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**from the editors**

Format for reporting refractive surgical data

## **Format for reporting refractive surgical data**

**W**ith the proliferation of refractive surgical procedures, it is essential that refractive surgical data be reported in a clear and consistent manner.<sup>1,2</sup> Regrettably, current data presentation is somewhat haphazard, and key data may be incompletely or unclearly described. To assist readers and authors alike, the editors of this journal wish to establish a standard format for data presentation that will be incorporated into the Instructions for Authors. The adoption of a standard format should also serve as a guide for developing a study design that will capture pertinent data in a systematic manner.

We describe the important structural and reporting elements of refractive surgical articles. Essentially all these elements are mandatory, although some could be omitted if not pertinent to the particular study.

### **Introduction**

The authors should succinctly (1) describe the background issues that stimulated the study and (2) indicate the purpose of the study, including the procedure, target population, and outcome measure(s).

### **Materials (Patients) and Methods**

All elements of this section should be described in sufficient detail for the informed reader to repeat the study. Numerical data should be reported using means, standard deviations, ranges, and, where appropriate, 90% confidence intervals.

**Demographic Data:** Number of eyes originally enrolled in the study, specifying patient age and gender, and inclusion and exclusion criteria.

**Baseline Refractive Error:** Grouped according to categories in accordance with prior publications and standards (e.g., myopia: 0 to -3.00 diopters (D), -3.12 to -6.00 D, -6.12 to -10.00 D, etc.).

**Procedures:** The methodology of all pertinent as-

pects of the examination techniques, operative procedures, and preoperative and postoperative treatments, indicating the individuals who performed the surgical procedure(s) and key elements of the examination. For postoperative secondary surgical interventions, the indications and procedures should be similarly defined.

**Period of Study:** The minimal follow-up interval and the number and percentage of patients seen at each follow-up examination. In general, 6 months is the recommended minimal follow-up interval, but this may vary according to the type of procedure and the nature of the study.

**Statistics:** Statistical analysis of all data comparisons with a description of the statistical tools used.

### **Results**

**Safety:** (1) Number and percentage of eyes losing two or more lines of best spectacle-corrected visual acuity (BSCVA). (2) *Safety index*, which is the ratio of mean postoperative BSCVA over mean preoperative BSCVA (i.e., [mean postop BSCVA]/[mean preop BSCVA]). (This is most easily calculated by converting the values of geometric mean acuities to decimal values.)

*Figure:* Bar graph depicting change in BSCVA from baseline to a defined postoperative interval. The x-axis has a central bar for no change or change of one line (not considered clinically meaningful) and then a loss of 1, 2, 3, etc. lines toward the left and a gain of 1, 2, 3, etc. toward the right. The y-axis depicts the range from 0 to 100%. The number of eyes reported is contained within a box inside the graph. The number (and percentage) of eyes losing two or more lines of BSCVA is also within an internal box.

**Efficacy:** (1) Percentage of eyes with uncorrected visual acuity (UCVA) of 20/20 and 20/40. (2) *Efficacy index*, which is the ratio of the mean postoperative UCVA to the mean preoperative BSCVA (i.e., [mean postop UCVA]/[mean preop BSCVA]). (This is most easily calculated by converting the values of geometric



mean acuities to decimal values.) This measure is particularly useful in describing outcomes of patients with high myopia when the preoperative BSCVA is worse than 20/20. (3) *Optional*: Changes in spectacle use or other measures of daily visual function.

**Figure:** Bar graph depicting UCVA. The x-axis depicts the range of visual acuities according to the standard LogMAR chart expressed as Snellen fractions: 20/12, 20/16, 20/20, 20/25, 20/32, etc. up to the final category of worse than 20/400. The y-axis reflects the percentage of eyes from 0 to 100. The number of eyes reported is presented in a box. In addition, the percentages of eyes seeing 20/20 or better and 20/40 or better preoperatively and postoperatively are presented in a box within the figure.

**Predictability—Spherical Equivalent:** (1) Mean, standard deviation, and range of postoperative spherical equivalent. (2) The percentage of eyes within  $\pm 1.00$  D and  $\pm 0.50$  D of desired postoperative refractive error, including a table categorizing refractive outcomes. (3) For myopic procedures, a clear indication of the number and percentage of eyes overcorrected by 1.00 D or more.

