



Quality of Life Assessment Before and After Laser in situ Keratomileusis

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ABSTRACT

Objective: To assess the health-related quality of life in patients who underwent conventional laser in situ keratomileusis (LASIK).

Methods: Eighty-five patients who underwent LASIK at the Excimer Unit at Siriraj Hospital were enrolled in the study. They were asked to complete a quality of life questionnaire before and after having an operation at 1, 3 and 6 months. The details of the questionnaire were published elsewhere. The questionnaire included 19 items in four categories and one independent item. Paired t-test, non parametric test and repeated measures were performed to compare pre- and post-operation results.

Results: Of the total, there were 51 females (58.6%). Patients' ages ranged from 16-50 years, with a mean age of 30.7 ± 8.7 (years $\pm$ SD). Cronbach's alpha coefficients of the questionnaire were 0.74-0.81. In one-month (n=67), three-month (n=42) and 6-month (n=14) follow-ups, patients tended to score better on visual tasks and had a significantly better score satisfaction and emotional feeling domain. However, their score on the eye symptoms domain was worse after one month and got better after three months. In general, patients were satisfied with the results of the operation on follow-ups.

Conclusion: The quality of life for patients undergoing LASIK has improved. Patients have better uncorrected vision, with more satisfaction and emotional feeling. Although they have more eye symptoms resulting from the operation, they were very satisfied with the results.

Keywords: Quality of life, laser in situ keratomileusis

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Studies about the quality of life and its visual aspects have been done over the past ten years.^{1,2} Laser correction by photorefractive keratectomy (PRK) in patients with refractive errors has a long period of recovery to stable refraction of almost 3 months, although most patients have functional vision at 1-2 weeks postoperatively. Moreover, problems of night vision, glare and halo around the light may disturb their daily life.³⁻⁵

At present, refractive surgery by laser in situ keratomileusis (LASIK) is a very popular procedure for treatment of refractive error worldwide, because of the short period of recovery and less pain, especially one day after surgery with high satisfaction.⁶ Most patients are happy with their outcome (99.5%), and would have LASIK again (98.5%).⁷ However, adverse events after LASIK surgery include decreased vision at night (24%), and dry eye during the first 6 months.^{7,8} Furthermore, glare or ghost images can occur more or less inadvertently. Any questionnaire about the quality of life after LASIK that is established and modified should be

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designed properly for the changes in visual outcomes. It should also differentiate the functional improvement and satisfaction among different visual results. The time for filling the questionnaire should take less than 10 minutes with questions dealing with no more than 40 items allowing for thoughtful time. The drafted questions are tested and evaluated by clinical impact analysis and factor analysis to reduce the items and reclassify them.⁹ Collection, improvement and assessment of the questionnaires for reliability, validity and consistency should be done if it is to be a good questionnaire for the quality of life in practice.

The purpose of this study was determined if the health-related quality of life of the patients do change after having LASIK or not.

MATERIALS AND METHODS

Patients with stable refractive error who planned to have laser correction volunteered to answer the modified questionnaires about the quality of life at the LASIK Center at Siriraj Hospital from July 2003 to January 2004. The inclusion criteria included patients who had had stable refraction for at least 1 year and understood the pros and cons of LASIK. The exclusion criteria were patients with keratoconus, severe dry eye, ocular infection, glaucoma, cataract, retinal diseases, diabetes mellitus, migraine, collagen vascular disease and high expectations.

This study was approved by the Ethics Committee on Research involving human subjects, Faculty of Medicine Siriraj Hospital, Mahidol University, based on the Declaration of Helsinki, on March 4, 2002 (No.28/2002). The informed consents were obtained before enrollment in the study. All patients were advised about the adverse effects of LASIK surgery before answering the questionnaires on the quality of life before the operation. History taking, all symptoms and eye findings were recorded. All patients were examined and measured by a slit lamp biomicroscope for visual acuities, corneal thickness, corneal topography, pupil size, axial length, manifest refraction, and cycloplegic refraction. Only suitable candidates for myopic LASIK surgery were asked to fill in the questionnaires before the operation and at 1 month, 3 months and 6 months postoperatively. All patients underwent conventional LASIK surgery in the usual manner with the Hansatome microkeratome and Technolas Z 217 excimer laser (Bausch & Lomb, Claremont, CA, USA) without complications.

