

Refractive Outcome of Femtosecond Assisted Laser *in situ* Keratomileusis in 1564 cases of Myopia and Compound Myopic Astigmatism

Sadia Humayun¹, Mazhar Ishaq², Aisha Fawad¹ and Sabahat Arzoo¹

¹Refractive Surgical Department, Armed Forces Institute of Ophthalmology, National University of Medical Sciences, Rawalpindi, Pakistan

²The Eye Consultants, Rawalpindi, Pakistan

ABSTRACT

Objective: To determine the outcomes of Femtosecond Assisted Laser *in situ* Keratomileusis (Femto LASIK) on eyes with myopia and compound myopic astigmatism in terms of efficacy, safety, accuracy, predictability, and stability of the procedure.

Study Design: Quasi-experimental study.

Place and Duration of the Study: Refractive Surgical Department, Armed Forces Institute of Ophthalmology (AFIO), Rawalpindi, Pakistan, from January 2014 to August 2019.

Methodology: Participants aged 18 years and above with upto -12D (dioptr of myopia, underwent preoperative detailed work-up with history, ocular examination, subjective refraction and assessment on topography, tomography, and aberrometry. Suitable candidates underwent Femto LASIK and were re-evaluated at 1st postoperative day, end of 1st week, 1 month, 3 months, 6 months and 1 year. Results were analysed and represented in form of standard graphs for refractive surgery.

Results: Postoperative UDVA (uncorrected distance visual acuity) of 20/40 was achieved in 99% of patients. Efficacy index was 1.02 ± 0.15 . Safety index was 1.04 ± 0.199 . None of the patients lost more than one line in postoperative CDVA (corrected distance visual acuity) when compared to preoperative CDVA. All the eyes (100%) were accurately treated within ± 1.0 DS of intended spherical equivalent (SEQ) range. Mean SEQ showed stability with 1% eyes recorded to have more than 0.5D change or more over 12 months.

Conclusion: Femto LASIK is an effective, safe, accurate, predictable, and stable procedure for correction of myopia and compound myopic astigmatism.

Key Words: Femtosecond, Laser *in situ* Keratomileusis, Refractive surgery, Myopia, Compound myopic astigmatism, Uncorrected distance visual acuity.

How to cite this article: Humayun S, Ishaq M, Fawad A, Arzoo S. Refractive Outcome of Femtosecond Assisted Laser *in situ* Keratomileusis in 1564 cases of Myopia and Compound Myopic Astigmatism. *J Coll Physicians Surg Pak* 2024; **34**(01):42-47.

INTRODUCTION

An array of surgical techniques exists which treat corneal shape with the help of lasers in order to cure refractive errors. These procedures aim to correct refractive errors and thus, relieve patients of their dependency on glasses and contact lenses. LASIK, first done in Europe in 1989 and first approved by FDA in 1995,¹ is one of the most commonly performed and established procedure amongst a list of refractive surgeries.² It is estimated that around 20-25 million eyes have been treated since the US FDA approval of LASIK and around 700,000 procedures are performed annually.³⁻⁵

Like any other surgical procedure, it has its limitations, precautions, and adverse effects, but overall consensus remains that more than 90% patients feel satisfied and happy with their postoperative results.⁶ The procedure, its protocols, the enigma of understanding the appropriateness of an individual for LASIK, its effects on vision and patient's lives are constantly undergoing active research worldwide and require input of data from all quarters.

In Pakistan, LASIK is widely popular with both surgeons and patients. Despite extensive refractive surgery practice in the country, there is a lack of scientific data that represents the performance of this procedure and its outcomes on Pakistani population specifically in the form of standardised graphs.

It is imperative to present the major side-effects of the procedure and the outcomes of Femto LASIK for myopia and compound myopic astigmatism in the form of standard graphs used for presenting the outcomes of refractive surgery.^{7,8} These graphs are considered a standard for clear communication between readers and researchers for quick comparative analysis between different studies as well as different procedures pertaining to refractive surgery.

