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Why Preoperative Acuity Predicts Postoperative Acuity in Wavefront-Guided LASIK

Michelle T. Aaron, OD, PhD, FAAO, Raymond A. Applegate, OD, PhD, FAAO, Jason Porter, PhD, Larry N. Thibos, PhD, FAAO, Steve C. Schallhorn, MD, Tyson J. Brunstetter, OD, PhD, FAAO, and David J. Tanzer, MD

United States Air Force, School of Aerospace Medicine, San Antonio, Texas (MTA), Visual Optics Institute, College of Optometry, University of Houston, Texas (RAA, JP), School of Optometry, Indiana University, Bloomington, Indiana (LNT), Medical Director, Optical Express, San Diego, California (SCS), and United States Navy, Navy Refractive Surgery Center, San Diego, California (TJB, DJT)

Abstract

Purpose—To critically evaluate the following clinical wisdom regarding custom (wavefront-guided) laser in situ keratomileusis (LASIK): that individuals with better-than-average best corrected visual acuity (BCVA) before surgery have a greater risk of losing BCVA postoperatively than do individuals with worse-than-average BCVA before surgery.

Methods—High contrast BCVA was measured once before and 3 months after custom LASIK in one eye of 79 individuals. Preoperative spherical equivalent refractive error ranged between -1.00 and -10.38 D. The sample was divided into one of two subsamples: eyes that had better-than-average preoperative BCVA (< -0.11 logMAR) and eyes that had average or worse-than-average preoperative BCVA (≥ -0.11 logMAR). Controls were implemented for retinal magnification and for the statistical phenomenon of regression to the mean of the preoperative acuity measurement.

Results—On average for the entire sample, moving the correction from the spectacle plane to the corneal plane increased letter acuity 4.7% (1 letter, 0.02 logMAR). For each subsample, the percentage regression to the mean was 57.24%. After correcting for magnification effects and regression to the mean, eyes with better-than-average preoperative acuity had a small but significant gain in acuity (~ 1 letter, $p = 0.040$) that was nearly identical to the gain for eyes with worse-than-average preoperative acuity (~ 1.5 letters, $p = 0.002$).

Conclusions—Custom LASIK produced a statistically significant gain in visual acuity after correction for magnification effects. Dividing the sample into two subsamples based on preoperative acuity confirmed the common clinical observation that eyes with better-than-average acuity tend to stay the same or lose acuity whereas eyes with worse-than-average acuity tend to gain acuity. However, when only one acuity measurement is taken at a single time point and the sample is subsampled nonrandomly, this clinical observation is due to a statistical artifact (regression to the mean) and is not attributable to the surgery.

Corresponding author: Lt. Col. Michelle Aaron, 2507 Kennedy Circle, Brooks City Base, TX 78235, michkoe7@yahoo.com.

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Keywords

LASIK; preoperative acuity; regression to the mean

Clinical experience suggests that patients with preoperative best corrected visual acuities (BCVAs) that are better-than-average are more likely to lose BCVA following corneal refractive surgery than are patients with preoperative BCVAs that are worse-than-average. To obtain objective evidence in support of this view, researchers have looked for a significant correlation between preoperative (pre-op) and postoperative (post-op) acuity. Erdem et al. found that patients with poor pre-op BCVAs had large improvements in post-op BCVA while those with good pre-op BCVAs had less improvement in post-op BCVA.¹ Before accepting such evidence, however, it is important to exclude confounding factors unrelated to the surgery that might account for this clinical observation. For example, changes in retinal magnification caused by moving a myopic spectacle correction to the corneal plane can alter BCVA.² Alternatively, making only single measurements of acuity at each visit while dividing the patient sample into groups based on preoperative BCVA may lead to mistaken conclusions because of a statistical artifact known as regression to the mean.³⁻⁶ This study investigates the above issues, taking potentially confounding factors into account, to determine if this “clinical wisdom” could be placed into the domain of evidenced-based clinical practice and risk management.

