



A COMPARATIVE STUDY ON VISUAL OUTCOMES IN MYOPIC ASTIGMATIC REFRACTIVE ERROR CORRECTION BY CUSTOMIZED FEMTOSECOND LASER AND MECHANICAL MICROKERATOME

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ABSTRACT

To compare the visual outcomes in myopic astigmatic refractive error correction by Customized femtosecond laser and Mechanical Microkeratome LASIK. This was a prospective observational study, performed on 200 eyes of 100 patients treated between 2016 to 2020 for myopia and astigmatism (sphere ≤ -6.00 Diopters; cylinder ≤ -6.00 Diopters). The first 100 consecutive eyes that had LASIK flaps created with a femtosecond laser were compared with the first 100 consecutive eyes that had flaps created with a mechanical microkeratome. All eyes received wavefront-guided LASIK treatments performed with a VISX S4 IR Advanced CustomVue excimer laser (AMO). Refractive predictability, change in mean spherical equivalent refraction, postoperative uncorrected visual acuity (UCVA), and best spectacle-corrected visual acuity (BSCVA) were compared at 1 day, 1 week and 1 month following surgery. The refractive accuracy was the same for both groups. At all follow-up, the percentage of eyes that achieved a postoperative UCVA of 20/20 or better was significantly higher in the femtosecond laser group than in the mechanical keratome group. In addition, a higher percentage of eyes in the femtosecond laser group achieved a postoperative UCVA of 20/16 at 1months. Creating LASIK flaps with the femtosecond laser resulted in faster visual recovery and better UCVA.

INTRODUCTION

LASIK is the world's most popular refractive surgery technique since the technique was presented at the beginning of the 1990s, its popularity has spread because of the unquestionable advantages it has one the surface techniques: rapid visual recovery, relative absence of pain, ease of performing the treatment and greater refractive stability (partial only) where hyperopic treatments are concerned. LASIK is commonly referred to as laser eye surgery or laser vision correction, is a type of refractive surgery for the correction of myopia, hypermetropia, and astigmatism. The LASIK surgery is performed by an ophthalmologist who uses a laser and microkeratome or Femtosecond Laser to reshape the cornea in order to improve visual acuity. For most patients, LASIK provides a permanent alternative to eyeglasses or contact lenses. Major side effects include halos, starbursts, night-driving problems, and eye dryness.

Compared to a flap created with a mechanical microkeratome, a femtosecond laser flap offers several potential advantages: more uniform flap thicknesses,

customizable flap diameter and hinge position, smoother stromal beds, and lower rates of flap creation complications. However, mechanical keratomes have a long record of success of safety, and they cost significantly less than a femtosecond laser.

A few published reports have compared these two competing techniques, but the results of these studies have been mixed. Some studies have shown equivalency between the femtosecond laser and the mechanical keratome whereas other studies have reported improved visual results with the femtosecond laser. The current study was designed to determine whether use of different flap creation techniques yields differences in visual outcomes and visual recovery.

PATIENTS AND METHODS

Data for this study were taken from patient records extracted between 2016 to 2020 from Ivue Laser Vision centre and Keshvi Eye Hospital clinical database. For both the mechanical microkeratome and femtosecond laser groups, the first 100 consecutive eyes that met the following conditions were included in the study:



1) Stable pre-operative spherical refractive error ≤ -6.00 D with Astigmatism ≤ -6.00 D 2) target refraction of emmetropia, 3) primary wavefront-guided ablation, and 4) 1-month examination data available. The femtosecond laser flaps were created using an IntraLase femtosecond laser, and the mechanical microkeratome flaps were created using the disposable blades in Amadeus II Microkeratome. The femtosecond laser flap diameter varied from 9.0 to 9.5 mm, with a programmed ablation depth between 90 μ m. The 140- μ m head was used for the mechanical microkeratome. Patients were educated about both methods of flap creation and selected the one they preferred for their procedure. The wavefront-guided treatments were performed using a VISX STAR S4 IR Advanced

CustomVue excimer laser (AMO) with an optical zone of 6.0 mm and transition zone of 8.0 mm. Postoperative examinations were conducted at Ivue Laser vision centre and Keshvi eye hospital. Demographic and other preoperative parameters were analyzed to ensure that the groups were well matched. Refractive predictability, change in mean spherical equivalent refraction, postoperative uncorrected visual acuity (UCVA), and loss of best spectacle- corrected visual acuity (BSCVA) were compared at 1-day, 1-week and 1-month follow-up.

Visual acuity was measured at each visit using a Snellen vision chart.

