

LASIK: Clinical Results and Their Relationship to Patient Satisfaction

Lien Thieu Tat

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School of Applied Vision Sciences
Faculty of Health Sciences
The University of Sydney
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Summary

Over recent years, a number of surgical procedures in ophthalmology have offered an alternative for glasses or contact lenses. One of the most popular is LASIK (Laser Assisted in-Situ Keratomileusis). The surgical objective of LASIK is to change the corneal curvature and, in turn, alter or reduce the eye's refractive error. As a result, the patient's dependence on glasses and/or contact lenses is reduced or dispensed with altogether.

A few studies have documented patient satisfaction after PRK, but only one reported patient satisfaction after LASIK. Earlier studies were too general, so that patients' unwanted signs and symptoms were often lost in the analysis. The aim of this study was to assess the safety and efficacy of LASIK as a refractive surgical procedure, using a repeated measures design to assess satisfaction of patients who had LASIK and to correlate clinical outcomes with detailed measures of patient satisfaction to document long-term viability, change over time, and patients' functional abilities long after the procedure has taken place. Non-LASIK patients were included as a control group, to compare and differentiate ocular symptoms and visual difficulties between LASIK and non-LASIK patients. The findings may help to better understand how patients evaluate satisfaction, better prepare patients with realistic expectations of the likely visual outcomes and functional results that may influence their final levels of satisfaction.

The clinical results in this study are comparable and in most aspects superior to those of other studies. The study showed that traditional clinical measures such as visual acuity and refraction inadequately describe the visual outcomes and experience of post-LASIK surgery. LASIK achieved relatively high patient satisfaction, and factors associated with satisfaction were predictable, but sources of dissatisfaction were more idiosyncratic. Contributing factors were identified. Complex variations in patients' education, mental state, purpose and expected benefit from the LASIK procedure, and individual visual needs in everyday life are dynamic, and all can play a role in patient dissatisfaction.

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Statement of authentication

The work described in this thesis was completed by the author under the supervision of Dr Robert Heard and Associate Professor Elaine Cornell.

The study comprises my own original work. Approval for the study was obtained from the Human Ethics committee of the University of Sydney. I designed the Questionnaire and collected all data. I have carried out the analysis and interpretation of the data presented in this thesis with assistance from Dr Rob Heard.

This study was not possible without the cooperation of several ophthalmologists, especially, Dr Stewart who allowed me access to patients in their refractive centres.

The thesis has not been submitted for a degree at any other university.

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Services were provided for this thesis by Joan Rosenthal, (business name Academic Editing, business registration number BN83493432). The services were proofreading and identification and provision of advice in matters of structure (the need to restructure and reword, deletions, additions); the conventions of grammar and syntax; use of clear language; logical connections between phrases, clauses, sentences, paragraphs, and sections; voice and tone; and avoiding ambiguity, repetition and verbosity. Joan Rosenthal does not have academic expertise in the area of the thesis.

Abstract

Purpose

The aim of this study was to evaluate the safety and efficacy of LASIK as a refractive surgical procedure, using a repeated measures design to assess satisfaction of patients who had LASIK and to correlate clinical outcomes with detailed measures of patient satisfaction to document long-term viability, monitor changes over time and patients' functional abilities post-operatively.

Method

In the study 216 post-LASIK subjects were randomly selected from among patients who underwent simultaneous bilateral LASIK using the Chiron Technolas 217C plano-scan excimer laser with the Chiron ACS (Automated Corneal Shaper) and the Hansatome microkeratome. The subjects were recruited from within one centre, and the procedures were performed by any one of three surgeons. The study also included 100 non-LASIK subjects as a control group, to compare and differentiate ocular symptoms and visual difficulties between LASIK and non-LASIK patients. Clinical data documented included visual acuity, subjective refraction, record of glasses and/or contact lenses prescription, corneal topography with EyeSys and Orbscan, slit lamp examination, surgical details, and any pre-existing eye disease/conditions and previous surgery or injury that might prevent the subjects from achieving their desired visual outcome post-operatively. Subjective patient satisfaction evaluation of the treatment group was assessed by subjects completing a survey questionnaire at 3 months, 6 months, 12 months and 24 months post-operatively. The control group subjects completed a comparable questionnaire and were assessed at baseline and 3 months later. Because the control group subjects did not have any surgical alterations, it was unnecessary for them to have more than one follow-up.

