Patient-Reported Outcomes After LASIK

A critical review of the literature.

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Patient-reported outcomes (PROs) are defined by the FDA as "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else."[1] Barely mentioned in the medical literature before 2002, PROs must now be studied by companies seeking FDA approval of a new drug or device. PROs are also becoming an increasingly important yardstick against which to measure the quality of health care—from cancer treatments to the management of chronic disease—or the success rates of surgical procedures.[2-6] Despite the recent emphasis on PROs, they remain challenging to assess scientifically because of their subjective nature and the paucity of validated tools by which to measure them.

We LASIK surgeons carefully scrutinize objective measures of our success and safety. How close did we come to our target refraction? Did our patient maintain his or her BCVA? As one of the most carefully studied elective procedures, LASIK's safety and efficacy have been documented in numerous scientific reports.[7-9] These objective measures of quality tell a very important part of the story, but PROs such as quality of vision, ocular comfort, and quality of life must also be considered. LASIK PROs can be influenced by a number of factors (see *Potential Factors Influencing Patient-Reported Outcomes After LASIK*).

PROs after LASIK came to the forefront following the 2008 FDA LASIK Quality of Life hearings, during which patients described symptoms ranging from glare and halos to debilitating ocular discomfort.[10,11] Millions of patients have benefited from LASIK, but the 2008 FDA hearings raised many questions. How frequent and significant are negative PROs such as glare, halos, and ocular discomfort? Can these patients' symptoms be attributed to older excimer laser technology using small optical zones? Did they have preexisting dry eye disease or corneal ectasia that would have flagged them as poor candidates for surgery according to current criteria? Are there objective measures that correlate to a patient's subjective symptoms so that those symptoms can be better understood and treated? Are there risk factors for poor PROs that can be detected before LASIK surgery to prevent operations on patients at risk?

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WHAT TOOLS DO WE HAVE TO MEASURE PROs AFTER LASIK?

Although there are many tools with which to look at pieces of the PRO puzzle, no single, comprehensive, validated instrument evaluates all areas of concern to the present-day LASIK surgeon and LASIK patient. In particular, we refractive surgeons lack a validated screening tool with which to preoperatively identify patients with unreasonable expectations regarding their surgical outcome. Validated instruments to which we do have access include the following.

Ocular Surface Disease Index

The Ocular Surface Disease Index (OSDI) was designed to measure subjective dry eye symptoms, and it has undergone psychometric testing. The OSDI has been used in clinical trials evaluating new treatments reviewed by the FDA, and it has undergone rigorous reliability and validity testing.[12-14] The OSDI has been used in many studies evaluating dry eye symptoms and has performed well.[12,14-19]

National Eye Institute's Refractive Error Quality of Life

The National Eye Institute's Refractive Error Quality of Life (NEI-RQL-42) was developed to augment the traditional clinical measures of visual function on health-related quality of life. The NEI-RQL-42 grew out of earlier work devoted to refractive surgery with the Refractive Status and Vision Profile.[20,21] The NEI-RQL-42 has been shown to be a reliable and valid measure by which to distinguish people with different types of refractive error, and it is responsive to changes in vision-targeted, health-related quality of life resulting from refractive surgery.[22-25] The NEI-RQL-42 includes questions on clarity of vision, near vision, far vision, glare, diurnal visual fluctuation, activity limitations, and worry.

Quality of Life Impact of Refractive Correction

This 20-item questionnaire was developed and validated in the United Kingdom. The Quality of Life Impact of Refractive Correction (QIRC) includes items about glare, driving, sports, and self-esteem.[26] The actual questionnaire has been published for use in future studies, and the QIRC distinguishes itself from the NEI-RQL-42 by using a Rasch scale that gives greater weight to tasks deemed more difficult than others. For example, night driving was deemed a more challenging task than daytime driving.

WHAT DOES THE LITERATURE SHOW?

Numerous studies have assessed PROs after LASIK. Some used the aforementioned tools, whereas others looked only at patients' satisfaction. This article highlights pertinent studies from the past decade.

