Table IV). Bilateral same-day surgery was not associated with increased risk.

Gender. For those 93 physicians, including those with multiple cases, named in a LASIK or PRK claim or suit, 87 (93.6%) were male and 6 (6.4%) were female. For the 58 physicians with a claim or suit identified from the survey, 56 (96.6%) were male and 2 were female. Using univariate analysis and without controlling for volume, the OR for a female physician incurring a claim or suit compared to a male was 0.24 (95% CI, 0.06-0.99; *P* = .048) (Table III). As the volume of surgery increased over 100 cases per year, multivariate analysis revealed a significant increased risk for male surgeons (*P* = .0001) (Table IV).

Advertising. The incorporation of advertising into a higher-volume refractive surgery practice showed a significant positive correlation with those who were involved in a claim or suit. Using univariate analysis, there was a 3.6 OR (95% CI, 2.0-6.4; *P* = .0001), indicating that advertising was a risk factor for incurring a claim or suit (Table III). With multivariate analysis and adjusting for volume, a significant correlation was exhibited only with surgical volumes greater than 100 cases per year (*P* = .0001) (Table IV).

Sixty-one refractive surgeons within the study with a claim or suit (93 of 100 responses) were using marketing, compared to 193 (37.4%) of 516 active refractive surgeons without claims or suits, according to data collected from the 2-year practice pattern survey (Figure 10).

Time Spent With Patient. Physicians were asked on the survey to estimate the average amount of time they personally spent with each patient prior to surgery (including examination and informed consent discussion). Of the 74 unique individuals having a claim or suit within the database, 58 (78.4%) completed this question on the practice pattern survey. These physicians estimated spending, on average, 55 minutes with each patient

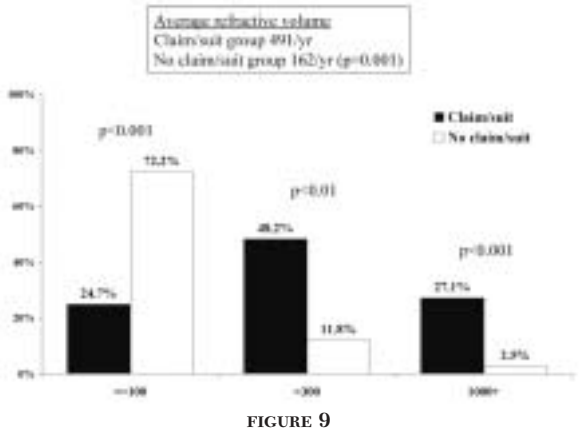

FIGURE 9

Refractive volume comparison between case study refractive surgeons and non–claim/suit refractive surgeons.

TABLE III: PHYSICIAN PREDICTORS FOR INCURRING A CLAIM OR SUIT*

PREDICTOR	CLAIMS†/N‡ (%)	UNIVARIATE MODELS OR	95%CI	*P*	CONTROLLED FOR PATIENTS/YR OR	95%CI	*P*
Surgical volume/yr							
5-20	4/276 (1.4)	Reference Category					
21-100	8/243 (3.3)	2.3	0.69 - 7.8	.1750	Not Applicable		
101-300	20/102 (19.6)	16.6	5.5 - 49.9	.0001	Not Applicable		
301-1,000	20/68 (29.4)	28.3	9.3 - 86.5	.0001	Not Applicable		
>1,000	6/19 (31.6)	31.4	7.9 – 125.0	.0001	Not Applicable		
Gender of surgeon§							
Male	56/621 (9.0)	Reference Category					
Female	2/87 (14.3)	0.24	0.06 - 0.99	.0485	0.39	0.09 - 1.7	.2195
Advertising							
No	19/416 (4.6)	Reference Category					
Yes	38/258 (14.7)	3.6	2.0 - 6.4	.0001	1.10	0.56 - 2.2	.7743
Minutes spent with patient¶							
0-30	19/126 (15.1)	Reference Category					
31-60	25/267 (9.4)	0.58	0.31 - 1.1	.0963	0.68	0.3 - 1.37	.2816
61-120	11/211 (5.2)	0.31	0.14 - 0.67	.0032	0.45	0.2 - 1.05	.0655
121+	2/36 (5.6)	0.33	0.07 - 1.5	.1508	0.57	0.1 - 2.82	.4905
Region of Country#							
East	17/224 (7.6)	Reference Category					
Central	12/237 (5.1)	0.65	0.30 - 1.39	.2673	0.87	0.4 - 1.96	.7388
Mountain	9/87 (10.3)	1.40	0.60 - 3.28	.4324	1.09	0.44 - 2.7	.8548
Pacific	20/159 (12.6)	1.8	0.89 - 3.46	.1067	1.50	0.7 - 3.14	.2775
Comanagement**							
No	26/470 (5.5)	Reference Category		Reference Category			
Yes	32/186 (17.2)	3.6	2.1 - 6.1	.0001	1.03	0.53 - 2.0	.93
Prior OMIC claims††							
None	46/681 (6.8)	Reference Category					
1 or more	12/27 (44.4)	11.0	4.9 - 25.0	.0001	6.4	2.5 -16.4	.0001

*Data from 708 pysician practice pattern surveys.
†Total number of 58 claims within the practice survey group.
‡Total N represents 708 cases.
§Number of males or females with a claim or suit compared to total number of males or females within the 708-physician survey cohort.
¶Time spent by the physician with patients prior to surgery.
#Location of physician practice.
**Preoperative and postoperative comanagement with optometrists.
††Prior claims or suits by physicians.

compared to the group of physicians (516) without a claim or suit, who estimated spending 73 minutes, on average, with each patient (Figure 11).

By dividing the time spent with patients into four categories of minutes (0 to 30, 31 to 60, 61 to 120, and 121+), an analysis was performed comparing each of the time groups with those physicians who have incurred a suit or claim. The data showed that spending more time with the patient lowered the risk of incurring a claim or suit *P* = .003) (Table III) and became increasingly significant with higher-volume surgeons (*P* = .0001) (Table IV).

Comanagement. Comanagement with an optometrist both preoperatively and postoperatively was documented in 52 (55.3%) of the cases studied with a claim or suit filed. There were no data on 6 of the 100 cases examined. In contrast, only 142 of 510 (27.8%) of refractive surgeons without a claim or suit responding to the practice pattern survey stated that they comanaged (*P* = .001) (Figure 12).

In examining the results from the practice pattern survey using multivariate analysis, surgeons performing over 100 cases per year and who comanaged demonstrated a significantly higher OR of incurring a claim or suit (OR,13.90; 95%; CI, 4.48-43.10; *P* = .0001) (Table IV).

TABLE IV: ADDITIONAL PREDICTORS OF INCURRING A CLAIM OR SUIT WITH INCREASING SURGICAL VOLUME*

PREDICTOR	OR	95% CI	*P* VALUE
Gender of surgeon			
Vol cat 101-300 vs 520	15.34	5.08-46.33	.0001
Vol cat 301-1000 vs 5-20	27.27	8.91-83.44	.0001
Vol cat 1001+ vs 5-20	28.25	7.06-113.06	.0001
Advertising			
Vol cat 101-300 vs 5-20	13.13	4.07-42.43	.0001
Vol cat 301-1000 vs 5-20	23.74	7.00-80.55	.0001
Vol cat 1001+ vs 520	26.14	6.21-110.00	.0001
Time spent with patient presurgery			
Vol cat 101-300 vs 5-20	11.90	3.92-36.11	.0001
Vol cat 301-1000 vs 5-20	21.24	6.88-65.55	.0001
Vol cat 1001+ vs 5-20	19.34	4.73-79.02	.0001
Comanagement			
Vol cat 101-300 vs 5-20	13.90	4.48-43.10	.0001
Vol cat 301-1000 vs 5-20	23.50	7.14-77.32	.0001
Vol cat 1001+ vs 5-20	25.36	5.79-111.04	.0001

*Physicians with surgical volume greater than 100 cases/year were compared to those with a lower surgical volume, between 5 and 20 cases per year. Predictors of litigation that were highly significant (P = .0001) and illustrated on this table included gender, advertising, time spent with patient, and comanagement.

Bilateral Same-Day Surgery. This was performed by 64 (67.4%) of 95 surgeons with a claim or suit and by 304 (58.9%) of 516 surgeons without a claim or suit. Thus, there was no statistical significance between these two groups.

PHYSICIANS AND ENTITIES WITH MULTIPLE CLAIMS OR SUITS

Of the 100 consecutive cases analyzed, there were a total of 62 cases (61 physicians and 1 entity) with only one claim or suit filed against them and a total of 38 cases involving a physician or entity with multiple claims or suits. Of the 38 cases, 32 (84.2%) were against 13 physicians and 6 (15.8%) were against 2 entities. Four (30.8%) of 13 physicians and both (2 of 2) entities had more than two claims or suits (Figure 7).

Analysis of the physician and entity group with multiple claims and suits was performed to determine if there were any specific factors that differentiated this group from those with only one claim or suit against them.

Of the 38 multiple claim or suit cases, the average physician age was 47.1. Twenty cases (52.6%) occurred in the Pacific, 10 in the Eastern, and 8 in the Central time zone. No physicians or entities with multiple cases occurred in the Mountain time zone (Figure 13). Thirty-two of these multiple claim or suit cases were attributable to 13 individual physicians, 11 (84.6%) of which were male and 2 (15.4%) female.

In addition, by reviewing those cases with a history of a prior claim or suit from the underwriting applications of this group, a similar pattern of regional distribution of insured physicians was evident. Of the 74 unique physician defendants, data were available for 71. Of 71, 53 (74.7%) had a history of a prior claim or suit. Twenty of the 53 (37.7%) were located in the Pacific, 12 (22.6%) in the Eastern, 13 (24.4%) in the Central, and 8 (15.1%) in the Mountain region (Figure 13).

Of the 74 unique physicians with a claim or suit within the database, 54 (73%) completed the practice pattern survey. Eleven of the 54 (20.4%) had multiple claims and suits. Forty-three of 54 (79.6%) had a single claim or suit. Using the survey data for this group, as well as information from the underwriting and case files, three specific practice trends emerged as significant risks for incurring a claim or suit for physicians with multiple cases:

Higher Volume

The average annual case volume for physicians with multiple claims or suits was 751 versus 430 cases per year for those with only a single claim or suit (P =.0001).

Use of Marketing

Ten (90.9%) of 11 physicians with multiple claims and suits advertised their services as compared to 26 (60.9%) of 43 physicians with a single claim or suit (P = .05).

Comanagement With Optometry

Of 11 physicians within the survey with multiple claims or suits, 9 (81.9%) participated in active comanagement of their patients with optometrists. This compared to 21 (48.8%) of 43 of physicians who comanaged and only were involved in a single claim or suit (P = .049)

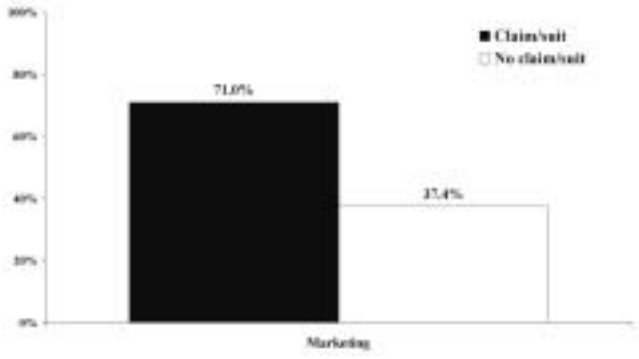

FIGURE 10
Marketing comparison between case study refractive surgeons and non–claim/suit refractive surgeons.

