ORIGINAL ARTICLE

Sources of Medical Error in Refractive Surgery

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ABSTRACT

PURPOSE: To evaluate the causes of laser programming errors in refractive surgery and outcomes in these cases.

METHODS: In this multicenter, retrospective chart review, 22 eyes of 18 patients who had incorrect data entered into the refractive laser computer system at the time of treatment were evaluated. Cases were analyzed to uncover the etiology of these errors, patient follow-up treatments, and final outcomes. The results were used to identify potential methods to avoid similar errors in the future.

RESULTS: Every patient experienced compromised uncorrected visual acuity requiring additional intervention, and 7 of 22 eyes (32%) lost corrected distance visual acuity (CDVA) of at least one line. Sixteen patients were suitable candidates for additional surgical correction to address these residual visual symptoms and six were not. Thirteen of 22 eyes (59%) received surgical follow-up treatment; nine eyes were treated with contact lenses. After follow-up treatment, six patients (27%) still had a loss of one line or more of CDVA. Three significant sources of error were identified: errors of cylinder conversion, data entry, and patient identification error.

CONCLUSION: Twenty-seven percent of eyes with laser programming errors ultimately lost one or more lines of CDVA. Patients who underwent surgical revision had better outcomes than those who did not. Many of the mistakes identified were likely avoidable had preventive measures been taken, such as strict adherence to patient verification protocol or rigorous rechecking of treatment parameters.

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Medical errors represent a costly, potentially devastating problem that affects every specialty in medicine. Heightened awareness of the incidence and sources of medical errors has led to implementation of numerous preventive measures designed to reduce their occurrence. In surgery, the "timeout," a mandatory pause prior to any procedure, is designed to give the physician and support staff the opportunity to reconfirm the intended procedure and patient identity, and has been implemented across the country. Despite this and multiple other safeguards, medical errors during surgery continue to be problematic, and refractive surgery is no exception. With the vast number of patients undergoing laser vision correction annually, medical errors during refractive surgery do occur. Yet, there are currently no established data regarding the incidence or cause of medical errors during refractive surgery, nor are there data on the postoperative sequelae in affected patients.

In this retrospective case series, we focused on errors that occurred during the preoperative period that were directly attributable to incorrect or inaccurate programming of the laser programming software. The goal of this study was to identify the causes of preventable errors during refractive surgery to increase the awareness among refractive surgeons and thereby help prevent future errors from occurring.

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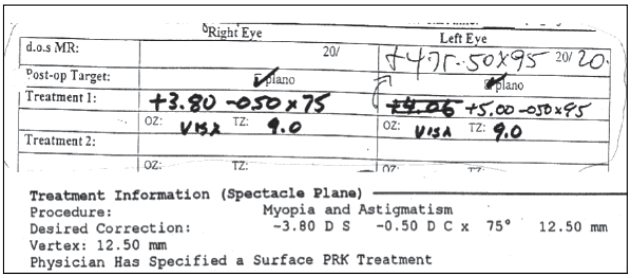

Figure 1. Sphere sign inversion during photorefractive keratectomy.

PATIENTS AND METHODS

The cases of 18 patients were identified by ophthalmologists around the United States in private practice and in academic institutions and were submitted to the researchers at The Moran Eye Center at University of Utah. In most cases, the patients had received their initial surgery at an alternate site and had been referred to the submitting surgeon for evaluation after the initial surgical error occurred. The data analyzed from each submitted case included the following: demographics, preoperative manifest refraction, preoperative corrected distance visual acuity (CDVA), programmed refractive data, type of procedure, type of error, postoperative manifest refraction, postoperative CDVA, follow-up treatment, and final visual acuity (VA). Following the categorization of the patients based on the identified source of the error, the postoperative treatment and visual outcomes were analyzed. In most cases, decisions regarding the postoperative treatment were made by the surgeon who committed the initial error. Patient data were analyzed in the order they were received and each patient was assigned a number as identification.