Quality of life questionnaire

A disease-specific questionnaire for LASIK was developed to cover a wide range of quality of life aspects. It was designed as a short form that could be self-administered. The initial draft questionnaire composed of 73 items.⁹ Items involving various aspects of daily life activities were compiled from literatures, standard questionnaires, a clinician's experience and interviewing with patients. Item reduction processes were performed using clinical impact analysis and factor analysis. Thus, the final version contains 19 items in four categories i.e. visual tasks (5 items: reading, vision at night, distant vision, computer, and sensitivity to wind), eye symptoms (6 items: dry eye, irritation, blurred vision, eye strain, halo or glare or ghost image, and photophobia), satisfaction (4 items: satisfied with

vision, more comfortable than before surgery, more convenience, and self confidence to their personality) and emotional feeling (3 items: need to be more careful on the eyes, worry about the result or problem afterwards, and fear of worse vision). Response options are on a 5-point scale (not at all, slightly, moderately, a lot, extremely). The authors will not allow for the tendency of Thais to mark questionnaires at the mid point when they are unsure which is a weakness of using 5 point scales. In the visual task dimension, patients were asked to mark on "Do not perform" if they do not do a task indicated and "No symptom" if they do not have such symptom in the eye symptom dimension. In addition, an independent item on satisfaction of the results of treatment on a four-point scale (very satisfied, somewhat satisfied, somewhat unsatisfied, very unsatisfied) is included. The score is from "1" to "5" in which a lower score indicates a better quality of life.

Data collection and analysis

In case of cancelled follow up, the questionnaires were sent by mail to fill up. The research assistant collected the completed questionnaire for analysis using SPSS version 9.0 statistical software. Paired t-test, non-parametric test and repeated measures were used in comparing between baseline and follow-ups and between follow-ups.

RESULTS

Subject demographics

The mean age of the subjects was 30.7 ± 8.7 (years $\pm$ SD), and they ranged 16-50 years. Of the total of 85 patients, there were 51 females (58.6%). The mean preoperative refraction of the patients was sphere -4.58 ± 2.61 Diopters (D); cylinder -0.94 ± 1.05 D; and spherical equivalents -5.05 ± 2.61 D. The mean post-operative spherical equivalent at one month was -0.22 ± 0.91 D. The mean uncorrected visual acuity log MAR at one month was 0.1 ± 0.1 . The number of subjects included in each follow-up was not equal since some patients did not come as scheduled. There were 67, 42 and 14 patients at one-, three- and six-month follow-ups, respectively. All patients had bilateral LASIK.

Quality of life scores

Cronbach's alpha coefficients of the questionnaire at baseline (before having the operation) were 0.74 to 0.81 (Table 1). A lower score indicated a better quality of life. Quality of life scores of patients at each visit were shown in Table 2. It could be seen that the scores of visual tasks were lower at one- and, three-month follow-up indicating a better quality of life than the baseline without statistical significance. Eye symptoms dimension was significantly worse on quality of life at one month after surgery but was better at three-month follow-up ($p=0.001$). Satisfaction after surgery at one-

TABLE 1. Demonstrate Cronbach's alpha coefficients of the questionnaire at baseline.

Dimension	Cronbach's alpha coefficients
Visual tasks	0.81
Eye symptoms	0.80
Satisfaction	0.74
Emotional feeling	0.76

TABLE 2. Quality of life scores before surgery and after surgery at one, and three months.

	Baseline n = 85	1-month n = 67	3-month n = 42	p-value
Visual tasks	2.79	2.58	2.40	0.103
Eye symptoms	2.15*	2.32*	2.12	0.001
Satisfaction	3.61* [#]	2.19*	2.04 [#]	0.001
Emotional feeling	2.74	2.51	2.37	0.060

*p=0.001, [#]p<0.001

and three-month follow-up was significantly better on quality of life. Emotional feeling was better correspondingly after the operation.

Scores of patients who came at baseline and one-month follow-up (n=67) were compared. It was found that patients' quality of life at one-month follow-up tended to be better than at baseline on visual tasks (2.68 & 2.48; p=0.146). However, eye symptoms dimension was significantly worse (1.64 & 2.13; p<0.001). Satisfaction (3.61 & 2.19; p=0.025) and emotional feelings dimensions (2.77 & 2.52; p<0.001) were significantly better.

For those who completed at three-month follow-up (n=42), a comparison among baseline with one- and three-month follow-up showed a trend of having better scores on all dimensions: visual tasks (2.81, 2.64, 2.40; p=0.072), eye symptoms (1.63, 2.13, 1.88; p=0.025), satisfaction (3.62, 2.10, 2.03; p<0.001) and emotional feeling (2.84, 2.50, 2.37; p=0.002) (Fig 1). Visual tasks dimension was the only dimension that had higher scores (worse quality of life) at one month after the operation.

