

**THE ASSESSMENT OF POSTPROCEDURE RESULTS
IN THE CASE OF PATIENTS OPERATED ON USING
THE FEMTOLASIK METHOD WITH THE
ALCON/WAVELIGHT FS200 FEMTO & EX500
EXCIMER REFRACTIVE SUITE**

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ABSTRACT:

THE ASSESSMENT OF THE RESULTS OBTAINED THROUGH THE FEMTO LASIK TECHNIQUE AS CONSEQUENCE OF THE REFRACTIVE SURGERY FOR THE CORRECTION OF REFRACTIVE ERRORS IN CASE OF 34 PATIENTS OPERATED USING THE WAVELIGHT (FS200 FEMTO LASER & EX500 LASER EXCIMER) REFRACTIVE SUITE, TRYING TO DEMONSTRATE THE EFFICIENCY, STABILITY AND SAFETY OF THE METHOD.

KEY WORDS: FEMTO LASIK, LASER EXCIMER, ABLATION, REFRACTION, REFRACTIVE SURGERY

INTRODUCTION

Myopia represents the most frequent refractive error, having as etiological factors both genetic and environmental factors, so that the ethiology cannot be accurate in all cases. (9).

The refractive errors at global level are thought to have affected around 2 billion people around the world.

The treatment of the refractive errors consists in optical correction – contact lens, glasses or surgical correction (the use of excimer laser or phakic implant).

One of the most promising and interesting discoveries in the refractive surgery of the last decades is, without a doubt, the apparition of the LASIK procedure (laser in situ keratomileusis).

LASIK is a fusion of old and new technologies, with roots in keratomileusis (from the Greek “keras”=cornea and “smileusis”= sculpture) and the automated lamellar keratoplasty (ALK).

The femtosecond laser has become in a short period of time the technology embraced by the majority of surgeons that use the LASIK technique (4), especially due to the decrease

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in the postprocedure inflammation, and due to the easiness with which the flap is elevated, using the last variants of these lasers (12).

Winkler von Mohrenfels et al (17) have reported in a pilot study performed in 20 eyes, the first clinical results by using the Femto LASIK technique, with sure, stable and efficient results.

MAIN TEXT

A descriptive-prospective study was performed on a number of 61 eyes subjected to a surgery intervention for the correction of different refractive errors (myopia and mixed astigmatism), by means of the Femto-LASIK method, using the refractive suite Alcon Wavelight composed of the femtosecond laser FS200 and the excimer laser EX500, operated and evaluated between May 2013 - July 2014. The study enrolled a lot of 34 patients, eligible for the Femto LASIK technique.

The purpose of the refractive surgery by using the FEMTO LASIK technique is to eliminate or reduce the dependence of contact lenses or glasses for the daily activities. Depending on the thickness of the cornea the myopia can be corrected up to -12 dioptries, provided that the thickness of the residual corneal stroma remains within the safety limits (minimum 300 μm). If the myopia is associated with astigmatism, it is indicated to correct a value as higher as possible of the astigmatism, but no more than 3-4 dioptries. For each dioptre, the cornea is thinned with approx. 14 μm .

The patient's refractive errors need to be stable for at least one year. The refractive stability is usually reached around 20-21 years old.

Preoperative evaluations of patients included uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), manifest and cycloplegic refractions, topography (Allegro Topolyzer and Allegro Oculyzer, WaveLight GmbH), pachymetry (Allegro Oculyzer, WaveLight GmbH), Schirmer test, measurement of the intraocular pressure. A complete anterior segment examination and a dilated fundus examination were performed.

After the surgical intervention, the ophthalmological reassessment of the patient (UCVA, BCVA, and manifest refraction) was made after one day, after one week, a month and after three months.

RESULTS AND DISCUSSIONS

A number of 61 interventions were performed on 34 patients (18 women and 16 men).

With most of the patients (80%), we chose to correct the refraction error in both eyes, in the same session, while 7 patients needed a unilateral intervention.

