Abstract

Background: Refractive surgery is performed to correct refractive error as an alternative to glasses or contact lenses.

Aims: To determine the types and frequency of subjective complaints for patients experiencing complications following refractive surgery.

Methods: Participation in the Complications of Refractive Surgery (CORS) survey was voluntary and self-initiated through subject contact with the Surgical Eyes Foundation web site. Patients initially provided an open-ended general complaint, and were later queried about depression, suicidal ideation, and overall success status as judged by their doctor.

Results: A total of 517 responses were submitted. After exclusion criteria, 392 responses were coded resulting in 36 separate subjective complaint categories. 195/392 (50%) responded to the three follow-up questions. 58 subjects reported suicidal ideation as a result of the surgical procedure, and 83% (48/58) of this group were referred to as successes by their surgeon. 115 subjects reported severe depression as a result of the surgical procedure, and 76% (87/115) of this group were referred to as successes by their surgeon.

Conclusions: A multitude of visual complaints and severe psychiatric morbidity may occur after elective refractive surgery. Physicians' and patients' evaluations of quality of life may differ drastically, as evidenced by large numbers of patients experiencing severe depression and suicidal ideation while simultaneously being referred to as a success by their surgeon.

Within refractive surgery, the notion of a "complication" conjures a dichotomous boundary between health and disease. Progressive corneal ectasia, for example, is a pathological process that is either present or absent, even though it may proceed at different rates in different individuals. For other post-surgery complications, however, a continuum of abnormal functioning exist that forces scientific observers to choose arbitrary threshold values when defining disease states. For example, it is generally accepted that the loss of two or more lines of Best Spectacle Corrected Visual Acuity (BSCVA) following a surgical procedure is a valid safety marker, even though a paucity of studies provide external validity for this cutoff value. In the absence of such studies, we can only say that a loss of two or more Snellen lines of vision (i.e. 10 letters) has been accepted as being clinically meaningful simply because a gain or loss of one line of vision can occur from one examination to another in unoperated eyes (particularly in individuals with vision measurements of 20/10, 20/12, and 20/16) (Waring et al., 1987).

In the absence of formal scientific inquiry, however, it is impossible to determine the relationship between quality of life and losses in BSCVA. Moreover, since BSCVA may remain constant while quality of vision is lost, overall quality of life may decline with no apparent measurement consequences in terms of Snellen eye chart scores. Hence, changes in Snellen vision following refractive surgery may not be a sufficiently sensitive outcome variable, and may result in underreporting of complications. For this reason, quality of life analysis (Vitale, Schein, Meinert, & Steinberg, 2000; Schein, Vitale, Cassard, Steinberg, 2001) and quality of vision analysis (McLeod, 2001) following refractive surgery are gaining popularity, as evidenced by the recent emphasis on wavefront studies, which attempt to quantify the functioning of the total optical system. As a pilot study, our initial purpose was simply to assess the primary complaints offered by visitors to the Surgical Eyes Foundation web page

(http://web.archive.org/web/20020613125146/http://www.surgicaleyes.org/index.html), and to examine these complaints in conjunction with three external validators: Self-reported severe depression, self-reported suicidal ideation, and surgeon judgment of success, as reported by the patient.

Materials and Methods

Participation in the CORS survey was voluntary and self-initiated through subject contact with the Surgical Eyes Foundation web page (http://web.archive.org/web/20020613125146/http://www.surgicaleyes.org/index.html). No effort was made to ensure comprehensive participation for all subjects visiting the Surgical Eyes Foundation site, although potential subjects were occasionally urged to participate in a non-systematic fashion through electronic mail and the foundation's bulletin board.

Lacking any well-defined taxonomy of complications, the first portion of the study was designed to discover the language in which patients think about, and communicate, their complications. The stimulus question was open ended, and simply asked for a general complaint following refractive surgery. Accordingly, subjects were free to provide answers of any length. No list of complications was provided that might standardize responses across subjects, since this could potentially bias the subjects thinking about their complications and thereby limit the scope of responses received.