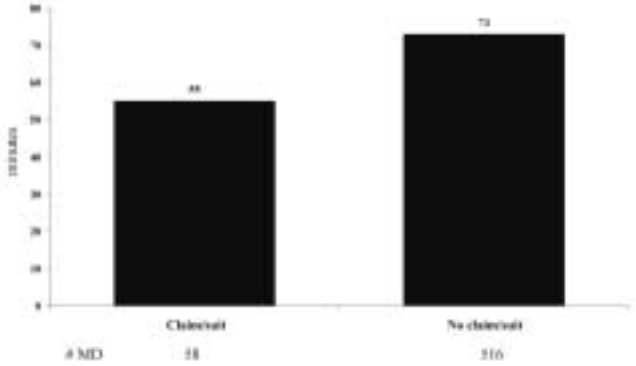

FIGURE 11
Surgeon time spent with patient prior to surgery.

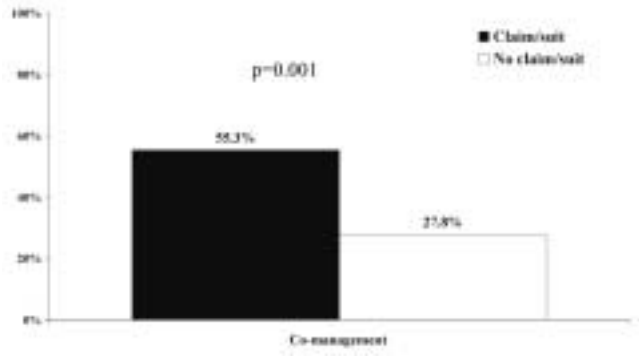

FIGURE 12
Comanagement comparison between case study refractive surgeons and non–claim/suit refractive surgeons.

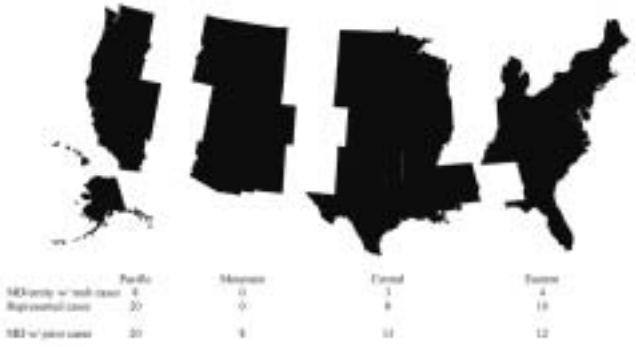

FIGURE 13
Regional distribution of refractive surgeons or entities with two or more cases against them and their case load (surgeon/entity = 15, which account for 38 total cases).

ADDITIONAL DATA COLLECTION

A large amount of additional information regarding the 100 legal cases was collected in an effort to identify specific findings that might be associated with a greater likelihood of legal activity. However, these data could not be appropriately compared to those that are currently available for the entire OMIC cohort or to the practice survey group with or without claims or suits. Additional topics that were studied included selected aspects of the informed consent process, a large variety of case elements, and patient background information.

Informed Consent Process

Analysis of the informed consent process for the 100 claims and suits was focused on the following information: timing of the consent process during the patient's preoperative visit(s), person(s) giving the informed consent, and documentation of the consent process in the medical record.

Timing of the Consent Process. This was divided into two major categories: (1) prior to the day of surgery and (2) the same day as surgery. If the consent process was started prior to the day of surgery and repeated again on the surgery day, it was counted as being given prior to surgery. In most cases, consent given prior to the day of surgery meant the day before and rarely extended earlier than the 1 day. Data were available for 82 of 100 cases. The informed consent was presented in 46 cases (56.1%) prior to the day of surgery and in 36 cases (43.9%) for the first time on the day of surgery (Figure 14).

Discussion of the Informed Consent. The informed consent process with the patient by one or more members of the medical team was analyzed and divided into several categories: surgeon, comanager, technician or other office staff, and combinations of the three. No data were available for 9 of the cases. The surgeon was involved in the consent process (either alone or in combination with others 76 times (83.5%). The surgeon was not involved in the process in 15 cases (16.5%) (Figure 15).

Documentation of Informed Consent Process. This consisted of the identification of a handwritten note by the surgeon in the medical record beyond simply including the printed informed consent form in the patient's chart. Data were available for 85 of 100 cases; 40 (47.1%) of the physicians had documentation of the consent process in the medical record, and 45 (52.9%) did not.

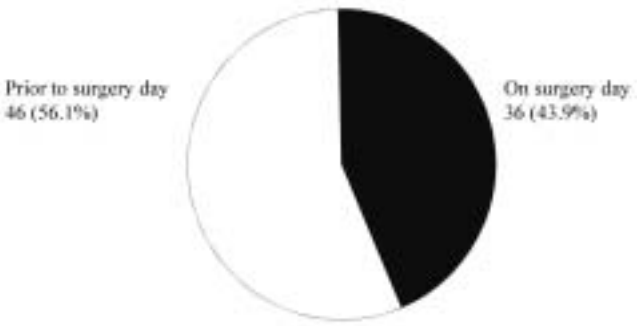

FIGURE 14
Timing of informed consent.

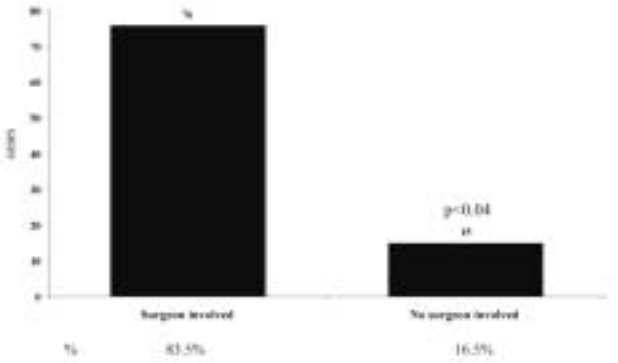

FIGURE 15
Individual performing consent.

Case Elements

Specific data were collected for each of the 100 claims or suits in the following two categories: (1) liability and insurance issues and (2) surgical case details.

Liability and Insurance Issues. Data regarding the following topics were collected and analyzed: incident to file time, open to close time, negligence, damages, and expenses.

Incident to File Time: The time between the date of surgery (incident date) and the filing of a claim or suit (open date) against the physician was rapid, with 53 (53%) occurring within the first 12 months and 27 (27%) occurring before 6 months; 38 (38%) were filed between 12 and 24 months and only 9 after 24 months (Figure 16).

Open to Close Time: The number of closed cases for both LASIK and PRK was 46 of 124 total cases (37.1%). Thirty-seven of 46 closed LASIK and PRK cases were included in the study. The length of time between the opening and closing for these cases varied between 13 cases (35%) closing within 12 months, 20 cases (54%) closing between 12 and 24 months, and 4 cases closing after 2 years (Figure 17).

Negligence: In analyzing the causes of negligence filed by the plaintiff for each of the 100 cases, five main categories were defined: (1) improper performance of the procedure, (2) informed consent process, (3) problems with equipment or data entry, (4) poor patient selection, and (5) advertising issues. Where there were multiple issues listed, the most dominant one appearing in the complaint was chosen. Data were available for 98 of the cases and revealed the following (Figure 18): improper performance of the procedure, 40 (40.8%); informed consent issues, 30 (30.6%); problems with equipment or data entry issues, 14 (14.3%); poor patient selection, 10 (10.2%); and advertising issues, 4 (4.1%).

Damages: Damages claimed by the patients (plaintiff) were classified into four main categories: (1) decreased acuity (best corrected), (2) visual symptoms (including glare, halos, ghosting, and difficulty with night vision and driving), (3) pain (including dry eye and headaches), and (4) structural damage to the eye (including scarring and ectasia). Once again, where there were multiple issues listed, the most dominant one appearing in the record was chosen. Data were available for 95 of the 100 cases and demonstrated the following (Figure 19): decrease in

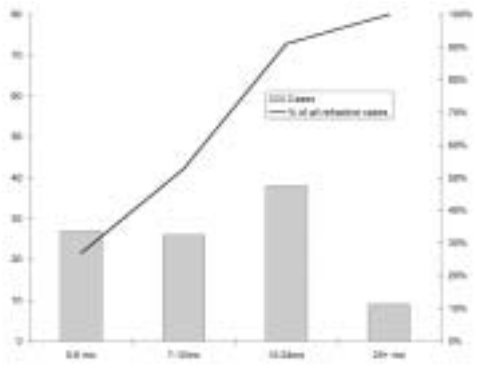

FIGURE 16
Time between incident occurrence and filing of case (n = 100 cases).

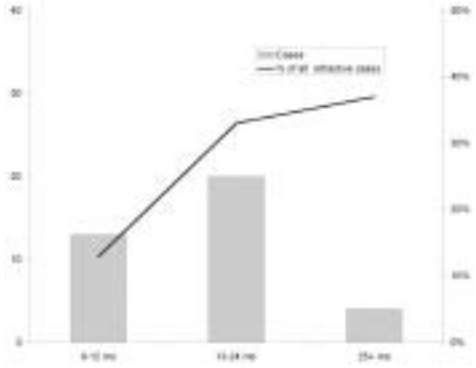

FIGURE 17
Time between case filing and case closing (n = 37, 37% of cases in study).

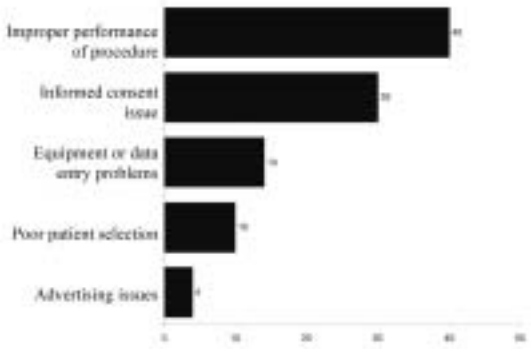

FIGURE 18
Negligence issue as filed by plaintiff (n= 98).

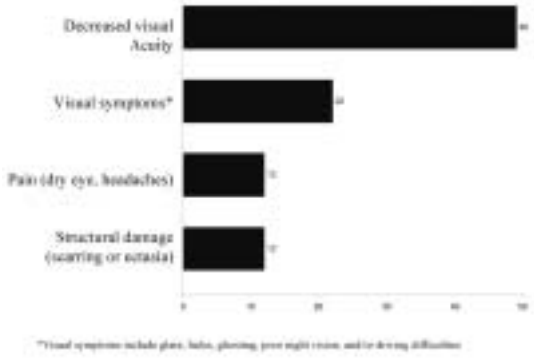

FIGURE 19
Damages claimed by plaintiff (n = 95).

best corrected visual acuity, 49 (51.6%); visual symptoms (glare, halos, ghosting, poor night vision, driving difficulties), 22 (23.2%); pain (dry eye and headaches), 12 (12.6%); and structural damage (scarring and ectasia), 12 (12.6%).

Expenses/Indemnity Paid and Reserved: The total cost involved in handling a malpractice claim or suit can be significant to both the physician and the malpractice liability carrier. The tangible costs to the liability company include the expenses incurred in preparing for the defense of the case, as well as any indemnity payment made to the plaintiff. In addition, at the time of the filing of the claim or suit, an estimated cash reserve is allocated to cover potential future expenses and indemnity payments. Data were available for 98 of the 100 cases included in this study. The financial groupings reported are consistent with those used within the Physician's Insurance Association of America (PIAA) database (Tables V and VI) (Figures 20 through 23).