Retinal magnification effects are a well-known consequence of moving a spectacle correction from the spectacle plane to the corneal plane as happens with contact lens corrections. A change in retinal image size could be partially responsible for the clinical and experimental observations of changes in BCVA following refractive surgery, as moving a myopic correction from the spectacle plane to the corneal plane magnifies the retinal image. Consequently, measuring acuity of myopic eyes with spectacle corrections before refractive surgery and without spectacles after surgery is equivalent to moving the acuity chart closer to the patient after surgery for some individuals. The resulting improvement in acuity could be partly due to a change in retinal magnification rather than the surgery per se.

Regression to the mean is a statistical phenomenon that occurs when a population is sampled nonrandomly. Creating a subsample of patients with worse-than-average BCVA is an example of nonrandom sampling of the greater population of patients who underwent corneal refractive surgery. Even if the surgery had no effect on BCVA, the mean BCVA of this subsample would tend to increase after treatment because of random fluctuations in BCVA for any given individual. One way to avoid regression to the mean is to take multiple measurements of BCVA for each individual, but this is rarely done in clinical practice. Consequently, no estimate is typically available for the mean acuity of each individual in the sample at any given time point of measurement. If such a surgical population is subsampled based on whether their initial acuity is better or worse than the total sample mean, it is expected (on statistical grounds) that the subsample of better eyes will have a mean acuity on retest that is slightly worse and the subsample of worse eyes will have a mean acuity on retest that is slightly better. That outcome is called regression to the mean and is independent of any treatment effect that can occur for the entire test population as a whole. A particularly clear explanation of regression to the mean and how to correct for it can be found on the web at <http://www.socialresearchmethods.net/kb/regmean.php>.

Understanding the mechanism(s) behind the clinically and experimentally observed changes in BCVA following corneal refractive surgery is important because the effects have broad implications. For example, clinical trials in the FDA approval process used to assess safety and efficacy could be biased by selecting patients based on their preoperative BVCA. If a clinical

study selected patients with preoperative BCVAs that were worse-than-average and measured BCVA only once, the study could have an increased probability of indicating better safety and efficacy than if patients with a full range of preoperative BCVAs were included in the study. The primary goal of our study was to experimentally examine whether the common clinical observation described above can be verified (i.e., do eyes with better-than-average preoperative BCVA, when measured once, have a greater risk of losing BCVA following custom LASIK than eyes with worse-than-average preoperative BCVA?). A secondary goal was to explore possible explanations for the effect.

METHODS

Subjects

One eye of 79 myopic subjects formed the sample for analysis. This sample was derived from two studies having identical experimental protocols except for the subject's level of preoperative myopia and the measurement of the vertex distance. Data for one eye of 64 subjects (N64 eye study group) were provided by the United States Navy (Navy Refractive Surgery Center, San Diego, CA) and had a mean age of 33.1 ± 6.9 years (range 23 – 51 years). The mean preoperative spherical equivalent (SE) refractive error was $-3.16 \text{ D} \pm 1.30 \text{ D}$ and ranged from -1.00 D to -5.38 D . In this group, the vertex distance for the preoperative phoropter correction at the time of measurement was not recorded, forcing an estimated vertex distance to be used in the calculation of magnification (see subsequent section on magnification effects below).

We initiated a second study (the N15 eye study) to add eyes with higher preoperative refractive errors. The N15 eye study consisted of 15 eyes of 15 myopic subjects with a mean age of 29.9 ± 5.6 years (range 20 – 40 years). The mean preoperative SE refractive error was $-6.78 \text{ D} \pm 1.45 \text{ D}$ and ranged from -4.75 D to -10.38 D . These patients were recruited and underwent surgery at the same surgical center (Navy Refractive Surgery Center, San Diego, CA) as the N64 group. All patients signed an informed consent approved by one (N64 eye study) or both (N15 eye study) independent institutional review boards (University of Houston Committee for the Protection of Human Subjects and Naval Medical Center, San Diego Clinical Investigations Department), consistent with the Declaration of Helsinki.