Since patient responses to an open-ended question may vary in length and complexity, a systematic coding system was developed by one of us (RD) to quantify the type and frequency of all patient-reported complications. Exclusion criteria for both the raw response data, and the tabulated complication categories, included the following: (a) duplicate, incomplete, false, or

incomprehensible responses, (b) responses without reported complications, (c) infrequent or uncommon surgical procedures or scenarios, (d) the absence of an antecedent refractive surgical procedure, (e) the circumstance of unilateral refractive surgery, and (f) infrequent complication categories that totaled three or less.

During coding of the responses, perceptual level visual symptoms and functioning were considered to represent relevant study variables, rather than examination findings or test results. Perceptual level variables were chosen simply because: (a) subjects are not ophthalmologists, and process their visual world at the level of perception, and (b) a single tissue variable, such as a central island, can produce multiple effects at the level of perception (e.g. "fuzzy vision" was included, whereas “decentered ablation” was not included). Moreover, we had no valid method to verify the veracity of examination findings, or test results, since the patient’s ophthalmologist(s) were not participants in the study.

Each participant in the final study sample was electronically mailed three additional questions: (a) Have you ever thought about suicide (regardless of whether you’d ever actually do it) because of the effects of your surgery?, (b) Have you ever been severely depressed because of the effects of your surgery?, and (c) Did your surgeon refer to you as a success?. To potentially increase the response rate, subjects were informed that they were being solicited to increase the “quality of the data,” and that the results would be tabulated for possible publication in a peer-reviewed ophthalmic journal. Moreover, subjects were informed that without sufficient participation, the study would be criticized on the grounds that only the most severely impaired individuals chose to respond. To ascertain if patients with more severe findings were more likely to respond to the follow-up questions, the mean number of positive responses was tallied across

all complaint categories, and a comparison was made between responders, non-responders, and those who could not respond because their e-mail address had changed.

Results

A total of 517 responses were submitted to the initial open-ended survey question. Of these, 37 responses were disqualified as being false or duplicate, 30 responses failed to provide comprehensible or adequate outcome data, 23 responses were disqualified as representing cases of multiple types of refractive surgery on both eyes or separate types of refractive surgery on each eye, 21 responses were disqualified for not reporting a complication, 8 responses were disqualified as representing uncommon or infrequent surgical procedures (e.g. ALK), 4 responses failed to specify the type of antecedent surgery, and 2 responses were disqualified for unilateral surgery. Thus, a total of 392 responses were coded, and comprise the final sample population.

A total of 36 response categories were generated: (1) Headaches, (2) Dry Eye, (3) Loss of Contrast Sensitivity, (4) Depth Perception, (5) Night Halos, (6) Night Driving Difficulty, (7) Low Light Problems, (8) Halos, (9) Ghosting, (10) Starbursts, (11) Double Vision or Polyopia, (12) Glare, (13) GASH (an informal term used among patients to connote the co-morbidity of glare, astigmatism, starbursting and haloes), (14) "Distorted or Weird or Warped Vision" (single category), (15) Haze, (16) Poor Distance Vision, (17) Photophobia, (18) Difficulty with Fluorescent Lights, (19) Eye Pain or Discomfort, (20) Eye Strain, (21) Eyes Don't Work Together, (22) Driving Problems, (23) Fluctuating Vision, (24) Floaters, (25) Flashes, Fog or Cloudiness, (26) Fuzzy Vision, (27) Smudged or Smeared Vision, (28) Hazy Images, (29) Acuity Issues Loss of BCVA, (30) Blurred Vision, (31) Reading Problems, (32) Poor Near

Vision, (33) Lack of Fine Detail or Sharpness, (34) Blurred Vision, (35) Poor Near Vision, and (36) Poor Distance Vision.

Electronic mail (i.e. the three additional questions) was sent to the entire 392 subject cohort comprising the final sample, eliciting 195 responses, 129 non-responders, and 68 instances of electronic mail being returned as undeliverable, thereby yielding a response rate of approximately 50% (195/392). The undeliverable group (n = 68) averaged 3.35 positive responses across the tabulated complaint categories, the responder group (n = 195) averaged 3.25 across the tabulated complaint categories, and the non-responder group (n = 129) averaged 3.19. Based upon these reasonably similar values, we have no reason to infer that only more severely impaired subjects were likely to respond to our request for additional information.