As of October 31, 2002, for 98 of the 100 claims and suits entered into the database, the average expenses paid per case were $13,858 and the average indemnity paid per case was $6,438 for a total of $20,296 per case (Figure 24). It is important to note that these figures would be considerably higher ($53,550) if they did not include the cases in which no expenses or indemnity were paid (OMIC, personal communication, January 2003). In addition, of 124 total PRK and LASIK claims and suits, only 46 (37.1%) are closed, leaving the majority (62.9%) of the cases to accumulate more cost in the future (Figure 25).

Surgical Case Details. The following information was collected and analyzed for each of the 100 cases: preoperative refraction, postoperative refraction, dominant eye, preoperative visits, postoperative visits, laser and microkeratome manufacturer, and consultations.

Preoperative Refraction: The preoperative status (spherical equivalent) of 90 cases for the dominant and nondominant eyes showed that 79 (87.8%) of the eyes were myopic and 11 (12.2%) were hyperopic. Within these groups, 27 (34.2%) were greater than –6.00 diopters (D) and 4 eyes were greater than +3.00 D. Twenty-six (28.9%) of the cases had preoperative astigmatism greater than 2.00 D (Figure 26).

Postoperative Refraction: The postoperative refractions for 72 of 100 cases indicated a definite hyperopic shift with 16 (22.9%) of the cases ending up hyperopic and 34 (48.6%) of the cases in the myopic range. Sixteen (22.9%) had one myopic eye and one hyperopic eye. Thirteen patients (18%) had residual astigmatism (regular and irregular) greater than 2.00 D. Only 6 of the patients were plano (Figure 27).

The more specific refractive errors of the cases are presented in Table VII and Figures 28 through 30.

Dominant Eye: Data was available on 57 of 100 patients. Forty-seven of 57 (82.5%) were right-eye dominant and 10 of 57 (17.5%) were left-eye dominant.

Preoperative Visits: Preoperative examinations by the insured were documented and collated based on the following categories: no visit (not seen), one visit, two or more visits, and established patient (many visits). Data were available for 84 cases (Figure 31): no preoperative visit, 14 (16.7%); one visit, 38 (45.2%); two or more visits, 23 (27.4%); and established patient, 9 (10.7%).

Postoperative Visits: Postoperative examinations by the insured were documented and divided into the following categories: not seen by surgeon, 1 to 5 visits, 6 to 10 visits, and reater than 11 visits. Data were available for 83 cases (Figure 32): no postoperative visit, 7 (8.5%); 1 to 5 visits, 29 (34.9%); 6 to 10 visits, 19 (22.9%); and greater than 11 visits, 28 (33.7%).

Laser and Microkeratome Manufacturer/Laser Location: The manufacturers of the laser (93 cases) and microkeratome (40 cases) were documented, as

TABLE V: EXPENSES PAID AND IN RESERVE FOR SERIES COHORT*

	EXPENSES PAID	EXPENSE RESERVE
None	18 (18.4%)	22 (22.5%)
$1.00-$5,000	38 (38.8%)	10 (10.2%)
$5,001-$10,000	13 (13.3%)	23 (23.5%)
$10,001-$20,000	14 (14.3%)	17 (17.3%)
$20,001-$50,000	8 (8.2%)	18 (18.4%)
>$50,000	7 (7.1%)	8 (8.2%)

*Data available for 98 of 100 cases studies.

TABLE VI: INDEMNITY PAID AND IN RESERVE FOR SERIES COHORT*

	INDEMNITY PAID	INDEMNITY RESERVE
None	83 (84.7%)†	35 (35.7%)
$1.00-$10,000	2 (2.0%)	9 (9.2%)
$10,001-$50,000	7 (7.1%)	46 (46.9%)
$50,001-$100,000	5 (5.1%)	4 (4.1%)
$100,001-$250,000	1 (1.0%)	3 (3.1%)
>$250,000	0 (0.0%)	1 (1.0%)

*Data available for 98 of 100 cases studies.
†63.2% of these cases are still open, and no indemnity has been paid on any of these cases.

TABLE VII: PREOPERATIVE AND POSTOPERATIVE REFRACTIVE STATES

	PREOPERATIVE	POSTOPERATIVE
<-6.00	27 (30.0%)	8 (11.1%)
-3.00 to –5.99	22 (24.4%)	4 (5.6%)
-0.25 to –2.99	30 (33.3%)	22 (30.6%)
Plano	0 (0.0%)	6 (8.3%)
+0.25 to +2.99	7 (7.8%)	14 (19.4%)
+3.00 to +5.99	3 (3.3%)	1 (1.4%)
>+6.00	1 (1.1%)	1 (1.4%)

well as the location of the laser surgery (92 cases). Of the lasers, 72 (77%) were VISX and 16 (21%) were Summit (Figure 33). The Hansatome microkeratome was used in 27 (67.5%) of the cases. Of the 92 laser locations, 47 (51.1%) were located in a community-owned laser center, 31 (33.7%) in a corporate chain laser center, and 14 (15.2%) in an academic or university setting (Figure 34).

Enhancements: Following the initial surgery, an enhancement or second operation was performed in 53 (57.0%) of the 93 physician cases with a claim or suit.

Consultations: Of 88 cases with data available having a claim or suit, 64 (72.7%) were seen by another physician for a second opinion consultation. Within this group, 47 (73.4%) were referred by the physician and 17 (26.6%) were self-referred (Figure 35).

Patient Background Information

Examination of the patient's (plaintiff's) personal information from medical records, as well as the case files, provided an opportunity to collect data to build patient profiles for detailed analysis. All data entries were masked to maintain total privacy for each of the patients.

Gender, Age, Marital Status. In the 100 consecutive cases studied, 51 (51%) were women and 49 (49%) were men (Figure 36). Average age of plaintiffs was 42.1 years with the median age 43 years. Of 95 plaintiffs in which the ages were known, 56 (58.9%) were older than 40 years and 26 (27.4%) were older than 50 years (Figure 37). Of 83 plaintiffs within the database, 53 (63.9%) were married and 30 (36.1%) were single. There were no marital data for 17 of the plaintiffs.

Occupations. The occupations of the patients were available for 88 of the cases. These were grouped into four categories: nonhealthcare professional (eg, accountants, engineers, teachers, business executives), 38 (43.2%);

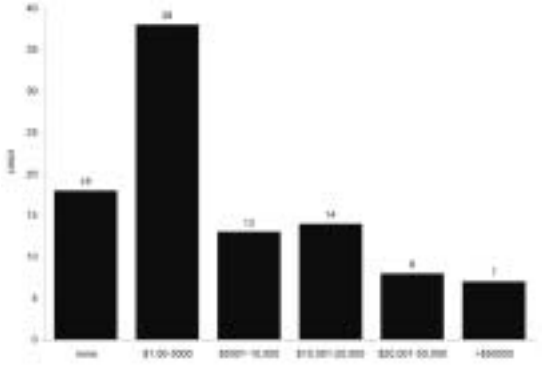

FIGURE 20
Expenses paid per case (n=98).

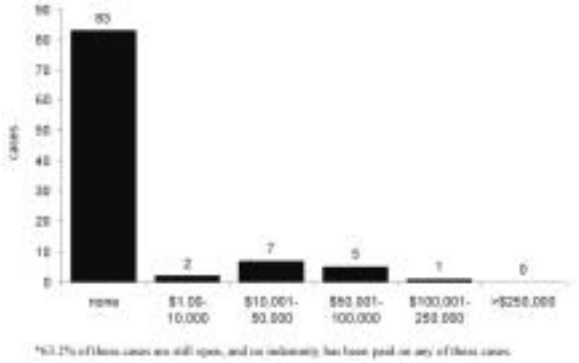

FIGURE 21
Indemnity paid per case (n=98).

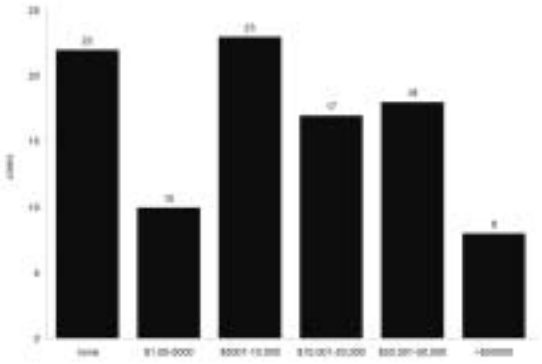

FIGURE 22
Expenses reserve (n=98).

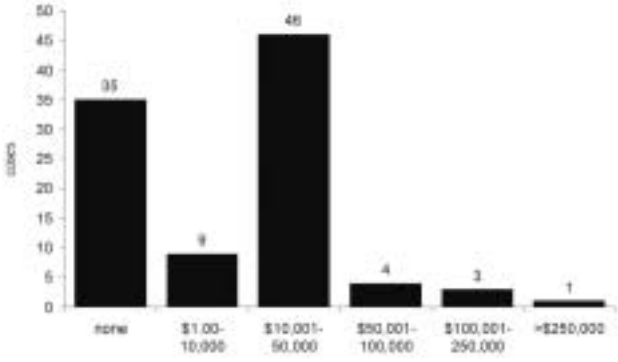

FIGURE 23
Indemnity reserve (n=98).

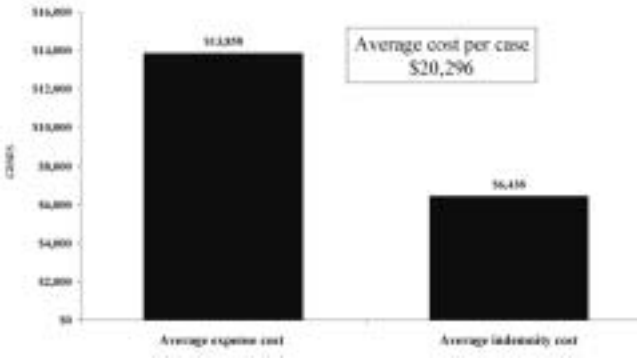

FIGURE 24
Average cost per case.

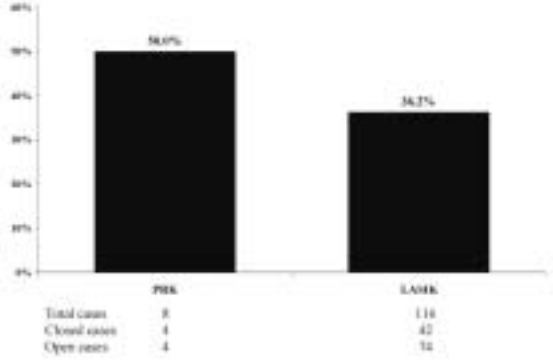

FIGURE 25
Percent of closed cases.

blue collar (eg, government workers, clerks, service workers), 32 (36.4%); unemployed or student (including retirees and homemakers), 12 (13.6%); and healthcare worker (eg, physicians, nurses, technicians), 6 (6.8%) (Figure 38).

Health and Medications. Information regarding patients' past and current health status and medication use was collected from their medical records and divided into four categories: history or current treatment for depression or anxiety, 27 (35.5%); obesity (as an indicator for poor body image), 10 (13.2%); other medical/cosmetic surgery issues, 23 (30.2%); and no health problems or medications, 16 (21.1%). Data were obtained from 76 of 100 patient records (Figure 39).

Prior Vision Correction. Vision correction prior to surgery consisted of either spectacles or contact lenses. Data from the medical records were available for 67 of 100 cases: 23 patients (34.3%) wore spectacles for correction of their refractive error, and 44 wore contact lenses (65.7%). Within the latter group, 33 (75%) wore soft lenses and 11 (25%) wore rigid lenses (Figure 40).