Correspondence to: Dr. Sadia Humayun, Refractive Surgical Department, Armed Forces Institute of Ophthalmology, National University of Medical Sciences, Rawalpindi, Pakistan
E-mail: sadia.humayun@yahoo.com

Received: March 25, 2023; Revised: June 19, 2023;
Accepted: November 21, 2023
DOI: <https://doi.org/10.29271/jcpsp.2024.01.42>

The objective of this study was to present outcomes of Femtosecond Assisted Laser *in situ* Keratomileusis (Femto LASIK) on eyes with myopia and compound myopic astigmatism in terms of efficacy, safety, accuracy, predictability, and stability of the procedure.

METHODOLOGY

It was a quasi-experimental study carried out at the Armed Forces Institute of Ophthalmology, Rawalpindi, Pakistan between January 2014 to August 2019. An approval from the Hospital Ethical Review Committee, AFIO, Rawalpindi was sought. A total of 1564 eyes were recruited over this duration through purposive sampling. Informed consents were taken from patients who fulfilled the criteria and were treated by either of the two surgeons, both having similar surgical technique and protocol. Patients over the age of 18 years, having myopia or compound myopic astigmatism up to -12D, estimated postoperative flat K value more than 34D, residual stromal bed of 280 microns or more and percentage of tissue altered <40% were recruited. Those with recent changes in refraction, pregnancy, lactation, any underlying systemic or ocular conditions like glaucoma, cataract, dry eye or ocular surface disease, suspicion of Keratoconus, previously done ocular or refractive surgery were excluded from this study. Contact lens-wearers were advised to discontinue for a period of one to two weeks and then, were reassessed. Thorough assessment of all individuals was carried out preoperatively. It included careful history and meticulous examination of uncorrected distance visual acuity (UDVA), subjective or corrected distance visual acuity (CDVA) and cycloplegic refraction, intraocular pressure measurement, anterior and posterior segment examinations on slit lamp, dry eye testing. All individuals were analysed on a set of diagnostics including Tomography (Wavelight Oculyzer II), Topography and Pupilometry (Wavelight Topolyzer Verio), and Aberrometry (Wavelight Analyzer). Finally, each individual was comprehensively analysed for suitability to undergo the procedure. Those found suitable were explained the benefits, possible side-effects, procedure details, postoperative care, and follow-up requirements. Written consent was taken from each patient as per the standard routine of the hospital as well as consent for use of their clinical data for the purpose of research.

Patients' subjective refraction was validated on the day of surgery and the data were entered into the planner of the excimer laser machine, targeting emmetropia with Wavefront Optimized ablation profile. An optical zone of 6-6.5 mm and ablation zone of 9 mm were maintained for all the patients. Flap thickness was kept between 100-120 microns depending on the availability of residual stromal tissue which was kept more than 280 microns under all circumstances.

Preoperatively, patients were instilled with 0.5% Proparacaine Hydrochloride drops as topical anaesthesia. Periocular skin was prepared with 7.5% Betadine antiseptic solution and positioned under the microscope of FS 200 Femtosecond laser (Wavelight GmbH Erlangen, Germany). Sterile drape and lid speculum were

placed. Ocular surface was rinsed with balanced salt solution to get rid of debris and Meibomian gland secretions. Laser was then docked and centration was confirmed on the screen. Once proper centration and immobilisation of eye were achieved, laser was fired to get the intrastromal and sidecut and then docking was released. The same procedure was followed for the other eye and patient was shifted to a position under the microscope of EX 500 Excimer laser (Wavelight GmbH Erlangen, Germany). Flap was lifted with the help of a spatula and reflected against the hinge to expose the stromal bed. Fixation was achieved and ablation was performed under pupil tracking while protecting the hinge. The bed was irrigated with the balanced salt solution and flap was gently stroked back in its position. Speculum was carefully removed. Patients were prescribed 0.5% Moxifloxacin, Tobramycin plus Dexamethasone combination and lubricant eye drops for every 2 hours for the first day. After that, Moxifloxacin was given 8 hourly for one week and Tobramycin plus Dexamethasone eye drops were given 8 hourly for two weeks. Lubricants were prescribed 4 hourly after the first day and gradually tapered over 6 months. Patients were called for a follow-up after one day, one week, one month, three months, six months, and a year. Patients' uncorrected, best corrected vision, ocular examination, topography, and tomography were recorded. Efficacy was when postoperative UDVA was compared to preoperative CDVA (efficacy index is postoperative UDVA / preoperative CDVA).¹ Safety of procedure was judged by comparing preoperative and postoperative CDVA (Safety index is postop CDVA/preop CDVA).⁹ Target induced astigmatism (TIA) is the change in astigmatism (magnitude and axis) intended by the surgery whereas surgically induced astigmatism (SIA) is the amount of astigmatic change (magnitude and axis), that the surgery actually induced.¹⁰