Patients evaluated their own visions as being "good" and "very good" after the operation at one month (74.6%) more than the baseline (11.9%) (Fig 2). In addition, the number of patients who stated that their visions were "bad" and "very bad" was reduced to nil after LASIK. Patient's satisfaction with the results of treatment were assessed at each follow-up (Fig 3). The percentage of patients who were somewhat satisfied with the result of treatment at each follow up was the highest at one month after having an operation. How-

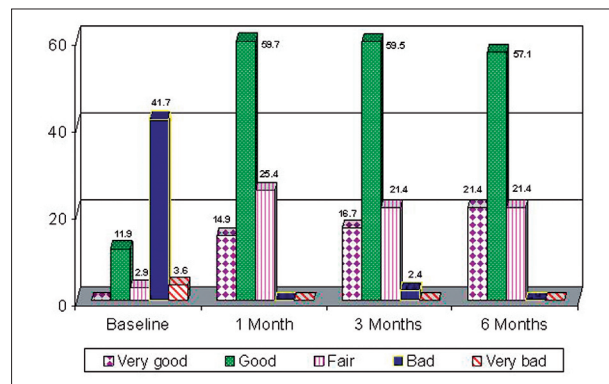


Fig 2. Patient self-assessment on their own vision without correction over time.

ever, patients who were very satisfied were the highest at three-month follow-up.

DISCUSSION

In this study, the quality of life of patients who underwent LASIK was assessed using a Thai questionnaire.⁹ The health-related quality of life involved broad aspects on patients' daily living and their expectations of treatment. In the view of surgeons, the overall goal of LASIK was to improve a patient's quality of life. However, effects on quality of life have not been established in most researches. Previous studies involved patients' satisfaction.^{7,10} Although patients had gone through a discussion about all possible effects, not only halo, starbursts and glare, which were associated with ablation depth and diameter, as well as amount of refractive error, but also problems with night vision from decreased contrast sensitivity and dry eye, they were willing to have an operation.⁷ Seeking freedom from spectacles or contact lens could be an important reason.

This questionnaire has a good reliability as Cronbach's alpha coefficients is over 0.7, similar to Lee's study.¹¹ The results in our study revealed a tendency of patients' having a better quality of life after LASIK except for the eye symptoms dimension. It was general-

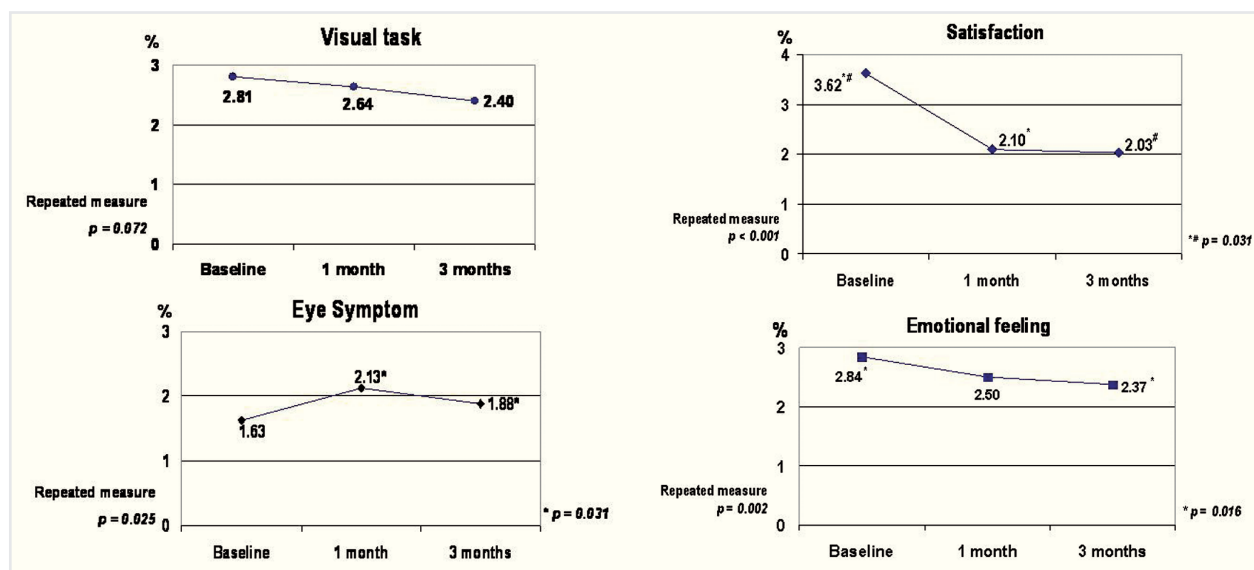


Fig 1. Quality of life scores of patients who underwent LASIK at baseline, one-, and three-month follow-ups (n=42).