Prior Disability Claims or Lawsuits. In 66 cases, data

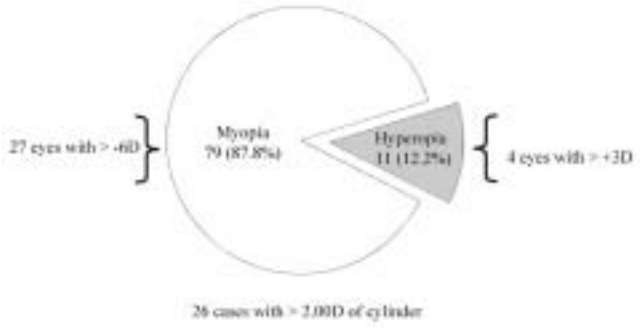

FIGURE 26
Preoperative refractive states.

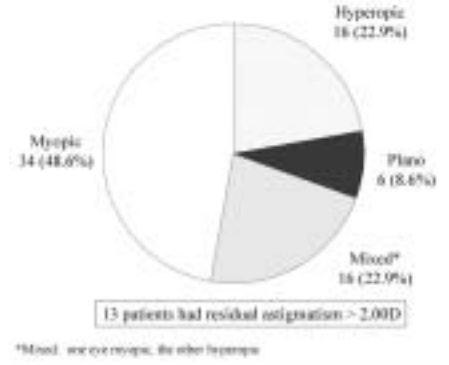

FIGURE 27
Postoperative refractive states.

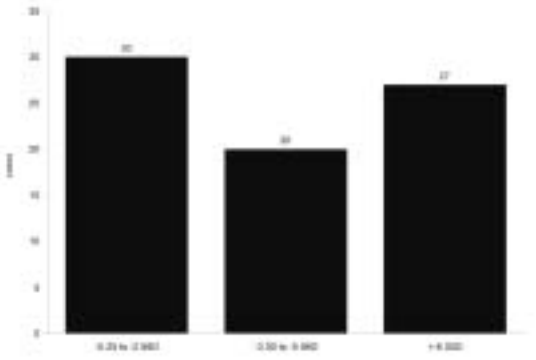

FIGURE 28
Preoperative myopic errors.

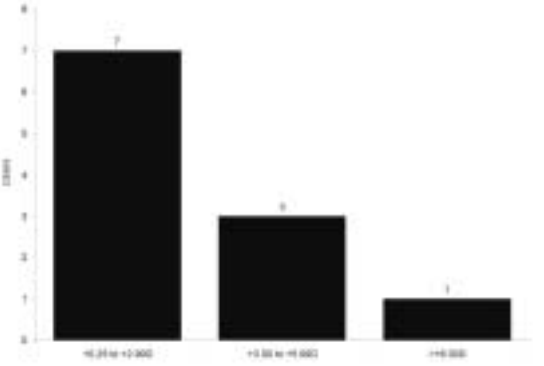

FIGURE 29
Preoperative hyperopic errors.

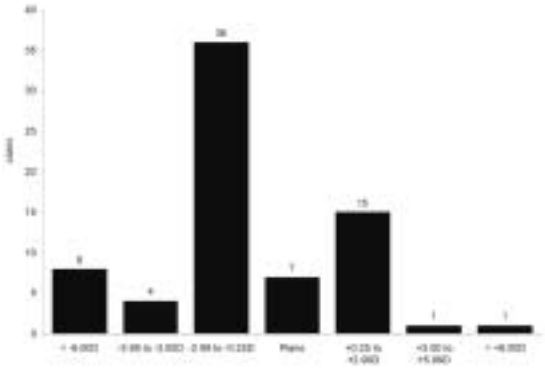

FIGURE 30
Postoperative refractions.

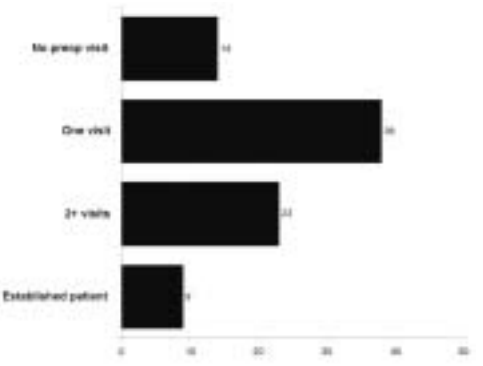

FIGURE 31
Preoperative visits.

was collected regarding any documentation that the patient had filed a previous disability claim for any prior injury or illness. This occurred in 14 (21.2%) of 66 cases. In addition, any evidence that the plaintiff had been involved in a prior claim or suit against anyone was documented. This occurred in 10 of 45 (22.2%) of the cases.

DISCUSSION

Using data obtained from OMIC refractive surgery claims and suits, as well as physician underwriting applications and surveys, this study produced information in a quest to identify physician, patient, and case details that might be associated with a relatively high risk of litigation. Limited data from the OMIC cohort and the physician survey made it difficult to establish the importance of insurance information, case details, and patient backgrounds associated with the 100 cases that were studied in detail. However, multiple physician predictors and risk factors that were associated with an increased likelihood of incurring subsequent malpractice litigation were identified. Examination of physician practice patterns as well as their

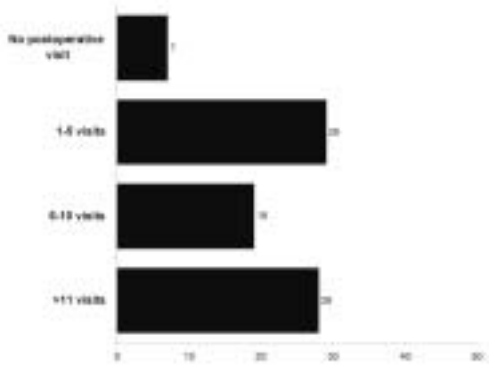

FIGURE 32
Postoperative visits.

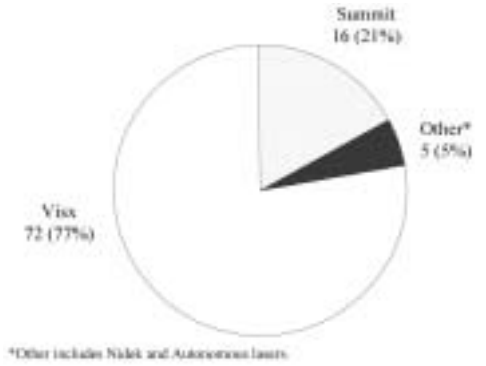

FIGURE 33
Refractive laser used in case series.

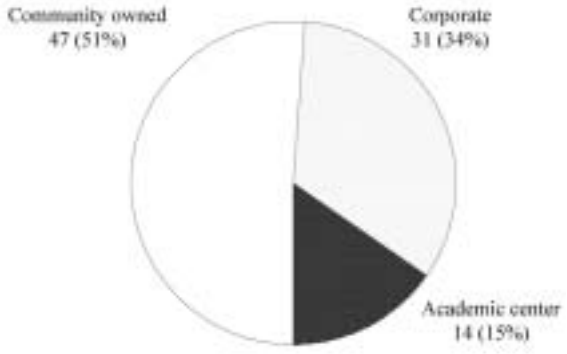

FIGURE 34
Refractive laser location used in case series.

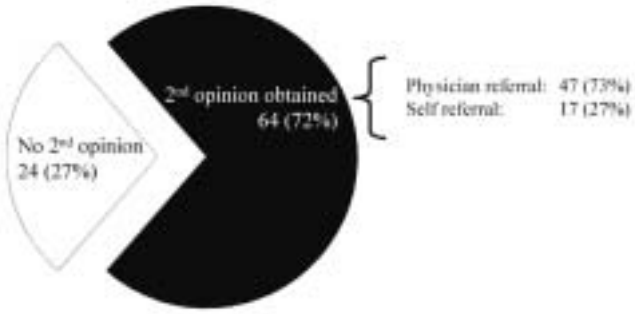

FIGURE 35
Plaintiffs receiving second opinions from another physician.

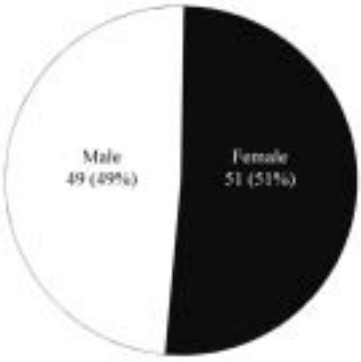

FIGURE 36
Gender breakdown of plaintiffs.

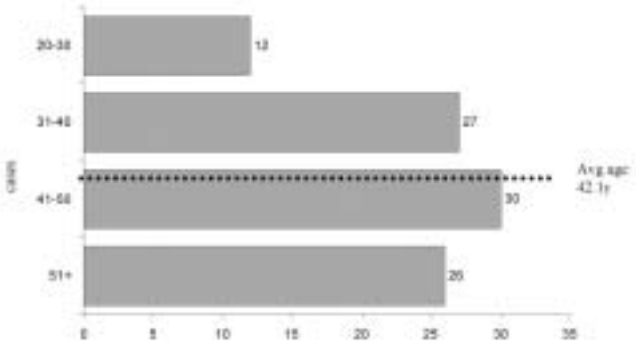

FIGURE 37
Plaintiff ages.

demographic information may provide helpful data to better understand why patients turn to litigation when something unexpectedly goes wrong.

A total of 146 refractive surgery claims and suits were filed with OMIC between January 1989 and September 2002 (12.75 years). Of these claims, 124 were for PRK or LASIK, with 116 (79.5%) of these filed solely for LASIK (Figure 4). There are many reasons for this high LASIK number. The volume of procedures, numbers of physicians performing them, and patient expectations are all high. In addition, there is aggressive marketing by many physicians, and risky practice behaviors aggravate the problem. Furthermore, the plaintiff's bar is well organized and has marketed directly to the (consumer) patients undergoing LASIK. With high jury awards, there is significant incentive to pursue these cases if a perceived outcome or level of expectation is not achieved. Since only a small number, 42 of 116 (36.2%), of the cases are currently closed (Figure 6), the true economic impact of the remaining cases has not yet been realized and is potentially profound.

The marked increase in malpractice litigation is not

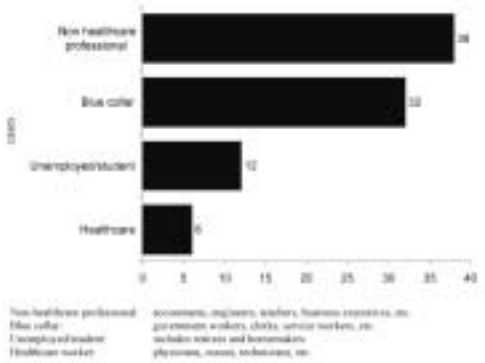

FIGURE 38
Plaintiff occupational groups.

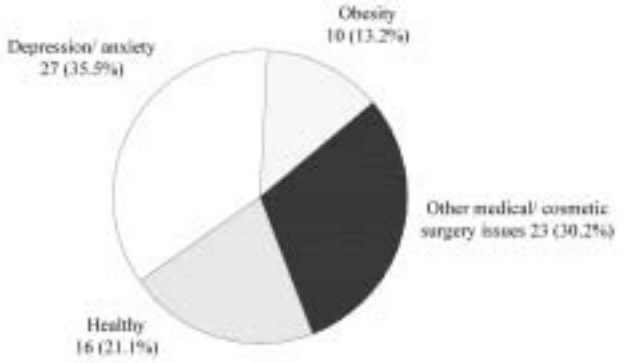

FIGURE 39
Treated plaintiff medical problems.

