EDITORIAL

Standard for reporting refractive outcomes of intraocular lens–based refractive surgery

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Following the 2014 update to the Graphic Reporting of Outcomes of Refractive Surgery[1] to include vector analysis of astigmatism,[2] the set of 9 standard graphs has provided a detailed 1-page summary for outcomes of corneal laser refractive surgery (laser in situ keratomileusis [LASIK], photorefractive keratectomy, and small-incision lenticule extraction [SMILE]). Until now, the data reporting quality for intraocular lens (IOL) surgery has not benefited from these efforts to enhance and standardize refractive outcomes reporting. For example, a significant number of cataract and lens refractive surgery publications do not include any refractive predictability outcomes, and visual acuity is often reported only as mean values rather than using histograms—a point that was raised in the 2009 editorial.[1]

In this editorial, we have considered these issues and have synthesized a solution by making some adjustments to the graphs when reporting IOL surgery outcomes. For phakic IOL outcomes, the original graphs[1,2] can typically be used without alteration, even though in reality the incision placement likely has some small effect on outcomes. Similarly, these same graphs can be used for refractive lens exchange (RLE); although there are complexities introduced by the corneal incision and removing the natural lens, the presence of a cataractous lens does influence the situation enough to render parts of the analysis inappropriate or unnecessary for a minimum standard. Because the primary indication for cataract surgery is a cataract-related loss of corrected distance visual acuity (CDVA), it remains important to report the surgically induced change in CDVA. However, this comparison is less informative about the refractive efficacy of the procedure. Thus, the basic standard for reporting cataract surgery refractive outcomes will now be a straightforward set of 4 graphs (Figure 1). In the sections below, the issues associated with each of the 9 graphs and the decision process to refine the cataract surgery graphs are discussed in the context of corneal and intraocular surgery.

EFFICACY: HISTOGRAM OF POSTOPERATIVE CDVA AND UDVA

In non-cataractous patients, it is important for all types of corneal or lens-based refractive surgery to report the postoperative uncorrected distance visual acuity (UDVA) in the context of the preoperative CDVA to avoid apparent differences in refractive efficacy between studies that were in fact simply the result of a difference in the CDVA. On the other hand, the preoperative CDVA is not helpful for assessing refractive outcomes in a cataract population because the removal of the lens will typically achieve a significant improvement in visual acuity independently of the refractive correction. Therefore, this graph will be adapted to show *postoperative* CDVA and *postoperative* UDVA for cataract populations. In this way, the UDVA will be reported in the context of the best measured visual acuity. This will be Figure 1, *A*, in the Standard Graphs for Cataract Surgery.

EFFICACY: HISTOGRAM OF LINES OF DIFFERENCE BETWEEN POSTOPERATIVE UDVA AND CDVA

As for the first efficacy graph, it is not appropriate in a cataract population to compare the preoperative CDVA to the