In a prospective study by Garamendi et al, 66 patients undergoing myopic LASIK completed the validated QIRC questionnaire pre- and postoperatively.[27] Most of the patients (95%) reported significant improvements in their quality of life after LASIK surgery, especially for items related to convenience, health concerns, and well-being.

Schmidt et al evaluated the relationship between ablation diameter, pupillary size, and visual function after LASIK. In this retrospective study, 300 patients who had undergone uncomplicated LASIK received the validated NEI-RQL questionnaire by mail. Among those who chose to participate (only 32.3%), residual refractive error was the biggest predictor of decreased satisfaction.[28]

POTENTIAL FACTORS INFLUENCING PATIENT-REPORTED OUTCOMES AFTER LASIK

QUALITY OF VISION (DAY AND NIGHT)
- Residual refractive error
- Dry eye/ocular surface disease
- Small optical zone
- Induced higher-order aberrations
- Increased astigmatism from corneal ectasia
- Presbyopia

OCULAR DISCOMFORT
- Transient light sensitivity
- Exacerbation of preexisting dry eye/ocular surface disease

UNREASONABLE EXPECTATIONS ON PART OF PATIENT
- Expectation of no residual refractive error
- Expectation of complete spectacle independence despite presbyopia

In a prospective, 1-year study, Mian et al used the OSDI to assess the effect of the hinge's position (temporal vs superior) on patients' corneal sensation and dry eye symptoms after LASIK with a femtosecond laser. The OSDI detected a statistically significant increase in dry eye symptoms through 1 month postoperatively, but results then returned to baseline. The position of the hinge had no effect on dry eye signs or symptoms.[29]

A retrospective meta-analysis of refractive surgery articles published from 1988 to 2008 identified 19 that included pertinent data on quality of life and patients' satisfaction after LASIK surgery. The researchers found that the overall satisfaction rate across all refractive errors was 95.4%. The surgeries included in the studies took place from 1995 through 2003, before the widespread implementation of larger optical zones and modern ablation profiles. The researchers concluded that visual results, and therefore satisfaction rates, might be even better using current technology.[30]

In a small, prospective study of 15 patients, investigators administered a six-item subjective questionnaire and confirmed that residual refractive error was the biggest predictor of unwanted subjective symptoms such as blur. Other tests such as contrast acuity and wavefront aberrometry were less predictive.[31]

A prospective study evaluated the safety and efficacy of LASIK using a femtosecond laser in navy pilots, naviga-

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tors, and aircrew. Treatments using a large optical zone and modern ablation profiles resulted in 20/20 UCVA in 98.3% of patients with myopia or mixed astigmatism and 95.7% of those with hyperopia at 3 months. The nonvalidated study questionnaire showed no difference in patients' reports of glare, halos, night vision, and visual sharpness 3 months after LASIK surgery compared with preoperatively. Furthermore, patients reported improved visual performance in operationally challenging conditions such as landing on an aircraft carrier and detecting an aircraft runway in low-contrast lighting situations.[32]

A retrospective study assessed the safety and efficacy of LASIK using the new iDesign Hartmann-Shack wavefront aberrometer (Abbott Medical Optics) in 243 eyes, 93.4% of which achieved 20/20 or better uncorrected vision. The study included a survey of patients' satisfaction; 98.5% reported being satisfied or very satisfied with the outcome of their procedure, 100% recommended the procedure, and 100% indicated that their vision met or exceeded their expectations.[33]

THE FUTURE

After the 2008 hearings, the FDA set out to develop and validate a comprehensive instrument with which to evaluate PROs after LASIK and then to test this instrument in several refractive surgery practices. The Patient-Reported Outcomes With LASIK (PROWL) studies are currently underway. Researchers at the Navy Refractive Surgery Center San Diego are conducting the instrument validation arm (PROWL-1), and investigators at several civilian refractive surgery centers are prospectively testing the new instrument (PROWL-2). The hope is that the PROWL studies will lead to the availability of an instrument that all of us LASIK surgeons can use to better assess all of the factors that lead to happy, satisfied LASIK patients. ■

The views expressed in this article are the author's and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the US Government.

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