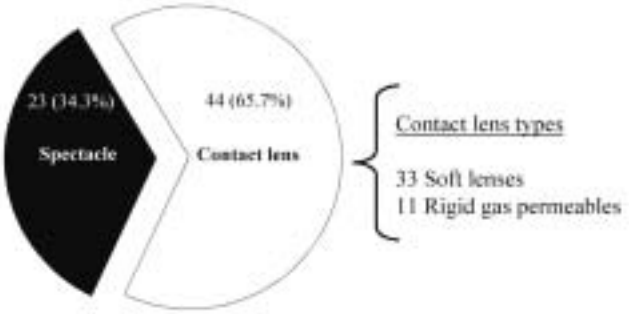

FIGURE 40
Preoperative vision correction.

unique to ophthalmology. Approximately 1 in 6 practicing physicians face a malpractice claim each year.[6] If an ophthalmologist practices for 35 years, there is a 95% chance that a claim or a lawsuit will be filed against him or her (unpublished OMIC actuarial data, October 1998). Although the first reported case of medical malpractice in the United States occurred in Connecticut in 1794,[7] medical liability claims were uncommon before 1970.[8-10] Between 1935 and 1975, 80% of all medical malpractice lawsuits were filed in the last 5 years of that period (1973-1975).[11] In addition, there has been a 60% increase over the past 5 years in average indemnity paid, with many awards now exceeding $100 million.[4] Even if a case has little merit, the average expenses incurred are approximately $23,000 per defendant.[4] If the case goes to trial, these expenses rise to $86,000 per defendant.[4] Although the physician typically wins 90% of the cases,[11] these added costs and burden to the healthcare system are staggering.

PHYSICIAN DEMOGRAPHICS

The OMIC insured database consisted of 2,933 physicians on October 31, 2002. Of this group, 971 (33.3%) had requested liability coverage for PRK or LASIK. Since OMIC insures physicians in 49 states plus the District of Columbia, this was believed to be an excellent geographic as well as representative sample of the percentage of US ophthalmologists currently performing or having had performed these two refractive procedures in the past. The average age of all OMIC insureds was 48.9 years and the mean age 48.0 years. The insured refractive surgeon average and mean age was 46 years. Comparing the geographic distribution of the OMIC refractive surgeons to the total group of OMIC insureds, there was a greater proportion practicing in the Mountain and Pacific regions than in the other two regions of the United States (Figure 2). Although not statistically significant (P = .278), this higher proportion of refractive surgeons matched the higher number of claims and suits in these regions compared to the other two regions (Figure 8).

Of the 100 consecutive OMIC cases studied, there were a total of 74 physicians and 3 entities (77 total). The remaining 23 cases (19 physicians and 4 entities) were second or additional claims or suits against this same group. In further analysis of the cohort, there were a total of 93 (74 + 19) physicians and 7 entities that were studied. Of the 74 unique individual defendants, 51 (68.9%) were aged 40 and older and 23 (31.1%) were younger than 40. The average and median age for the entire physician group with a claim or suit was 46.0 years compared to 48.9 (average) and 48.0 (mean) years for all OMIC insured, and these differences are not statistically significant.

PHYSICIAN PREDICTORS FOR A CLAIM OR SUIT

There were two highly significant predictors for physicians that correlated with a higher risk for a claim or suit being filed against a LASIK or PRK surgeon. These were a high surgical volume and a prior claim or suit filed against the physician. Risk factors that increased in importance and became statistically significant as surgical volume rose above 100 cases per year were physician gender, advertising, time spent with the patient prior to surgery, and patient comanagement with optometry.

Surgery Volume

In examining the database of 100 OMIC cases with a claim or suit, volume data were available for 85 cases. There appeared to be a substantial difference in increased volume for these cases compared to those without a claim or suit, with only 23 surgeons (27%) performing 100 cases or less per year, 43 surgeons (50.6%) performing more than 300 cases per year and 25 surgeons (29.4%) performing more than 1,000 cases per year. The number of cases for this group averaged 491 cases per year, and this was significantly higher than for the group of refractive surgeons without a claim or suit (P = .001) (Figure 9).

The survey of insured refractive surgeons demonstrated that physicians without a claim or suit performed an average of 162 cases per year compared to 491 cases per year for those surgeons with a claim or suit. Of surgeons performing 300 cases or more per year, there were 61 of 516 (11.8%) within the survey not involved in litigation compared to 43 of 85 (50.6%) within the database that were involved in litigation (Figure 9). These data were highly significant (P = .001).

Surgical outcomes of PRK and LASIK were studied by Yo and colleagues,[12] who compared experienced to beginning surgeons. Their data suggested that results achieved by low-volume, beginning surgeons were comparable to those reported by experienced surgeons. Greater surgical experience (higher volume) showed no correlation with a lesser incidence of incurring a claim or suit; in fact, the opposite was true. Intuitively, based on volume alone, there is a higher total number of potential complications that may occur compared to the lower-volume surgeon. This factor certainly may play a role in the higher incidence of claims or suits filed against higher-volume surgeons; however, there are no published data to support this concept.

There are many additional factors, however, that may contribute to the higher incidence of claims or suits for the higher-volume refractive surgeon. Among these are gender, more aggressive marketing, less time spent with the patient, and more frequent use of comanagement. In the statistical analysis, these four issues became increasingly significant as the volume of surgery rose (Table IV), as noted later.

Prior Malpractice Claim or Suit

Examination of the underwriting applications of the 77 individual defendants within our study indicated that 18 of 77 (23.4%) had no history of prior claim or suit for their entire practice. Similar to the below-referenced studies, however, 25 of 77 (32.5%) had one or two prior claims or suits, and 28 of 77 (36.4%) had three or more claims or suits. In addition, in the practice survey, there was an OR of 6.4 for physicians with prior claims or suits who incurred an additional case compared to those without a prior case. These data proved to be a highly significant predictor (P =.0001) (Table III).

Several studies have examined this same issue and discovered that a previous claims history was statistically related to a physician incurring subsequent claims.[13,14]

Having any baseline activity for a claim or suit statistically puts one at a higher risk for subsequent claims.[13,14] Even having a single unpaid claim doubled the odds of subsequent litigation.[13] Presumably, this reflects a multitude of factors relating to the physician's abilities, practice patterns, and case mix, as well as his or her personality and ability to communicate with patients.

Gender

Comparing those physicians within the study named in a claim or suit (93 of 100) to those physicians within the practice survey not involved in a claim or suit (516 of 574 [89.9%]), the percentage of male surgeons without a legal case compared to those with cases *increased* from 86.8% to 93.6%. On the other hand, the percentage of female surgeons without a claim or suit compared to those with cases *decreased* from 13.2% to 6.6%. Therefore, male surgeons appeared to have a higher risk of incurring a claim or suit compared to female surgeons (P = . 048)

A similar conclusion was reached by Sloan and associates,[14] who found that female physicians practicing obstetrics or anesthesiology tended to have a more favorable claims experience than their male counterparts. In addition, Hickson and colleagues[15] reported that female physicians were less likely than male physicians to generate complaints, necessitate risk management interventions, or provoke lawsuits.

Advertising

In this study, physicians who performed more than 100 LASIK or PRK cases per year and utilized marketing in their practices showed a significantly higher incidence of incurring a malpractice claim or suit compared to those physicians who did not advertise (P =.0001) (Table IV).

Ophthalmic marketing consists of communications to prospective or current patients for the purpose of soliciting or encouraging the use of the physician's services.[16] Advertising may be oral or written and includes the internet, magazine or newspaper ads, radio and television pieces, promotional flyers, leaflets, and brochures.[17] Physician advertising must be truthful, must not be misleading, and must not omit essential or material facts.[16,17] While advertising, in general, has resulted in more informed and better educated patients, it is not uncommon for the marketing material to create misconceptions or unrealistic expectations. This can negatively influence the informed consent discussions and lead to a

higher incidence of a claim or suit being filed against the surgeon.

Time Spent With Patient Prior to Surgery

Using the refractive surgery practice pattern survey, physicians were requested to estimate the average amount of total time they personally spent with a patient prior to surgery. A total of 58 responses (78.4%) of the 74 individual physicians with a claim or suit reported spending an average of 55 total minutes with each patient. This compared to the group of physicians without a claim or suit (516), who estimated their preoperative time with a patient to be 73 minutes (Figure 11).

Spending more time with a patient prior to surgery lowered the risk of incurring a claim or suit and became increasingly significant with higher-volume surgery (P = .0001) (Table IV).

The preoperative time spent by the surgeon with a patient provides an opportunity to develop rapport and assess the patient's personality quirks and unrealistic expectations of the surgery.[17] Hickson and colleagues[15] have suggested that the physician's ability to establish rapport, provide access, and communicate effectively with the patient is as important as technical competence in protecting against litigation. Beckman and associates[18] reported that many claims and suits centered on issues of a poor physician-patient relationship and lack of communication with the patient. Levinson and coworkers[6,19] found that effective communication enhanced patient satisfaction and overall health outcomes and reduced the risk for litigation. In addition, they showed that the length of time spent with the patient was inversely related to the likelihood of incurring a lawsuit.[19]

Comanagement

In 94 of 100 claims or suits in which data were available, 52 cases (55.3%) were associated with optometric comanagement. Within the practice survey group, only 142 (27.8%) of 510 physicians without a claim or suit participated in a comanagement arrangement (Figure 12). When comparing the comanaging physicians to those who do not comanage, the risk of incurring a claim or suit rose significantly in those physicians who performed over 100 cases per year and also comanaged their patients with optometrists (P = .0001) (Table IV).

Comanagement may be defined as the sharing of postoperative responsibilities between the operating surgeon and another healthcare provider.[20,21] Results of the 2002 ASCRS refractive surgery member survey revealed that 28.2% of respondents were currently participating in a comanagement relationship with either an ophthalmologist or an optometrist.[22] Twenty-five percent comanaged only with an optometrist and 2.5% only with an ophthalmologist. Of this group, 11.4% responded that they comanaged their LASIK patients more than 50% of the time. Eighty percent of the survey respondents stated that they followed the AAO/ASCRS comanagement guidelines.[22,23]

In any LASIK lawsuit, comanagement is the simplest issue for attorneys to understand and master.[20] In most cases, discovery regarding a patient's allegations of comanagement leads to multiple potential legal pitfalls for the defendant.[20] These may include issues involving division of fees for services rendered, communication between comanaging partners, and levels of expertise of the optometrist in the preoperative assessment and postoperative management of the patient.

PHYSICIANS AND ENTITIES WITH MULTIPLE CLAIMS AND SUITS

Examination of the database and the practice pattern survey allowed analysis of practice trends that proved to be significant risk factors for physicians with multiple claims or suits. By cross-referencing the 74 physicians in the database with those completing the practice pattern survey, 54 physicians with at least one claim or suit were identified. Eleven of the 54 (20.4%) had multiple claims or suits. A comparison between physicians (43) with one claim or suit was made to those (11) with multiple claims or suits. Higher case volume, use of marketing, and comanagement with optometry emerged as the major risk factors for physicians incurring multiple claims or suits.

As already noted, a prior claim or suit places a physician at higher risk of subsequent litigation,[13,14] and similar factors appear to be associated with both initial and multiple defendant practice patterns.

ADDITIONAL DATA COLLECTION

A large amount of additional information regarding the informed consent process, liability/insurance issues, surgical case data, and patient backgrounds was collected for the 100 cases involving claims and suit. However, these data could not be appropriately compared to those of the entire OMIC cohort or to the practice survey group with or without claims or suits. Hopefully, this information will be of greater value in future studies regarding risk factors for litigation. The potential relevance of these data is briefly discussed below.

Informed Consent Process

An analysis of 83,510 closed malpractice claims and lawsuits compiled by the PIAA showed that 20,877 (25%) of the claims alleged nonmedical issues as the basis for the claim against the physician.[24] Of this group, lack of informed consent was the leading cause with 7,000 (33.5%) of the cases.

