Diplopia and Strabismus After Corneal Refractive Surgery

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ABSTRACT Introduction: Diplopia and strabismus are known complications after corneal refractive surgery (CRS). Within the U.S. Armed Forces, refractive surgery is used to improve the operational readiness of the service member, and these complications could cause significant degradation to their capability. This study was performed in order to identify the incidence of strabismus and diplopia following CRS within the U.S. Military Health System. Methods: A retrospective review of all patients who underwent photorefractive keratectomy (PRK) or laser-assisted in situ keratomileusis (LASIK) in the Department of Defense from January 2006 through September 2013 was designed and approved by the Naval Medical Center Portsmouth Institutional Review Board. The military health system data mart was queried for all patients who underwent one of these procedures and subsequently had an International Classification of Disease-9 code for any strabismus or diplopia through 2014 allowing at least 1 year of follow-up. We then calculated the incidence of both diplopia and strabismus for these procedures as the primary measure and the overall prevalence as a secondary measure. Results: A total of 108,157 patients underwent PRK or LASIK during our study period with 41 of these patients subsequently having a diagnosis of diplopia or strabismus. After chart review, 16 of these patients were excluded resulting in 25 patients for inclusion in either the strabismus (23 patients, 0.02%) or diplopia (3 patients, 0.003%) cohorts with one patient having both. Of the 23 patients with postoperative strabismus, 4 were new cases giving an incidence of 0.004% and 2 new cases of diplopia for an incidence of 0.002%. Conclusion: Diplopia and strabismus are rare complications after CRS in the U.S. military population. These procedures continue to increase the operational readiness of our service members with minimal risk of these potentially debilitating complications. Overall, this study provides support for the continued use of PRK and LASIK despite study limitations related to the use of large databases for retrospective review. Future prospective studies using delineated preoperative and postoperative examinations with sensorimotor testing included may be able to resolve the limitations of this study.

INTRODUCTION

Corneal refractive surgery (CRS), particularly photorefractive keratectomy (PRK) and laser-assisted in situ keratomileusis (LASIK), is performed to reduce a patient's reliance on spectacles to achieve their best vision. These procedures are considered safe; however, cases of postoperative diplopia and strabismus have been described.[1–3] Causative mechanisms included technical and surgical errors that lead to the induction of monocular diplopia, decompensation of previously well-controlled strabismus, or induction of aniseikonia.[4–15] Although screening tools and guidelines have been developed to minimize the risk of these postoperative complications, the incidence of postoperative diplopia and strabismus has not been well characterized.

METHODS

A retrospective analysis was conducted after approval from the Naval Medical Center Portsmouth Institutional Review Board for all patients who underwent PRK or LASIK in the U.S. Military Health System (MHS) from January 2006 through September 2013. A sub-query within this group using International Classification of Disease-9 (ICD9) codes for strabismus and diplopia was then performed to identify the initial cohort for this study. ICD9 code 368.2 was used for diplopia, and all codes between 378.00 and 378.9 were used when searching for strabismus in order to include all forms of strabismus. Exclusion criteria included age less than 18, surgery outside the dates of the study, or incorrectly coded diagnosis or procedure. The charts of the patients who met criteria were then reviewed for demographic and ophthalmic data. Medical records were reviewed through 2014 allowing at least 1 year of follow-up after surgery for each patient.

All patients underwent preoperative evaluation that included cycloplegic refraction, corneal topography, slit lamp exam, and dilated fundus exam. Preoperative evaluation of the sensorimotor status was variable and ranged from asking patients about any strabismus history to performing detailed oculomotor examination. Preoperative data collected from patients' charts included age, sex, manifest and cycloplegic

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TABLE I. New Cases of Postrefractive Surgery Strabismus

Patient	Age	Sex	Preoperative Manifest Refraction	Postoperative Manifest Refraction	Strabismus	Follow-up Length (years)
3	23	M	OD: −6.00 + 0.25 × 085 OS: −6.25 + 0.50 × 100	OD: 0.00 OS: −0.75 + 0.50 × 097	"High" exophoria at near	3.75
11	27	F	OD: −3.75 + 1.00 × 070 OS: −4.00 + 1.25 × 100	OD: −0.50 + 0.25 × 160 OS: −0.50 + 0.25 × 110	25PD esophoria at post-op month 1 only	2.13
24	22	M	OD: −6.25 + 1.50 × 125 OS: −7.75 + 2.25 × 055	OD: −0.75 sph OS: −0.50 + 0.25 × 057	6PD exophoria	1.79
25	41	M	OD: −6.75 + 0.75 × 020 OS: −6.00 sph	OD: Pl +0.50 × 097 OS: Pl +0.50 × 095	1-2PD left hyperphoria	1.23