Statistical analysis was performed on MS Excel 2013. Preoperative readings were compared to post-operative ones using paired sample t-test, and p-value <0.05 was considered to be significant. The categorical variables were expressed as counts and percentages, and continuous variables were expressed as mean and SD.

RESULTS

A total of 1564 eyes were recruited for the study, amongst which 34.8% were males and 65.2% were females, amounting to 544 and 1020 of the total sample, respectively. The study groups' mean age was calculated to be 25.99 ± 6.04 years.

Mean preoperative UDVA, CDVA, and spherical equivalent (SEQ) which is the algebraic sum of sphere and half of cylinder, were recorded and compared with mean postoperative values (Table I).

At 12 months, 1552 eyes, i.e. 99% of the sample achieved equal or better than 20/40 postoperative UDVA. Around 1536 eyes (98%) achieved 20/30 postoperative UDVA (Figure 1A). To begin with, all the study patients did not have 20/20 preoperative CDVA. Around 82% participants had CDVA of 20/20 preoperatively. In comparison, postoperative UDVA was 20/20 in 84% of cases. Efficacy index was calculated to be 1.02 ± 0.15 .

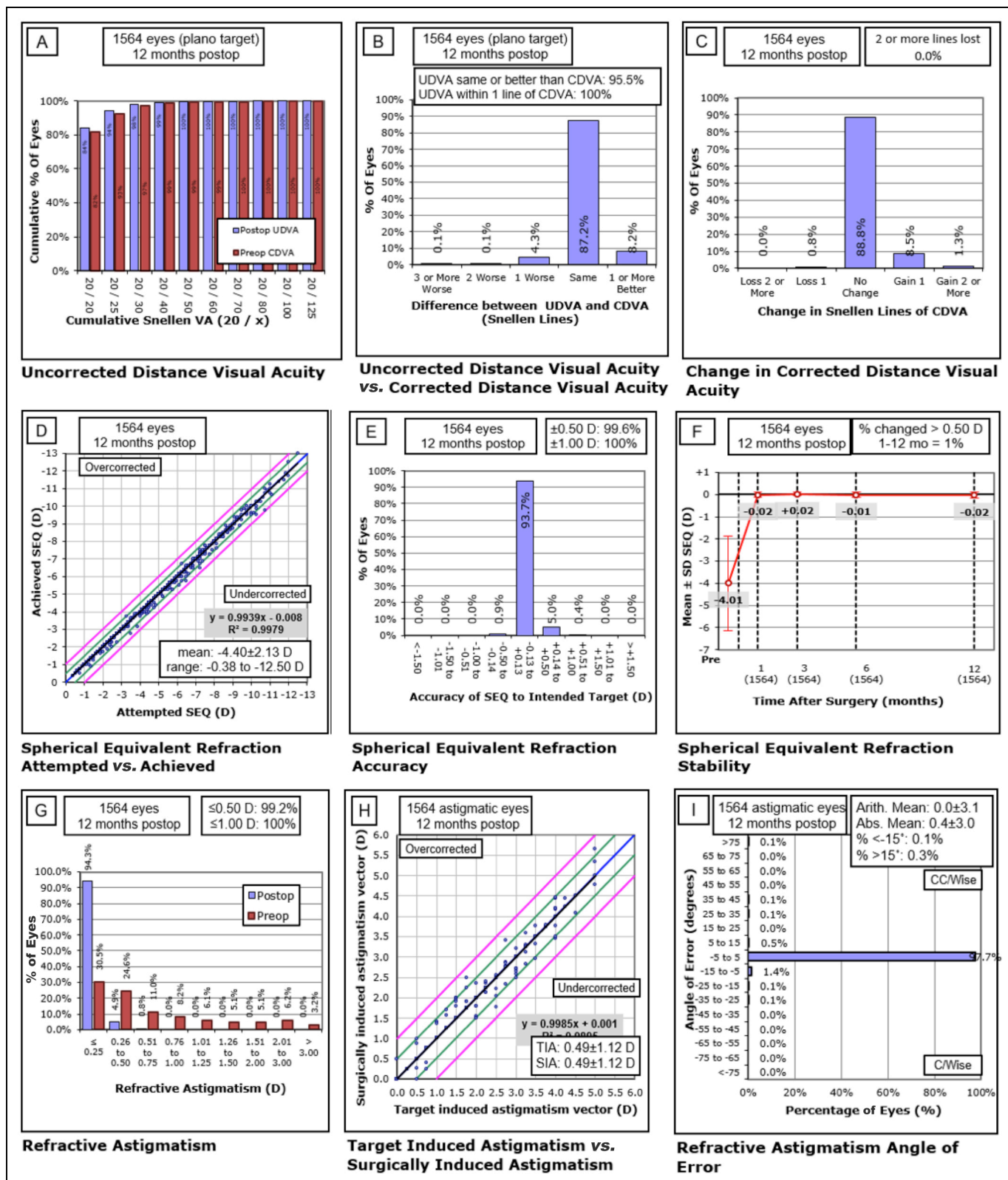