The patients' average age was 32.7 years old (with variations between 22 - 51 years old). Image no. 1 shows the distribution per age groups of patients subject to a FEMTO LASIK technique:

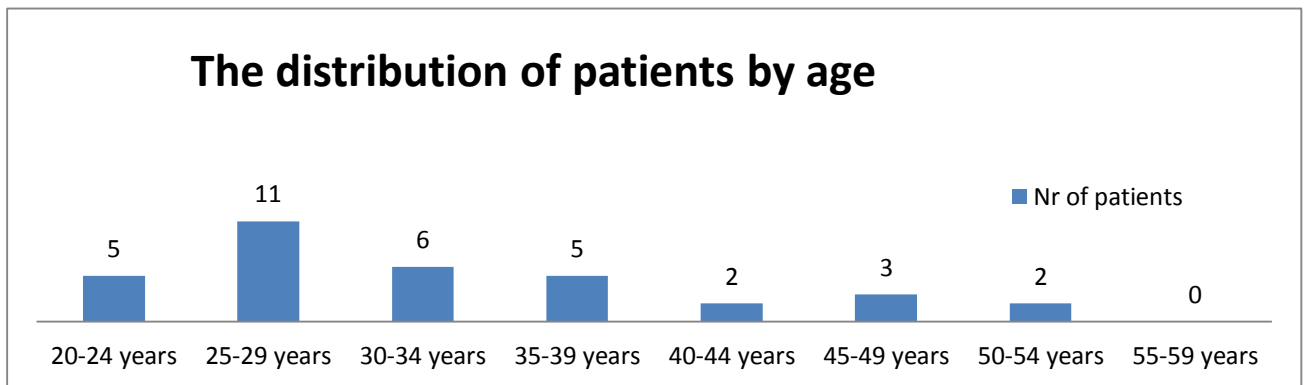


Image no. 1. Distribution of patients by age groups

Mean preoperative spherical refraction was -3.87 (with a standard variation of 2.24), the smallest spherical dioptre treated being -0.75 and the biggest dioptre of -12.5 .

The astigmatism can be associated with myopia and is asymptomatic especially with values higher of $1D$.

80% of the operated myopic eyes have associated a certain degree of astigmatism, nevertheless 70% presented a physiological astigmatism ($<1D$), which does not need an optical correction. (Image no. 2)

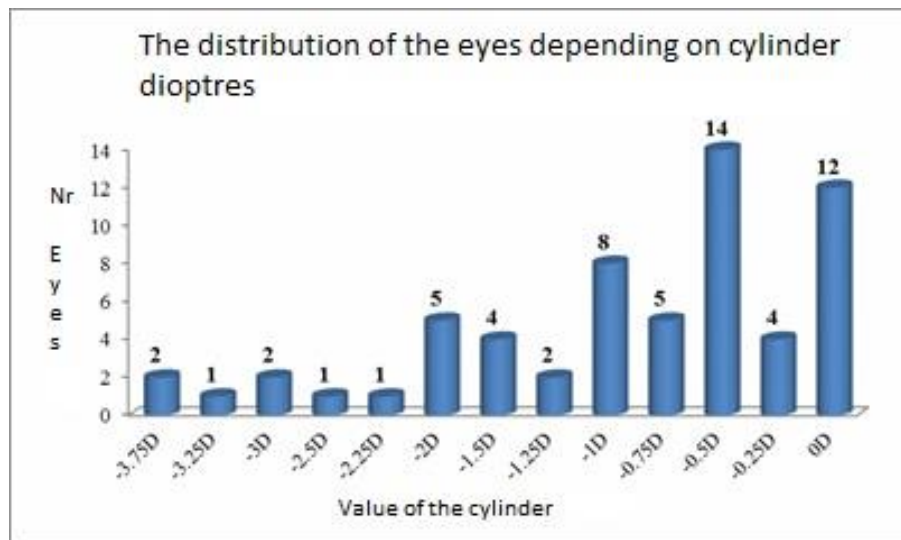


Image no.2. The distribution of the eyes depending on cylinder dioptries

The mean of the preoperational cylindrical lens was of -0.98 (standard deviations of 0.96) with values comprised between 0 and -3.75 .

The mean of the preoperational spherical equivalences was of -4.25 (standard deviation of 2.63) with values between -0.75 and -13.75 .

