LASIK intraocular refractive surgery in high myopia long-term effects

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ABSTRACT

Objective: this review consists of the analysis of various studies that examine the effects on long-term vision after one year or more in patients who have undergone LASIK refractive surgery for high myopia. It also deals with the rate of side effects and the time of their prevalence among the patients.

Methods: of the 858 articles found in the initial search in PubMed after applying inclusion criteria, 7 studies on the subject were collected. The reasons for exclusion from this study was that there were too few participants, myopia less than -5.50D, and dealing with a rare side effect.

This study reviews 7 articles on post-LASIK side effects in patients with high myopia over -5.50 diopters. All patients were above the age of 18, with stable refractive error for at least 3 months prior to the procedure. The studies used data from 3 months to 10 years post LASIK. This study collects data from these studies and compares them.

Results: according to this study, the effectiveness of LASIK for refractive surgery for high myopia (<-5.50D) is good and remains stable over time. However, side effects such as some myopic regressions, peripheral epithelial ingrowth and increase in spherical aberration have been observed to develop over time, but they are not consistent.

Conclusion: there are little side effects like some myopic regression, peripheral epithelium ingrowth and increase in spherical aberration. There is a need for more high-quality studies and standardization of results that follow up over a longer period of time.

Keywords: Lasik, high myopia, side effects, follow up, regression

INTRODUCTION

Myopia is an ocular condition in which the refractive power of the eye is greater than required, resulting in blurred distance vision, caused by light from distant objects being focused in front of the retina, instead of directly on it, resulting in blurred distance vision. The most commonly used methods of correcting myopia are spectacle or contact lenses wear. Both methods have limitations such as reduction of the visual field, dependence of the glasses or contact lenses, and with contact lenses an increased risk of visual danger due to corneal infection and complications. Surgical procedures have been developed to provide alternatives to glasses or contact lenses to try to permanently correct myopia (Shortt et al., 2006; Moreno-Barriuso et al., 2001).

Myopia is the most common cause of visual disability throughout the world. According to The World Health Organization, Myopia is one of the leading causes of blindness and vision impairment in the world (WHO) (Barsam et al., 2012).

Myopia is a refractive error that can be caused by many multifactorial factors such as lack of sufficient exposure to the sun, genetics, environment and possibly a lot of near work. Despite this, the pathophysiology of this phenomena is still unclear. The prevalence of myopia in the western population is in the region of 25%, compared to its high prevalence in selected areas of Asia of approximately 70% to 90%. High myopia is classified as being 6 diopters or higher (Vega-Estrada et al., 2019).

Today, there are surgical refractive techniques for correcting high myopia such as CLE (clear lens extraction); pIOL (phakic intraocular lens implantation), with potential for intraocular risks and complications (Vega-Estrada et al., 2019);Photorefractive keratectomy (PRK), with disadvantages of corneal haze, postoperative pain, and slow visual rehabilitation; laser epithelial keratomileusis (LASEK) that is suitable for thin corneas; epi-LASIK, that reduces risk for complications related to the flap (Na et al., 2012), and LASIK (laser in situ keratomileusis) that consists of extraocular surgery that has minimal complications and risks to the internal structures of the eye (Vega-Estrada et al., 2019).

LASIK has become the most common form of refractive surgery and has gained wide popularity as the procedure of choice to correct refractive errors (Gazieva et al., 2011; Yamane et al., 2004). LASIK reduces myopic by removing a small amount of the cornea stroma. A small flap in formed using the laser, and then a part of the cornea stroma is removed, and then the flap is returned to its position (Gazieva et al., 2011; Shortt et al., 2006).

LASIK has been performed since 1991 and is the most recommended as a surgical procedure for the correction of myopia, myopic astigmatism and mild to moderate hyperopia. This is because it is the most painless procedure and gives the fastest vision rehabilitation (O'Doherty et al., 2006; Oruçoğlu et al., 2012).

However, LASIK for the correction of high myopia above -5.50D has been controversial because of its side effects that include higher order corneal disturbances and instability due to the removed corneal tissue that caused visual performance disturbances in patients (Vega-Estrada et al., 2019; Tabernero et al., 2007).

Due to the deterioration of the quality of vision and the presence of regression, the initial limitation for this analysis was gradually lowered. In 1998, high myopia was defined as a potential risk factor to LASIK procedure due to a large volume of tissue ablation that can cause

post ectasia. Nevertheless, some studies have supported the safety and efficacy of LASIK for myopia correction but with short follow-up (Oruçoğlu et al., 2012).