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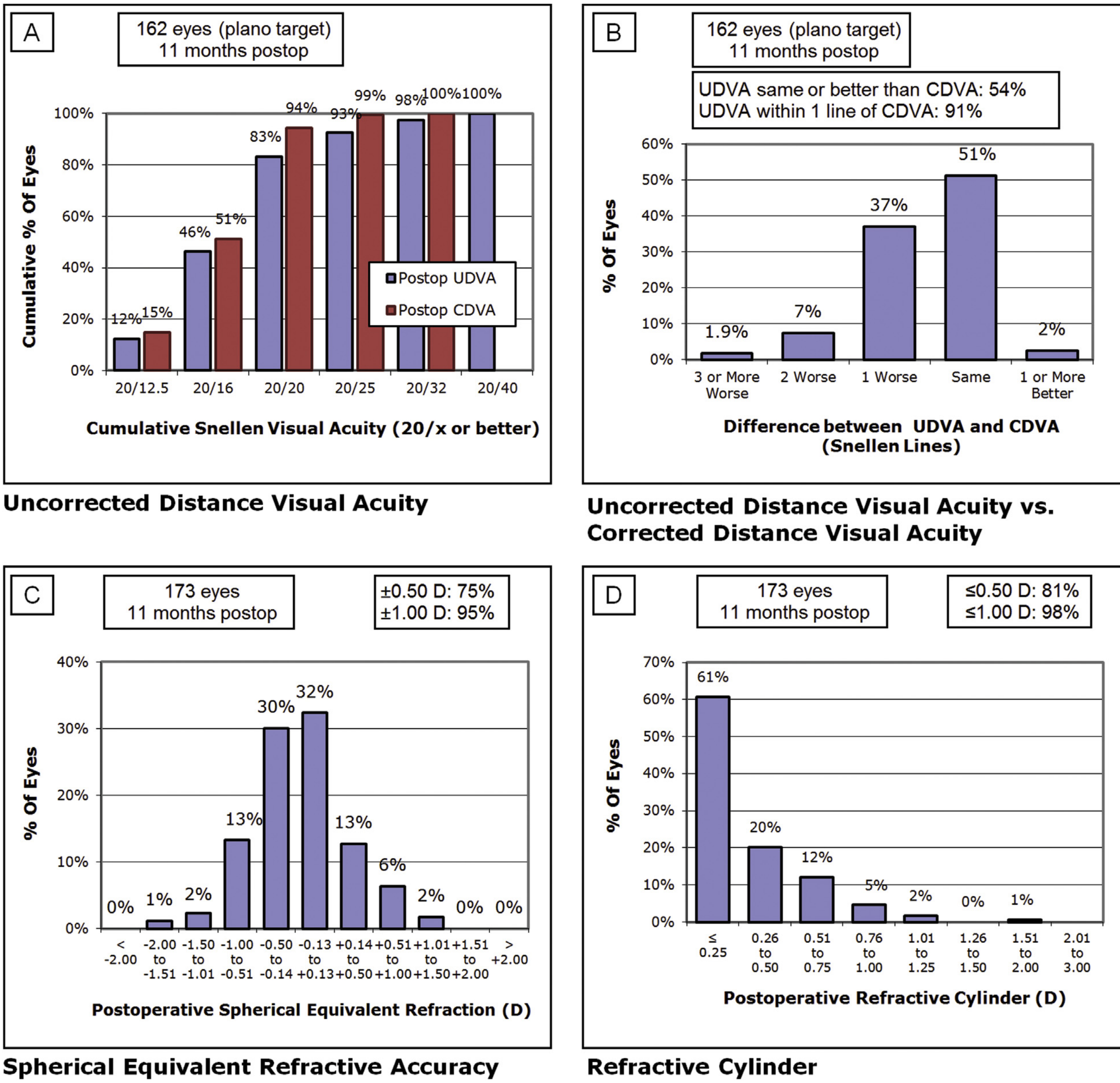

Figure 1. Standard graphs for reporting refractive outcomes for intraocular lens–based procedures in a cataract population. *A*: Uncorrected distance visual acuity. *B*: Uncorrected distance visual acuity versus corrected distance visual acuity. *C*: Spherical equivalent refraction accuracy. *D*: Postoperative refractive cylinder (CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity).

postoperative UDVA; it is more appropriate to use the *postoperative* CDVA. In this way, the efficacy is normalized to the best measured visual acuity for the population, making this directly comparable between studies. This will be Figure 1, *B*, in the Standard Graphs for Cataract Surgery.

SAFETY: HISTOGRAM OF LINES OF DIFFERENCE BETWEEN PREOPERATIVE AND POSTOPERATIVE CDVA

As for the 2 efficacy graphs, the change in CDVA for a cataract population will be dominated by the removal of the cataractous lens. This outcome parameter therefore does not provide information relevant to the performance of the procedure from a refractive surgery point of view. Therefore, this graph can be excluded when reporting outcomes for a cataract population. Although it is still important to report the preoperative and postoperative CDVA for a cataract population, this is an instance in which mean visual acuities would be sufficient. However, it is important to also report the percentage of eyes in which the postoperative CDVA was worse than the preoperative (with cataract) CDVA.

ACHIEVED VERSUS ATTEMPTED SPHERICAL EQUIVALENT REFRACTION SCATTER PLOT

This graph is compromised when analyzing the outcomes of surgery on eyes with cataract because of the reduced reliability of the preoperative manifest refraction. Therefore, this graph may be excluded from the Standard Graphs for Cataract Surgery.