Results

LASIK achieved relatively high patient satisfaction, with only a small number of dissatisfied patients. It was effective in correcting myopia, hyperopia and astigmatism. However, there was some persistent under-correction in myopic spherical and minus cylindrical refractive errors. Hyperopic spherical correction was less effective, as there were more under- as well as over-correction, and the plus cylindrical correction tended to be under-corrected. The LASIK subjects' post-operative distance uncorrected visual acuity

was not as good as their pre-operative best corrected visual acuity, but it did not significantly correlate with patient satisfaction. The findings were consistent with other studies and confirmed the concept that patient satisfaction is not unidimensional and is not related to outcome solely in terms of visual acuity and residual refractive errors. Other contributing factors included problems with glare, rating of unaided distance and near vision, ability to drive at night, change in ability to perform social/recreational, home and work activities, change in overall quality of life, amount of information given prior to surgery, rating of surgery success, and surgery outcome relative to pre-operative expectations. These variables demonstrated distinctive differences between subjects who were satisfied and dissatisfied.

Conclusions

The findings of this study are consistent with those of earlier studies. However, the repeated measures design and the comparisons between LASIK subjects and the control group revealed some new insights that were previously undocumented. LASIK achieved high patient satisfaction, and factors associated with satisfaction were predictable, but sources of dissatisfaction were more idiosyncratic and contributing factors were identified.

Introduction

Over recent years, a number of possible surgical procedures in ophthalmology have offered people an alternative for the need to wear glasses or contact lenses. Since 1991¹ the Australian public has been exposed to information about refractive surgery via the media, local optometrists, ophthalmologists, friends who have already had the procedure, and/or a combination of the above. The most popular refractive surgery is LASIK (Laser Assisted in-Situ Keratomileusis). This procedure consists of two stages:

1. Automated Lamellar Keratoplasty (ALK), in which a microkeratome is used to create a hinged corneal flap. The flap is folded back revealing the stromal bed.
2. Photorefractive Keratectomy (PRK), in which an excimer laser is used as a surgical device, driven by a sophisticated computer system, to reshape the stromal layer of the corneal tissue. The corneal flap is then returned to its original position and air is used to seal the flap back in place.

The surgical objective of LASIK is to change the corneal curvature and, in turn, alter or reduce the eye's refractive error. As a result, the patient's dependence on glasses and/or contact lenses is reduced or dispensed with altogether.

Only a few studies to date have documented patient satisfaction after PRK, and there has been limited research into post-LASIK patient satisfaction. Apart from clinical evaluations, subjective impressions are equally if not more important, because patient satisfaction influences both the future and popularity of the procedure. In earlier patient satisfaction post-PRK studies, most surveys were generalized to the degree that patients' unwanted signs and symptoms were often lost in the analysis. Furthermore, the survey questions were structured to assess primarily whether patients were satisfied with the result of the LASIK procedure overall, despite unforeseen specific difficulties or outcomes, and whether they would recommend the procedure to others. Such surveys are far from a patient-centred approach. It has been said that they are rather a means to reassure the surgeon and to predict how quickly the procedure would popularize.

The concept of patient satisfaction and its study have appeared in the medical and nursing literature since 1965, and in 1994 alone over 1000 such publications were reported. Yet during the past decade, most studies of patient satisfaction after PRK or LASIK have not discussed or acknowledged this literature. Instead, they present objective clinical results and provide little to no subjective detail about aspects such as patients' perspectives as to whether the procedure had achieved their goals and expectations, issues such as visual ability in everyday situations, whether patients were experiencing symptoms, and where they were having the most difficulties. Rather, they simply asked "Are you satisfied with the procedure overall?"

This lack of subjective feedback reveals a need to present patients' clinical results (to evaluate the safety and efficacy of the procedure) together with a more sensitive, multi-dimensional, patient-oriented questionnaire which targets the specific quality of vision in order to expose and evaluate reasons for any subtle dissatisfaction. There is a need for a longitudinal study to test for long-term viability – with repeated measures to detect change over time, monitoring the surgical stability of the procedure, subtle subjective changes, and patients' functional abilities long after the procedure has taken place. There is also a need to differentiate between patients who may use visual acuity as a criterion of satisfaction with the surgery and those who use other criteria to make this judgment. Lastly, there is a need to include non-LASIK patients (as a control group), not merely to illustrate the effectiveness of the LASIK surgical procedure, but also to compare and differentiate ocular symptoms and visual difficulties between LASIK and non-LASIK patients. This in turn may identify the pre-existing factors which may exacerbate post-LASIK, and those which may contribute to patient satisfaction. By doing so, perhaps we can address shortcomings that earlier studies may not have identified.

Purpose of Study:

The aim of this study is to assess the satisfaction of patients who have undergone LASIK, to correlate surgical clinical outcomes with detailed measures of patient satisfaction, and to compare LASIK with non-LASIK patients. It is hoped that the findings will help to better prepare patients with realistic expectations of the likely visual outcomes and functional results that may influence their final levels of satisfaction.

In order to understand the LASIK procedure, one must first understand human refractive error.