

THE LITERATURE



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Modern Laser In Situ Keratomileusis Outcomes

Sandoval HP, Donnenfeld ED, Kohnen T, et al¹

ABSTRACT

Sandoval and colleagues performed a summary of objective clinical outcomes of LASIK reported in the peer-reviewed literature between 2008 and 2015. The investigators compared these results with historical clinical outcomes found in original FDA approval studies for the laser systems as well as in the Patient-Reported Outcomes With Laser In Situ Keratomileusis (PROWL) Studies conducted by the FDA as part of the LASIK Quality of Life Collaboration Project.²

All 97 articles representing 67,893 eyes provided a positive or neutral impression of LASIK. More than 30 different modern excimer laser systems and microkeratomes were represented in the data collected. Laser profiles were categorized as conventional for standard treatments and advanced for wavefront-guided, wavefront-optimized, and topography-guided treatments.

The investigators evaluated LASIK's safety in terms of the percentage of eyes that lost corrected distance vision. A significantly lower percentage of the advanced group lost best-corrected vision compared to the conventional group (0.6% vs 0.94%). No loss of 2 or more lines of corrected distance visual acuity was reported in 82% of the advanced treatment articles. These results were found to be consistent with those reported in PROWL-1 (0.44%) and PROWL-2 (0%).²

The researchers assessed LASIK's efficacy in terms of the percentage of eyes achieving an uncorrected distance visual acuity (UDVA) of 20/20 and 20/40. Overall for all eyes in this study, 99.5% had 20/40 UDVA, and 90.8% had 20/20 UDVA. Postoperative UDVA was statistically better in the advanced versus conventional group. No significant difference was found among advanced treatment groups (wavefront-guided, wavefront-optimized, and topography-guided). The PROWL-1 study found 20/20 UDVA in 97% of right eyes and 98% of left eyes. The PROWL-2 study found 20/20 UDVA in 91% of right eyes and in 92% of left eyes. The FDA standard for efficacy is 20/40 UDVA in 85% of eyes.³⁻⁵

The investigators evaluated LASIK's predictability as the

percentage of eyes with a postoperative spherical equivalent refraction within ± 1.00 D and an outcome within ± 0.50 D of the target refraction. Overall for all eyes in the analysis by Sandoval and colleagues, 98.6% were within ± 1.00 D, and 90.9% were within ± 0.50 D of the target refraction. In more than half of the articles reviewed, comprising 80.7% of eyes (48,684/60,329), 99% of eyes achieved a result within ± 1.00 D of the target refraction. The FDA standard is 75%.

In the studies reporting on LASIK patients' satisfaction, only 1.2% expressed dissatisfaction with the procedure. This statistic appears to be consistent with the satisfaction results of PROWL-1 and PROWL-2 (98% and 96%, respectively). Dry eye data could not be aggregated owing to a lack of uniform reporting, but one study with 32,569 eyes reported a 0.18% postoperative rate of dry eye disease. In PROWL-1, no corneal staining was reported in 90.9% of eyes preoperatively and 87.3% of eyes postoperatively. In PROWL-2, no corneal staining was reported in 78.7% of eyes preoperatively and 83.5% of eyes postoperatively.^{2,6}

The modern LASIK aggregate data appear to be better than data reported in earlier studies of LASIK refractive surgery systems.

DISCUSSION

LASIK surgeons have seen significant improvements in patients' outcomes over the past 2 decades, an impression corroborated by Sandoval and colleagues' review. Within this group of modern LASIK results, the advanced group achieved higher safety and efficacy results than the conventional group. With rare exceptions (extreme patient populations in a few articles), the results reported in the literature review are as good as or better than those reported in studies used to achieve FDA approval of the currently available LASIK technology. Overall, the review demonstrates an extremely high level of safety, efficacy, predictability, and patient satisfaction for the procedure.

The PROWL studies were an important part of the FDA's LASIK Quality of Life Collaboration Project and confirmed that the procedure improves quality of vision.² The trials' results were reported only 3 months postoperatively, however, and many symptoms such as dryness and night vision disturbances would be expected to continue to improve thereafter. In addition, patients in the PROWL studies were not permitted to undergo refractive enhancement procedures, and residual refractive error would likely contribute to the overall patient satisfaction rates reported in both trials. The PROWL studies showed that many patients with

preoperative visual symptoms experienced their resolution after surgery and that a minority of patients who were asymptomatic preoperatively developed new symptoms after LASIK. Most of the symptoms reported were mild and not significant.