Figure 1: Standard graphs for refractive surgery outcomes. (A) Efficacy profile (postoperative UDVA vs. preoperative CDVA), (B) Safety profile (change in CDVA in form of loss or gain of lines), (C) Predictability profile (intended vs. achieved spherical equivalent), (D) Accuracy profile (percentage of patients within ± 1.00 D), (E) Refractive astigmatism (percentage of patients within ± 1.00 D), (F) Stability profile (change in mean SE over time), (G) Refractive astigmatism, (H) Target induced astigmatism vs. surgically induced astigmatism, (I) Refractive astigmatism Angle of Error.

Table I: Visual and refractive outcomes (Mean, SD, and Paired Two-Sample t-test).

Parameter	Preop mean (M±SD)	Postop mean (M±SD)			p-value (two-tail)			
		1 month	6 months	1 year	Preoperative vs. 1 month	Preoperative vs. 6 months	Preoperative vs. 1 year	6 months vs. 1 year
UDVA (LogMAR)	1.215 ± 0.353	0.031 ± 0.078	0.023 ± 0.066	0.024 ± 0.068	<0.001	<0.001	<0.001	0.002
SEQ (D)	-4.421 ± 2.169	0.033 ± 0.093	-2.166 ± 1.075	-0.037 ± 0.144	<0.001	<0.001	<0.001	<0.001
CDVA (LogMAR)	0.030 ± 0.081	0.023 ± 0.067	0.018 ± 0.060	0.018 ± 0.058	<0.001	<0.001	<0.001	0.309

UDVA: Uncorrected distance visual acuity, CDVA: Corrected distance visual acuity, SEQ: Spherical equivalent, D: Dioptre, SD: Standard deviation, Preop: Preoperative, Postop: Postoperative.

Preoperative CDVA was compared with postoperative UDVA in each case in terms of loss or gain of lines. About 95.5% (1493) achieved either the same or better UDVA after one year of the procedure (Figure 1B). Around 99.7% participants had postoperative UDVA within 1 line of preoperative CDVA.