The raw frequencies concerning subjects who reported severe depression and suicidal ideation due to the effects of their refractive surgery are reported in Table 1, and further divided according to the surgeon's judgment of a successful outcome, as reported by the patient. For the group who experienced suicidal ideation as a result of their refractive surgery (n = 58), 83% (48/58) were referred to as a success by their refractive surgeon. For the group who experienced severe depression as a result of their refractive surgery (n = 115), 76% (87/115) were referred to as a success by their refractive surgeon (while all suicidal subjects are likely to be severely depressed, not all severely depressed subjects are suicidal).

Table 2 reports various complication categories and the frequencies of psychological complications and surgeon judgment of success for all patients, and is presented to answer two questions: (1) Of patients who complain of X as a complication (and for which data on severe depression and suicidal ideation are available), what percentage admit to having been severely depressed, or having experienced suicidal ideation, because of the results of their refractive

surgery?; and (2) Of the total patients in the sample who complain of X as a complication, what percentage are judged a success by their surgeons?" Note that Table 2 does not answer questions about the relationship between the co-morbidity of complications and the presence of severe depression and suicidal ideation. Table 2 discloses that the findings are roughly consistent across all major categories of patient complaints, both for depression and suicidal ideation.

Tables 3 and 4 report subjective complaints of patients experiencing suicidal ideation and severe depression, specifically confined to LASIK. Since most patients report three or more coded complications, a given subject can be listed in more than one complaint category.

Discussion

The current study suffers from a number of limitations that should be acknowledged at the outset. First, the subject sample self-selected into the study, both for the original survey question and for the subsequent follow-up survey questions. Hence, the authors do not maintain that the sample is representative of the universe of all refractive surgery outcomes, of all LASIK outcomes, or even representative of visitors to the Surgical Eyes Foundation web page. Second, no list of complications was provided that would standardize response options throughout the sample. Consequently, some subjects described their complications in idiosyncratic or unusual ways that could not be coded, and therefore, could not be subjected to statistical analysis. Moreover, although all subjects averaged just over three subjective complaints, there is no guarantee that descriptions given by any particular subject is complete, or comprehensive. We might argue, for example, that subjects experiencing extensive co-morbidity of complications are likely to give descriptive bias to those that salient on a particular day. Third, due to their visual compromise, some subjects complained that they could not see the print as they were typing,

which may have limited complete responses. Fourth, some subjects are simply more verbal than others, and are therefore more likely to attempt a complete response, whereas subjects who are less verbal are likely to express less detail when responding to open ended questions. Fifth, it is possible that depressed subjects may not have described their visual situation as completely as those who were not depressed. Poverty of expression is a well-known characteristic of depression, sometimes resulting in depressive pseudodementia in severe cases (Gregory, 1987). Sixth, some subjects preferred to describe their situation in terms of medical terminology (e.g., irregular astigmatism), while others preferred perceptual-level reports (e.g., ghosting), further decreasing response standardization. Moreover, it is uncertain whether subjects preferring medical terminology were self-diagnosed, diagnosed by their eye care provider, and whether each subject was provided with an exhaustive description of their complications by their provider(s), if at all. Seventh, it is possible that more severely impaired subjects provided less detail about their condition, in order to minimize the response burden of the open-ended format.

Keeping the limitations of the data firmly in mind, the results of this study raise many more questions than they answer, providing fertile ground for further research. Some of these questions focus narrowly on the internal validity of the present study: Can we be certain, with regard to Tables 3 and 4, for example, that mesopic/scotopic problems are more or less important than ghosting in their contribution to suicidal ideation or severe depression? Can we be certain that other complications are less important than Dry Eye Syndrome as the most frequently reported complication among patients experiencing suicidal ideation? Our answers to these questions are "No," simply because of the lack of reliability inherent in the open-ended response format. Moreover, it should not be assumed that complications that do not appear in Tables 3 and 4 are not associated with depression or suicidal ideation (i.e. correlations are different from

positive predictive power). Rare complications that are particularly severe when they do occur can, for example, be expected to show higher positive predictive power for psychological and emotional trauma (e.g. blindness due to any cause).

