

Our Fifteen-Year Experience with Lasik

ORIGINAL ARTICLE

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SUMMARY

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Aim: The authors report on results of correcting refractive errors by LASIK in patients suffering from low, middle and high myopia.

Method: A retrospective comparative study.

Results: The authors have been using this refractive method since 1996 and evaluate the postoperative outcome of their own work in the two refractive centers, equipped with sophisticated Instrumentation, in the period given above. Group B of years 2007–2010 compared to the older group A from 1999–2005 indicates a decrease in the variance of the results by 40–50 %, and moreover, in this set extreme results are virtually eliminated. In the case of the Uncorrected Visual Acuity (UCVA), the Best Corrected Visual Acuity (BCVA), the index of the effectiveness and safety similar mean values can be seen in both sets, but the variability was significantly greater among the older group A.

Conclusion: On their groups of patients the authors present and compare on their groups of patients considerable long-term LASIK results, which confirm the effectiveness and safety of this refractive surgical procedure.

Key words: LASIK, the effectiveness index, the safety index

Čes. a slov. Oftal., 68, 2012, No. 1, p. 17–21

INTRODUCTION

The European Society of Refractive and Cataract Surgeons announced the year 2010 as the “European Year of LASIK”, to mark the occasion of the 20th anniversary of the introduction of this method in refractive surgery by the Greek professor I. Pallikaris. With regard to the fact that we have been using this technique ourselves since 1996, this is without doubt a sufficiently long period for us to contemplate our results.

The aim of our comparative retrospective study was to compare and evaluate over the long term the results of the refractive method LASIK from two refractive centres following the correction of a myopic error, in combination with a cylindrical error if applicable. We compared selected characteristics of conventional excimer – laser procedures of LASIK performed by the Planoscan method on relatively large observed samples of patients. We confirmed the internationally recognised and irreplaceable role of the LASIK method in refractive

surgery by means of the high effectiveness index and safety index in both compared groups.

SAMPLE AND METHOD

The observed samples consist of clients who underwent a LASIK refractive procedure between 1999 and 2005 at the ELAS refractive centre at the Královské Vinohrady University Hospital, i.e. the first sample (A) of 1445 eyes on 880 clients, and these results were compared with a relatively smaller sample (B) of 588 eyes of 330 clients, who underwent LASIK during a shorter period, from 2007 to 2010 in the Refractive Centre Prague Ltd. The values of spherical equivalent before surgery in both groups of clients were within the range of -3.0 to -10.0 dioptres. The average age of the clients in the first group was 31 years \pm 9 (range from 18 to 67 years), the average age of the second group was 32 years \pm 6 (range from 19 to 51 years). We analysed the results of operations performed in the case of the first group using a class IV Keracor 117 Chiron Technolas argon-fluoride

excimer laser using the Planoscan method, with a Hansatome (Chiron) microkeratome used for the formation of lamellas. In the case of the second group the operations were performed on a Zyoptix® TECHNOLAS Z 100 argon-fluoride excimer laser, which is specific due to the combination of three sub-units, namely a TECHNO-LAS 217 Z 100 excimer laser, an Orbscan II Z topograph and a ZYWAVE II aberometer. The multidimensional eyetracker and iris recognition system enable precise measurement of the instrument on the stated individual landmarks of the iris and it is the only system in use which is capable of eliminating error in the torsional movement of the eye in our experiences, in contrast with the assertions of Tantai [10]. All the observed patients in the samples received laser treatment by the Planoscan method, an XP Microkeratome (Bausch & Lomb) was used for the formation of lamellas. The preoperative examination always involved adhering to the principles and international recommendations for the elimination of clients in whom there was a risk of the development of

Table 1. Overview of basic statistical characteristics: arithmetical averages and standard deviations of values Dsph, Dcyl, SE in [D] before operation, 1st and 12th month after operation – for groups A and B. Statistically significant differences are shown in bold italics

(D)	Before op.		1st month after op.		12th month after op.	
	A	B	A	B	A	B
Dsph – average	-5.56	-5.45	0.01	-0.01	-0.07	-0.11
Dsph – standard deviation	1.71	1.72	0.41	0.19	0.42	0.27
Cyl. – average	-0.74	-0.60	-0.14	-0.13	-0.13	-0.17
Cyl. – standard deviation	0.72	0.55	0.53	0.32	0.48	0.32
SE – average	-5.93	-5.75	-0.06	-0.08	-0.14	-0.19
SE – standard deviation	1.80	1.78	0.50	0.24	0.51	0.30

