

# Identifying Potentially Unhappy LASIK Patients

The Joint LASIK Study Task Force is working to identify preoperative factors that may have an impact on patients' satisfaction and quality of life after LASIK.

BY STEVEN C. SCHALLHORN, MD

**T**wo ophthalmic societies and two federal agencies have formed a joint task force to look beyond the safety and efficacy of LASIK—which has been well established in clinical trials—to the procedure's impact on patients' ability to perform their daily activities. The Joint LASIK Study Task Force includes representatives from the ASCRS, the AAO, the National Eye Institute, and the FDA. The study of quality of life is a relatively new field, and few LASIK clinical trials to date have included measurements of this parameter. In a review of the literature, Kerry Solomon, MD, a co-chair of the task force, identified 19 studies that measured patients' satisfaction. In those studies, 95.4% of 2,200 patients said they were satisfied or very satisfied with LASIK. This figure compares favorably with similar reviews in other elective cosmetic surgical fields, but satisfaction is only one element of quality of life. The task force has proposed a large, multicenter, prospective study in an effort to improve the care of LASIK patients.

## THE BEGINNING

The Joint LASIK Study Task Force was initiated approximately 1.5 years ago in response to complaints sent to the FDA and Congress by dissatisfied LASIK patients. In November 2006, the FDA approached the ASCRS, AAO, and National Eye Institute about conducting a postapproval LASIK quality-of-life study. The president and president elect of the ASCRS at the time,

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Samuel Masket, MD, and Richard L. Lindstrom, MD, respectively, became engaged in the effort. Dr. Solomon undertook a comprehensive review of the world literature on satisfaction after LASIK. I also joined the task force and was the chair of the Protocol Development Subcommittee for the proposed study.

## THE PROPOSED STUDY

Many of the study's details are still being developed, but the goals are to (1) assess the level of satisfaction after LASIK, (2) evaluate changes in quality of life after surgery, and, most importantly, (3) identify preoperative factors associated with postoperative satisfaction and quality of life. We hope that the outcomes of the potential study will help us refine the methods we use to screen patients and recommend additional counseling to improve the informed consent process, thereby reducing the chance that patients will be dissatisfied with the outcomes of LASIK.

We refractive surgeons want to meet or exceed the expectations of all LASIK patients and improve their quality of life. We hit this target in almost everyone we

treat. Dr. Solomon's review of the literature, however, suggests that we could do better in approximately 5% of LASIK patients.

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From previous research, we have identified some risk factors for dissatisfaction after LASIK, including suboptimal visual acuity, dry eyes, and night vision symptoms.<sup>1-4</sup> Advances in our understanding of these issues and improvements in laser technology, surgical techniques, and postoperative medications have made significant advances in our ability to alleviate post-LASIK problems. There is more to the story, however. Some LASIK patients may be satisfied with their outcomes, whereas others who have the same level of ocular dryness could be very upset and describe the condition as compromising their quality of life. The dissimilarity between these patients is likely multifactorial, such as different expectations, lifestyles, coping skills, and personality traits.

We still do not have a thorough understanding of how psychological factors affect patients' satisfaction with LASIK, although unpublished research by the Navy showed that preoperative levels of depression and negativity are independently associated with dissatisfaction. These outcomes are not surprising, because this association has been demonstrated with other types of elective procedures. This association points to other factors, however, completely unrelated to the surgery or surgical outcome that need to be considered when trying to understand why some patients are dissatisfied. The proposed study will evaluate some of these psychological issues.

Another possible area of focus for the study is the informed consent process, especially as it relates to the patient expectations postoperatively. In some sense, we are the victims of our own success. As the results of refractive surgery improve, patients' expectations of excellent outcomes also increase. When these outcomes are coupled with an inherently high level of satisfaction among patients, there is an expectation that everyone will achieve a satisfactory result. Patients can be dissatisfied after surgery, however, if their personal expectations are not achieved. Understanding these expectations and how best to counsel patients in this regard is an area where further study is needed.

## CONCLUSION

Conducted with due diligence by all involved, I have no doubt that the proposed study will benefit both patients and surgeons and will further improve LASIK, a procedure that has already enhanced the vision and quality of life of millions of people. ■

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