Informed consent is based on a shared discussion and decision between the physician and the patient. It is a process of disclosure whereby mutual information sharing and deliberation by the patient and physician permits a patient to make a reasoned health care decision[25,26] Although others may participate in the process, it is the physician's duty to interact directly with the patient at some point prior to a commitment to surgery and review the risks, benefits, alternatives, and complications of the specific treatment offered.[27-31] Often there are one or more members of the medical team other than the surgeon who provide a portion or all of the informed consent. Some staff members meet with the patients prior to the surgeon, others meet with the patients after the surgeon, and some are the only individuals meeting with the patients.

In this study, the surgeon was involved in the consent process 76 of 91 times (83.5%) (Figure 15). In addition to the printed informed consent document, a handwritten note by the surgeon was present in the medical record in 45 (52.9%) of 85 available charts. Documentation in the medical record of the informed consent process is extremely important. It is essential to record the patient's authorization of treatment, as well as acknowledge the discussion regarding possible risks, benefits, alternatives, and complications, since it may be the only legal proof available to defend against and refute any possible allegation that the informed consent discussion did not take place. A lack of adequate informed consent was said to be the basis of a claim or suit for negligence in 30 (30.6%) of 98 cases.

Timing of the informed consent discussion is crucial and should be done well in advance of surgery and prior to the patient's decision to proceed with the procedure. Meeting with the surgeon and discussion of the informed consent information were performed either prior to the day of surgery (56.1%) or on the same day (43.9%) for the claims and suits within the study (Figure 14). Performing the informed consent on the day of surgery does not allow the patient a reasonable time to digest the information presented, since the patient has already committed to undergoing the surgery.

Liability and Insurance Issues

With the high volume of refractive surgery procedures, particularly LASIK, over the past several years, the increasing frequency of claims and suits is not surprising. The increase in LASIK litigation does not appear to be disproportionate to the number of physicians and entities covered for this procedure by OMIC. In 1999, LASIK cases represented 10% of all open OMIC claims (unpublished OMIC data, 2000). By 2001, the number of open claims, defined as the date the claim or suit was filed, had risen to over 20%.[32] By October 2002, the number of open claims had jumped to an astonishing 63.2% (unpublished OMIC data, 2002). This reflects the steep upturn in opened cases over the past 18 months (Figure 5).

In general, the time between the date of surgery (incident date) and the claim filing date against the physician or entity was shorter (53% occurring in the first 12 months) for refractive surgery compared to nonrefractive cases (37%) in the first 12 months (personal communication, T. Ghezzi, actuarial data, Tillinghast-Towers Perrin, January 2003). This rapid time sequence for filing of a refractive surgery claim or suit is most likely attributable to the unrealistic expectations many patients have related to their visual outcome.

In this study, the two primary causes of negligence filed by the plaintiff in this series were improper performance of the procedure (40 of 98 cases [40.8%]) and lack of adequate informed consent (30 of 98 case [30.6%]). Flap complications were the dominant issue for improper performance of the procedure. A decrease in best corrected visual acuity was the leading claim of damage to the patient's eye.

The expenses incurred by a medical malpractice liability company in defending a claim or suit can be significant. These data are summarized in Table VII. The indemnity paid to the plaintiff has been rising yearly.[32] In cumulative data from the PIAA between January 1, 1985, and December 31, 2001, the average indemnity paid for all ophthalmology cases was $157, 492 (written communication, PIAA, December 2002). For 2002, the average OMIC indemnity payment for all claims and suits was slightly lower, $131,436 (unpublished OMIC data, Jan 2003). The average OMIC indemnity payment for LASIK cases (where payments were made) in 2002 was $53,550. The largest single OMIC indemnity payment for LASIK was $118,000. If all cases, including those with no indemnity payment, are included, the average indemnity paid was only $6,438 per case. Refractive cases are settled with an indemnity payment to the plaintiff more often (37%) than other types of ophthalmic claims (22%).[5] This suggests that the standard of care for LASIK has been reasonably well defined with less disagreement between plaintiffs and defendants than in other subspecialty areas.[5]

Surgical Case Details

Most patients in this series were myopic (87.8%) with over one third (34.2%) greater than –6 D. Of the hyperopic group (12.2%), 4 eyes had corrections greater than +3 D. Within both the myopic and hyperopic groups, 26 (28.9%) of the eyes had astigmatism greater than 2 D.

The postoperative refractive outcomes showed a definite hyperopic result, with 23.6% of all cases resulting in a hyperopic correction. In addition, 13% of the eyes had residual astigmatism greater than 2 D. With the average

patient age in the early presbyopic range, this refractive outcome most likely contributed as a factor in the patient's filing of a claim or suit against their surgeon. However, appropriate data in the OMIC files or physician survey were not available to allow a comparison to these 100 cases.

As stated earlier, timing of the informed consent discussion is important in building trust and rapport between the surgeon and patient. Most often this is done during the preoperative examination. In addition, evaluation of the patient's expectations and facial anatomy, as well as an eye examination, are performed at this preoperative visit. In this study, in 14 of 84 cases with responses (16.7%), the preoperative visit was performed by the comanager and not by the surgeon. In 45% of the cases, one preoperative visit occurred with the surgeon, and in 27.4%, two or more visits took place.

Similarly, postoperative visits are equally important in building and maintaining good rapport with the patient, especially following an adverse or unexpected outcome. Vincent and associates[33] surveyed 227 patients and relatives who were pursuing legal action against physicians and found several important risk factors in the care process. Following a complication or unexpected outcome, insensitive handling and poor communication by the physician were primary factors. They found that the patient blamed the physician, not so much for the original problem, but more for lack of openness or willingness to explain what happened and for lack of compassion.[19,33] These patients require additional attention and visits during the postoperative period.[34]

In this study, more than 50% of the patients were seen 6 or more times following their LASIK or PRK surgery, and 33.7% were seen more than 11 times. Only 7 of 83 available cases were not seen by the surgeon following the procedure.

Timely referral of a patient for a second opinion or additional care is fundamental to providing good patient care and reducing the risk for litigation.[35] The physician should not wait for the patient to seek another opinion and should proactively recommend referral when appropriate. Referring a patient to a respected colleague does not indicate a weakness or inability on the part of the referring physician.[35] Of 88 cases within this series, 64 (72.7%) were referred to another physician for consultation. Forty seven (73.4%) were referred by the physician, and 17 (26%) were self-referred.

Patient Background Information

Patient profiles were examined to see if there were any correlations with personal background information. For the 100 LASIK and PRK cases, the average plaintiff's age was 42.1 and the median age 43 years; 51% were women and 49% were men (Figure 36). Occupations were available for 88 of 100 patients and reflected a relatively high percentage of nonhealthcare professionals (43.2%). These included engineers, accountants, teachers, social workers, financial managers, and other business executives. Many of these individuals were described in the medical record as being "compulsive," having a "type A personality," or "aggressive."

An attempt was also made to gather information regarding the patient's general health status and medication use. The leading diagnosis for 76 of 100 cases where data were available revealed that depression and anxiety were present in 27 of 76 patients (35.5%) and other medical issues, including obesity, were present in 30.2% of patients. These underlying conditions, in combination with a less than desirable surgical outcome, were believed to be contributory factors toward the filing of a claim or suit.

Finally, data were collected in 66 of 100 cases documenting any previous disability claim or suit filed by the patient. Since one of the leading causes of filing a claim or suit by the patient is to gain compensation for loss, as well as for pain and suffering, a correlation with this type of activity was examined.[33] In 14 cases (21.2%), patients demonstrated this history. In addition, any other personal legal activity was documented in another 10 of 45 available cases (22.2%).

DISCUSSION

The most important findings of this study in identifying medical malpractice predictors for refractive surgeons were a high surgical volume and a history of a prior claim or suit. Using a statistical adjustment for volume, the risk of incurring malpractice litigation was significantly greater in higher-volume refractive practices compared to lower-volume practices. Additional risk factors for surgeons performing more than 100 cases per year were associated with gender (male), advertising, preoperative time spent with the patients, and comanagement with optometrists. Thus, a high-volume male refractive surgeon who advertises, comanages, and spends little time with his patients is at a relatively high risk for subsequent litigation, and once a claim is filed, he has an increased chance of incurring additional legal action.

The importance of developing rapport with the patient prior to surgery and maintaining it after surgery if there has been a less than desired or unexpected outcome is strongly supported in the results of this study. Other factors examined, including the patient's medical and social background, as well as many specific elements of the surgical case, may all have played some role in creating a recipe for potential litigation. These additional factors will

need to be studied in more depth in the future.

LASIK surgery has often been portrayed as nonessential cosmetic surgery performed as a business and not a medical procedure. Aggressive marketing, with a focus on price and a volume business model, provide significant jury appeal for the plaintiff's attorney. By identifying some of the risk factors associated with potential malpractice litigation in this study, it is hoped that a change in physician practice patterns will occur. Ultimately, this should help improve the overall quality of care provided to refractive surgery patients and alter the image this procedure has acquired within the legal community and the public.

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The heart and soul of this study revolved around the extensive collection of OMIC medicolegal case information, underwriting data, and survey information. This was followed by an analysis of this database, which took over 2 years to complete. Without the hard work and consistent efforts of Richard Oh, MD, a senior resident at the Jules Stein Eye Institute, and Mariko Bird, a fourth-year medical student at the University of California, San Francisco, this project would not have succeeded. Their dedication and loyalty to the project were phenomenal.

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APPENDIX 1

APPLICATION FOR PROFESSIONAL LIABILITY INSURANCE COVERAGE OPHTHALMIC MUTUAL INSURANCE COMPANY

OMIC
OPHTHALMIC MUTUAL INSURANCE COMPANY
(A Risk Retention Group)

655 BEACH STREET, SAN FRANCISCO, CA 94109-1336 P.O. BOX 880610,
SAN FRANCISCO, CA 94188-0610
Phone: (800) 562-6642 Fax: (415) 771-7087
Email: omic@omic.com Web: www.omic.com

Please PRINT or TYPE your answers and personally sign and date the application. Signature stamps are not acceptable. ***Please answer all questions COMPLETELY since incomplete information may delay processing****. If a question does not apply, use N/A.*

1. Your full name: _____
   First *Middle* *Last*

2. Name under which you do business (include DBA's):_____

3. A. Mailing Address: _____
   B. Office Phone: ( ) _____
   C. Fax Number: ( )_____ D. Email: _____

4. Status of AAO membership: ❒ Active ❒ Applicant **Please note: AAO membership is mandatory.**

5. Date of birth: _____ 6.Social security number: _____

7. **Please attach a curriculum vitae listing your medical education, Board certification, licensure, and hospital affiliation.**

Also explain any gaps of more than six months in training or practice (i.e. military service, maternity leave, etc.)

8. State the month and year you began practicing: . . . . . _____

9. Do you currently maintain active hospital privileges in each of the cities/ counties in which you practice?
   ❒ Yes ❒ No

If no, please explain. _____
If your hospitals require proof of your professional liability insurance, please provide a list of such facilities and complete mailing addresses for each.

10. At how many office locations do you practice? . . . . . _____

11. Please list the counties and states in which you practice (or intend to practice, if new to practice). Also indicate the average number of hours you practice at each and the approximate percentage of income derived from each location. Percentages must add up to 100%.