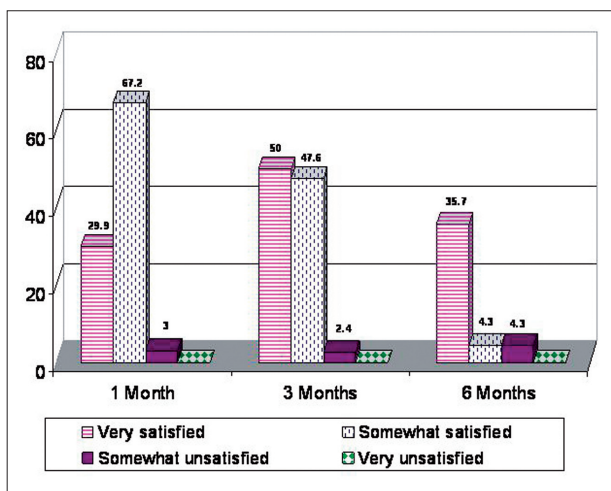


Fig 3. Patient satisfaction on the results of treatment at each follow up.

ly predictable that LASIK could cause dissatisfaction effects such as glare, halos or problems with night vision, especially dry eye. These symptoms might sustain for sometime and became improved afterwards. It was noted that improved facility in performing activities was an important concern for patients and this resulted in improving the quality of life.^{11,12}

Patients in our study were satisfied with the results of LASIK. Similar to Bailey's study, which reported that subjects in their study were satisfied with their vision after LASIK and 97% of them would recommend LASIK to their friends, although 30% of their subjects experienced halos, 27.2% reported glare and 24.5% reported starbursts.¹³ However, the group of not satisfied with vision after LASIK was associated with increased age (10-year difference, odds ratio 1.68 with 95% confidence interval 1.10, 2.56, $p=0.02$), so would not recommend LASIK to a friend.¹³ Their study had also confirmed a tendency of high levels of satisfaction among patients beyond the six-month follow-up period. Likewise, Tahzib and colleagues reported high patient satisfaction with their result after LASIK (92.2%).¹⁰ Our study revealed that patients' eye symptoms bothered them a lot during one month after LASIK but tended to decrease over time, although a higher level of satisfaction (97.6%) was achieved at three-month follow-up. These eye symptoms especially blurred vision in dim light may be due to decreased contrast sensitivity.¹³ Bailey's study raised a plausible explanations - the possibility that patients adapt to their new condition.¹⁴ Other reasons might be a "psychological process" of maintaining their beliefs and expectations of treatment. This phenomenon could have a great effect when asking a question on overall satisfaction of the operation.

Our clinic attempted to give information of all possible adverse effects to the patients. We also provided comments from previously treated patients to new patients before they decided to have an operation. This was corresponding to Koch's and Khan-Lim study that the reason for patients having a high level of satisfaction was that surgeons provided a thorough preoperative counseling.¹⁵⁻¹⁶

There were limitations to have all patients coming back in each follow-up. Thus the results of this study might be biased as patients who came for a follow-up

could be the ones who had good results or those with dissatisfy symptoms. The quality test of modified questionnaires also included validity (content, criterion and construct), reliability and responsiveness.¹⁷⁻²¹ Questions were regrouped to adjust to evaluate the relationship among items in each dimension to reflect the most common effect of the operation. However, the 19 chosen items might be too small numbers to measure the change in quality of life. Adding more items with higher scores may be necessary to improve the reliability of the questionnaires. Furthermore, some questions were replied as "not do" or "no symptom" resulting in decreasing the mean. Therefore a larger sample size is needed to assess test-retest reliability in the future to improve the good questionnaires of the quality of life. However, the attempt of the study was to highlight the importance of using an instrument to assess a patient's quality of life. We believe that further prospective studies using such instruments can determine the long term effects of LASIK in a broader view along with patients' needs and expectations.

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