

OUTCOME COMPARISON OF LASER-ASSISTED IN SITU KERATOMILEUSIS IN VARIOUS DEGREE OF MYOPIA

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ABSTRACT

Introduction: The femtosecond Laser-Assisted in Situ Keratomileusis (fs-LASIK) procedure is commonly used for myopia correction because of good efficacy, safety, and predictability. The aim of this study was to compare the outcome of the fs-LASIK procedure among myopia groups in Cicendo Eye Hospital from January to December 2021.

Methods: This retrospective study included 212 patients (399 eyes) and the data were obtained from medical records from January 2021 to December 2021 using ICD-10 coding for LASIK (S0800), consisting of fs-LASIK procedures. The outcome variables were safety index, and efficacy index.

Results: The median of safety index was not statistically significant different between groups, 1,00(0,50-1,67) in low myopia, 1,00(0,20-1,43) in moderate myopia, and 1,00(0,30-3,33) in high myopia. The median of efficacy index was statistically significant different between groups, 1,00(0,40-1,67) in low myopia, 1,00(0,20-1,43) in moderate myopia, and 1,00(0,30-3,33) in high myopia. The proportion of eye with UCVA > 6/12 on the first month after the procedure was higher in the mild myopia group (223;99,2%) than in moderate myopia (87;98,8%) and high myopia (77;88,5%) with $p=0,0001$. The proportion of eye with BCVA > 6/12 on the first month after the procedure was also higher in the mild myopia group (224;100%) than in moderate myopia (87;98,8%) and high myopia (82;94,3%) with $p=0,0001$.

Conclusion: There was no statistically significant difference of the safety index between groups. The efficacy index was statistically significant different between groups.

Keywords: efficacy index, LASIK, myopia, outcome, safety index

INTRODUCTION

Myopia is a refractive error characterised by an image that is focused in front of the retina. Myopia is caused by either an increase in the cornea's radius of curvature or an axial lengthening of the eyeball. Uncorrected refractive error is the primary cause of vision impairment and the second-leading cause of blindness worldwide, behind cataracts. Adults around the world have a myopia prevalence of between 4 and 51%. Longer formal education, more near-work activities, and fewer outdoor activities are all associated with a higher prevalence.

Refractive surgery, contact lenses, and glasses are all options for correcting refractive problems.¹⁻⁴ Refractive surgery treatment known as laser-assisted in situ

keratomileusis (LASIK) is frequently used to treat refractive errors. LASIK flattens the centre of cornea, thereby making the image more sharply focused on the retina. The refractive surgery techniques have a high level of effectiveness and safety, as well as predictability. Some of the outcomes of the LASIK operation that can be evaluated are safety and efficacy index.⁵⁻⁸

The research of Gomel et al. showed a correlation between a safety and efficacy index and mild myopia. The 8.755 eyes in the study after LASIK for more than 13 years revealed that the group with mild myopia had a greater safety and efficacy index than those with high myopia. According to a study by Niparugs et al.

comparing the results of LASIK in 161 eyes with mild-moderate myopia and 93 eyes with extreme myopia, the mild-moderate myopia group had better Uncorrected Visual Acuity (UCVA) one month after surgery. A study by Wallerstein et al. involving 114 eyes with high myopia found that the safety and efficacy indices 24 months following LASIK surgery were 1,05, 0,12, and 0,93 0,20, respectively.⁹⁻¹¹

According to the findings of Anggriany et al.'s study at the Cicendo Eye Hospital in 2010, 82,33% of patients who underwent LASIK using the microkeratome technique had the same postoperative UCVA as their preoperative Best Corrected Visual Acuity (BCVA). During a one-month observation period, Chairini et al.'s study at Cicendo Eye Hospital in 2016 obtained findings that femtosecond-LASIK were effective for correcting myopia and myopic astigmatism. There is no research comparing the safety and effectiveness of LASIK at Cicendo Eye Hospital among various myopia degree groups.^{12,13}

The aim of the study is to compare the outcomes of LASIK surgeries performed at Cicendo Eye Hospital between January and December 2021 on patients with varied degrees of myopia problems.