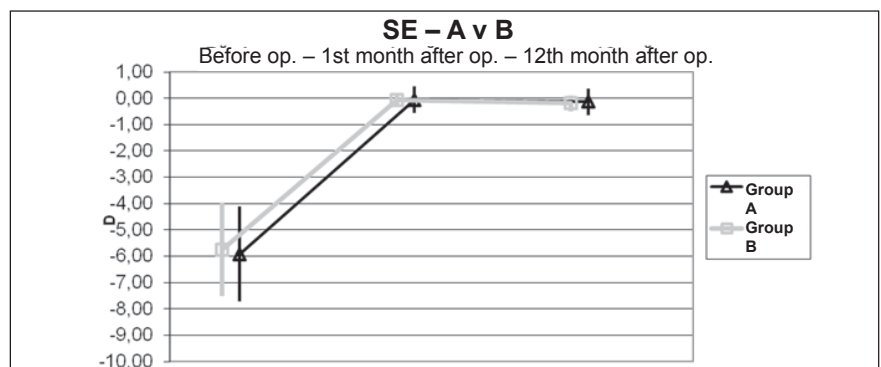
an ectatic disorder. In recent years we have abided by the recommendations according to Randleman [7, 8, 9]. The observed postoperative parameters in the 1st and 12th month following the operation were uncorrected (UCVA) and best corrected visual acuity (BCVA), spherical equivalent or resulting postoperative refraction, as well as the effectiveness index (UCVA after operation/BCVA before operation) and the safety index (BCVA after operation/BCVA before operation) of this procedure.

Methods of processing

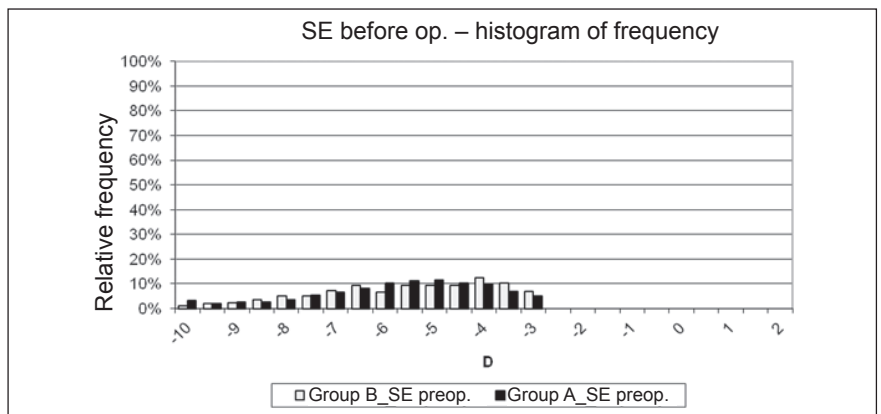
Within the framework of a retrospective comparative study we used histograms of relative frequencies in order to display the distributions of quantities in the input groups. The fundamental statistical parameters (arithmetical average, standard deviation σ , minimum, maximum) served us as a basis for comparison of our groups. From the statistical tests a T-test was used in order to verify the hypotheses regarding the congruity of the median values of the groups with normal distribution. A single-selection t-test was used to verify the specific median values of the selection from the normal distribution. A pair t-test was then used to verify the congruity of the median values of the selections in the case of mutually interlinked pairs. And finally we used a double-selection T-test in order to verify the congruence of the median values of two normal distributions, from which our two independent random selections originate. We also used the F-test to verify the congruence of the dispersion of two random selections. We conducted the testing on a 5% level of significance.