PREDICTABILITY: HISTOGRAM OF POSTOPERATIVE SPHERICAL EQUIVALENT REFRACTION RELATIVE TO THE INTENDED TARGET

This graph is required for all studies, including those in cataract populations. As above, the analysis should be done by adjusting the postoperative spherical equivalent (SE) refraction to the intended target refraction. This will be Figure 1, *C*, in the Standard Graphs for Cataract Surgery.

STABILITY: LINE PLOT OF STABILITY OF SPHERICAL EQUIVALENT REFRACTION

Whereas stability is an important outcome measure for corneal refractive surgery procedures, there are few reasons for refractive instability after cataract surgery. Therefore, this graph will be excluded for cataract studies, although it can be included at the author's discretion if a stability issue is noted.

REFRACTIVE CYLINDER: HISTOGRAM OF PREOPERATIVE AND POSTOPERATIVE REFRACTIVE CYLINDER

This graph is required for all studies to show the distribution of manifest refractive cylinder before and after surgery. However, because of the unreliability of the preoperative manifest refraction in the presence of a cataract, only the *postoperative* data are necessary for a cataract population. This will be Figure 1, *D*, in the Standard Graphs for Cataract Surgery.

VECTOR ANALYSIS OF REFRACTIVE CYLINDER

Corneal laser refractive surgery outcomes are rarely reported for spherical corrections only; however, spherical corrections are common for IOL studies in which a monofocal IOL has been used. For any study that did not aim to correct refractive cylinder, these 2 graphs do not apply and can be excluded.

If toric IOLs have been used, then these graphs can be considered. For cataract studies, these graphs can be excluded, again due to the unreliability of the preoperative manifest refraction. For RLE studies, as with SE refraction, the validity of analyzing refractive cylinder outcomes is compromised somewhat by the variation of lens power within the population when correcting the same manifest refractive cylinder. However, the same reasoning applies as before that although it might be of interest to evaluate the lens in isolation, the core outcome is the effectiveness of the procedure as a whole. Therefore, these graphs of vector analysis based on manifest refraction will be required for all RLE studies using toric IOLs. Further optional analysis is described in the sections below to specifically analyze the effect of the lens in isolation and the effect of the corneal incision.

REPORTING VECTOR ANALYSES FOR LENS-BASED PROCEDURES

The analysis of astigmatism for IOL procedures has greater complexity than for corneal laser refractive surgery, and there are differences between using monofocal and toric lenses. This analysis can be cumbersome and nearly prohibitive for some studies, especially retrospective analyses. The following section describes the different permutations and the analysis that is available in each instance.

CORNEAL VERSUS LENS PROCEDURES

The most obvious difference with lens surgery is that refractive cylinder is influenced by both the IOL and the corneal incision, and these have to be analyzed independently. Therefore, both the *Journal of Refractive Surgery* and the *Journal of Cataract & Refractive Surgery* will now encourage a separate analysis of the astigmatic effect of the corneal incision. This can include:

1. The location of the incision site (and whether this was the same for all patients or different, such as always placing the incision at the steep meridian).
2. A histogram of the corneal astigmatism before and after surgery to provide an overall picture of the change in corneal astigmatism.
3. The mean magnitude (and standard deviation, minimum, maximum) of the flattening effect (FE) to provide the astigmatic change at the meridian of the incision because this is the relevant value when calculating the IOL power.[3–6]
4. The mean magnitude (and standard deviation, minmum, maximum) of the surgically induced astigmatism (SIA) vector to provide the total astigmatic change, including both the flattening and torque effects (the SIA will therefore always be larger than the FE magnitude). Because the torque effect only acts to rotate the astigmatism and does not change the power, using the SIA magnitude for the IOL power calculation will overestimate the astigmatic effect of the corneal incision. The torque effect can be specifically reported if a significant torque effect is found because this would affect the optimum orientation of the lens.[7]

Further analysis can be included where relevant at the author's discretion. For example, the summated vector mean (SVM) may also be reported, but only for populations in which the incision site was consistent for all eyes treated. If the incision site varied between eyes, the SVM will lose any clinical relevance because the multiple incision sites will influence the averaging. In such studies where the incision site varied, a more complex analysis could be performed to investigate the difference between incision sites or comparing the effect relative to the location of the steep or flat meridian. This kind of advanced analysis was performed in a recent study by Alpins et al.,[8] who found some fascinating results. The FE was found to be greater for superior incisions than for temporal incisions, was greater for right eyes than for left eyes, was greater when the incision was performed at the steep meridian of the astigmatism, and was almost astigmatically neutral when performed at the flat meridian. Another example of more complex analysis is the recent study by Chang et al.,[9] who found that the corneal astigmatic effect of the incision was influenced by the magnitude and meridian of the preoperative corneal astigmatism, as well as by the size of the incision.