OD, right eye; OS, left eye.

refractions, history of diplopia, strabismus, and amblyopia. All cases were performed using standard refractive surgery techniques, utilizing either the VISX Star 4 or Allegretto Wavelight platforms with all LASIK flaps created using the iFS® femtosecond laser. Intraoperative data collected included type of surgical procedure, type of machine, intended correction, and ablation zone. Postoperative data included manifest refraction as well as subjective complaint or objective findings of diplopia or strabismus. Statistical analysis was conducted by using Microsoft Excel to calculate the prevalence and incidence of both diplopia and strabismus over the study period. Incidence calculations were made using only new cases of strabismus or diplopia after CRS.

RESULTS

Our review identified 108,157 patients who underwent PRK or LASIK during our study period. Forty-one patients met the inclusion criteria of also having an ICD code for diplopia or strabismus in the postoperative period; however, 16 of these patients were excluded upon further chart review. Reasons for exclusion included refractive surgery performed outside of inclusive date range (13 patients) and incorrectly coded as having undergone CRS (3 patients).

Final analysis was performed on 25 patients. Their ages ranged from 20 to 57 years (mean ± SD, 29.2 ± 9.6 years) and the sex distribution was 19 males and 6 females. The postoperative follow-up period averaged 2.2 ± 1.1 years. In the preoperative state, 19 of the patients had strabismus and 2 had diplopia. Both of the patients with preoperative diplopia also had preoperative strabismus. Postoperatively, there were two new cases of diplopia, of which both were monocular diplopia, and four new cases of strabismus (Table I). Including all cases, the postoperative prevalence of diplopia and strabismus was 0.003 and 0.02%, respectively. When evaluating only new cases of diplopia or strabismus, the incidence was 0.002% (2 patients) and 0.004% (4 patients), respectively. In our cohort, we did not have any patients with preoperative strabismus who decompensated resulting in postoperative diplopia.

Postoperative Strabismus

The four new cases of strabismus were varied in presentation (Table I). The first patient (no. 3) was a 23-year-old male who underwent PRK as a 6 Diopter myope (spherical equivalent) with a plano refractive result. At his 1-week follow-up visit, he was noted to have a "high exophoria" at near with a normal near point of convergence. He did not complain of diplopia and his strabismus resolved by his 6-month follow-up and was never reported again over a 4-year period. The second case (no. 11) was a 27-year-old female who underwent PRK with approximately 4D of myopia with a final refractive result of low myopic astigmatism. At her 1-month postoperative visit, she was noted to have 25 prism diopters (PDs) of right esotropia with a left eye preference. Five months later when her postoperative refraction was performed, there was no mention of this esotropia nor through the remainder of her 2-year follow-up period.

The third patient (no. 24) underwent LASIK with a preoperative refraction of −5.50D OD and −6.75D OS (spherical equivalent). After treatment, he had a low residual myopic refraction, but was noted to have a 6 PD exophoria. The patient had no complaints of diplopia or strabismus and was followed for nearly 2 years without further concerns. The final patient (no. 25) was a 41-year-old male who underwent PRK for his approximately 6 diopters of myopia. Prior to surgery, he had two notes documenting orthophoria with cover testing; however, postoperatively, he developed a small, asymptomatic, left hyperphoria, which was not mentioned at any future visits over the next year.

Postoperative Diplopia

Two patients developed new diplopia in this study. The first patient was a 46-year-old male who had a preoperative cycloplegic refraction of −2.25 sph in the right eye and −3.00 sph in the left. He underwent PRK with an 8 mm ablation zone, and at 4 days postoperative, he noted monocular diplopia in both eyes without abnormal findings on examination. His postoperative course was otherwise unremarkable, and by 6 months, the diplopia had resolved.