The visual acuity optimally corrected with the help of lens was, in proportion of 77%, maximum. Therefore, a number of 47 eyes had a visual acuity of 1CC (with correction)(results in Table no. 1).

Table no.1 The distribution of patients depending on the preoperational BCVA

BCVA	Number of patients
1 with correction	47
0.9 with correction	6
0.7 with correction	1
0.6 with correction	4
0.5 with correction	2
0.3 with correction	1

A percentage of 70% from the interventions obtained at one day after the surgery, an optimal visual acuity, of 1 without correction. The rest of 10% each obtained a visual acuity of 0.9 without correction, 0.7 without correction and respectively 0.6 without correction. (Image no. 4)

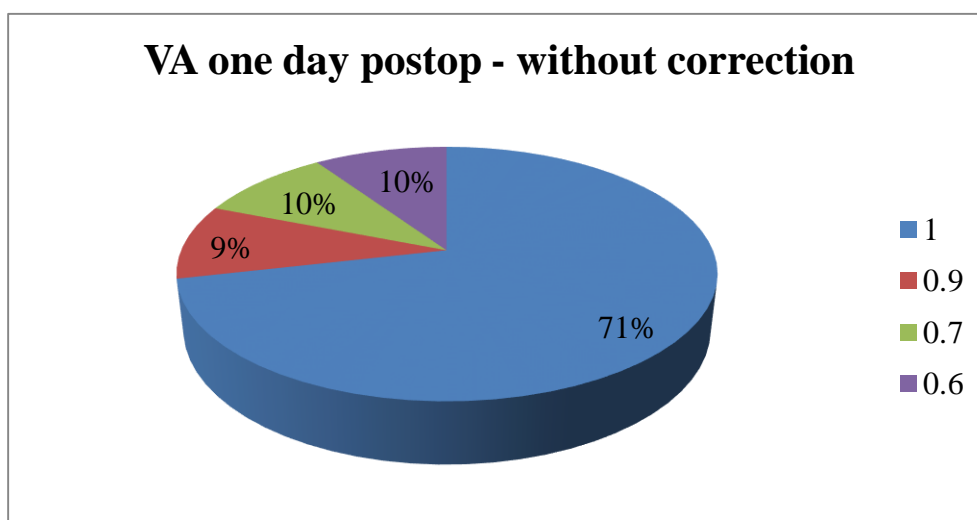


Image no. 4. Percentage distribution VA one day after the surgery

A week after the operation, the percentage of the interventions with optimal result (AV de 1 without correction) increases with 2%, reaching at 72%; at the same time, the percentage of the eyes with AV of 0.9without correction increases from 10% to 12%; 8% from the eyes reach an acuity of 0.8without correction , and another 8% have the acuity of

0.7 without correction . No intervention has, at this point, a visual acuity of less than 0.7 without correction . (Image no. 5)