TORIC IOLs: GUIDE FOR ADVANCED GRAPHICAL ANALYSIS

As described above, in a procedure in which the natural lens has been removed, the refractive outcome can be analyzed as either the procedure as a whole or based on the lens in isolation. To achieve this, further vector analysis can be done using the hybrid method as described by Alpins et al.[10] In this method, the preoperative astigmatism is taken to be the corneal astigmatism after including the predicted effect of the corneal incision, so that the refractive cylindrical correction of the IOL is isolated from the astigmatic effect of the corneal incision, which has already been handled separately and described above. The postoperative astigmatism is then taken to be manifest refractive cylinder (adjusted to the corneal plane). The target induced astigmatism is provided by the IOL power calculated at the corneal plane, and the SIA can be calculated as the difference between the preoperative corneal astigmatism and postoperative refractive cylinder, each as defined above. The vector analysis can then be performed as normal using these values.

CORNEAL INCISIONS FOR ASTIGMATIC CORRECTION AT THE TIME OF LENS-BASED SURGERY

Corneal incisions in the form of limbal relaxing incisions[11,12] or astigmatic keratotomy[13,14] are often used in combination with IOL procedures for reduction of corneal astigmatism. Corneal incisions are used most commonly with nontoric IOLs, but in some cases these are used together with toric IOLs. With the advent of femtosecond laser–assisted cataract surgery, intrastromal astigmatic keratotomy is gaining popularity.[15,16] In terms of analyzing the astigmatic change, the inclusion of corneal incisions introduces another slightly different set of analyses. Given that the change is on the cornea, graphs H and I should ideally be included but analyzed based on the change in corneal astigmatism.

In studies including corneal incisions, the change in astigmatism would likely be a main focus, in which case a more comprehensive vector analysis (both corneal and refractive) might be expected. Certainly complex analysis is necessary in studies in which both corneal incisions and toric IOLs are used, but this is outside the scope of this editorial. As with the previous 2014 editorial, there are no restrictions on astigmatic analysis included in addition to minimum standard recommendations.

TOTAL CORNEAL ASTIGMATISM

The confounding influence of posterior corneal astigmatism when not aligned with anterior corneal astigmatism has been identified as an important factor to consider for toric IOL power calculation.[17,18] The use of total corneal astigmatism has also been shown to improve the correlation of corneal astigmatism with manifest refractive cylinder[19] and improve the prediction of the residual cylinder after toric IOL implantation.[20] The use of measurements of total corneal astigmatism is therefore emerging as an improved method for both IOL power calculation and analysis of change in corneal astigmatism. It is outside the scope of this editorial to make specific recommendations on how posterior or total corneal astigmatism should be analyzed, and current analyses are based on anterior corneal astigmatism; however, authors are encouraged to include posterior corneal astigmatism as part of the analysis if they wish.

SUMMARY

Although there are inherent differences between corneal and IOL-based refractive surgery procedures, the aim of the procedure is the same in each case, so it makes sense that the 9 standard graphs be applied unaltered to corneal laser refractive surgery, phakic IOL implantation, and RLE. Cataract surgery is a different scenario that warrants a simplified version of the standard graphs. By considering these issues, we hope to standardize the quality of reporting for lens-based procedures from its current level and strive to encourage authors to go beyond these basic graphs to match the standard of studies reporting outcomes of corneal refractive surgery that now have good adherence to the standard graphs. Only by homogenizing the reporting of outcomes as a first step can we hope to glean comparative information among published studies.

LINK TO STANDARD GRAPHS ON WEBSITE

http://www.healio.com/ophthalmology/journals/jrs/refractive-outcome-graphs-visual-acuity-conversion

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