The second patient to develop postoperative diplopia was a 26-year-old female with a preoperative refraction of $-3.75 + 0.25 \times 090$ in the right eye and -2.75 sph in the left. PRK was performed with a 9.1 mm ablation zone in the right eye and a 7.1 mm ablation zone in the left. The difference in ablation zones was not discussed further in her record and is of unknown significance. She noted diplopia at her 1-week postoperative visit, which was not further described; however, it had resolved without any intervention by her next postoperative visit.

DISCUSSION

This study indicates that diplopia and strabismus are rare findings after refractive surgery in the U.S. MHS. Furthermore, there were no episodes of decompensated strabismus leading to diplopia. Multiple causes for postrefractive surgery strabismus have been described, and it appears that the patients in this study also follow this varied pattern.[1,4,7–12,15]

Previous case reports[4,8] have described multiple causes of esotropia following refractive surgery including residual hyperopia in those with pre-existing accommodative esotropia, overcorrected myopia in patients with history of accommodative esotropia, or residual accommodation in patients with accommodative esotropia. In the case of patient no. 11, we are not able to elucidate further why he had documented a large angle esotropia at his 1-month visit. He had no history of accommodative esotropia, was not overcorrected, and did not complain of any diplopia. It is therefore possible that this was not a true finding. Given the patient population of military members, it is also possible that fear of career implications may have precluded the patient from self-reporting diplopia, which further clouds the cause of this apparently resolving large angle esotropia.

Patient no. 24 had well-controlled exophoria at distance measuring 6PD, without any reported diplopia. He had no previous history of intermittent exotropia or evidence of myopic overcorrection, which has been previously described as causes of exodeviation.[9–11] Lastly, one patient (no. 25) displayed an asymptomatic small left hyperphoria of 1-2 PD. He had no previous history of congenital fourth nerve palsy or decentration of the ablation zone, which has been previously reported as causes for postoperative vertical deviations.[1,4,13]

The reason for such a low prevalence and incidence may be due to the initial screening requirements that are performed prior to joining the U.S. military. Patients with underlying diplopia or strabismus may be excluded from service or not attempt to enter the military. However, the MHS also provides a unique opportunity to track postoperative complications, as patients receive continued care under a unified system, providing readily available, postoperative access to optometrists, refractive surgeons, and strabismus surgeons.

There are significant limitations of this study due to the retrospective nature of the data. As a result, it is unclear whether refractive surgery was the cause of the four new cases of strabismus, as other cofounders may have been unaccounted. Additional limitations to this study are introduced due to the variability of the preoperative sensorimotor examination. Each refractive surgery center in this study had their own requirements as to the level of detail for the preoperative sensorimotor examination, which led to some patients with pre-existing strabismus not undergoing a full evaluation. Each refractive surgery center in this study has their own requirements for preoperative sensorimotor examination. Whereas we found overall few patients with preoperative strabismus, a prior prospective study found 47% of patients had preoperative asymptomatic ocular misalignment.[12] Beyond the variability of preoperative strabismus screening, it is likely that by limiting our data search to patients with strabismus diagnoses only after the date of refractive surgery we have excluded patients with asymptomatic strabismus in the preoperative period that did not have further testing postoperatively. The variability of the postoperative examination is also an important limitation of this retrospective study. As there is no standard postoperative strabismus evaluation performed on every patient, it is likely that this study did not capture patients with small, asymptomatic eye misalignment. An additional significant limitation of this study is the reliance on proper coding. It is highly likely that some patients with either postoperative diplopia or strabismus were not included due to lack of coding or improper coding of the ICD diagnosis. This limitation is minimized by the large denominator of patients in the study thereby requiring a large number of missed patients to make a clinically relevant change to the incidence or prevalence of diplopia or strabismus.

CONCLUSION

Despite the known presence of diplopia and strabismus as possible complications after CRS, there has been scant data on their incidence. We present that these are rare complications in the U.S. MHS. Furthermore, none of the patients with postoperative strabismus had symptomatic diplopia, and out of the patients with diplopia, none of them had symptoms lasting greater than 6 months. As this study was not powered to evaluate or identify risk factors for diplopia or strabismus, we are unable to comment beyond providing the case details for those effected. Care must be taken when applying this study across the general population, as the population of this study was screened for military service, thus potentially excluding patients who may be at a higher risk for developing strabismus following refractive surgery. We also caution that it is quite likely that some patients were not captured in this retrospective cohort and the true incidence could be higher than we have reported. Further prospective study using standardized preoperative and postoperative sensorimotor examination may be able to improve upon these data.

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