Any loss of lines postoperatively was considered against safety of the procedure. Out of 1564 eyes, 0.8% of participants (13) experienced loss of one line in postoperative CDVA (Figure 1C). Rest of the 99.2% (1551) of cases either experienced better or the same corrected visual acuity as preoperative CDVA. None of the eyes had more than one loss of line. Safety index remained more than 1, that is 1.04 ± 0.199 .

Comparison of intended and achieved SEQ was carried out to see how predictable the results were at 12 months. In Figure 1D, the scattergram shows that all the achieved points fell within the $\pm 1D$ intended SEQ range.

The accuracy profile in Figure 1E revealed that 99.6% (1557) of eyes were accurately treated within $\pm 0.5D$ of the intended SEQ target.

Mean SEQ at different times (preop, 1 month, 3 months, 6 months, and 12 months) was recorded to see the stability of results. Postoperatively, the SEQ remained essentially stable. Around 1% (15) of eyes were recorded to show a change of more than 0.5D over a span of 11 months (from 1 month to 12 months postoperatively).

In this study, the target was to achieve emmetropia. Postoperative astigmatism was recorded. In 1 year, 99.2% of eyes were within 0.5D astigmatism. All the eyes (100%) had postoperative astigmatism within 0.75D.

When compared, 99.9% of SIA points were within $\pm 1D$ of TIA range. Only one of the points fell outside the purple ($\pm 1D$) lines in Figure 1H scattergram. Angle of error is the angle described by the vectors of achieved (SIA) versus intended (TIA) correction.¹⁰ In Figure 1I, 97.7% (1528) of treated eyes had Angle of Error within ± 5 degrees and 99.6% (1558) had Angle of Error within ± 15 degrees.

Adverse effects encountered postoperatively included ectasia in two patients. Diffuse lamellar keratitis (Grade 1) had

to be managed in 12 patients and pressure-induced stromal keratitis in one patient; both conditions were treated medically and brought under control with no effect on the final visual outcome. Around 43 patients were steroid responders.

DISCUSSION

Femto LASIK has gained popularity as well as trust of both surgeons and patients for the treatment of myopia.¹¹ In this study, the prime aim was to produce and publish refractive results of this procedure as per the standard requirements. Efficacy, safety, predictability, and accuracy of results were compared with other similar studies.

The efficacy at 12 months was 99% of participants achieving equal or better than 20/40 postoperative UDVA. A total of 84% had 20/20 postoperative UDVA (when only 82% had 20/20 CDVA before the procedure).

A study by Chua *et al.* carried out primarily on Asian eyes revealed that efficacy remained >99% reaching 20/40 UDVA or better and around 70% reaching 20/20 mark after 18 years of follow-up. They had reported efficacy index of 0.91¹² as compared to the efficacy index of 1.02 ± 0.15 in this study.

A study by Kim *et al.* reported similar results on Korean population despite the difference in follow up duration when compared to the current study. They reported 96.3% of patients achieving 20/40 and 69.9% achieving 20/20 UDVA at the end of three months.¹³ The same study reported efficacy index of 0.95 at the end of 3 years duration postoperatively.

There remains a solid concern for developing corneal ectasia after LASIK despite its excellent efficacy.¹⁴ Two participants showed signs of ectasia, one eye in one participant and both eyes in the second participant despite all normal scans and parameters during one year follow-up period. Both underwent immediate collagen cross-linking and are still under observation.

Tabacaru and Stanca conducted one-year study on cases of myopia treated with Femto LASIK and concluded that none of their patients experienced loss of lines in CDVA postoperatively.¹⁵ In contrast to this study, the present authors encoun-

tered 0.8% of participants who lost up to one line when preoperative CDVA was compared with postoperative CDVA. This difference can be attributed to major dissimilarity in the sample size of the two studies (60 vs. 1564 eyes).