CASE REPORTS

PATIENT 9 – DATA ENTRY ERROR

A 56-year-old man presented for photorefractive keratectomy. The patient was hyperopic with a manifest refraction of +3.50 -0.50 × 075 in the right eye. The intended treatment was +3.80 -0.50 × 075 in the right eye, but the sphere sign was incorrectly entered as negative (-), resulting in a treatment of -3.80 -0.50 × 075 in the right eye (**Figure 1**). The patient received a myopic rather than hyperopic treatment. At 3 weeks postoperatively, uncorrected distance visual acuity (UDVA) was 20/400 in the right eye and CDVA was 20/20 with a manifest refraction of +6.00 +0.75 × 070. The treating surgeon decided the patient was not a candidate for additional surgical treatment so the patient was treated with soft contact lenses of +6.00 sphere in the right eye resulting in a contact lens CDVA of 20/25.

PATIENT 16 – CYLINDER CONVERSION ERROR

A 36-year-old man presented for LASIK. This patient's preoperative manifest refraction was -6.00 -2.00 × 180 in the right eye. His intended treatment was -8.00 +2.00 × 90 in the right eye, but the data were incorrectly entered as -8.00 +2.00 × 180 due to cylinder conversion error. Postoperative manifest refraction in the right eye was -1.00 +4.25 × 100 (**Figure 2**). Postoperative UDVA was 20/60 and CDVA was 20/30 with contact lenses. The treating surgeon determined the patient was a good candidate for LASIK enhancement to correct this error. During enhancement, a second cylinder conversion error occurred. The intended revision was -1.00 +4.25 × 100 in the right eye, but the manifest refraction data were entered as -1.00 +4.24 × 010, doubling the patient's astigmatism (from +4.25 to +7.50 diopters [D]). His manifest refraction after the second error was +1.25 +7.50 × 130 in the right eye with UDVA of 20/100. At this point, the treating surgeon decided the patient was not a candidate for further LASIK enhancement. The patient received limbal relaxing incision followed by a second limbal relaxing incision with hyperopic photorefractive keratectomy. His final CDVA was 20/40 with spectacles.

PATIENT 11 – PATIENT IDENTIFICATION ERROR

A 47-year-old man presented for LASIK. His preoperative manifest refraction was -7.00 +1.00 × 100 in the right eye and -6.00 + 1.00 × 080 in the left eye. He was misidentified as another patient in the waiting room, and received another patient's treatment of -3.00 +0.50 × 009 in the right eye and -3.00 +1.00 × 005 in the left eye. Postoperatively, his manifest refraction was -3.00 +1.00 × 105 in the right eye and -2.50 +1.75 × 095 in the left eye. The treating surgeon decided the patient was a candidate for LASIK enhancement to correct this error. The patient received LASIK retreatment, which resulted in a final UDVA of 20/20.

RESULTS

Twenty-two cases of error were identified in 18 patients; 15 were unilateral, 3 were bilateral, and 2 errors occurred in the same eye during separate procedures in one case. Mean preoperative CDVA was 20/20.45 ± 2.13 (range: 20/20 to 20/30, n = 22). Three causes of error were identified: cylinder conversion (12 eyes), data entry (7 eyes), and patient identification (4 eyes) (**Table 1**). Mean CDVA after initial surgery was 20/24.50 ± 9.86 (range: 20/15 to 20/60, n = 21). Seven of 22 eyes (32%) experienced an initial loss of CDVA of at least one line; two lost one line, three lost two lines, and two lost three lines. The safety index was 1.20 (mean postoperative CDVA/mean preoperative CDVA). Postoperatively, all patients required additional correction (**Figure 3**).