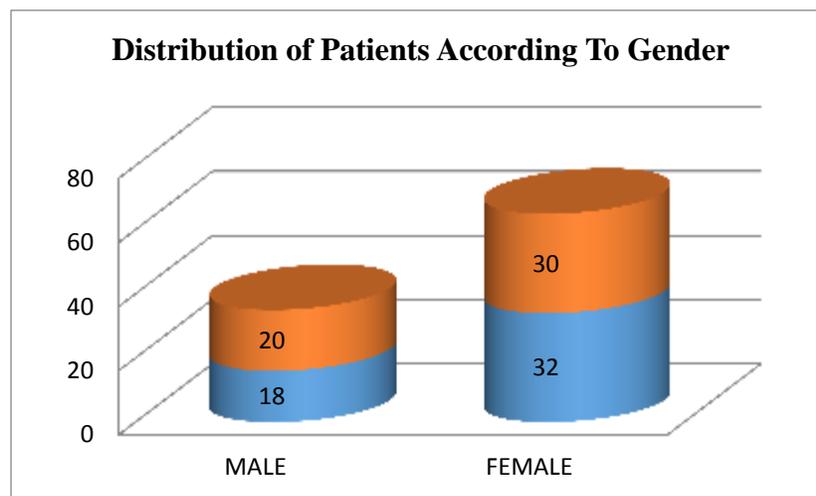
Tabulations of data and statistics were performed with SSPS 7.0 and Microsoft Office Excel 7.0.

Table 1

| Demographic and Preoperative parameters in eyes that underwent LASIK flap creation with a Femtosecond Laser or Mechanical Microkeratome | | | |
|---|---------------------------------------|---------------------------------------|----------|
| Parameter | Mean \pm Standard Deviation (Range) | | P Value* |
| | Femtosecond Laser (n=100 eyes) | Mechanical Microkeratome (n=100 eyes) | |
| Male/female (no. of patients) | 18/32 | 20/30 | 0.3796 |
| Age (y) | 25.22 \pm 4.81 | 24.82 \pm 5.64 | 0.0019 |
| Sphere (D) | -2.765 \pm 1.16 | -3.17 \pm 1.60 | 0.1748 |
| Cylinder (D) | -1.12 \pm 0.35 | -1.18 \pm 0.37 | 0.4142 |
| Mean Spherical Equivalent Refraction (D) | -3.324 \pm 1.69 | -3.76 \pm 1.69 | 0.1332 |
| Pupil size (mm) | 6.3 \pm 1.1 | 6.3 \pm 1.0 | 0.2095 |

*For continuous variables, a two-sample t test was used to measure significance. For categorical variables, a chi-square test was used. All assumptions were met for these respective tests.

Fig 1: Gender Distribution





RESULTS

The two groups were well matched in terms of gender, sphere, cylinder, mean spherical equivalent refraction, and pupil size (Table 1). The mean preoperative sphere was -2.765 D for the femtosecond laser group and -3.17 D for the mechanical microkeratome group; the mean cylinder was -1.12 D for the femtosecond laser group and -1.18 D for the mechanical microkeratome group. A small difference in mean age was noted between groups (femtosecond laser: 25.22 years; mechanical keratome: 24.82 years), but this difference was not deemed clinically relevant. Both groups achieved similar refractive predictability results. Both groups also achieved similar levels of refractive stability, with eyes in both groups remaining close to Plano from the 1-day follow-up through the 1-month follow-up. Although refractive results were

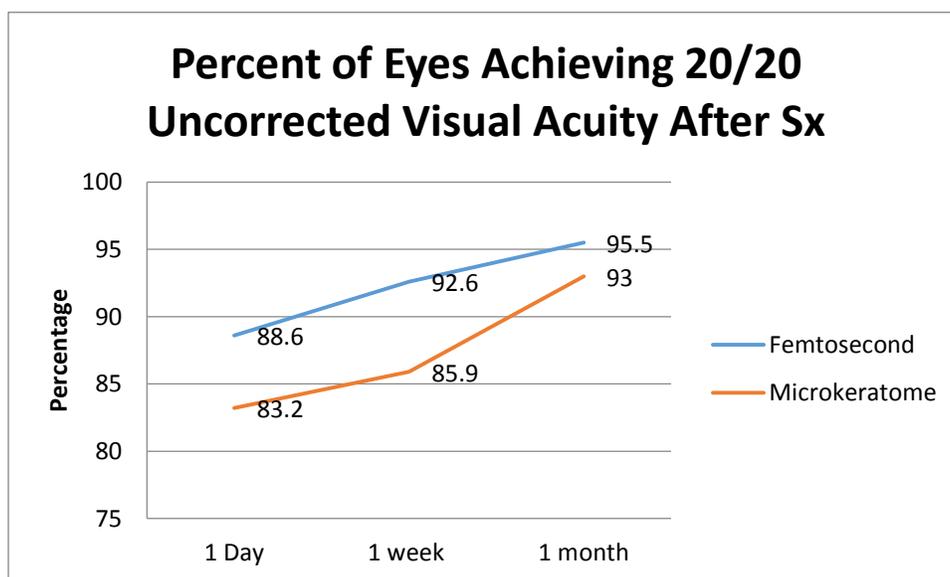
similar, a significant difference was observed in the percentage of eyes that achieved a postoperative UCVA of 20/20 or better (Table 2). At 1-day follow-up, 88.6% of eyes in the femtosecond laser group achieved UCVA of 20/20, compared to 83.2% of eyes in the mechanical microkeratome group (P=.0005). Both groups showed improvement with continued follow-up, but a higher percentage of eyes in the femtosecond laser group achieved 20/20 UCVA at each time point (Fig 2). Fewer eyes in the femtosecond laser group experienced a loss of two or more lines of BSCVA in the early postoperative period. At 1-week postoperative, only 0.9% of eyes in the femtosecond laser group had lost two or more lines of BSCVA, compared to 2.8% in the mechanical microkeratome group. By 1 months postoperatively, however, both groups showed similar results.