COUNTY	STATE	HOURS PER WEEK	PERCENTAGE OF INCOME
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

12. How is your practice organized? (*Please check one*)
- ❒ Sole Proprietorship (*unincorporated*)
- ❒ Sole Shareholder Professional Corporation
- ❒ Multi-Shareholder, Single-Specialty Corporation
- ❒ Multi-Shareholder, Multi-Specialty Corporation

❒ Partnership ❒ Other (Specify on the Comments page)

Name of Legal Entity:_____

13. Are you the only physician practicing in your office? . . . . . ❒ Yes ❒ No

If no, *list all physician members of your practice and the status of each using the codes below. Begin with yourself as "A."*

Continue on the attached ***Comments page****, if necessary. If any associates are not insured by OMIC,* ***submit a copy of the Declarations page from their current policy.***

STATUS CODES: **P** = Partner **S** = Shareholder **R** = Employer
E = Employee **I** = Independent Contractor **O** = Other

RELATIONSHIP CODES: **C** = Corporation **P** = Partnership
O = Office Sharing Arrangement

A. (Your Name):_____ Status:_____ Relationship:_____

B. _____ Status:_____Relationship:_____

C. _____ Status:_____Relationship:_____

14. Would you like OMIC to also insure your corporation or partnership as a separate entity at separate limits?
❒ Yes ❒ No

15. Do you own and operate a separately incorporated optical shop? ❒ Yes ❒ No

16. Do you operate a Surgi-Center or allow other physicians to use your in-office surgical suite? . . ❒ Yes ❒ No

Would you like OMIC to also insure your Surgi-Center? . . . . . ❒ Yes ❒ No

If yes*, a* ***Supplemental Surgi-Center Questionnaire*** *will be forwarded to you for completion.*

17. On ***average***, how many hours per week do you practice:

A. Direct patient care? . . . . . _____
B. Related administrative activities? . . . . . _____

18. How many patients do you encounter on an average day of clinical practice? _____

19. **A**. If you employ or contract with optometrists, nurse anesthetists, or anesthesiologists, please specify the number of each below and ***submit a copy of the Declarations page from each of their current policies***. ❒ None

	EMPLOYED	CONTRACTED
❒ Optometrists	_____	_____
❒ Nurse Anesthetists	_____	_____
❒ Anesthesiologists	_____	_____

B. Would you like to insure your employed optometrist(s)/CRNA(s) as additional insureds at ***shared*** limits under your policy? . . . . . ❒ Yes ❒ No

If yes*, an application for each employed optometrist and/or nurse anesthetist indicated will be forwarded to you for completion.*

20. Please attach a copy of your office letterhead.

21. Do you advertise (other than a general yellow pages listing) ? . . ❒ Yes ❒ No

If yes, submit copies of print, audio (i.e., radio), video (i.e. television), and Internet advertising currently used.

22. Please check your principal subspecialty. If you practice in more than one area, give the approximate percentage in each area.

❒ General Ophthalmology	%	Medical Retina	%
❒ Anterior Segment	%	Corneal & External Diseases	%
❒ Refractive Surgery	%	Oculoplastics	%
❒ Uveitis	%	Neuro-Ophthalmology	%
❒ Ophthalmic Pathology	%	Pediatric Ophthalmology	%
❒ Ocular Oncology	%	Glaucoma	%
❒ Retinal & Vitreal Surgery	%		%

23. For each of the following, please check the appropriate range for the number of procedures you have performed in the last 12 months. If you perform more than 500 of a specified procedure, indicate the approximate number of such procedures performed. If you anticipate a significant change in your surgical and/or medical activities within the next 12 months, please describe the change on the ***Comments page***. If you are new to practice, indicate the anticipated number of procedures you will perform within the next 12 months.

MEDICAL PROCEDURES	NONE	1-20	21-100	101-300	301-500	Over500
A. Fluorescein angiography	❒	❒	❒	❒	❒	_____
B. Prescription of contact lenses/glasses						
C. Botox injections (cosmetic)						

Appendix 1

SURGICAL PROCEDURES	NONE	1-20	21-100	101-300	301-500	Over500
A. Corneal transplants	❒	❒	❒	❒	❒	_____
B. Cosmetic procedures:						
blepharopigmentation						
blepharoplasty						
laser facial resurfacing						
full face lifts						
liposuction						
C. Enucleations/eviscerations						
D. Insertion of foreign matter into the eye other than IOL implants (silicone, Molteno-type valve, etc.)						

E. Lacrimal surgery:
- DCR/intubation
- probing nasal lacrimal duct

F. Laser treatments related to:
- diabetic retina
- macular degeneration
- retinal hole/tear

SURGICAL PROCEDURES	NONE	1-20	21-100	101-300	301-500	Over500
G. Lid surgeries:						
entropion/ectropion	❒	❒	❒	❒	❒	_____
functional blepharoplasty						
malignancies						
ptosis						

H. Orbital surgery:
- fracture repair
- tumors

I. Intraocular lens implants:
- phacoemulsifications
- extracapsular extractions
- intracapsular extractions
- secondary IOL's

Percentage of IOL implants which were: _____% anterior _____% posterior

J. Pterygia
K. Scleral buckle
L. Strabismus
M. Trabeculectomy
N. Vitrectomy:
- anterior
- posterior

LIMITED SURGICAL PROCEDURES	NONE	1-20	21-100	101-300	301-500	Over500
A. Laser capsulotomy	❒	❒	❒	❒	❒	_____
B. Laser iridotomy						
C. Laser iridoplasty						
D. Laser trabeculoplasty						
E. Surgical assists						

REFRACTIVE SURGERY PROCEDURES
A. Clear Lens Extraction (Refractive Lensectomy)
B. Conductive Keratoplasty (CK)
C. Epikeratophakia/Epi-grafts
D. Intrastromal Corneal Rings (Intacs)
E. LASIK/LASEK/Intralase
F. LTK
G. Phakic implants (for refractive purposes
H. Photorefractive Keratectomy (PRK)
I. Radial and/or Astigmatic Keratotomy

(*Limbal relaxing incisions performed for the purpose of reducing or eliminating astigmatism in conjunction with corneal transplant or cataract surgery is not considered "astigmatic keratotomy" for coverge purposes.)*

J. Other: _____

*If you indicated any of the above refractive surgery procedures, a **Refractive Surgery Questionnaire** for each procedure checked will be forwarded to you for completion. **No coverage for any of these procedures applies until the applicable questionnaire has been reviewed and approved**. Once approved, coverage for the specified refractive procedure(s) will be provided at full policy limits.*

24. Do you perform any procedures not related to the practice of ophthalmology? ❒ Yes ❒ No
If yes, list them on the **Comments page** and estimate the percentage of practice hours devoted to non-ophthalmic procedures.

25. Do you render your patients' pre-operative, intra-operative and post-operative care?
❒ Yes ❒ No **If no**, please provide details on the **Comments page.**

IF YOU ANSWER "YES" TO ANY OF QUESTIONS 26 THROUGH 30, PLEASE PROVIDE DETAILS ON THE COMMENTS PAGE.

26. Has any medical professional liability insurer canceled, declined coverage, refused renewal, or renewed your coverage under restrictive conditions or have you ever withdrawn your application for coverage or voluntarily canceled due to unfavorable underwriting review? ❒ Yes ❒ No

27. Have you ever been treated for mental illness, alcoholism, narcotics addiction, or other chemical dependency? ❒ Yes ❒ No

***If yes**, also include a letter from your treating physician outlining the dates of treatment and current status.*

28. Do you have ***any*** medical condition which might impair your ability to practice ophthalmology? ❒ Yes ❒ No
***If yes**, also include a letter from your treating physician describing the medical condition and outlining the dates of treatment and current status.*

29. Has ***any*** investigation, revocation, suspension, restriction, denial, other disciplinary action, or change in status occurred with respect to your license to practice, your BNDD (DEA) license, your privileges or participation at any hospital, health maintenance organization, or other medical facility, or your certification by or membership in any medical association, medical society, or medical board? ❒ Yes ❒ No

30. Has a fee complaint or professional conduct complaint ever been registered against you? ❒ Yes ❒ No

***If yes**, please provide a copy of the complaint, your answer and, if resolved, the final resolution from your Medical Board. For professional conduct complaints, also submit copies of the patient charts and operative notes if these documents are a matter of public record.*

31. A. Have any professional liability or premises liability claims or suits ever been brought against you?
❒ Yes ❒ No

B. Have you ever reported any other incidents or potential claims to your present or previous carriers?
❒ Yes ❒ No

C. Are you aware of any facts or circumstances which may give rise to a claim or suit in the future?
❒ Yes ❒ No

***If you answered "yes" to any of the above**, please complete a **Prior Claims Information** Supplement for each circumstance. For more than one incident or claim, please use photocopies of the form.*

32. List the names of all professional liability insurance carriers which have insured you during the past five years and the dates of such coverage. (Continue on the attached Comments page, if necessary.)

A. Carrier:_____From:_____To:_____

Mailing Address:_____

B. Carrier:_____From:_____To:_____

MailingAddress:_____

33. Attach a copy of the Declarations Page(s) and all applicable Endorsements from your current policy.

34. Is your current coverage on a . . . . . ❒ claims-made ❒ occurrence basis?

IF CLAIMS-MADE:

A. What is your retroactive date? . . . . . ._____

B. Do you wish to buy prior acts coverage from OMIC to insure you for new, unreported claims arising from services you provided while you were insured with your present carrier? ❒ Yes ❒ No

C. If no, do you intend to purchase extended reporting endorsement ("tail") coverage from your present carrier? . . . . . ❒ Yes ❒ No

35. What date would you like coverage to begin? . . . . . _____

36. Check the limits of liability you would like. We will provide quotations for more than one limit if requested.
❒ $100,000/$300,000* ❒ $500,000/$1,500,000 ❒ $3,000,000/$6,000,000

❒ $200,000/$600,000* ❒ $1,000,000/$3,000,000 ❒ $5,000,000/$10,000,000

❒ $250,000/$750,000* ❒ $2,000,000/$4,000,000
*Available only in states with Patient Compensation Funds

37. What class of coverage would you like?

❒ Medical ophthalmology and specified minor office procedures

❒ Limited Surgical ophthalmology

❒ Surgical ophthalmology (also includes Medical and Limited Surgical procedures)

Minor office procedures allowed under Medical ophthalmology are biopsy of lid tumors, biopsy of the conjunctiva, chalazions, epilation, incision and drainage, non-incisional entropion or ectropion repair, papillomas, punctal closure with plugs, removal of cysts and other non-cancerous skin lesions and tumors, removal of corneal epithelium, removal of superficial foreign bodies from the cornea or conjunctiva, removal of sutures, repair of minor lid lacerations limited to the skin and/or muscle, repair of minor conjunctival lacerations, laser hair removal, and tear duct probing or irrigation done under local anesthetic.

Surgical procedures allowed under Limited Surgical ophthalmology are laser capsulotomy, laser iridotomy, laser iridoplasty, laser trabeculoplasty, wedge resection for non-cancerous tumors, suture tarsorrhaphy, marginal adhesion tarsorrhaphy without incision into the tarsus, laser punctal closure, and assisting in surgery. All Medical ophthalmology procedures are also included.

APPENDIX 2

OMIC
OPHTHALMIC MUTUAL INSURANCE COMPANY
(A Risk Retention Group)

SUPPLEMENTAL QUESTIONNAIRE – **PRK and/or LASIK**
(including LASEK, Intralase, and Custom-Contoured Ablation)

OMIC requires special underwriting review of physicians requesting coverage for the performance of refractive surgical procedures. ***Coverage is not included under the policy until and unless approved and specifically endorsed***.

TRAINING AND EXPERIENCE

1. What training did you receive specific to the performance of the following procedures? **Attach a copy of your certificate(s) of completion of training.**

Procedure	PRK	LASIK
Course Title	_____	_____
Dates	_____	_____
Location	_____	_____
Sponsor	_____	_____
Laser System	_____	_____
Instructor	_____	_____

Please note that physicians must be appropriately trained and certified on the laser to qualify for coverage of laser refractive surgery. The laser manufacturer may require that LASIK surgeons complete a separate certification course in PRK to become certified on the laser. Separate training/certification is required for Custom-Contoured Ablation ("Custom-CAP"). Please check with the laser manufacturer to confirm certification requirements.