Another study conducted by Shehadah *et al.* performed Wavefront Optimized LASIK on 326 (myopic and myopic astigmatic) eyes and concluded that none of their participants lost any lines of CDVA at 12 months.¹⁶

On the contrary, a study carried out by Brar *et al.* performed Femto LASIK on 328 myopic eyes on two different machines. At 12 months, both groups had 1% and 3% of participants who encountered loss of 1 line in CDVA.⁹ Safety index however remained more than one. Another study using similar platforms of femtosecond and excimer laser concluded that 86% of their myopic patients either had same or better CDVA and 14% experienced loss of 1 line at 1-year follow-up. None of their patients had loss of two lines or more.¹⁷

Predictability is evaluated by comparing attempted versus achieved spherical equivalent. Similar to this study's observation, a study by Agarwal *et al.* also concluded 100% of participants achieving intended spherical equivalent within ± 1.0 DS range.¹⁸ FDA trials and Singapore National Eye Centre trial had reported achievement of 90 and 94% within the target spherical equivalent, respectively.¹² The same studies reported 72 and 70% of participants within ± 0.5 DS of intended spherical equivalent as compared to the present study where 99.6% of the patients were treated accurately within this range.

A study compared outcomes of LASIK in 6.0 and 6.5-mm optical zone myopic cases and concluded that 11 out of 2664 (1332 in each group) patients were either over corrected or under corrected when SIA and TIA were plotted in comparison.¹⁹ Mean Angle of Error was 1.1 ± 18.5 for 6.0 mm group and 0.5 ± 17.2 for 6.5 mm group. In this study, only one patient was recorded out of ± 1.0 DS range, thus, showing better astigmatic results. Also, arithmetic and absolute mean Angle of Error concluded in this study were 0.0 ± 3.1 and 0.4 ± 3.0 , respectively. The duration of follow-up was same for both the studies. However, the sample size was double the size of this study. Another study by Khalifa *et al.* was carried out to compare astigmatic outcomes of Wavefront Guided and Wavefront Optimized LASIK on 220 eyes.²⁰ They reported mean Angle of Error for low and moderate myopia as -0.04 ± 0.87 and -1.15 ± 12.36 respectively, at 6 months follow-up. Thus, the results of current study proved to be better in terms of correction of astigmatism.

The main strength of this study was a large-sized sample. However, the quality of vision after this procedure needs to be explored to ascertain its exact effect on patients' quality of life.

CONCLUSION

Femto LASIK is an effective, safe, accurate, predictable, and stable procedure for eyes with myopia and compound myopic astigmatism.

ETHICAL APPROVAL:

An approval was granted by the Hospital Ethical Review Committee, AFIO, Rawalpindi, on 1 January 2014.

PATIENTS' CONSENT:

Informed, written consents were taken from patients for both the treatment and publication of the data.

COMPETING INTEREST:

None of the authors had any conflict of interest to declare.

AUTHORS' CONTRIBUTION:

SH: Conception and design of the work, data analysis.

MI: Final approval of the manuscript, data interpretation.

AF: Drafting of the work.

SA: Data acquisition.

All authors approved the final version of the manuscript to be published.

REFERENCES

1. Donnenfeld ED. Debunked: LASIK myths and misconceptions. *Cataract Refract Surg Today* 2016;59-63.
2. Kohnen T, Strenger A, Klaproth OK. Basic knowledge of refractive surgery: Correction of refractive errors using modern surgical procedures. *Dtsch Arztebl Int* 2008; **105** (9):163-70.
3. Jones C. Refractive Surgery Market Report. *MarketScope* 2019; **2020**:1-283.
4. Joffe SN. The 25th anniversary of laser vision correction in the United States. *Clinical Ophthalmology (Auckland, NZ)* 2021; **15**:1163.
5. Rogers C. LASIK: Know the rewards and the risks [Internet]. WebMD; 2022 [cited 15 February 2022]. Available from: <http://www.webmd.com/eye-health/news/20180727/lasik-know-the-rewards-and-the-risks>.
6. Eydelman M, Hilmantel G, Tarver ME, Hafmeister EM, May J, Heard K, *et al.* Symptoms and satisfaction of patients in the patient-reported outcomes with Laser *in situ* Keratomileusis (PROWL) studies. *JAMA Ophthalmol* 2017; **135**(1):13-22. doi:10.1001/jamaophthalmol.2016.4587.
7. Reinsteint DZ, Archer TJ, Randleman JB. JRS standard for reporting astigmatism outcomes of refractive surgery. *J Refract Surg* 2014; **30**(10):654-9.
8. Waring III GO, Reinsteint DZ, Dupps Jr WJ, Kohnen T, Mamalis N, Rosen ES, *et al.* Standardized graphs and terms for refractive surgery results. *J Refract Surg* 2011; **27**(1):7-9.
9. Brar S, Rathod DP, Roopashree CR, Ganesh S. One-year visual and refractive outcomes following LASIK for myopia and myopic astigmatism with MEL 90 versus Schwind Amaris 750S Excimer Laser: A comparative study. *J Ophthalmol* 2021; **2021**:9929181.