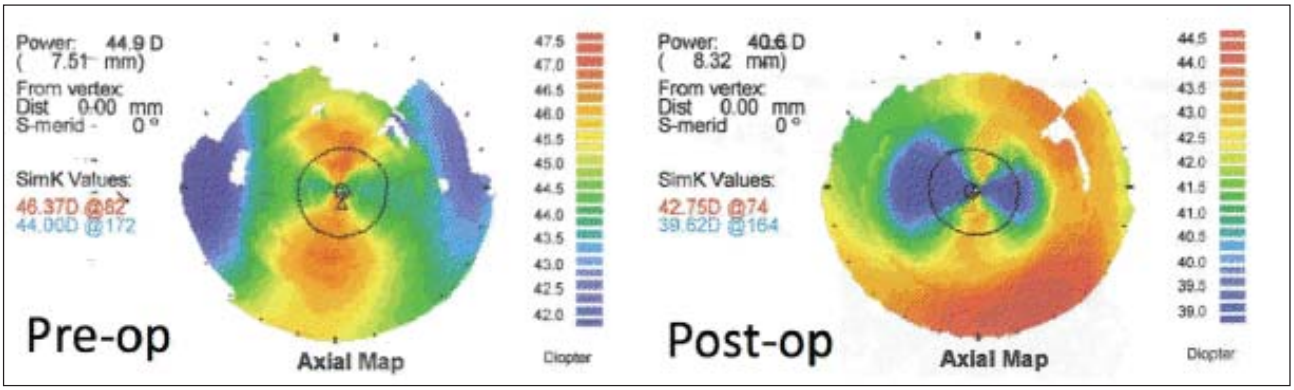

Figure 2. Preoperative (left) and postoperative (right) topography for a patient who experienced cylinder conversion error in the left eye. Preoperatively, the patient had 2.37 diopters (D) of cylinder with a steep K at axis of 82°. Postoperatively, this increased to 3.12 D of cylinder with a steep K of 74°.

TABLE 1
Patient Demographics

Case	Age (y)	Gender	Eye	Preoperative CDVA	Procedure	Error Type	Notes
1	49	N/A	Unilateral	20/20	LASIK	Data Entry	Cycloplegic refraction used in place of manifest refraction
2	38	N/A	Unilateral	20/20	LASIK	Timeout	
3	38	Male	Unilateral	20/20	LASIK	Cylinder Conversion	
4	40	Female	Unilateral	20/20	LASIK	Cylinder Conversion	
5a[a]	29	Female	Bilateral	20/20	PRK	Data Entry	Decimal point in wrong location
5b[a]	29	Female	Bilateral	20/20	PRK	Data Entry	Decimal point in wrong location
6	47	N/A	Unilateral	20/20	LASIK	Data Entry	Patient's pupil size used for cylinder value
7a[a]	27	N/A	Bilateral	20/20	PRK	Cylinder Conversion	
7b[a]	27	N/A	Bilateral	20/20	PRK	Cylinder Conversion	
8	N/A	N/A	Unilateral	20/20	LASIK	Cylinder Conversion	
9	N/A	Male	Unilateral	20/20	PRK	Data Entry	Sphere sign inversion
10	35	Female	Unilateral	20/20	LASIK	Cylinder Conversion	
11a[a]	49	Male	Bilateral	20/20	LASIK	Timeout	Patient responded to wrong name in waiting room
11b[a]	49	Male	Bilateral	20/20	LASIK	Timeout	Patient responded to wrong name in waiting room
12	N/A	Male	Unilateral	20/20	LASIK	Timeout	Doctor called patient by the wrong name during time out
13	N/A	Female	Unilateral	20/20	LASIK	Data Entry	Original LASIK treatment used in re-treatment
14	49	Female	Unilateral	20/20	LASIK	Cylinder Conversion	
15	54	Female	Unilateral	20/20	LASIK	Cylinder Conversion	
16[b]	36	Male	Unilateral	20/20	LASIK	Cylinder Conversion	Second cylinder conversion error occurred during revision of initial cylinder conversion error
16[b]	36	Male	Unilateral	20/30	LASIK	Cylinder Conversion	
17	36	Male	Unilateral	20/20	LASIK	Data Entry	
18	54	Male	Unilateral	20/20	LASIK	Cylinder Conversion	

CDVA = corrected distance visual acuity; N/A = data not available; data entry = errors associated with incorrect entry of refraction data into the laser system; time-out = efforts associated with failure to correctly or completely comply with proper timeout procedure; PRK = photorefractive keratectomy
[a]*Experienced bilateral errors.*
[b]*Experienced separate errors during two separate procedures in the same eye.*

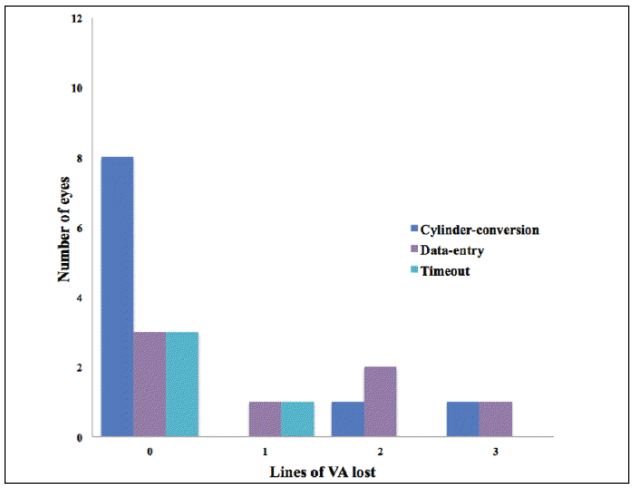

Figure 3. Lines of corrected distance visual acuity (VA) lost due to laser programming error, by error group, prior to re-treatment.