Surgical Procedure

For all eyes, ablation profiles were generated by importing the subject's wave aberration data (WaveScan aberrometer) into the VISX S4 excimer laser using CustomVue software (AMO, Abbot Park, IL, U.S.A.). Prior to ablation, an IntraLase femtosecond laser (AMO, Abbot Park, IL, U.S.A.) was used to cut a 9.5 mm LASIK flap. The minimum optical zone was set to 6.0 mm with a transition zone from 6.0 mm to 8.0 mm. The maximum optical zone was determined by the CustomVue software based on the relationship between sphere and cylinder and the total ablation zone (optical and transition zones). The goal of all treatments was emmetropia.

Experimental Measurements

The following measurements and calculations were made (in order) both before and at 3 months after LASIK.

1. Best correction: For all eyes, subjective refraction was measured once (using the technique of maximum plus to best visual acuity) to define the best correction for each subject. Spherical equivalent spectacle correction was defined as the sphere power plus half the cylinder power.
2. Visual acuity: Acuity for each patient's study eye was measured once while viewing a back-illuminated ($100 \pm 8 \text{ cd/m}^2$), translucent ETDRS-type (Sloan letter) high

contrast chart (Precision Vision, La Salle, IL) at 4 meters through either a phoropter-based correction (N64 eye study) or trial frame correction (N15 eye study). For all eyes, credit was given for all letters read correctly until two letters were missed in any given line.

3. Calculation of magnification effects on logMAR acuity: For the N15 eye study, the vertex distance of the trial frame was recorded for each subject and used in conjunction with the SE spectacle correction to calculate the induced magnification. The change in magnification was calculated using the method described by Applegate & Howland:²

$$\Delta \text{Acuity} = \log\left(\frac{1}{1 - V * SE}\right) \quad (1)$$

Where: ΔAcuity = the change in logMAR acuity due to moving the refractive correction

from the spectacle plane to the corneal plane

V = vertex distance (meters)

SE = preoperative spherical equivalent refractive error (diopters)

To illustrate, consider a patient wearing a preoperative spectacle correction of -10 D at a vertex distance of 15 mm. When viewing a distant acuity chart during the preoperative acuity measurement, this eye will see a minified acuity chart (by 13%). If this eye views the same acuity chart following a successful emmetropic LASIK correction, it would experience an increase in acuity of -0.06 logMAR simply due to the magnification produced when shifting the spectacle correction to the corneal plane (13%). To fairly compare postoperative acuity to the preoperative acuity, we subtracted this magnification gain from the postoperative acuity. For example, if the measured postoperative acuity was -0.12 log MAR in our hypothetical eye with a preoperative best spectacle correction of -10 D (vertex = 15 mm), the magnification corrected postoperative acuity would be equal to $-0.12 - (-0.06) = -0.06$ logMAR.

As vertex distance was not recorded in the N64 eye study, the magnification correction was made assuming a 13 mm vertex distance. This vertex distance was selected after having 3 technicians at the Navy Refractive Surgery Center, San Diego measure vertex distance on 4 patients using the same equipment and procedures as in the N64 eye study. The mean vertex distance of all measurements was 13 mm with a range of 11 to 16 mm. Given that preoperative refractive errors were relatively low in this sample (average $SE = -3.16$ D), small variations in vertex distance (e.g., 11 – 16 mm) made only a small difference in final acuity (typically less than 1 letter).

4. Division into subsamples: The 79 study eyes were divided into two groups. One group comprised those eyes having better-than-average preoperative BCVA (< -0.11 logMAR, i.e., better than $\sim 20/16$) and the other group comprised those eyes having average or worse-than-average preoperative BCVA (≥ -0.11 logMAR, i.e., equal to or worse than $20/16$).
5. Percentage regression to the mean: Given that the two subsamples from step 4 were not drawn from the total sample randomly, and acuity was only measured once preoperatively and once at the three month postoperative visit, the estimated percent

regression to the mean (P_{rm}) of the postoperative acuity for the two subsamples was calculated using the following formula:

$$P_{rm} = 100(1 - r) \quad (2)$$

where:

r = the correlation between preoperative and postoperative logMAR acuities of the total sample.