METHODS

The study used a retrospective cohort design. Data were collected retrospectively from the medical records of PMN RSMC patients who underwent LASIK procedures between January and December 2021, according to the International Classification Code (ICD)-9 CM S0800, which included femtosecond-LASIK procedures (fs-LASIK). The study employed a total sampling method, with a minimum sample size of 99.

The inclusion criteria were met by all patients who received fs-LASIK between January and December 2021 and were

between the ages of 18 and 40. Exclusion criteria for this study included patients with intraoperative complications, inadequate medical record data, and patients who did not attend for a follow-up visit one month following the procedure.

Age, sex, place of residence, level of education, occupation, reason for surgery, preoperative BCVA, and severity of myopia were all recorded. A spherical equivalent (SE) of higher than or equal to -3,00 diopters (D) is considered mild myopia; SE between -3,00 and -6,00 D is considered moderate myopia; and SE lower than -6,00 D is considered high myopia. The outcomes were postoperative UCVA, postoperative BCVA, safety index, and efficacy index. The safety index is defined as the ratio of BCVA after surgery to BCVA prior to surgery. The efficacy index is defined as the ratio of UCVA after surgery to BCVA prior to surgery.

The data analysis tool utilised was SPSS 26. The Kolmogorov-Smirnov test is used to determine whether the data is normally distributed. Categorical data is presented using percentages and amounts. Numerical data is presented using the median and range. The Kruskal-Wallis test was used to analyse the numerical and categorical data because the data were not normally distributed. A p value of less than 0,05 was regarded as statistically significant.

RESULTS

LASIK procedures were performed on 341 patients between the ages of 18 and 40 from January to December 2021, according to information obtained from the medical records. 121 patients were excluded because they did not come visit one month after surgery, and 8 patients were excluded because of the uncompleted data. There were 212 patients (399 eyes) who participated in this study. There were 224 eyes (118 patients) in the mild myopia group, 88

eyes (46 patients) in the moderate myopia group, and 87 eyes (48 patients) in the high myopia group. The baseline characteristics of the patients in the form of age, sex, address, educational level, occupation, purpose of surgery, and preoperative BCVA are shown in table 1.

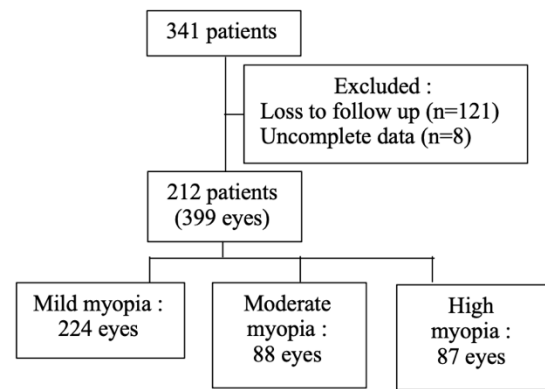


Figure 1. Flowchart of participants

Table 1. Baseline characteristics

Variables	Degree of Myopia		
	Mild N=118 (224 eyes)	Moderate N=46 (88 eyes)	High N=48 (87 eyes)
Age			
Median	19	18	22
Range	18-38	18-37	18-38
Gender			
Male	93(78,8%)	26(56,52%)	12(25%)
Female	25(21,2%)	20(43,48%)	36(75%)
Address			
Bandung	16(13,55%)	15(32,6%)	11(22,92%)
West Java (outside Bandung)	93(77,81%)	20(43,48%)	27(56,25%)
Outside West Java	9(7,63%)	11(23,91%)	10(20,83%)
Education			
Junior High School	1(0,85%)	3(6,52%)	0(0,0%)
Senior High School	89(75,42%)	30(65,22%)	29(60,42%)
College	28(23,73%)	13(28,26%)	19(39,58%)
Occupation			
Student	89(75,42%)	30(65,22%)	29(60,42%)
Civil servant	9(7,63%)	4(8,70%)	2(4,17%)
Private officer	18(15,25%)	11(23,91%)	12(25%)
Housewife	1(0,85%)	1(2,17%)	3(6,25%)
Others	1(0,85%)	0(0,0%)	2(4,17%)
Purpose of surgery			
Academic entry requirements	76(64,40%)	31(67,39%)	9(18,75%)
Cosmetic	39(33,05%)	15(33,61%)	39(81,25%)
No data available	3(2,54%)	0(0,0%)	0(0,0%)
Preoperative BCVA			
≥6/12	224(100,0%)	88(100,0%)	81(93,10%)
≥6/18-<6/12	0(0,0%)	0(0,0%)	6(6,90%)
≥6/60-<6/18	0(0,0%)	0(0,0%)	0(0,0%)
≥3/60-<6/60	0(0,0%)	0(0,0%)	0(0,0%)
<3/60	0(0,0%)	0(0,0%)	0(0,0%)