Sixteen eyes (73%) were determined to be acceptable surgical candidates by their treating surgeon and were offered further surgical correction, but three declined further surgery. Of the 13 patients re-treated surgically, 2 patients required multiple procedures. Seventeen total procedures were performed on 9 eyes, an average of 1.31 ± 0.85 (range: 1 to 4, n = 13) per eye. Of the surgically treated eyes, 11 of 13 had a final VA of 20/25 or better. The only eyes that did not achieve a VA of 20/25 or better belonged to patient 16. There were 9 eyes treated with contact lenses. Of these, 6 represented eyes judged to be poor surgical candidates by their treating surgeon; these eyes had a contact lens CDVA of 20/27.5 ± 11.29 (range: 15 to 40, n = 6). Three of the nine eyes treated with contact lenses were offered further surgical treatment but declined; they achieved a mean contact lens CDVA of 20/20 ± 0. The mean VA for

TABLE 2

Follow-up Treatment and Outcomes

Case	Error	Postoperative CDVA	Surgical Candidate for Re-treatment	Follow-Up Treatment	Postoperative Follow-Up CDVA
3	Cylinder Conversion	20/20	Yes	LASIK revision	20/20
4	Cylinder Conversion	20/15	Yes	LASIK revision	20/20
7a[a]	Cylinder Conversion	20/20	No	Contact lenses	20/15
7b[a]	Cylinder Conversion	20/20	No	Contact lenses	20/15
8	Cylinder Conversion	20/20	Yes	Astigmatic keratotomy	20/20
10	Cylinder Conversion	N/A	Yes	LASIK revision	20/25
14	Cylinder Conversion	20/20	Yes	LASIK revision	20/20
15	Cylinder Conversion	20/20	Yes	LRI, LRI, PRK, PRK	20/20
16[b]	Cylinder Conversion	20/30	Yes	LASIK revision[b]	20/60
16[b]	Cylinder Conversion	20/60	Yes	LRI, LRI, & hyperopic PRK	20/40
18	Cylinder Conversion	20/20	Yes	Contact lenses	20/20
1	Data Entry	20/25	Yes	Conductive keratoplasty	20/20
5a[a]	Data Entry	20/30	No	Contact lenses	20/40
5b[a]	Data Entry	20/30	No	Contact lenses	20/40
6	Data Entry	20/40	No	Contact lenses	20/30
9	Data Entry	20/20	No	Contact lenses	20/25
13	Data Entry	20/20	Yes	Contact lenses	20/20
17	Data Entry	20/20	Yes	Contact lenses	20/20
2	Timeout	20/20	Yes	LASIK revision	20/25
11a[a]	Timeout	20/20	Yes	LASIK revision	20/20
11b[a]	Timeout	20/20	Yes	LASIK revision	20/20
12	Timeout	20/20	Yes	LASIK revision	20/20

CDVA = corrected distance visual acuity; N/A = data not available; LRI = limbal relaxing incision; PRK = photorefractive keratectomy
[a]*Cases wherein the patient experienced bilateral errors.*
[b]*Error occurred during follow-up treatment.*

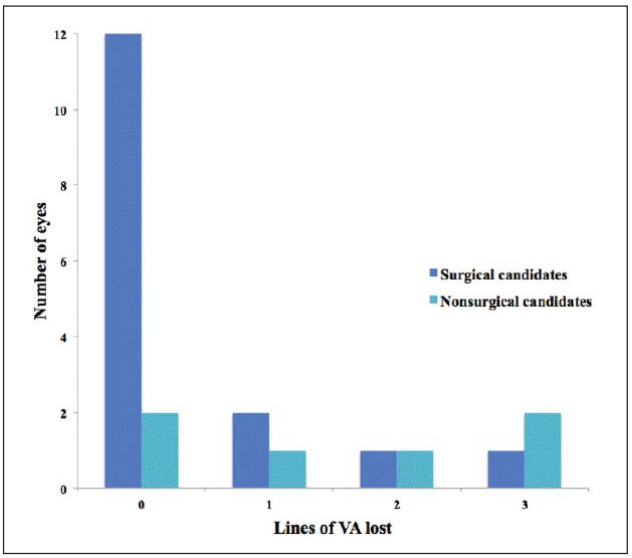

Figure 4. Final lines of visual acuity (VA) lost by surgical versus nonsurgical candidates.