6. Corrected mean BCVA after surgery due to regression to the mean for the two subsamples: The predicted mean BCVAs for both sub-samples after correction for regression to the mean ($\bar{x}_{BE}$ and $\bar{x}_{WE}$) were calculated as follows:

$$CF = |P_{rm} \times \Delta\bar{x}| \quad (3)$$

$$\bar{x}_{BE} = \bar{x}_{BENC} + CF \quad (4)$$

$$\bar{x}_{WE} = \bar{x}_{WENC} - CF \quad (5)$$

where:

CF = Correction factor in logMAR acuity due to regression to the mean

P_{rm} = estimated percentage regression to the mean

$\Delta\bar{x}$ = Difference between the mean value of the measured preoperative logMAR acuity for the subsample of interest and the value of the mean measured preoperative acuity for the total sample

$\bar{x}_{BE}$ = Predicted mean post-op logMAR acuity corrected for regression to the mean for the subsample with better-than-average preoperative acuity

$\bar{x}_{WE}$ = Predicted mean post-op logMAR acuity corrected for regression to the mean for the subsample with average or worse-than-average preoperative acuity

$\bar{x}_{BENC}$ = Mean post-op logMAR acuity not corrected for regression to the mean for the subsample with better-than-average preoperative acuity

$\bar{x}_{WENC}$ = Mean logMAR acuity not corrected for regression to the mean for the subsample with average or worse-than-average preoperative acuity

7. Test for a significant treatment and/or learning effect: A two-tailed paired t-test ($p \leq 0.05$) was performed comparing the mean magnification corrected acuity before and after surgery for the total sample.
8. Test for a significant difference between mean acuities measured before and after refractive surgery: We corrected the preoperative mean acuity of each subgroup for regression to the mean (i.e., we estimated the mean acuity of each subsample assuming that acuity had been measured a second time prior to refractive surgery). We then tested whether the mean preoperative acuity (corrected for regression to the mean) was significantly different than the actual postoperative acuity (corrected for only

magnification effects) using the standard error of the mean and assuming the variances remained the same pre- to postoperatively.

RESULTS

Whole Sample Results

Basic statistics for preoperative logMAR BCVA are provided in Table 1. The average preoperative BCVA for the N15 (-0.093 logMAR) and N64 groups (-0.118 logMAR) is consistent with other larger population studies of normal individuals.⁷ An unpaired t-test revealed no significant difference in average preoperative BCVA ($p = 0.2692$) between the N15 and N64 studies. We therefore combined the two samples to form the N79 sample for subsequent analyses.

Table 2 displays basic statistics for the study sample for preoperative acuity, postoperative acuity not corrected for magnification effects, and postoperative acuity corrected for magnification effects. The apparent improvement in visual acuity is reduced but not eliminated once the magnification correction is applied. Prior to correction for magnification, there was a small average gain in acuity of -0.05 logMAR (2.5 letters on an ETDRS-type chart) following surgery for the sample as a whole. A paired student t-test revealed this change in acuity to be significant ($p < 0.0001$). After compensating for the magnification effects, the mean gain was smaller (as expected). Nonetheless, there remained a small acuity benefit of -0.03 logMAR (~ 1.5 letters on an ETDRS-type chart; $p = 0.0009$).

Subsample Results

To evaluate the clinical observation that motivated our study, the N79 sample was subdivided into two groups based on preoperative BCVA. The first subsample consisted of 29 eyes with a pre-op visual acuity better than the mean acuity of the whole sample (< -0.11 logMAR). The 50 remaining eyes formed the second subsample consisting of eyes with a pre-op visual acuity equal to or worse than the mean acuity of the whole sample (≥ -0.11 logMAR).

