An Evidence-based Approach to Patient Selection for Laser Vision Correction

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ABSTRACT

PURPOSE: To describe the process used by Optical Express, a large corporate refractive surgery provider, to develop evidence-based patient selection guidelines for laser vision correction.

METHODS: The evaluation of patient selection criteria for laser vision correction is part of a larger corporate process of continuous quality improvement and clinical due diligence. The procedures used to evaluate patient selection criteria are described in detail and the benefits of this process are explained. The criterion review process involves the company's International Medical Advisory Board (IMAB) and includes an evaluation of the published literature and analyses generated from the large Optical Express clinical outcomes database. This article offers a case study in which the IMAB used the criterion review process to examine the upper limit for estimated postoperative keratometry in hyperopic laser vision correction.

RESULTS: The patient selection criteria undergo continuous scrutiny and are modified whenever medical evidence indicates that change is appropriate.

CONCLUSIONS: Using an established protocol for reviewing patient selection criteria, Optical Express continuously measures its patient selection criteria against both external (published) and internal data sources. This process ensures that decisions about patients' suitability for surgery are based on the best-available current medical evidence. [J Refract Surg. 2009;25:S661-S667.] doi:10.3928/1081597X-20090611-07

Although most people with refractive error can safely undergo laser vision correction, a subset of individuals who present for the procedure are not suitable candidates. To achieve consistently good outcomes while minimizing the risk of complications, refractive surgery providers must decide which patients to approve for surgery and which to guide towards alternative treatments. The ultimate determination of suitability for surgery is made by the operating surgeon. A multifaceted process, this decision includes a consideration of data generated in the patient's ocular examination, an assessment of the patient's medical health, and a determination that the patient can make an informed decision based on realistic expectations.

THE EVOLUTION OF PATIENT SELECTION CRITERIA

Typically, eye care providers base patient selection decisions on community standards that have evolved over time. These standards represent a set of informal selection criteria to which most clinicians in the field adhere. Although some of these standards are based on rigorous clinical studies, many are derived from less methodically scrutinized sources, including case reports, studies with small sample sizes, or medical reasoning.

In the absence of strong evidentiary support, many surgeons apply these community standards conservatively. Although it may seem reasonable to exclude from surgery every patient who is outside of today's community standards, these standards may unnecessarily disqualify individuals who could be treated safely and would benefit from the life-changing experience of laser vision correction. Conversely, there may be community standards that unnecessarily expose patients to risk.

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Optical Express, Europe’s largest provider of laser vision correction, recently established a systematic process for reviewing patient selection guidelines (Table 1). Applied on an ongoing basis, this process engages Optical Express’ International Medical Advisory Board (IMAB) to perform a comprehensive review of patient selection guidelines based on a thorough review of the available literature (including regulatory and organizational guidance) and analysis of the Optical Express database.

**TABLE 1**

<table>
<thead>
<tr>
<th>Process for Evaluating Patient Selection Guidelines</th>
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<tbody>
<tr>
<td>Current Optical Express standard</td>
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<tr>
<td>Basis of the current Optical Express standard</td>
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<tr>
<td>Number of patients deemed unsuitable each year based on the standard</td>
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<tr>
<td>Potential concerns/risks</td>
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<tr>
<td>Literature search</td>
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<td>Regulatory/organizational guidance</td>
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<td>Optical Express experience/data</td>
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<td>IMAB discussion (risk vs benefit)</td>
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<td>IMAB consensus</td>
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IMAB = International Medical Advisory Board

In determining whether a patient is a suitable candidate for laser vision correction, eye care providers must consider a number of factors: the nature, degree, and stability of the refractive error; corneal shape, thickness, and topography; the health of the ocular surface; and the presence of any systemic medical conditions or ocular pathology. Because clinical findings related to any one of these factors may make a patient unsuitable for surgery, patient selection guidelines must address a wide range of criteria.

For each selection criterion, the Optical Express review process begins by evaluating the current guideline in the context of its scientific basis or origin. In many cases, the IMAB will judge the current criterion to be well supported, in which case the standard can be accepted without further review. In other cases, the current standard simply reflects a previously established medical consensus, and further review is needed.

After identifying the guidelines that are well supported, an assessment of the remaining guidelines is then conducted. The relative risk and benefit of performing laser vision correction in patients with various preoperative conditions is carefully considered, as is the community incidence of the condition or clinical issue under review.

In the most recent IMAB review session, this initial screening process revealed a total of 17 guidelines that required in-depth review (Table 2).

**REVIEWING AVAILABLE DATA**

For each criterion, the next step of the process involves a comprehensive review of laser vision correction literature published in the English language. For the latest review, the PubMed literature search engine was employed using the following search terms: laser in situ keratomileusis, LASIK, photorefractive keratectomy, PRK, LASEK, and epi-LASIK, in combination with other search terms related to each particular issue being studied (eg, autoimmune, rheumatoid, collagen vascular, Crohn’s, Lupus, etc).

This initial search yielded a total of 1486 citations related to the 17 guidelines being considered. Encompassing the vast spectrum of published literature, these citations included human clinical trials, case reports, letters, and editorials.