10. Zhou J, Gu W, Gao Y, He G, Zhang F. Vector analysis of high astigmatism (≥ 2.0 diopters) correction after small-incision lenticule extraction with stringent head positioning and femtosecond laser-assisted Laser *in situ* Keratomileusis with compensation of cyclotorsion. *BMC Ophthalmology* 2022; **22(1)**:1-10.
11. Hashmani N, Hashmani S, Ramesh P, Rajani H, Ahmed J, Kumar J, *et al.* A comparison of visual outcomes and patient satisfaction between photorefractive keratectomy and femtosecond laser-assisted *in situ* keratomileusis. *Cureus* 2017; **9(9)**:e1641.
12. Chua D, Htoon HM, Lim L, Chan CM, Mehta JS, Tan DT, *et al.* Eighteen-year prospective audit of LASIK outcomes for myopia in 53 731 eyes. *Br J Ophthalmol* 2019; **103(9)**: 1228-34.
13. Kim JY, Lee H, Joo CK, Hyon JY, Kim TI, Kim JH, *et al.* Three-year follow-up of Laser *in situ* Keratomileusis treatments for myopia: Multi-centre cohort study in Korean population. *J Pers Med* 2021; **11(5)**:419.
14. Ambrósio Jr R. Post-LASIK ectasia: Twenty years of a conundrum. *Semin Ophthalmol* 2019; **34(2)**:66-8. doi: 10.1080/08520535.2019.1569075.
15. Tabacaru B, Stanca HT. One year refractive outcomes of Femtosecond-LASIK in mild, moderate and high myopia. *Rom J Ophthalmol* 2017; **61(1)**:23-31. doi: 10.22336/rja/2017.5.
16. Shehadeh MM, Akkawi MT, Aghbar AA, Musmar MT, Khabbas MN, Kharouf MF, *et al.* Outcomes of wavefront-optimized laser-assisted *in-situ* keratomileusis and photorefractive keratectomy for correction of myopia and myopic astigmatism over one year follow-up. *Open J Ophthalmol* 2018; **12**:256-63.
17. Niparugs M, Tananuvat N, Chaidaroon W, Tangmonkongvoragul C, Ausayakhun S. Outcomes of LASIK for myopia or myopic astigmatism correction with the FS200 femtosecond laser and EX500 excimer laser platform. *Open J Ophthalmol* 2018; **12**:63-71.
18. Agarwal S, Thornell E, Hodge C, Sutton G, Hughes P. Visual outcomes and higher order aberrations following LASIK on eyes with low myopia and astigmatism. *Open J Ophthalmol* 2018; **12**:84-93.
19. Moshirfar M, Huynh R, Bundogji N, Tukan AN, Sant TM, McCabe SE, *et al.* Comparison of 6.0 mm versus 6.5 mm optical zone on visual outcomes after LASIK. *J Clin Med* 2021; **10(17)**:3776.
20. Khalifa MA, Alsahn MF, Shaheen MS, Pinero DP. Comparative analysis of the efficacy of astigmatic correction after wavefront-guided and wavefront-optimized LASIK in low and moderate myopic eyes. *Int J Ophthalmol* 2017; **10(2)**: 285-92. doi: 10.1824/ijo.2017.02.17.

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