RESULTS

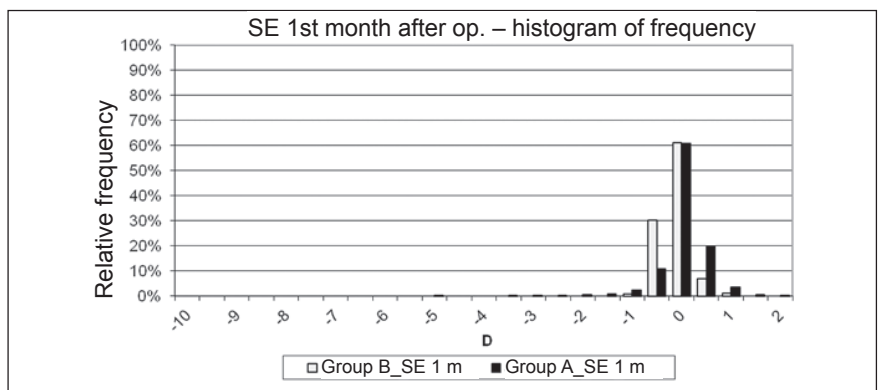
We compared the results of the groups of medium to severe short-sighted clients with preoperative myopia



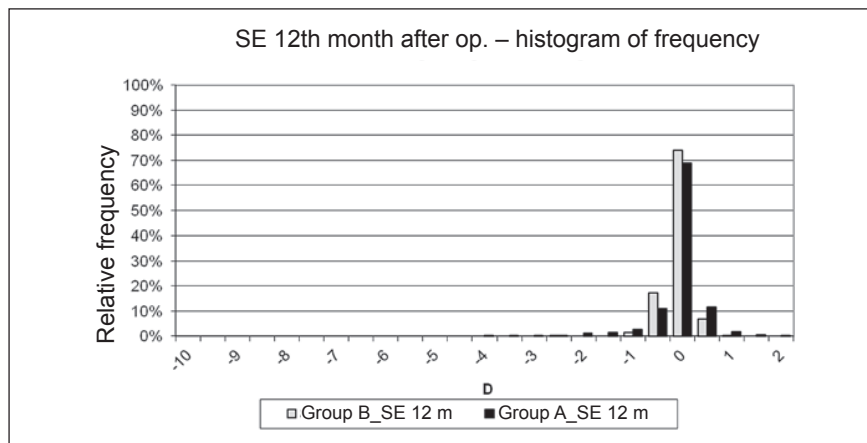
Graph 1a



Graph 1b



Graph 1c



Graph 1d

Graphs 1a, b, c, d. Time development of spherical equivalent – comparison of groups A and B – average and standard deviation (1a), histograms of relative frequencies before operation (1b), 1st month (1c) and 12th month after operation (1d)

within the range of -3.0 to -10.0 Dsph in two groups, namely group A including 1445 eyes from the years 1999-2005 and group B including 588 eyes from 2007-2010.

In both groups data is available for a comparison of spherical (Dsph) and cylindrical errors, with a calculated spherical equivalent (SE), obtained subjective measurement always before the operation, and also 1 and 12 months after the operation (usually the last check).

For a comparison of the individual characteristics (Dsph, Cyl, SE) we use basic statistical characteristics, i.e. averages, standard deviations. An overview of the values is presented in table 1.

Spherical equivalent SE

For a graphic illustration of the results we present graphs 1a, 1b, 1c and 1d, as well as histograms of relative frequency and t-tests in order to determine the sig-

nificance of the deviation of both groups. The preoperative values of spherical equivalent (see histogram 1b) follow the spherical error to a considerable extent; the initial division is similarly configured at a value close to -3.0 D; it is possible to assume that a full group would manifest signs of normality. Both input groups are very similar, the partial deviation of the average of approx. 0.2 D does not play a significant role in the further comparison.

The postoperative results of spherical equivalent (see graph 1a) show a markedly lower variation in the more recent group B. In general in this group B it is possible to see a shift of values towards the negative, i.e. slightly myopic. Paradoxically the larger resulting value of spherical equivalent -0.19 D is therefore essentially favourable, since a slight shift towards short-sightedness together with lower variation practically eliminates the probability of a resulting positive error

(markedly negative changes to hypermetropia) to only 7%, with a maximum of +0.5 D (as against 15% in group A, with a maximum above +1.5 D).

Results of UCVA, BCVA, effectiveness index, safety index

These results are summarised in table 2 and illustrated in graphs 2a, 2b, 3a and 3b.

A comparison of UCVA and BCVA points to the different variability of both groups, which may be influenced not only by the method of determining UCVA and BCVA (or used scale of values).