While important, such questions are perhaps the most uninteresting aspect of the current study. Of the 192 subjects responding to our follow-up psychological questions, 115 subjects reported severe depression while 58 subjects reported suicidal ideation as a result of their refractive surgical procedure (Table 1). The finding that suicidal ideation and severe depression may be associated with any complication of refractive surgery is both novel and dramatic, especially given the elective nature of procedure itself. Of course, we are limited by the fact that we do not know each patient's pre-morbid psychiatric status. However, the mere fact that optical correction (i.e. spectacles) is the time honored alternative to refractive surgery, which is both 100% safe and readily available, should drastically lower our threshold for accepting severe psychiatric complications that carry profound morbidity.

Also concerning is the finding that a large percentage of patients were considered a success by their surgeons, as reported by the patient, and yet were experiencing severe depression and/or suicidal ideation. While it may seem counterintuitive to the medical community that refractive surgeons cannot reliably judge success or failure for their own patients, published literature supports the tenet that physicians' and patients' evaluations of surgical results may differ dramatically, especially when the patient is not satisfied with the outcome (Haworth, Hopkins, Ells, Ackroyd, Mowat, 1981; Jachuck, Brierley, Jachuck, & Wilcox, 1982; Slevin, Plant, Lynch, Drinkwater, Gregory, 1988; Lieberman et al., 1996). For example, following total hip arthroplasty, Lieberman and colleagues (1996) reported that physicians' had significantly better ratings than the patients themselves in the areas of general

heath, walking ability, pain in the thigh, and improvement in overall quality of life, disclosing the difficulty physicians' experience analyzing the outcome of a particular therapeutic intervention objectively. Explanations for the differences between physicians' and patients' evaluations may include: (1) physicians and patients may have different expectations after an operative procedure, (2) physicians and patients may have a different definition of what constitutes an excellent outcome, (3) patients may not communicate their problems clearly for fear of disappointing the physician, (4) the physician may not comprehend the true nature of the patient's problems and/or dissatisfaction, and/or (5) the patient's assessment of the procedure may be influenced by the quality of the doctor-patient relationship (Lieberman et al., 1996). Based upon these data, and our striking psychiatric morbidity findings, it is clear that physicians' and patients' may evaluate a given outcome from markedly different perspectives, further substantiating the need for validated quality of life survey instruments when scientifically evaluating refractive surgery outcomes. Although Snellen vision scores were not included as a dependent variable in the current study, we can speculate that Snellen scores may be partially responsible for the discrepancy between patient and provider judgment of success, given that loss of Snellen BSCVA has been generally accepted as a primary safety marker among the refractive surgery industry, and refractive surgeons. Clearly, Snellen visual acuity cannot describe the totality of patients' subjective visual function. In agreement with prior investigators, (Haworth, Hopkins, Ells, Ackroyd, Mowat, 1981; Jachuck, Brierley, Jachuck, & Wilcox, 1982; Slevin, Plant, Lynch, Drinkwater, Gregory, 1988; Lieberman et al., 1996) our findings support the inclusion of patient generated quality of life data when validating refractive surgical procedures.

Further research is warranted in order to better define rates of various visual complications from a patient's perspective, both in terms of overall quality of life and quality of

vision. Specifically, the co-morbidity of visual complications requires detailed investigation since many subjects in our cohort reported the simultaneous existence of seemingly disparate visual complaints, and it is not known how various complications interact to yield an increased risk of psychiatric morbidity. Clearly, the finding that suicidal ideation and/or severe depression may occur in association with a refractive surgical procedure warrants further comprehensive investigation to better determine incidence and prevalence figures. To this end, we wholeheartedly endorse the use of validated quality of life survey instruments, both preoperatively and postoperatively, to better assess patient outcomes following refractive surgical procedures.

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