2. During your training, how many cases did you:

	Observe?	Assist?	Perform?
PRK/LASEK/Intralase/Custom-CAP			
a. Live:	_____	_____	_____
b. Human Cadaver/Animal:	_____	_____	_____

	Observe?	Assist?	Perform?
LASIK			
c. Live:	_____	_____	_____
d. Human Cadaver/Animal	_____	_____	_____

3. How many of the following procedures have you performed as primary surgeon (rough estimates are acceptable):

	PRK/LASEK/Intralase/Custom-CAP	LASIK
a. Since completion of your training?		
b. In the past 12 months?		
c. Anticipated for the next 12 months?		

4. If you have no experience as primary surgeon for laser refractive surgery procedures, do you intend to be proctored for your first several cases?
❒ Yes ❒ No

Physicians who have performed fewer than 10 surface PRKs **must be proctored** for their first five LASIK cases.

PATIENT SELECTION

5. Who conducts the pre-operative evaluations? (Check all that apply)
❒ Surgeon ❒ Surgeon's non-physician staff ❒ Laser center staff ❒ Referring optometrist

6. Criteria for degree of myopia, hyperopia, and astigmatism must fall within FDA-approved guidelines. Off-label treatment of up to 6.0D astigmatism, -15.0D myopia, and +6.0D hyperopia permitted subject to special consent language. Patients with more than the FDA-approved degree of astigmatism, myopia, or hyperopia must be advised of the laser's off-label use. This must be documented in the written consent. You must also document in the patient's medical record that the anticipated residual of X was demonstrated to and accepted by the patient.

INFORMED CONSENT

OMIC has developed sample consent forms for PRK and LASIK. Copies are attached. In addition, OMIC has approved the consent forms developed by Patient Education Concepts, Infotronics, and others. Which consent form will you use?
❒ OMIC ❒ Patient Education Concepts ❒ Infotronics ❒ Other (**please submit a copy)**

8. **Submit** a copy of your **informational video**, if any, and your **patient education literature** for these procedures, *if other than those produced by the AAO, Patient Education Concepts, or Infotronics***.**

OPERATIVE PROCEDURES

9. Where do you perform this procedure? (Please check all that apply)
❒ Your office ❒ Local physician-owned ASC
❒ Commercial laser center ❒ Academic facility

10. Are you employed or contracted by a laser center?
❒ No ❒ Employed ❒ Contracted

Do you perform this procedure in any states/counties other than the county and state of your primary practice location? ❒ Yes ❒ No

If yes, please indicate which state(s)/county(ies), how frequently you travel to that location, and for what duration:

_____

12. Which laser and technique do you follow:
❒ VISX ❒ Alcon Summit ❒ Alcon Ladar Vision
❒ Nidek ❒ B&L Technolas ❒ Other

13. Once a physician has performed 10 PRK/LASEK/Intralase cases with results satisfactory to both the patient and the surgeon, coverage for bilateral simultaneous PRK/LASEK/Intralase may be granted. Separate provisions, including underwriting review and approval, apply. (See attached request form)

Do you intend to perform bilateral simultaneous PRK/LASEK/Intralase?
❒ Yes ❒ No

14. Once a physician has performed 10 LASIK cases with results satisfactory to both the patient and the surgeon, coverage for bilateral simultaneous LASIK may be granted. Separate provisions, including underwriting review and approval, apply. (See attached request form)

Do you intend to perform bilateral simultaneous LASIK? ❒ Yes ❒ No

15. Enhancements may be performed as soon as the patient's refraction has been stable (i.e. not more than a one-half diopter change) for at least two months and the residual error is at least 0.75 D.

16. Have you obtained an IRB site approval for Custom-CAP treatment?
❒ Yes ❒ No

POST OPERATIVE CARE

17. Do you co-manage? ❒ Yes ❒ No

If yes, refer to OMIC's post-operative care guidelines.

ADVERTISING

18. Do you advertise your availability to perform laser refractive surgery?
❒ Yes ❒ No

If yes, submit a copy of your advertisement (print, audio, video, or internet). Forward to us any new advertisements or changes in your advertisements as they occur.

"I have read and hereby agree to comply with OMIC's underwriting guidelines specific to laser refractive surgery and with OMIC's standard refractive surgery guidelines. I will obtain prior approval from OMIC on a case-by-case basis for any deviation from the company's underwriting guidelines. I also agree to notify OMIC prior to implementing any intended changes to my responses above. **I understand that failure to comply with OMIC's underwriting guidelines (other than deviations specifically approved by OMIC) or to notify OMIC promptly of changes in my protocol may result in uninsured risk or termination of coverage.**"

Signature of applicant

Date

Name (type or print)

Please remember to submit the following documents with your application:

- Your certificate(s) of completion of training.
- Your consent forms (if other than OMIC, Patient Education Concepts or Infotronics).
- Your informational video, if any.
- Your patient education literature, for any.
- Your advertisements, if any.

APPENDIX 3

OMIC

OPHTHALMIC MUTUAL INSURANCE COMPANY
(A Risk Retention Group)

STANDARD REFRACTIVE SURGERY GUIDELINES

(Applicable to all refractive surgery procedures)

OMIC requires special underwriting review of physicians requesting coverage for the performance of refractive surgical procedures. A supplemental questionnaire is required for *each* type of refractive surgery procedure performed. ***Coverage is not included under the policy until and unless approved and specifically endorsed.***

PATIENT SELECTION

- Prior to surgery, the surgeon must perform and document an **independent evaluation** to determine the patient's eligibility for surgery.
- As part of the independent evaluation, the surgeon must **personally examine** the patient's eyes and ocular adnexa, perform a slit lamp exam, and carefully review topographies, pupil size, pachymetry, refractive stability, eye health history, and prior records.
- The surgeon must **carefully analyze** the patient's expectations and, when appropriate, discuss mono-vision.

Patients must meet the following eligibility criteria:

- Patients must have realistic **expectations**.
- Patients must be at least **age** 18; however, OMIC recommends that all patients be age 21 or older. For refractive surgery performed on patients between the ages of 18 and 21, refractions must be stable a minimum of 18 months, and the patient must be informed of the additional risk of progressive myopia and under-correction. This discussion must be documented in the medical record or consent form. (LTK/CK patients must be age 40 or older.)
- Patients must have a clinically demonstrable **refractive stability** over a six-month period. A 12-month or longer period of refractive stability is ideal. (Refractive stability is defined as a change of one-half diopter or less.)
- Rigid-contact lens wearers should remain **contact lens-free** until refractions and topography or keratometry readings are stable on successive readings, taken at least one week apart. (Neither topography nor keratometry readings are required for clear lens extraction.)
- Patients must undergo a comprehensive baseline **eye exam**. Cycloplegic refractions and slit lamp exams must also be performed. Corneal topography and keratometry readings on all patients (other than those undergoing clear lens extraction) are also recommended.

INFORMED CONSENT

- You, the physician, must have an informed **consent discussion** with each patient. Although other health care professionals may be involved in the informed consent process, this duty may not be delegated exclusively to non-physician staff.

- Consent must be obtained in writing. The consent form must be signed and dated by the patient **prior to surgery**.

- You must write a note in the **patient's medical record** that the risks, benefits, complications, and alternatives were discussed with each patient.

- **Each patient must receive a copy** of the consent form **prior** to the day of surgery.

POST OPERATIVE CARE

- Although other health care professionals may participate in the postoperative management of patients, **you or a designated ophthalmologist** must perform the first postoperative visit. Please also refer to Exclusion VI.A.13 of the OMIC policy regarding OMIC's postoperative care requirements (copy attached). A copy of OMIC's sample comanagement consent form is also attached.

- The first **post-operative visit** must occur within the first 24 hours (72 hours for RK/AK).

- Patients must be **followed a minimum** of 60 days.

APPENDIX 4

OMIC
OPHTHALMIC MUTUAL INSURANCE COMPANY
(A Risk Retention Group)

GUIDE TO OMIC REFRACTIVE SURGERY GUIDELINES*

OMIC believes that prudent refractive surgery underwriting guidelines help protect both the company and its insureds. These guidelines, based on sensible medical practice and sound risk management principles, were developed by practicing refractive surgeons to reduce the likelihood of claims and to aid in the defensibility of any resulting claims. OMIC is proud that its claims experience is significantly better than industry average, and we believe this is due in large part to the company's underwriting guidelines.

OMIC routinely reviews its refractive surgery guidelines and modifies them when warranted. To date, all revisions have served to expand, rather than reduce or restrict, coverage.

All procedures

- Prior to surgery, surgeon must perform and document an independent evaluation of the patient's eligibility for surgery, including slit lamp exam, review of topography, pachymetry, pupil size, and monovision option for presbyopic patients
- Patient age: at least 18 years old, stable refraction without contact lenses (off-label for Summit patients <21) for RK/AK, PRK, LASEK, LASIK, Intralase, Custom-Contoured Ablation, and Intacs; over 40 years old, stable refraction without contact lenses for LTK and CK
- Operating surgeon must conduct informed consent discussion
- Surgeon must document in medical record that risks, benefits, alternatives, and complications were discussed
- Each patient must receive a copy of the consent form prior to the day of surgery
- Surgeon or a designated ophthalmologist must perform the first postoperative visit
- Advertisements (print, audio, video, Internet) must not be misleading or guarantee results
- Surgeon must follow FDA and FTC advertising guidelines

LASIK

- Surgeon must be certified on the laser to be used as well as be certified on the microkeratome
- Criteria for degree of myopia, hyperopia, and astigmatism must fall within FDA-approved guidelines. Off-label treatment of up to 6.0D astigmatism, -15.0D myopia, and +6.0D hyperopia permitted subject to special consent language.
- Bilateral simultaneous requires previous LASIK experience (10 cases) + special OMIC consent form

PRK/LASEK/Intralase/Custom-Contoured Ablation

- Surgeon must be certified on the laser to be used
- Criteria for degree of myopia, hyperopia, and astigmatism must fall within FDA-approved guidelines. Off-label treatment of up to 6.0D astigmatism, -15.0D myopia, and +6.0D hyperopia permitted subject to special consent language.
- Bilateral simultaneous requires previous unilateral PRK experience (10 cases), no off-label use, special OMIC consent form
- Retreatment permitted after documented refractive stability

APPENDIX 5

SAMPLE MISSING INFORMATION LETTER

Date

Re: OMIC Insured: Dr Name
Plaintiff: Name
OMIC Claim Number: 100000

Dear Attorney:

OMIC is carrying out research on medical malpractice claims and lawsuits arising from LASIK and other refractive procedure. You handled a claim or claim/suit involving ***Dr defendant*** sued by ***patient plaintiff.*** There was data regarding that claim that we do not have in your file at our office. We would greatly appreciate your assistance in providing the following data:

Did the office use a consent form?

Which eye is the patient's dominant eye, OD or OS?

Did the plaintiff have any prior lawsuits, if so, how many?

What is the latest post-op refraction available, before enhancements?

You can fax or mail the response to these questions to my attention. We have provided a self-addressed stamped envelope. You can contact me or my assistant regarding any questions that you might have.

We understand that some of this data may be hard to locate and want you to know we appreciate any effort you can make to locate it. If you cannot find the data, please let us know by simply faxing the letter back to me 415-771-7087 with the statement "CANNOT FIND DATA".

We will contact you in the near future, if we have not heard from you.

Sincerely