Table 3 specifies each subsample's statistics prior to correcting for regression to the mean. The difference in mean preoperative SE for eyes with better vs. worse-than-average preoperative acuity was not statistically significant ($p = 0.576$, unpaired t-test). We found a slightly larger than one line difference (0.114) in average preoperative BCVA between subsamples with better-(Table 3A) and worse- (Table 3B) than-average preoperative BCVA. As expected, this difference was statistically significant ($p < 0.0001$, unpaired t-test). Magnification effects accounted for a one letter decrease in the magnification corrected postoperative mean acuity (0.022 and 0.020 logMAR acuity for better- and worse-than-average eyes, respectively). Without magnification correction, eyes with better-than-average preoperative acuity experienced a mean change in acuity of -0.003 logMAR (far less than 1 letter on an ETDRS-type chart) while eyes with worse-than-average preoperative acuity experienced an average gain of -0.077 logMAR (~ 3 letters on an ETDRS-type chart). A similar observation was noted when incorporating magnification correction, as eyes with better-than-average preoperative acuity experienced a mean decrease in acuity of 0.018 logMAR (~ 1 letter on an ETDRS-type chart) while eyes with worse-than-average preoperative acuity still experienced an average gain in acuity of -0.057 logMAR (~ 3 letters on an ETDRS-type chart).

Correction for Regression to the Mean

To correct for regression to the mean, it is necessary to calculate the correlation coefficient (r) between preoperative acuity and magnification corrected postoperative acuity for the sample as a whole. This correlation was 0.427 for all eyes in the combined N79 sample. Thus the percentage regression to the mean (P_{rm}) for both the better-than-average and worse-than-

average subsamples was calculated to be 57.24% using Eq. (2). Given the postoperative acuity measurement was a second measure of acuity; we can assume it includes the regression to the mean. Consequently, to properly compare preoperative acuity to postoperative acuity, the preoperative data needs to be corrected for regression to the mean (i.e., we wish to compare preoperative eyes that have not experienced regression to the mean to postoperative eyes that have experienced regression to the mean). Given a percentage regression to the mean of 57.24%, the mean preoperative acuity of the better-than-average BCVA subsample regressed to a worse acuity by 0.042 logMAR and the mean preoperative acuity of the worse-than-average BCVA sub-sample regressed to a better acuity by -0.024 logMAR. These results are summarized in Table 4 which compares the preoperative mean acuities corrected for regression to the mean and the postoperative mean acuities corrected for magnification. The average gains in acuity for both subsamples were small (-0.023 logMAR and -0.033 logMAR for the better- and worse-than-average subsamples, respectively) but significant ($p = 0.040$ and $p = 0.0018$, respectively). These gains are most likely attributable to surgical and/or learning effects experienced by the test sample as a whole and are not unique characteristics of the subsamples.

DISCUSSION

While the “clinical wisdom” was confirmed in our study, our analysis demonstrates that the majority of the observed effect is accounted for by the statistical phenomenon called regression to the mean. Nonetheless, correcting for regression to the mean did not eliminate the significant change in acuity for the sample as a whole. We calculated a statistically significant surgical and/or learning effect of -0.03 logMAR (~ 1.5 letters on an ETDRS-type chart) in the total sample where eyes, on average, saw slightly better postoperatively than preoperatively. This gain cannot be accounted for by eyes having better- or worse-than-average preoperative acuity once the data is corrected for regression to the mean. This conclusion is supported by the observation that adding the learning and/or surgical effect to mean preoperative logMAR acuities (corrected for regression to the mean for both sub-samples) yields predicted postoperative mean acuities that are not significantly different from the magnification corrected postoperative acuities. Future studies should include a control group to test for a possible learning effect so that determination of a treatment effect versus a learning effect could be made. While it is exciting to ponder a true treatment effect in BCVA after custom LASIK, it is debatable whether this statistically significant gain in acuity has a significant amount of clinical relevance.

