The Benefits of Standardization in Laser Refractive Surgery

Standardizing surgical techniques can reduce the risk of complications and minimize variation in refractive outcomes.

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Obtaining consistent visual outcomes with low complication rates is the hallmark of achievement for refractive surgeons. Reducing retreatment rates not only increases patient satisfaction and confidence but also enhances productivity within the treating facility. This article highlights the regulation of pre-, intra-, and postoperative variables that can help maximize the consistency of surgical outcomes in laser refractive surgery.

PREOPERATIVE REFRACTION

Measurement of refractive error involves a subjective component that is open to inter- and intraobserver variability. It is important to know the size of this variability in order to qualify comparisons between measurements and to detect significant changes. The accuracy of refractive surgery depends on nomogram optimization (discussed below), which, in turn, depends on the accuracy of refraction (ie, agreement between measured and actual refraction) and the reproducibility of refraction (ie, concordance between observers), both preoperatively for surgical planning and postoperatively for outcomes feedback.

In any refractive surgery clinical setting, it is important that the accuracy and reproducibility of manifest refraction within and between clinicians is optimized to improve clinical outcomes. For refractive surgery, it is also vital that the manifest refraction is not influenced by the patient’s accommodation, so that the true refraction is measured.

All of these goals can be achieved by the use of a standardized protocol, so that a consistent endpoint for refraction can be achieved irrespective of the observer. As medical director of LASIK Vision (Vancouver, Canada), Professor Reinstein developed an algorithm for manifest refraction. All clinicians at LASIK Vision were trained to refract using this protocol. The protocol is ideally done using a phoropter, and the cross-cylinder technique is used for cylinder refinement. The algorithm relies on pushing plus in the sphere and maximizing cylinder. Such endpoint goals reduce the variability often found in refraction for spectacle prescriptions and relate more closely to the goal of corneal refractive surgery, which is to eliminate refractive error.

Professor Reinstein has since implemented this protocol at London Vision Clinic, and we recently published a study reporting the reproducibility of manifest refraction among two surgeons and seven in-house optometrists. Our preoperative assessment is split into two parts, with the first done by an optometrist and the second in a consultation with the surgeon; manifest refraction is performed at both visits. Before the optometrist’s examination, the refraction of any spectacles is measured with a lensometer, and a refraction is obtained using the Wavefront Supported Custom Ablation (WASCA) Analyzer (Carl Zeiss Meditec). The WASCA refraction is then used as the starting point for the manifest refraction. Following this, cycloplegic refraction is also recorded. The patient returns at least 1 day later for consultation with the surgeon, who performs a second manifest refraction. The surgeon then has the benefit of reviewing the four previous refractions.

The cycloplegic sphere is of particular value, as this indicates to the clinician the amount of latent hyperopia present for pushing plus sphere during the manifest refraction. The availability of the other refractions also helps reduce the chances of refractive surprise related to things like contact lens warp-age, tear film irregularity, and accommodative spasm.

In our study, we retrospectively compared the optometrist- and surgeon-recorded manifest refractions and found a mean surgeon-optometrist power difference of 0.21 D.
This degree of interobserver repeatability is comparable with that reported in controlled intraobserver repeatability studies and, therefore, demonstrates the benefit of using a standardized protocol.

One may question if manifest refraction is still the gold standard or whether it has been superseded by aberrometry. This is particularly relevant to wavefront-guided ablations because many systems force the use of the aberrometric refraction, meaning that the refractive accuracy of the treatment will ultimately depend on the accuracy of the aberrometric refraction.

In a recent study, we compared patients’ manifest refractions to their WASCA aberrometric refractions and then calculated the predicted outcome had the WASCA refraction been used instead of the manifest refraction. We found that the number of eyes within ±0.50 D of target refraction would have been 10% lower in myopic eyes and 11% lower in hyperopic eyes if the aberrometric refraction had been used. This provides evidence that manifest refraction currently remains the gold standard.

EXCIMER LASER CALIBRATION
Consistent calibration of the excimer laser before each procedure will reduce errors associated with the effect of environmental factors (eg, humidity and temperature) on the fluence of the laser and account for variation in the laser fluence output itself. Documenting the change in temperature and humidity over the course of a treatment day allows highs and lows in energy settings to be predicted, particularly as seasons change. Air conditioning, dehumidifiers, and dust-particle extractors also help to optimize environmental consistency.

Additionally, in our clinics we analyze the 1-day refractive outcomes of patients treated the previous day (adjusted for the average regression expected between 1 day and 3 months depending on the refraction treated) in order to evaluate whether the calibration setting used was correct.

SURGICAL TECHNIQUE
Standardizing intraoperative surgical technique is vital to optimize the accuracy of treatments and minimize the risk of complications. Professor Reinstein first developed a standardized protocol for refractive surgery as medical director at LASIK Vision. A recommended surgical treatment protocol (RSTP) was derived from this process, and all surgeons were trained to follow this during surgery.

The RSTP has since been refined and updated according
to advances in excimer laser, microkeratome, and femtosecond laser technology. The current RSTP that we use with the MEL90 excimer laser and VisuMax femtosecond laser (both by Carl Zeiss Meditec) includes a total of 75 steps.6

The two most significant influences the surgeon can have intraoperatively on refractive outcome are through (1) centration of the refractive ablation pattern on the patient’s visual axis and (2) control of the hydration of the stromal bed. All treatments should be centered on the patient’s visual axis (or closest approximation) rather than the pupil center in order to maintain the axis of the existing optical system of the eye.7 This is of increased importance in hyperopic patients, as there is a higher incidence of large angle kappa in this group.