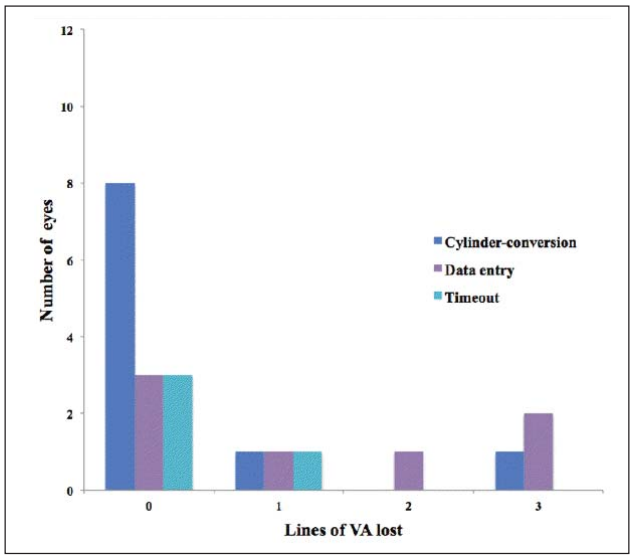

Figure 5. Final lines of visual acuity (VA) lost, by error group, after treatment to correct the initial surgery.

TABLE 3

Cylinder Conversion Errors: Preoperative, Treatment, and Postoperative Manifest Refraction

	Preoperative MR			Treatment MR			Postoperative MR				
Case	Sphere	Cylinder	Axis	Sphere	Cylinder	Axis	Sphere	Cylinder	Axis	Change in Cylinder	Lines of VA Lost After Re-treatment
3	-5.87	1.75	71	-5.25	1.75	171	-1.25	2.25	70	0.50	0
4	-8.50	1.75	65	-7.38	1.75	153	-4.00	2.75	75	1.00	0
7a[a]	-9.25	0.75	72	-8.00	1.50	165	-0.25	2.00	83	1.25	0
7b[a]	-10.75	1.25	65	-9.25	2.00	165	-1.00	2.50	80	1.25	0
8	-4.00	2.00	150	4.00	2.00	70	-2.50	4.00	150	2.00	0
10	-8.50	2.50	85	-7.25	2.50	175	-3.50	3.50	175	1.00	1
14	-6.00	1.75	90	-6.00	1.75	180	-0.75	2.75	90	1.00	0
15	-9.50	4.50	19	-5.87	7.00	120	-5.25	6.25	13	1.75	0
16	-8.00	2.00	90	-8.00	2.00	180	-1.00	4.25	100	2.25	4
17	-1.00	4.25	100	1.00	4.25	010	1.25	7.50	130	3.25	3
18	-2.25	1.25	90	-3.50	1.25	180	1.00	0.00	0	1.25	0

MR = manifest refraction; VA = visual acuity
[a]Error occurred in bilateral eyes.

all 22 eyes after last follow-up treatment was 20/25.23 ± 10.74 (range: 20/15 to 20/60, n = 22). Seven eyes (38%) lost at least one line of CDVA (**Table 2**, **Figures 4** and **5**).

Cylinder Conversion Error

Cylinder conversion errors occurred in 11 eyes (**Table 3**). Initial mean postoperative CDVA was 20/22.2 ± 7.17 (range: 20/15 to 20/40, n = 10). Mean increase in cylinder power after error was 1.27 ± 0.87 D (range: 0.50 to 3.25 D, n = 11). The average percent increase in cylinder power was 167%. Nine of 11 eyes (81%) were determined to be candidates for enhancement surgery by their treating surgeon; of these, 1 patient (1 eye) declined further treatment. Eight eyes were re-treated surgically. A total of 13 follow-up treatments were performed (LASIK = 5, astigmatic keratectomy = 1, limbal relaxing incisions = 4, photorefractive keratectomy = 3). The average number of procedures per eye was 1.63 ± 1.18 (range: 1 to 4, n = 8). Three eyes were treated with contact lenses. Final VA was 20/25 or better for 83% (10 of 12).