Table 2 and Figure 2 show the outcome comparison of the LASIK in terms of the degree of myopia. Because the data were not normally distributed, the Kruskal-Wallis test was used to analyse the safety and efficacy index. The median safety index was 1,00 (0,50-1,67) in the mild myopia group, 1,00 (0,20-1,43) in the moderate myopia group, and 1,00 (0,30-3,33) in the high myopia group. There was no statistically significant difference in the

safety index median between the groups with mild, moderate, and high myopia ($p > 0,05$). Mild myopia had a median efficacy index of 1,00 (0,40-1,67), moderate myopia had 1,00 (0,20-1,43), and high myopia had 1,00 (0,30-3,33). There was a statistically significant difference in the efficacy index median among the mild, moderate, and high myopia groups ($p < 0,05$).

Table 2. Outcome Comparison of LASIK Procedure in Various Degree of Myopia

Variables	Degree of Myopia			P value
	Mild	Moderate	High	
	N=118 (224 eyes)	N=46 (88 eyes)	N=48 (87 eyes)	
Safety index				
Median	1,00	1,00	1,00	0,113
Range	0,50-1,67	0,20-1,43	0,30-3,33	
Efficacy index				
Median	1,00	1,00	1,00	0,035*
Range	0,40-1,67	0,20-1,43	0,30-3,33	

Notes: Numeric data analysis used *Kruskal Wallis* test. P value < 0.05 means statistically significant.

*P value < 0,05.

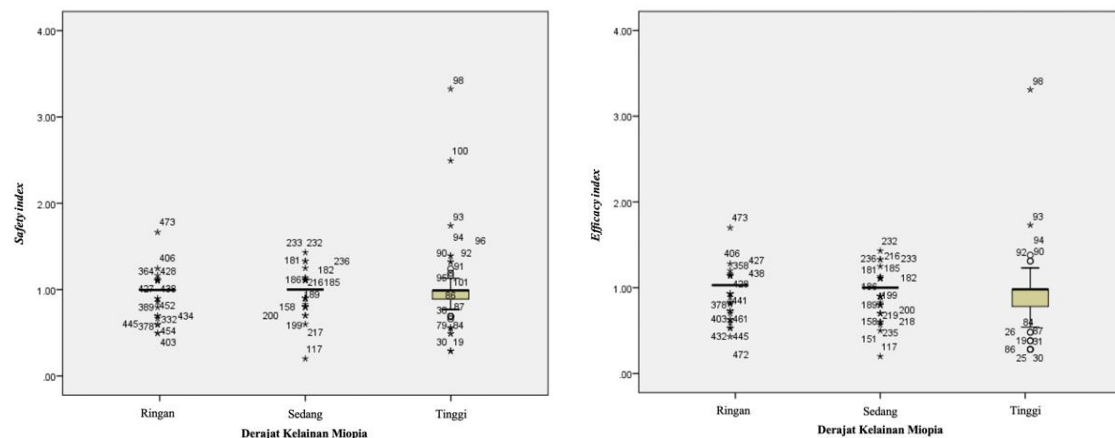


Figure 2. Graph of Outcome Comparison of LASIK Procedure in Various Degree of Myopia

Table 3 shows the improvement of visual acuity following LASIK among the degree of myopia groups. 223 eyes (99,2%) in the group with mild myopia, 87 eyes (98,8%) in the group with moderate myopia, and 77 people (88,50%) in the group with high myopia had UCVA $\geq 6/12$ in 1 month after surgery. There was a statistically significant difference in the

proportion of UCVA 1 month after surgery among the mild, moderate, and high myopia groups ($p < 0.05$). BCVA 1 month after surgery with category $\geq 6/12$ was 224 (100,0%) in the mild myopia group, 87 (98,8%) in the moderate myopia group, and 82 (94,3%) in the high myopia group. Preoperative BCVA of $>6/18$ - $6/12$ and $>6/60$ - $6/18$ were present in 5 patients

with high myopia related to refractive amblyopia. There was a statistically significant difference in the proportion of

the BCVA 1 month after LASIK among the group of patients with mild, moderate, and high degrees of myopia ($p < 0,05$).