The citation titles were then reviewed and abstracts were obtained for those titles that appeared to have relevance to surgical suitability. After 139 abstracts were reviewed, 63 full text articles were obtained and deemed sentinel for this evaluation. These 63 articles were then subdivided based on the criterion to which each article applied (see Appendix).

The IMAB next examined other evidence related to each suitability criterion. This evidence included device labeling and the summary of safety and effectiveness reports from the US Food and Drug Administration (FDA), as well as position statements from the European and American Societies of Cataract and Refractive Surgery, the American Academy of Ophthalmology, the Royal College of Ophthalmologists, and the American Optometric Association.

For certain patient selection criteria, an analysis of the Optical Express clinical outcomes database was also performed to provide additional information. The large sample size available in this database provided a high degree of statistical power even for low-incidence conditions.

To illustrate the strength of the Optical Express data, consider the amount of information available regarding clinical outcomes for hyperopic LASIK. The literature review for this topic included 16 sentinel reports with a combined total of 3504 eyes; the average sample size in these studies was 219 eyes. The FDA clinical trial of wavefront-guided LASIK with the VISX laser (Abbott Medical Optics, Santa Ana, Calif) consisted of 131 eyes.
In contrast, the Optical Express database included outcomes on 5099 treated eyes, a sample size that allowed for analyses of high statistical power (Table 3).

After careful consideration of all of this information, proposed changes (if any) to the existing patient selection criteria are drafted, thoroughly discussed, and voted on by the IMAB. A unanimous vote is required to change a guideline.

**AN EXAMPLE OF THE REVIEW PROCESS**

During the latest review meeting, one of the patient selection criteria the IMAB evaluated was the maximum safe value for estimated postoperative keratometry following hyperopic LASIK. The previous Optical Express guideline for this criterion, which was based on the current medical consensus, limited estimated postoperative keratometry to a maximum value of 48.00 diopters (D) in the steepest meridian.

The initial literature search for relevant articles yielded 137 citations. A review of abstracts produced 6 full articles with direct clinical relevance to this topic, with sample sizes in these articles ranging from 43 to 376 eyes. The conclusions of the articles were mixed, with some studies showing a correlation between outcomes and pre- or postoperative keratometry and others showing no association.
One article of particular interest to the IMAB was a study by Williams et al.\textsuperscript{7} which found that preoperative keratometry >44.00 D following hyperopic LASIK was associated with an increased incidence of loss of best spectacle-corrected visual acuity and decreased patient satisfaction. The sample size of this study was 49 eyes.

In addition to the literature search, other sources of data also informed the IMAB’s deliberation. Food and Drug Administration guidance related to hyperopic LASIK states that safety and effectiveness of hyperopic corrections have not been established if the anticipated postoperative keratometry is >50.00 D in any meridian. Guidance provided by the American Academy of Ophthalmology likewise states that postoperative keratometry steeper than 49.00 to 50.00 D may be associated with quality of vision problems.

To further evaluate the association between postoperative keratometry and visual outcomes, an analysis of Optical Express clinical outcomes data (n=1695 eyes) was performed.\textsuperscript{2} The large sample size available for this analysis allowed sub-analyses of single variables while controlling for other variables (specifically, preoperative keratometry and the degree of spherical correction, both of which are related to postoperative keratometry). The conclusion of this analysis was that preoperative sphere is the dominant determinant of visual outcomes after hyperopic LASIK, and that postoperative keratometry was not associated with adverse outcomes.

Based on a review of all the clinical data and other information available, the IMAB voted unanimously to increase the selection criterion for estimated postoperative keratometry to 50.00 D in the steepest meridian.

**SETTING EVIDENCE-BASED PATIENT SELECTION CRITERIA**

Using this system for each patient selection criterion under review, the IMAB recently modified 11 of the 17 guidelines they considered. Some criteria were replaced with more restrictive guidelines, whereas others were replaced with guidelines that expanded the indications for laser vision correction. Whatever the outcome, all of these changes were supported by a rigorous, evidence-based, scientific review process performed by a panel of refractive surgery experts.

**CONCLUSION**

By using evidence-based selection criteria to evaluate each patient’s suitability for laser vision correction, eye care professionals can have greater confidence in the scientific foundation supporting their recommendations. A systematic process such as the one described herein represents a valuable tool to help surgeons improve patient selection—that is, more confidently offer a life-enhancing treatment to patients who can safely undergo laser vision correction while steering others toward alternative treatment options.

**REFERENCES**

APPENDIX

List of articles considered by the Optical Express International Medical Advisory Board during a recent review of patient selection criteria

**AMBYLOPIA**


**AUTOIMMUNE CONDITIONS**


**DIABETES**


**GLAUCOMA**


HYPEROPIA
Kohnen T, Mahmoud K, Bühren J. Comparison of corneal higher-order aberrations induced by myopic and hyperopic LASIK. Ophthalmology. 2005;112:1692.

NYSTAGMUS

POSTOPERATIVE KERATOMETRY

THIN CORNEA/PACHYMETRY