Table 2

| Percent of Eyes Achieving 20/20 Uncorrected Visual Acuity After LASIK With the Femtosecond Laser or Mechanical Microkeratome | | | | |
|--|--------------------|--------------------------|------------|----------|
| | Percentage of Eyes | | | |
| Time Duration | Femtosecond Laser | Mechanical Microkeratome | Difference | P Value* |
| 1 Day | 88.6 | 83.2 | 5.4 | 0.0005 |
| 1 Week | 92.6 | 85.9 | 6.7 | <0.0001 |
| 1 Month | 95.5 | 93.0 | 2.5 | 0.0166 |

*Chi-square test.

Fig 2: Percentage of eyes that achieved uncorrected visual acuity of 20/20 or better was higher for the femtosecond laser group at all follow-ups.





DISCUSSION

As this study shows, the femtosecond laser significantly improves both the speed of visual recovery as well as UCVA through 1 month postoperative. This improvement occurred despite similar refractive predictability in both the femtosecond laser group and mechanical microkeratome group. Thus, the improved UCVA was not due to residual refractive error in the mechanical microkeratome group.

Although this difference disappeared by 1 month postoperative, the initial disparity further indicates a faster visual recovery when flaps are created with the femtosecond laser.

Given that most patients prefer LASIK over surface ablation in part because LASIK offers a more rapid improvement in vision, the enhanced speed of visual recovery after a femtosecond laser procedure represents a significant advantage. Speed of visual recovery also has implications for when patients can return to work after surgery, particularly for patients who have jobs that require excellent vision. The results of previous studies comparing the outcomes of femtosecond laser LASIK with mechanical keratome procedures have been varied. A study by Patel et al¹ examined 21 patients who had a femtosecond laser flap created in one eye and a mechanical microkeratome flap created in the other eye, and they found that the method of flap creation did not affect visual outcomes. Similarly, Lim et al² (n=55 eyes) and Kezirian and Stonecipher³ (n=375 eyes) concluded that use of a femtosecond laser failed to produce any statistically significant difference in postoperative UCVA at 3 months postoperative. In contrast, Durrie and Kezirian⁴ (n=102 eyes) reported that the femtosecond laser-created flaps produced a statistically better UCVA. Several reasons for these different results are possible, including the relatively small sample sizes of these studies, which may be partially responsible for their lack of agreement.

Although the Prospective nature of the current study is a drawback, the study design also has several strengths. The large sample size (200 well-matched eyes) allowed for statistically valid conclusions; limiting the study to consecutive treatments minimized selection bias. Also, the limits on preoperative myopia and cylinder reduced the confounding influence of unpredictable clinical results that can occur when treating higher levels of ametropia. In addition, all treatments were performed between 2016 to 2020 using the latest technology and the same wavefront-guided ablation profile, therefore the study is representative of

modern clinical practice. Because this study was intentionally confined to eyes with moderate preoperative myopia and cylinder, it cannot predict results for hyperopia or high myopia treatment. However, clinical reasoning suggests that similar results would be expected for a wide range of ametropia. Although it is not readily apparent why the femtosecond laser improves visual outcomes, several possible explanations include the more predictable planar flap, more accurate repositioning of the flap at the end of the procedure, and/or improved smoothness of the stromal bed. Particularly for procedures that use complex ablation patterns, such as wavefront-guided treatments, minimizing stromal bed imperfections and maximizing the predictability of the flap dimensions may help in achieving optimal results.

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