**Figure:** Scattergram of intended versus achieved refractive change. The x- and y- axes have the same scale with the size of the steps determined by the range of refractive errors depicted. The 0 line would be a 45-degree diagonal and lines for  $\pm 0.50$  D and  $\pm 1.00$  D would be added. One dot would represent each eye. The number of eyes is inserted within the figure in a box. The smallest refractive error treated is represented at the junction of the x- and y-axes with the numbers increasing horizontally and vertically.

**Figure:** Bar graph depicting the refractive outcomes. The x-axis has plano in the middle with minus numbers represented to the left and plus numbers to the right in the following categories: plano to  $-0.50$  D,  $-0.51$  to  $-1.00$  D, etc. in 1.00 D steps in the minus direction and  $+0.10$  to  $+0.50$  D,  $+0.51$  D to  $+1.00$ , etc. in 1.00 D steps in the plus direction. The y-axis indicates the percentage of eyes. The number of eyes is reported in a box within the graph. In addition, the number of eyes within  $\pm 0.50$  D,  $\pm 1.00$  D, and  $\pm 2.00$  D of intended refractive outcome is presented in boxes within the graph. The scale on the y-axis should extend from 0 to 100% regardless of the outcomes.

**Predictability—Astigmatic Correction:** (1) Mean, standard deviation, and range of postoperative astig-

matism clearly defined as refractive, keratometric, or derived by computerized videokeratography. (2) Surgically induced astigmatism calculated by vector analysis. (3) *Optional*: More advanced astigmatic analyses, as described by Alpíns<sup>3</sup> and by Holladay and coauthors.<sup>4</sup>

**Optional Figure:** Scattergram of surgically induced astigmatism as a doubled-angle plot.<sup>4</sup>

**Stability:** (1) The number and percentage of eyes with a change in spherical equivalent of manifest refraction of  $\geq 1.00$  D within a specified interval; the recommended minimal interval is 6 months. (2) Figure or table showing spherical equivalent of manifest refraction plotted against time for the same cohort of patients followed throughout the postoperative period.

**Figure:** Line graph depicting change over time of mean spherical equivalent of manifest refraction. The x-axis would show the times of the examinations on a linear scale, beginning with the preoperative value. The y-axis would show the mean spherical equivalent of manifest refraction at each interval; error bars would show  $\pm 2.00$  SD or 90% confidence intervals. The number of patients examined at each interval would be indicated.

**Quality of Vision:** Despite the lack of standardization in this area, studies of measurements of contrast sensitivity and/or glare acuity should be included when appropriate.

**Secondary Surgical Modification:** Number (percentage) and outcomes of eyes having secondary surgical procedures.

**Reversibility:** Outcomes of eyes having reversals, indicating the number (percentage) of eyes returning to baseline refractive error and BSCVA.

**Complications:** Careful tabulation and discussion of all sight-threatening complications. Non-sight-threatening complications such as postoperative pain should also be discussed.

## Discussion

In this section, authors should briefly and concisely (1) discuss the principles, relationships, and implications of the study results; (2) describe any outliers or discrepancies in the data; (3) compare their results with those in previously published work (tables are particu-

larly helpful when comparing a large number of articles); (4) state their conclusions; (5) highlight the unresolved issues and propose studies to address these issues.

We believe that a standard format for data reporting in scientific manuscripts assists investigators in organizing their data and readers in understanding and placing these data in context. It greatly facilitates the comparison of similar procedures performed by different surgeons and of different procedures performed for the same condition. Consistency in data reporting is in no way antithetical to scientific or literary creativity. On the contrary, the originality and clinical significance of the investigator's work are most clearly displayed in a well-organized and well-written manuscript.

We hope that our readers and contributors find

these guidelines helpful. We welcome comments as we seek to further refine these criteria.

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## References

1. Waring GO III. Standardized data collection and reporting for refractive surgery. *Refract Corneal Surg* 1992; 8(suppl):1-42
2. Koch DD. Refining analysis of refractive surgical outcomes. *J Cataract Refract Surg* 1995; 21:109-110
3. Alpins NA. A new method for analyzing vectors for changes in astigmatism. *J Cataract Refract Surg* 1993; 19:524-533
4. Holladay JT, Dudeja DR, Koch DD. Evaluating and reporting astigmatism for individual and aggregate data. *J Cataract Refract Surg* 1998; 24:57-65