Table 3. Comparison of the Proportion of Improvement in Visual Acuity After LASIK Procedure in Various Degree of Myopia

Variables	Degree of Myopia			P value
	Mild N=118 (224 eyes)	Moderate N=46 (88 eyes)	High N=48 (87 eyes)	
UCVA 1 month				
≥6/12	223(99,2%)	87(98,8%)	77(88,5%)	0,0001**
≥6/18-<6/12	1(0,8%)	1(1,2%)	8(9,2%)	
≥6/60-<6/18	0(0,0%)	0(0,0%)	2(2,3%)	
≥3/60-<6/60	0(0,0%)	0(0,0%)	0(0,0%)	
<3/60	0(0,0%)	0(0,0%)	0(0,0%)	
BCVA 1 month				
≥6/12	224(100,0%)	87(98,8%)	82(94,3%)	0,0001**
≥6/18-<6/12	0(0,0%)	1(1,2%)	4(4,6%)	
≥6/60-<6/18	0(0,0%)	0(0,0%)	1(1,1%)	
≥3/60-<6/60	0(0,0%)	0(0,0%)	0(0,0%)	
<3/60	0(0,0%)	0(0,0%)	0(0,0%)	

DISCUSSION

Keratorefractive surgery modifies the cornea to change the refractive status. Patients who desire to use contact lenses or glasses less frequently are considered for this procedure. One of the most popular keratorefractive surgery procedures is LASIK. Age of 18 years or older, mesopic pupil size of less than 7 mm, residual stromal bed of more than 250 micrometres, central corneal thickness of more than 475 micrometres, refractive stability of more than a year, and postoperative keratometry expected to range from 35 to 47 diopters (D) are the requirements that must be fulfilled before performing LASIK treatment.^{4,6}

During the fs-LASIK procedure, a hinged flap composed of epithelium, Bowman's membrane, and superficial corneal stroma is produced. The flap is repositioned after the corneal stroma is restructured through tissue ablation using an excimer laser. This myopia correction technique is predictable, secure, and effective. According to research by Ang et

al., 87% of patients who underwent LASIK achieved 20/20, with a safety index of 1.1 ± 0.2 .^{4,7,8}

Compared to the groups with mild and moderate myopia, there were fewer eyes in the high myopia group in this study. The prevalence of high myopia in the global population is 4,0%. The previous research found that mild myopia affected 83,9% of the population. This explains why the number of individuals with mild myopia is higher than that of other myopia subgroups.^{2,14}

The median ages of mild, moderate, and high myopia were 19, 18, and 22, respectively. Myopia is more common in young people due to lifestyle modifications brought on by near-sight activities, level of education, and outdoor activity exposure. According to the patients' demographic information, the majority of the patients had recently completed high school or were employed as students. The median age in the mild and moderate groups was lower because most of the patients in these groups sought surgery in

order to be admitted to police or military academies. Most patients with high myopia seek cosmetic surgery with the intention of minimizing their need for glasses, so that the median age in the high myopia group is higher.

There were more men than women in the study's group of patients with mild to moderate myopia. There were more female patients than male patients in the high myopia group. Ang et al.'s research indicates that there is no direct correlation between gender and myopia. According to studies conducted by Mori et al. on the adult population in Japan, women (5,9%) had a higher prevalence of high myopia than men (3,8%). However, no research has established a causal relationship between gender and excessive myopia. There were more men in the mild myopia and moderate myopia groups in this study because the majority of patients intended to use their condition as a criterion for admission to the military or police academy. The majority of those with high myopia are women because they typically have surgery to lessen their need for glasses or for cosmetic reasons.^{14,15}