It is worth emphasizing that the issues associated with regression to the mean can be minimized by measuring acuity pre- and post-surgery several times to establish a good estimate of each patient's average acuity before and after surgery. If multiple measures were routinely gathered, the change in each patient's mean acuity in the sample would be more predictive without the need to correct for regression to the mean. It is also important to note that retinal image quality at any given acuity can vary widely. As a consequence of this variance in quality of vision, a given patient may not lose or gain acuity after treatment and yet may experience an increase or decrease in retinal image quality that makes the patient pleased or dissatisfied with their surgical outcome.^{8,9}

In conclusion, the clinical observation that eyes with better-than-average preoperative acuity are at risk of losing acuity and eyes with worse-than-average preoperative acuity stand to gain acuity is accounted for by two factors: retinal magnification due to moving the refractive correction from the spectacle plane to the cornea, and regression to the mean. After appropriate corrections for these two factors, the mean acuity for the study sample improved a small but significant amount (~ 1 letter on an ETDRS-type chart) following custom LASIK.

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Table 1

Preoperative BCVA for the N15, N64 and combined N79 samples.

Pre-op BCVA (logMAR)			
	N15	N64	N79
Count	15	64	79
Average	-0.093	-0.118	-0.113
SD	0.142	0.052	0.077
Maximum	0.260	0.000	0.260
Minimum	-0.260	-0.220	-0.260

Table 2

Basic statistics for preoperative, postoperative (no magnification correction), and postoperative (magnification corrected) BCVA for the study sample.

	Pre-op BCVA (logMAR)	Post-op BCVA (logMAR) No Mag Correction	Post-op BCVA (logMAR) Mag Corrected
Count	79	79	79
Average	-0.113	-0.163	-0.143
SD	0.077	0.063	0.063
Maximum	0.260	0.020	0.049
Minimum	-0.260	-0.320	-0.287

Preoperative spherical equivalent (SE), preoperative BCVA, postoperative BCVA as measured (Post No Mag Cor), magnification corrected postoperative BCVA (Post Mag Cor), and change in BCVA for the better-than-average acuity (3A) and worse-than-average (3B) eye subsamples.

Table 3

Better-than-Average Preoperative Acuity						
3A	Pre-op SE (D)	Pre-op BCVA (logMAR)	Post-op BCVA As Measured (logMAR)	Post-op BCVA Mag Cor (logMAR)	Change in BCVA [Post No Mag Cor – Pre] (logMAR)	Change in BCVA [Post Mag Cor – Pre] (logMAR)
Count	29	29	29	29	29	29
Average	-4.02	-0.186	-0.189	-0.167	-0.003	0.018
SD	1.79	0.031	0.061	0.058	0.057	0.055
Max.	-1.00	-0.140	-0.100	-0.074	0.100	0.126
Min.	-7.25	-0.260	-0.320	-0.287	-0.120	-0.096
Worse-than-Average Preoperative Acuity						
3B	Pre-op SE (D)	Pre-op BCVA (logMAR)	Post-op BCVA As Measured (logMAR)	Post-op BCVA Mag Cor (logMAR)	Change in BCVA [Post No Mag Cor – Pre] (logMAR)	Change in BCVA [Post Mag Cor – Pre] (logMAR)
Count	50	50	50	50	50	50
Average	-3.75	-0.072	-0.149	-0.129	-0.077*	-0.057*
SD	2.05	0.064	0.061	0.062	0.075	0.072
Max.	-1.00	0.260	0.020	0.049	0.020	0.049
Min.	-10.38	-0.100	-0.280	-0.229	-0.320	-0.269

Changes in acuity that are significant are marked with an * (p<0.05).

Table 4

Mean postoperative BCVA corrected for magnification and mean preoperative BCVA corrected for regression to the mean for both the better-than-average eyes and worse-than-average eyes.

	Mean post-op BCVA corrected for magnification (logMAR)	Mean pre-op BCVA corrected for regression to the mean (logMAR)	Mean post-op corrected gain in BCVA (logMAR)
Better-than-average pre-op acuity eyes	-0.167	-0.144	-0.023
Worse-than-average pre-op acuity eyes	-0.129	-0.096	-0.033