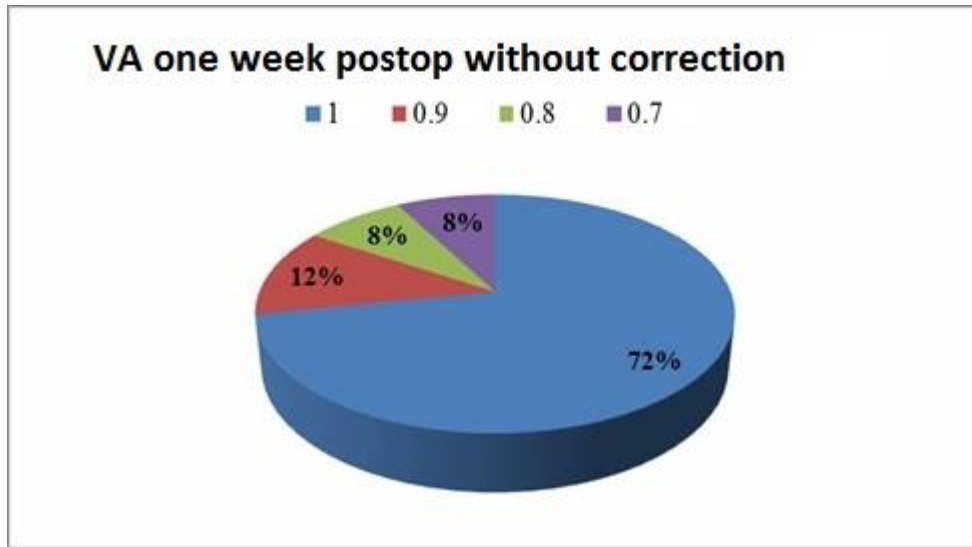


Image no. 5. Percentage distribution of AV one week after the operation

One month after the operation, the percentage of the eye balls operated with AV increases from 1 without correction to 77% and the percentage of the ones with AV decreases from 0.9 without correction to 7%.

Three months after the operation, the visual acuities stabilized at 1 without correction for 75% of the interventions, 0.9 without correction for 13% of the operated eye balls, 0.8 without correction for 8% and 0.7 without correction for 4%. Although the percentage of interventions with maximum result decreases with 2%, the percentage of the ones with weaker results decreases considerably as well (Av of 0.7 without correction decreases with 4%), and the percentage of eyes with AV of 0.9 without correction grows with 6%. (Image no. 6).

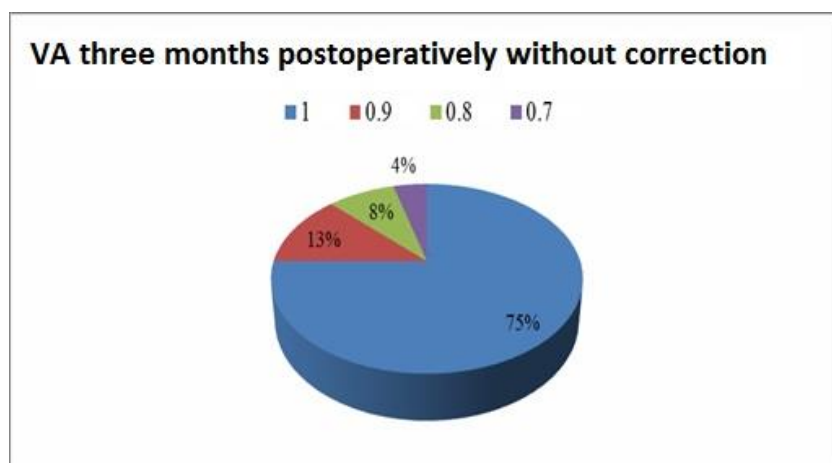


Image no. 6. Percentage distribution of AV after 3 months post operation

The spherical average refraction after 3 months post operation is of 0.25D (with a standard variation of 2), while the average cylindrical refraction is of 0.25D (with a standard variation of 0.4).

In order to prove the degree of efficiency, it was intended to highlight the interventions with maximum results in comparison with the ones which had satisfactory results. Thus, in 3 months, an increase of the eyes that see perfectly (from 71% to 75%) was noticed, among the number of the eyes with satisfactory results (from 80% to 96%) (Image no. 7).