TABLE 4

Data Entry Errors: Preoperative, Treatment, and Postoperative Manifest Refractions

	Preoperative MR			Treatment MR			Postoperative MR			
Case	Sphere	Cylinder	Axis	Sphere	Cylinder	Axis	Sphere	Cylinder	Axis	Lines of VA Lost After Re-treatment
1	-8.50	0	0	-10.50	0	0	3.00	0	0	0
5a[a]	-2.00	1.25	110	7.37	1.25	110	4.50	0.75	70	3
5b[a]	-0.75	1.00	90	7.25	1.00	90	5.25	0.50	5	3
6	-1.50	0.75	135	-7.00	6.50	135	1.25	3.25	45	2
9	3.00	0.50	165	-4.30	0.50	165	6.00	0.75	70	1
13	-0.75	0	0	-2.00	0.75	175	1.00	0.50	80	0
17	-6.00	0.50	120	-6.00	0.50	12	Plano	0.50	90	0

MR = manifest refraction; VA = visual acuity
[a]Error occurred in bilateral eyes.

TABLE 5

Patient Identification Errors: Preoperative, Treatment, and Postoperative Manifest Refractions

	Preoperative MR			Treated MR			Postoperative MR			
Case	Sphere	Cylinder	Axis	Sphere	Cylinder	Axis	Sphere	Cylinder	Axis	Lines of VA Lost After Re-treatment
2	2.00	0	0	-4.50	1.75	90	2.00	2.00	70	1
11a[a]	-7.00	1.00	100	-3.00	0.50	9.00	-3.00	1.00	105	0
11b[a]	-6.00	1.00	80	-3.00	1.00	5.00	-2.50	1.75	95	0
12	-1.50	1.75	70	1.43	0.50	140	-2.25	2.25	160	0

MR = manifest refraction; VA = visual acuity
[a]Error occurred in bilateral eyes.

Data Entry Error

Data entry errors occurred in seven eyes (**Table 4**). Causes of incorrect data were variable (**Table 1**). After initial surgery, mean CDVA was 20/26.42 ± 7.48 (range: 20/20 to 20/40, n = 7). Three eyes of 7 patients (43%) were determined to be adequate surgical candidates for re-treatment by their treating surgeon; of these, one eye was treated surgically and two patients (2 eyes) declined further surgical intervention. One follow-up procedure was performed. Six eyes received contact lenses. Final VA was 20/25 or better in 57% (4 of 7 eyes).

Patient Identification Error

Four eyes received the wrong treatment due to incorrect identification (**Table 5**). Mean postoperative CDVA was 20/21.25 ± 2.50 (range: 20/20 to 20/25, n = 4). All patients were determined to be adequate candidates for surgical enhancement by their treating surgeon and all opted for LASIK enhancement. The total number of follow-up procedures performed was four; the average number of procedures performed per eye was one. The final VA was 20/25 or better in 100% (4 of 4 eyes).

DISCUSSION

Medical mistakes are an important topic in elective refractive surgery. When errors occur that compromise CDVA, this represents a significant adverse outcome for the patient, even if only one line of vision is lost. It is therefore critical to take all possible measures to reduce the risk of errors during laser vision correction. Although medical errors have been extensively studied in other fields, there is currently a paucity of data on this topic within refractive surgery. This case series represents the largest collection of data to date on the errors committed during laser programming. Rodriguez-Zarzuelo et al.[1] presented a case report of a bilateral cylinder conversion error during LASIK, and Karthikappallil[2] described a case of data entry error secondary to misreading a handwritten chart. Rodriguez-Prats et al. presented three cases of programming errors during LASIK; two errors were related to cylinder conversion and one to data entry error.[3] The patients described in these reports were all re-treated with LASIK and achieved satisfactory visual outcomes.