The superior LASIK outcomes that today's patients achieve may be attributed to several factors, including improved candidate selection, better excimer and femtosecond laser technology, and an increase in surgeons' experience and nomogram refinement. Although the outcomes in this study were excellent overall, the advanced technology achieved statistically significantly better safety and efficacy outcomes. It is reasonable to expect that LASIK outcomes and patients' satisfaction will continue to improve in the future.

Patient-Reported Outcomes 5 Years After Laser In Situ Keratomileusis

Schallhorn SC, Venter JA, Teenan D, et al⁷

ABSTRACT

Schallhorn and colleagues performed a retrospective analysis of 2,530 patients returning for a follow-up examination 5 years after having LASIK. They represented 8.2% of 30,905 patients treated consecutively between October 1, 2007, and September 30, 2008, by 19 surgeons at 33 surgical centers. Patients' mean age at the time of surgery was 42.4 years, with a preoperative manifest spherical equivalent ranging from -11.00 to +4.88 D.

Five years postoperatively, 77.7% of eyes had a monocular UDVA of 20/20, 90.6% of patients had a binocular UDVA of 20/20 or better, and 79.3% of eyes were within ± 0.50 D of the refractive target. Ninety-one percent of patients reported satisfaction with their current vision, and 94.9% did not wear distance correction. Less than 2% reported noticing visual phenomena (glare, halos, or starbursts).

The major predictors of patients' satisfaction 5 years postoperatively were postoperative binocular UDVA (37.6% contribution), lack of visual phenomena (15.0% contribution), pre- and postoperative sphere (11.6%), and eyesight-related difficulties (night driving, outdoor activities, and reading; 10.2% contribution).

DISCUSSION

Most studies report high rates of satisfaction after LASIK but survey patients within the first 12 postoperative months.⁸ The study by Schallhorn and colleagues is the first to look at clinical outcomes and patients' satisfaction in the long term. After 5 years, 91.0% of subjects remained satisfied, 94.7% said that they would have the same procedure again, and 96.5% said that they would recommend LASIK to their friends and family.



AT A GLANCE

- Researchers compared objective clinical outcomes of LASIK reported in the peer-reviewed literature between 2008 and 2015 with those of the original FDA approval studies for the laser systems as well as those of the Patient-Reported Outcomes With Laser In Situ Keratomileusis (PROWL) Studies. Although the outcomes in this study were excellent overall, the advanced technology (ie, wavefront-guided, wavefront-optimized, and topography-guided treatments) achieved statistically significantly better safety and efficacy outcomes than standard treatment.
- A retrospective analysis of 2,530 patients returning for a follow-up examination 5 years after having LASIK demonstrated excellent outcomes and a high level of satisfaction. Understanding what contributes to patients' long-term satisfaction with the procedure should help surgeons further improve results.

The results of this study are affected by a negative selection bias. Patients with less-than-perfect outcomes are far more likely than those with perfect outcomes to return for follow-up visits. Because these results represent only 8.2% of the eyes treated during the time period, it is reasonable to assume that the other 91.8% of eyes had better results. In addition, this study included both myopic and hyperopic LASIK results, but the latter are known to be less successful, especially for the higher ranges of treatment used in some eyes in this study. These factors would negatively affect the results of this research compared with a study that had 100% follow-up and only myopic LASIK results.

Patient-reported quality of life and satisfaction rates remained high 5 years after LASIK despite a shift from emmetropia over time. In a similar study of 13,655 patients,⁹ 1 month postoperatively, 95% of patients reported a very high level of satisfaction with visual results, and 94.2% of patients reported that the surgery had improved their lives. In comparison, this 5-year study by Schallhorn and colleagues found that only 79.3% eyes that were targeted for emmetropia were within ± 0.50 D. It is likely that many patients who were dissatisfied in the early postoperative period either underwent an enhancement procedure or adapted to their vision.

The research by Schallhorn and colleagues highlights the importance of evaluating and understanding the patient's perception of the surgical outcome and its effect on his or her lifestyle. In addition to postoperative UDVA and high pre- or

postoperative refractive error, patients' dissatisfaction depended on eyesight-related difficulties with performing activities (ocular discomfort or visual phenomena) and the postoperative use of spectacles or contact lenses.

Age did not seem to contribute to patients' dissatisfaction, but the number of enhancement procedures did. Although 86.8% of patients who had undergone an enhancement said that they were still satisfied, some patients likely perceive the need for an enhancement as a failure of the LASIK procedure.

Even with the negative selection bias and the broad range of refractive errors reported in this study, the results demonstrated excellent outcomes and a high level of satisfaction. Understanding the long-term reasons for patients' dissatisfaction should help refractive surgeons to address these areas better in the future with improved patient selection, informed consent, and postoperative treatment. ■

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