LASIK outcomes: How are we doing and can we do better?

More than 16 million laser in situ keratomileusis (LASIK) surgeries have been performed globally in the procedure's 25-year history. By all measures, LASIK is not only one of the most common surgical procedures performed, it is also one of the most successful.

In this month’s issue of the JCRS, Sandoval et al. present a major review of the recent published literature on LASIK outcomes (pages 1224–1234). As perhaps the largest aggregation of data of its kind, it is one of the most important assessments of LASIK safety and effectiveness in the literature. It is also the most up-to-date, and for those readers who perform LASIK, I recommend putting it at the top of your summer reading list. This review presents an excellent opportunity for surgeons to assess their own outcomes in the context of the worldwide experience of LASIK. For those of us who do not already have a system in place for tracking LASIK outcomes, it provides an impetus to start. Through the strength of large numbers and a systematic approach to reviewing the literature, the authors leverage the variety of treatment platforms, ablation strategies, refractive errors, and some interesting nonclinical study characteristics to make useful observations, pointing not only to what makes LASIK successful but also to how it can be improved.

The review encompassed a global sampling of published outcomes for primary LASIK procedures published from January 2008 to August 2015. Search terms in PubMed produced candidate articles that were down-selected to 97 relevant articles based on a focus on primary LASIK in previously unoperated eyes. These references were then graded according to 2 systems for evaluating the level of clinical evidence. Clinical results were then abstracted and analyzed, and the results were compared with reference data from publicly available U.S. Food and Drug Administration (FDA) studies, including the FDA-initiated Patient-Reported Outcomes with LASIK (PROWL) studies that included a total of 534 patients. The 97 references produced a total of 67,893 eyes for analysis. Eyes that were treated for myopic astigmatism (97.3%) dominated the sample; however, all qualifying references on hyperopic and mixed astigmatism results were also analyzed.

The results suggest a high level of safety and effectiveness, with outcomes that appear to be better than those reported for earlier laser refractive surgery systems. The overall rate of loss of 2 or more lines of corrected distance visual acuity (CDVA) was 0.61%, less than one half the number of eyes that had an increase in CDVA of 2 lines or more (1.45%). The percentage of eyes achieving an uncorrected distance visual acuity (UDVA) of 20/20 or better was 90.8%, and 99.5% achieved 20/40 or better. The spherical equivalent refraction was within ±0.50 diopter (D) of the target in 90.9% of eyes and within ±1.00 D of the target in 98.6% of eyes. In the much smaller subset of studies reporting patient satisfaction, 1.2% of patients (129/9726) were dissatisfied with LASIK. Newer wavefront-guided, wavefront-optimized, and topography-guided ablation modes were associated with a UDVA nearly a full line better than in eyes treated with conventional ablation, and no significant differences were observed between the wavefront-guided, wavefront-optimized, and topography-guided modalities.

Some nonclinical data analyzed by the authors lead to interesting observations about the nature of published clinical research related to LASIK. In 34% of the articles, 1 or more authors reported a financial interest related to the laser or the procedure. However, there was no relationship between presence of a conflict of interest and the “impression” projected by the article’s authors about LASIK. This subjectively graded impression, defined as positive, negative, or neutral, was positive in 73% of studies and no studies projected a negative impression of LASIK. Similarly, there were no significant differences in impression (positive versus neutral) as a function of the study quality score. Although these results suggest that financial conflicts of interest were not linked to the tone of statements made about LASIK, the absence of negative statements limits the resolution of this comparison. The lack of negative impressions could be explained by a tendency in writing to emphasize positive study outcomes; however, they might also reflect the legitimately excellent outcomes observed in most studies.

Where is improvement needed, and how can we do better? More thorough documentation of safety and effectiveness metrics in clinical research is critical. Surprisingly, only 64% of the included studies provided data on gain or loss of CDVA, a core safety metric for refractive surgery. The adoption of consensus-based standardized graphs for reporting refractive surgery results by several major journals should address this shortcoming in the literature and support comparability of outcomes. Hyperopic corrections, although
representing less than 3% of the eyes in this review (1738 of 67,893 eyes), showed a higher percentage of eyes with a loss of 2 or more lines of CDVA compared with myopic treatments (2.13% versus 0.95%). Furthermore, the only groups losing 2 or more lines of CDVA at rates higher than the FDA’s nominal safety threshold of 5% were hyperopic corrections over 5.00 D and astigmatic corrections between 1.00 D and 4.00 D. The greater sensitivity of visual optics to centration of hyperopic ablation profiles and to torsional alignment of astigmatic treatments increases the risk for induced abberations and probably accounts for the majority of lost CDVA in such cases. Advances in technologies for eye tracking, visualization of torsional alignment, biomechanical measurement, treatment planning with nomograms or simulations, and continued research on optimum centration of laser refractive treatments all have the potential to improve outcomes in these and other challenging cases. Another confounder of outcomes in hyperopia and higher astigmatism is refractive regression, and the use of corneal crosslinking as an adjunct to laser treatment offers an exciting emerging option for controlling refractive outcomes.

Laser in situ keratomileusis is a major success story. Throughout its 25-year history, LASIK has provided a remarkably safe and effective mechanism for refractive surgeons to positively affect millions of lives. Through thoughtful collaboration between clinicians, patients, scientists, industry, and regulators, the safety and predictability of LASIK and other forms of refractive correction will reach new heights.

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REFERENCES