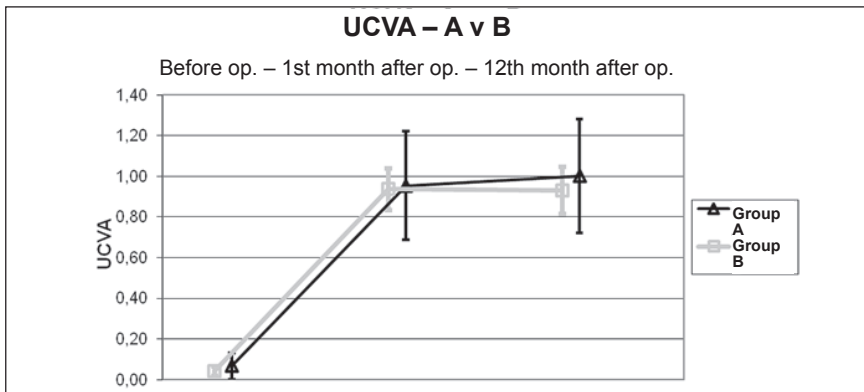
In general it is possible to state that the results of the operations were very good in both groups. The postoperative values of UCVA and BCVA are very close to 1. Similarly the effectiveness and safety indexes in both groups are close to 1. In the case of the more recent group B, it is possible to observe a fundamentally lower variability of the UCVA and BCVA values and those of both indexes (smaller variation in comparison with the older group A). The results are comparable with the results published in the Czech and foreign literature [2, 5]. The results of group B are positively influenced by the use of a “multidimensional eyetracker and iris recognition system”, which provide better compensation of cyclotorsion present before and during laser ablation [4, 3, 10, 11]. In the more recent group it is possible to expect better stability, and also better predictability of the result of the operation.

DISCUSSION

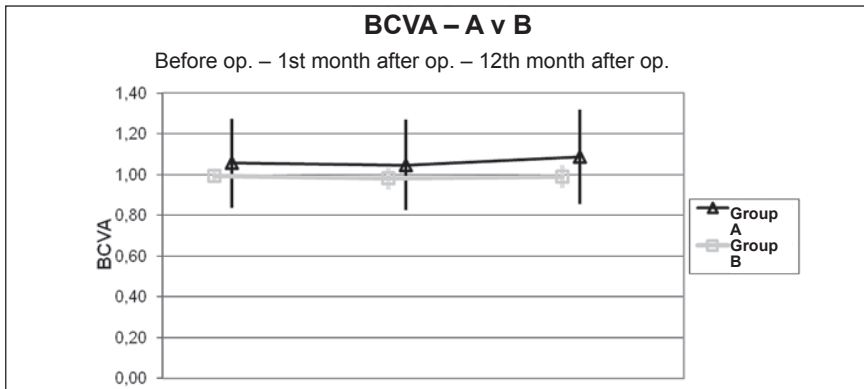
On the basis of a comparison of the two groups of patients with medium to severe myopia (-3.0 to -10 D), it is possible to state that in the older group of 1445

Table 2. Overview of values of UCVA, BCVA, effectiveness index (UCVA after operation / BCVA before operation) and safety index (BCVA after operation / BCVA before operation) – arithmetical averages and standard deviations of values always before operation, 1st and 12th month after operation – for groups LASIK and 2010. Statistically significant differences according to the t- and F- tests are shown in italics

LASIK	Before op.		1st month after op.		12th month after op.	
	2005	2010	2005	2010	2005	2010
UCVA – average	0.07	0.04	0.95	0.94	1.00	0.93
UCVA – standard deviation	0.07	0.02	0.27	0.10	0.28	0.12
BCVA – average	1.06	0.99	1.05	0.98	1.09	0.99
BCVA – standard deviation	0.22	0.03	0.22	0.06	0.23	0.06
Effectiveness index – average			0.93	0.94	0.97	0.93
Effectiveness index – std. dev.			0.35	0.10	0.36	0.11
Safety index – average			1.02	0.99	1.06	1.00
Safety index – std. dev.			0.32	0.05	0.33	0.06