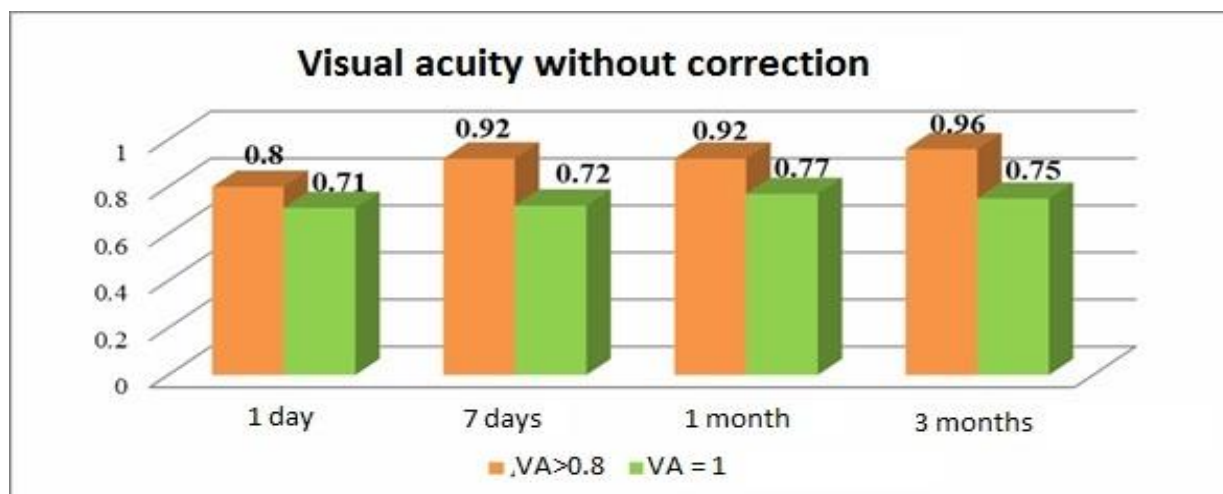


Image no. 7. The percentage of the eyes operated with $AV \geq 0.8$ and $AV > 1$ (at 1 day, 1 week, 1 months and 3 months post operation)

The efficiency may also be assessed through the value of the spherical equivalent (SE) obtained post operation. This refers to the number of spherical dioptres corresponding to a number of cylindrical dioptres and represents the sum between the spherical dioptres and $\frac{1}{2}$ from the cylindrical dioptres.

In what concerns the stability, there may appear significant refractive alterations in the first 3 months post operation (11), although regression may develop up to 2 years after LASIK (8). Usually, the regression is correlated with the hyperplasia of the corneal epithelium post operation (7) with the profoundness of the ablation, with the flattening of the corneal curvature and the humidity (16).

CONCLUSION

Our study shows that the uncorrected AV is rapidly improving, reaching values of 1 since the first days post operation and being maintained after three months. After 3 months postLASIK an uncorrected visual acuity of >0.8 in 96% of the cases was obtained, while 75% of the operated eyes showed uncorrected $AV = 1$. Thus we observe that post operation, the uncorrected AV was similar with the postoperative AV, corrected with lens.

After one month, 77% from the cases in our study reached the uncorrected AV of 1 without correction as compared to other authors such as Durrie¹ who reaches a percentage of 96% or Lim (82.1%). After the visit at one month it reached 77%, in contrast with Durrie (96%) or Lim (82.1%) (6).

The average value of the spherical dioptres at 3 months post operation was of 0.25D (with a standard variation of 2), and the cylindrical average dioptres were still 0.25D (with a standard variation of 0.4). The small values, almost insignificant of the postoperative refraction are an indicator of the stability of the results.

Our study shows that the FemtoLASIK technique for the creation of the corneal flap in case of the 61 eyes operated was efficient and safe and the results obtained were stable for more than 3 months; the femtosecond laser implies a rapid recovery of sight.

Tanna and collab. have performed a study on 2000 eyes, through which they showed that the femtosecond laser improves equally the postoperative recovery time, as well as the uncorrected visual acuity at 3 months, as compared to the microkeratome (14). The study explained that the improvement took place in spite of the similar predictability of the two pieces of equipment in performing the flap. More exactly, no matter when the postoperative assessments were made, the percentage of eyes that performed a visual acuity of 1 without correction was significantly higher than the group treated with femtolaser than in the group treated with the mechanical microkeratome.

Moreover, Durrie et al. (2) demonstrated that the femtosecond laser produces statistically better results both visual, as well as in terms of contrast sensitivity.

As far as the apparition of complications is concerned, in our study, no re-intervention was necessary, in neither of the operated cases.

While performing the flap, the loss of suction did not appear in any of the 61 operated eyes. At the same time, no epithelial growths were noticed, to invade the edge of the flap or other complications mentioned in other studies, such as the diffuse lamellar keratitis (15), the presence of bubbles in the anterior chamber (5), severe disorders of the sensitivity to light (13).

Our study, to which numerous international studies are added, shows a higher precision and a safety of the Femto LASIK.

ACKNOWLEDGEMENT: This paper is supported by the Sectorial Operational Programme Human Resources Development (SOP HRD), financed from the European Social Fund and by the Romanian Government under the contract number POSDRU/159/1.5/S/132395

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