A procedure is said to be safe if it does not reduce the patient's preoperative best corrected vision (BCVA). A safety index value below 0,85 indicates an unacceptable loss of two or more lines of BCVA after refractive surgery. The median and range of the safety index in this study did not differ significantly between all myopia groups. The results of Gomel et al.'s research showed that the safety index was higher in the myopia group with a lower spherical equivalent. Park et al.'s research obtained a safety index that was not significantly different between mild myopia, $1,18 \pm 0,17$, and high myopia, $1,15 \pm 0,20$. The safety index for high myopia, according to research by Wallerstein et al., has an average of $1,05 \pm 0,12$. Safety was correlated with younger age and male gender. In this study, the

mild myopia and moderate myopia groups had a younger median age and were mostly male.^{10,11,17}

Efficacy is related to the improvement in uncorrected visual acuity (UCVA) obtained by the patient after surgery. An efficacy index value below 0,8 indicates the loss of more than two lines of UCVA, resulting in not achieving optimal UCVA after refractive surgery. The median and range of the efficacy index differed significantly between all groups in this study. Chua et al.'s research obtained the highest efficacy results in the mild myopia group. Gomel et al. showed similar results: the efficacy index was higher in the myopia group with a lower spherical equivalent. Park et al.'s research obtained a mean efficacy index that was not significantly different between mild myopia ($1,05 \pm 0,18$) and high myopia ($1,01 \pm 0,15$). Efficacy was correlated with younger age, male gender, and lower spherical equivalent myopia. In this study, the mild and moderate myopia groups had a younger median age and were mostly male.⁹⁻¹¹

The results of this study showed that the proportion of eyes that had a postoperative UCVA $>6/12$ was higher in the mild myopia group than in the moderate and severe myopia groups. This is similar with previous research, which stated that the mild-moderate myopia group had a greater proportion of postoperative UCVA than high myopia. Chua et al. stated that mild myopia achieved a postoperative UCVA $>6/12$ of 99,2%. The results of Wallerstein et al.'s research showed that 95,6% of high-myopia patients achieved UCVA $>6/12$ after LASIK.⁹⁻¹¹

The proportion of eyes achieving postoperative BCVA $>6/12$ was higher in the mild myopia group than in the moderate and severe myopia groups in this study. The results of Niparugs et al.'s research stated that postoperative BCVA

was not significantly different between the myopia groups. Chua et al.'s study found a percentage of eyes with postoperative BCVA that was the same or better than preoperative BCVA of 95,43%. The results of post-surgical BCVA in high myopia patients were better or equal to preoperative BCVA in 95,61% of patients in the study of Wallerstein et al.^{9,11,16}

In this study, there was a difference in the proportion of UCVA and BCVA after 1 month of the procedure compared to preoperative BCVA. One eye in the mild myopia group had a 1-month UCVA >6/18 - <6/12 due to residual astigmatism after the procedure. The patient achieved a BCVA of 6/6 after glasses correction. One eye in the moderate myopia group had a 1-month UCVA >6/18 - <6/12. The patient experienced complications after the fs-LASIK procedure, namely corneal striae, so that the 1-month BCVA remained in the >6/18 - <6/12 category.

A total of 2 eyes with high myopia had a 1-month UCVA >6/60 - <6/18 because the patient had experienced amblyopia before the procedure was performed. After correction, one eye reached a BCVA of 6/12, while the BCVA of the other eye was still <6/18. A total of 8 eyes in the high myopia group had 1-month UCVA >6/18 - <6/12. Three eyes were designed using the femto standard due to inadequate corneal thickness. Two eyes experienced undercorrection. High myopia is a risk factor for undercorrection. After glasses correction, all five eyes achieved BCVA >6/12. Three eyes experienced amblyopia before the procedure. After glasses correction, the BCVA remained in the >6/18 - <6/12 category. Even though the UCVA and BCVA 1 month after the procedure did not match the BCVA before the procedure, the outcome of the procedure was still good because the median safety index and efficacy index reached 1,00.¹¹

Limitations of this study include the retrospective research design, sample selection in the form of total sampling, and limited research time. It is recommended to conduct prospective research with a longer study period to investigate LASIK outcomes among groups of degrees of myopia.

CONCLUSION

In conclusion, The LASIK outcomes in this study, which were defined as the safety index and efficacy index, showed that the safety index did not differ significantly between all myopia degree groups, while the efficacy index differed significantly between all myopia degree groups. The efficacy index of the mild myopia group was higher than that of the moderate myopia and severe myopia groups.

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