Diurnal variations in temperature and humidity will affect not only the laser fluence but also the speed of drying of the stromal bed. Consistent hydration of the corneal bed is crucial. To address this, our protocol includes a standardized method of wiping the stromal bed and an effort to always leave the same time between wiping the bed and applying the laser ablation. If delays are encountered, we may consider replacing the flap with minimal fluid in the interface before starting the process again.

From the standpoint of complications, the most important part of the surgical technique is the replacement of the flap, particularly with the goal of minimizing microfolds and epithelial ingrowth. The concept behind the technique used in the RSTP is to minimize flap manipulation—especially to avoid bending, stretching, or pulling of the flap—and irrigation. Irrigation is performed using a 27-gauge anterior chamber cannula to expel 1 cL of fluid in 1 second so that there is a high fluid pressure stream. This avoids hydrating the flap or bed while effectively blowing particles from the interface. One or two wipes are usually all that is needed to return the flap to its exact anatomic position without microfolds.

When replacing the flap, the goal is to see no gutter (ie, no space between flap and bed). A gutter will often be left if extensive irrigation has been performed, as flap swelling due to hydration causes retraction of the flap diameter.

Epithelial cells can then grow into the space left at the gutter, so that there is not enough space for the flap to expand into as it dehydrates after the procedure, resulting in microfolds. Alternatively, hydration may cause the flap to swell asymmetrically. In that case, as the flap is repositioned so that the ink marks are aligned, there may be insufficient space on one side of the flap for it to expand as it dehydrates, again resulting in microfolds.

Both surgeons in our study have undergone extensive training based on this RSTP. Successful standardization between the two surgeons was demonstrated in a recent study of 30 consecutive bilateral simultaneous LASIK procedures.8 In this study, the times taken to perform each step in the procedure were compared between surgeons and found to be similar. For example, the mean time difference between surgeons for flap replacement was 1 second.

In another study, we found that the visual and refractive outcomes achieved by the two surgeons were identical.6 This study also showed the effectiveness of the fellowship training program focused on the RSTP, as it included the first 200 eyes treated by Dr. Carp compared with 200 treated by Professor Reinstein, who had performed more than 11,500 procedures before the study period. Also of note is that the incidence of intra- and postoperative complications was identical between surgeons. For a video of this side-by-side comparison, visit eyetube.net/?v=iwipo.

**NOMOGRAMS**

Optimizing the outcomes of laser refractive surgery requires the generation and use of a nomogram specific to the refracting surgeon or optometrist, the surgeon’s technique, laser, and location. The built-in nomogram of an excimer laser is rarely 100% suited to a particular clinical setting, given differences in surgeon technique and laser units and environmental variations between locations (eg, temperature, humidity, and altitude). Also, the technique for measuring manifest refraction can make a significant difference, as discussed above. For optimal nomogram development, it is vital that the manifest refraction be reproducible between surgeons and comanaging optometrists and, most important, that postoperative refractions be done to the true endpoint (including pushing cylinder), rather than stopping once the patient achieves 20/20.

A nomogram is based on an analysis of spherocylindrical refractive outcomes; however, a number of other factors may influence the outcome, including age, sex, cylinder coupling, flap diameter and thickness, flap edge geometry, optical zone, spherical aberration, corneal curvature, and pachymetry. It must be reiterated that standardization of surgical technique

**TAKE-HOME MESSAGE**

- The accuracy and reproducibility of manifest refraction within and between clinicians must be optimized to improve clinical outcomes.
- Standardizing intraoperative surgical techniques is vital to optimize the accuracy of treatments and minimize the risk of complications.
- Optimizing outcomes of laser refractive surgery requires the use of a multivariate-based nomogram specific to surgeon, laser, and location.
Proper protocol for measuring manifest refraction is crucial to achieve reproducibility among clinicians, to ensure that true preoperative refraction is measured, and to avoid postoperative refractions being biased toward emmetropia so that nomogram development can be reliable.

is crucial to minimize intraoperative sources of variation, as this scatter cannot be addressed by a nomogram.

In order to address all of these sources of error, a multivariate regression analysis can be performed. To do this, a baseline analysis is done first, including only the laser sphere and cylinder. Each parameter is then added one at a time and retained for the next analysis only if it makes a statistically significant difference. Following the development of the nomogram, the potential improvement can be assessed by applying the difference in laser settings to the actual outcomes of the population. For example, our most recent multivariate nomogram predicted a 6% improvement in the accuracy within ±0.50 D.

Nomogram development is ideally done based on refractive data acquired at a time when the patient’s refractive stability has been achieved. For myopic patients, 3-month data are usually sufficient, but it is better to use 1-year data for hyperopic patients, given the greater refractive regression in this group. If changes are made to the surgical protocol (eg, a new laser, flap-creation technique, or ablation profile), data from earlier time points (eg, 1 month) can be used to make an initial rough adjustment to the nomogram, and full nomogram analysis can be performed when sufficient data are available.

CONCLUSION

Standardization plays an important role in optimizing the visual and refractive outcomes and the safety of laser refractive surgery. Proper protocol for measuring manifest refraction is crucial to achieve reproducibility among clinicians, to ensure that true preoperative refraction is measured, and to avoid postoperative refractions being biased toward emmetropia so that nomogram development can be reliable. Standardization of surgical technique reduces the risk of intra- and postoperative complications and minimizes variations in refractive outcome due to the surgeon, as this scatter is not addressed by a nomogram.

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