All of the errors identified in this case series were preventable. Errors of cylinder conversion were the

most common, both in our case series and in the existing literature. The source of cylinder conversion error was most frequently related to simple mistakes committed while converting cylinder notation from negative to positive (or vice versa). Data entry error was the second leading cause of error. Although there was significant variation in how these errors occurred, such as incorrect decimal point placement or switching the sphere sign, these errors should be avoidable with adequate preventive measures. The final source of error, treating the wrong patient, is entirely avoidable when proper timeout procedure is followed.

Overall, 27% of eyes with laser programming errors ultimately lost one or more lines of CDVA. The best outcomes were observed in eyes that were candidates for follow-up surgery. Patients who could not be retreated surgically had the worst outcome. Every eye in this group was dependent on contact lenses, and four eyes lost at least one line of CDVA despite corrective contact lenses.

When analyzed by error, the eyes in the patient identification failure group and cylinder conversion groups had similar outcomes. The patients in the data entry group had the worst outcome; their mean final VA was almost two lines worse than the other groups. Our sample size is too small to determine whether this finding represents a trend or is simply coincidental. We hypothesize that outcome is not related to the type of error that occurred, but more research and a larger data set are needed to test this.

Although the implications of these data may be that most patients can achieve good outcomes after such errors, we argue that any loss of vision or any case that requires additional surgery to achieve their preoperative CDVA represents a poor result. The potential for disastrous results is real and although many patients in this group were fortunate, we expect a larger study may reveal different outcomes.

Unfortunately, little information is available on this topic. An internal review of refractive surgery at the Moran Eye Center over 15 years yielded four cases of similar errors among roughly 10,000 cases, an incidence of 1 in 2,500. This incidence is small, but not insignificant. Assuming our institution is representative of most refractive centers, and given that 700,000 to 1,000,000 patients receive refractive surgery annually, we expect 280 to 400 similar errors occur each year. This further suggests that many refractive surgical errors go either unrecognized or unreported.

By identifying sources of programming errors, this case series offers valuable insight into existing safety gaps. We consistently found cylinder conversion to be a leading cause of error; as such, it would seem a better, fail-safe system is needed to ensure errors of conversion do not occur. Data entry is a significant problem throughout the healthcare field. Data entry and transcription errors are responsible for roughly 26% of all medication errors, and the error rate in clinical database entry is between 2.3% and 26.6%.[4,5] Although these numbers may not be directly applicable to refractive surgery, this case series suggests data entry error is a significant problem.

We believe the timeout initiative offers a reasonable solution. In refractive surgery, the timeout should always include a comparison of the data programmed into the laser system to the data in the patient's chart. If performed consistently before every surgery, this will reduce the incidence of data entry error. Additionally, consistent adherence to proper timeout protocol will prevent treating the wrong patient. Despite new advances to laser surgery technologies allowing for the direct transfer of data to the laser platform for custom treatments, most laser platforms still require manual entry for conventional treatments. Therefore, as long as physicians continue to use conventional treatments, manual data entry will continue to be a possible source of error in refractive surgery.

It is impossible to discuss medical errors without considering the ethical and legal dilemmas such errors cause. Informing the patient of an error can be difficult, especially given the litigious nature of society, and the desire for honesty is often tempered by fear of legal action. The surgeon may feel compelled to disguise the error and simply re-treat the patient without ever disclosing any error occurred.[6] It should be noted that evidence strongly recommends against this course. Numerous studies have shown a patient's decision to sue is based more on the perceived lack of communication between patient and physician than the actual error that occurred.[7,8] Furthermore, when hidden errors are eventually uncovered, the repercussions for the surgeon are significant and often disastrous. We therefore strongly recommend the surgeon immediately inform the patient in the event of any error during surgery.

Understanding the sources of error during refractive surgery is a critical step in prevention. With increased awareness of the sources of these errors, we may better identify methods to eliminate such errors. Clearly, more research is warranted to better understand the frequency of these errors, patient outcomes, and the efficacy of basic preventative measures in eliminating programming errors as a source of medical error during refractive surgery.

AUTHOR CONTRIBUTIONS

Study concept and design (MM, WWC, WBT); data collection (SBD, WWC, SEP, NAS, DBC, WBT); analysis and interpretation of

data (RGS, SBD, SMC, JNE, SEP, NAS); drafting of the manuscript (MM, RGS, SMC, JNE); critical revision of the manuscript (MM, RGS, SBD, SMC, JNE, WWC, NAS, DBC, WBT); supervision (MM, JNE)

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