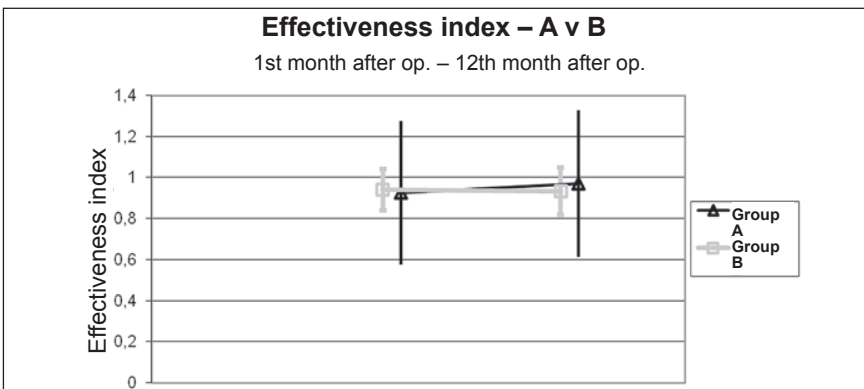


Graph 2a

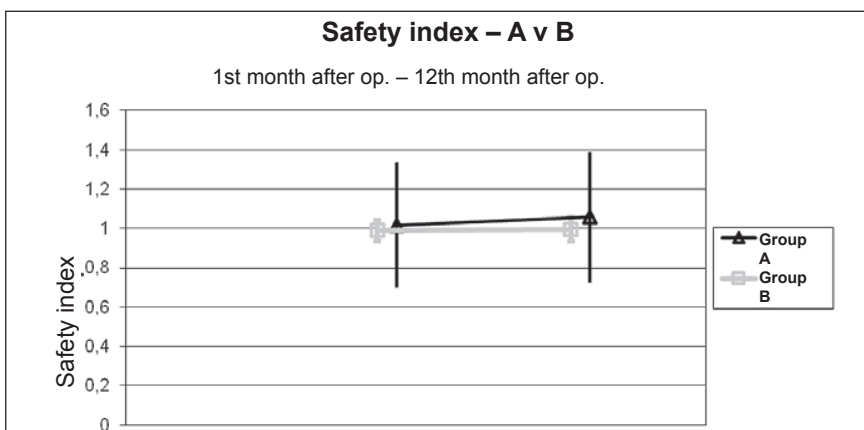


Graph 2b

Graphs 2a, b. Time development of UCVA and BCVA – comparison of groups LASIK and 2010 – average and standard deviation of UCVA (a) and BCVA (b) before operation, 1st month and 12th month after operation



Graph 1b



Graph 1b

eyes from the period 1999-2005, operated on using the LASIK method, there were greater variations of the resulting values of spherical and cylindrical error and subsequently also the spherical equivalent. The more recent group B from the period 2007-2010 points to a reduction of the variability of results by 40-50%, in addition extreme results are practically eliminated (e.g. resulting mild hypermetropia or positive cylindrical error exceeding +0.5 D). The average postoperative values are very close to 0 D in both groups; the more recent group B rather shows a very slight resulting residual myopia (approx. -0.2 D), which however is more acceptable for originally myopic patients and practically eliminates the chance of a potential undesirable shift into positive values. In the case of UCVA, BCVA, the effectiveness and safety indexes it is possible to observe similar median values in both groups, although there is perceptibly greater variability in the older group A (as against the more recent group B); it is therefore possible to point to a statistically more significant predictability of the procedures in the case of the more recent group.

CONCLUSION

In the last twenty years LASIK has become one of the most popular methods of refractive surgery used for the correction or elimination of myopic refractive error, especially thanks to the high level of effectiveness and safety of the procedure, which we attempted to demonstrate by comparing two samples very distant in time, namely group A from the time of the introduction of this method into practice in the Czech Republic, and group B, from the recent period [1, 2, 5, 6]. It is necessary to emphasise that since the beginning of use of LASIK in our refractive centres, we have had the opportunity to work with top quality laser instruments, thanks to which we have been able to help a large percentage of our clients who wished to be free of the need for eyeglasses



Graphs 3a, b. Time development of (a) effectiveness index (UCVA after operation / BCVA before operation) and (b) safety index (BCVA after operation / BCVA before operation) – arithmetical averages and standard deviations of values, always 1st month and 12th month after operation for groups A and B

within the framework of myopic error. However, the advantage of our long-term continuous statistical observations, thanks to which we are able to

specify the normograms for the specific laser instrument, as is evident from the result of group B, cannot be overlooked. Only by permanent

observation of long-term results is it possible to attain ever more precise predictability of the desired postoperative result.

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