LASIK when used for high myopia is an invasive procedure that involves the formation of a flap at a level of 160 µm from the corneal surface, which can disturb the organisation of collagen fibres that make up the corneal stroma at this level, which could damage the corneal strength. Thus, there has been concern expressed over the long term refractive and biomechanical stability associated with LASIK surgery for high myopia (O'Doherty et al., 2006). These side effects and limitations were commonly seen in the early laser studies (Vega-Estrada et al., 2019).

Many surgeons prefer not to operate on patients with myopia higher than 10 diopters using LASIK due to concerns about the effectiveness and safety of the procedure. These complications are caused, among other things, by the less advanced generation laser that caused loss of corrected distance visual acuity and a reduction in the quality of vision due to the fact that surgery was performed on a small of the cornea, and causing increase in spherical aberrations, flat corneal curvatures, and high rates of microstriae (Lim et al., 2016).

Additional concerns of LASIK for high myopia are due to the situations where there is undercorrection, high recurrence rates, insufficient corneal ablation tissue for primary or secondary treatment, and a high risk of corneal ectasia (Wallerstein et al., 2020). Also, LASIK has unique risks, including flap-related complications, such as free cap, incomplete flap, buttonholes, epithelial ingrowth, lost flaps, and deep lamellar keratitis (Na et al., 2012).

In addition, refractive surgery for high myopia is a risk factor for long term regression (that can be caused from changes in corneal refraction of the corneal anterior surface, higher degree of astigmatism, axial length elongation during the long-term follow-up period, hardening of lens nucleus by age and more (Lim et al., 2016; Ogasawara et al., 2016).

LASIK surgery results can be affected by many factors such as the type of laser device used, the type of cutting blade and the patient's prescription before surgery (Gazieva et al., 2011).

Constant improvements in the original techniques make the surgical procedure more accurate and safer and can be repeated in certain cases of unsatisfactory results (Gazieva et al., 2011). Developments of new surgical techniques and improvements in the laser systems has led to an enormous increase of the number of patients undergoing refractive surgery (Moreno-Barriuso et al., 2001).

These improvements were caused by the creation of new surgical equipment such as flying-spot laser systems and the incorporation of eye trackers for compensation of eye movements during surgery that have led to better results and to a higher degree of satisfaction by the patients (However, there may be more complaints of seeing glare and halos at night) (Moreno-Barriuso et al., 2001).

In addition, laser-assisted in situ keratomileusis (LASIK) technique overcomes many of the problems of the older techniques such as refraction stability or painful recovery. Other improvements include the increase of the diameter of the optical zone or the ablation of a wider transition zone to smooth out the steep edges at the border of the ablation zone (Moreno-Barriuso et al., 2001).

Despite of the many procedures are performed each year, relatively few studies have been collected that deal with LASIK for high myopia and that collected a quantity of eyes from continuous patients throughout the study. The

range of myopia before surgery often varies between different studies and there is no distinction between eyes treated primarily versus secondarily while the efficacy and complications are noted in the studies (Gazieva et al., 2011).

Despite this, the advancement of technology and the various improved methods and the addition of the knowledge accumulated over the years in surgery and refractive treatments, helped to overcome the continuation of the aforementioned leaderships. Nevertheless, there are no sufficient scientific works to make a future decision about the long-term results of LASIK for myopia correction and future studies are needed (Vega-Estrada et al., 2019).

The research hypothesis

This study will present the long-term effects on vision from LASIK refractive surgery with high myopia, from various studies. It is assumed that a correlation will be found between the length of time that has elapsed since the surgery, and the extent of the side effects. Therefore, that there are less comprehensive side effects during the first year after the surgery than after one year and further (Wilkinson et al., 2017; Wallerstein et al., 2020; Oruçoğlu et al., 2012).

Purpose of research

The aim of this study is to examine the effects on long-term vision after one year or more in patients who have undergone LASIK refractive surgery for high myopia. We would also like to check what percentage of patients will suffer from new visual disturbances due to the surgery.

The research will be carried out by collecting data from different studies and comparing them.

METHODS

This literature review pursued a bilateral research approach to investigate the existing literature on the subject. An extensive literature review about LASIK intraocular refractive surgery in high myopia long-term effects took place via different scholarly journals and approaches, using database parameters such as PubMed and Google Scholar to Google to find articles in related fields. The second part of the bilateral approach were different case studies directly related to LASIK intraocular refractive surgery in high myopia long-term effects. The search words were: “LASIK” and “high myopia”.

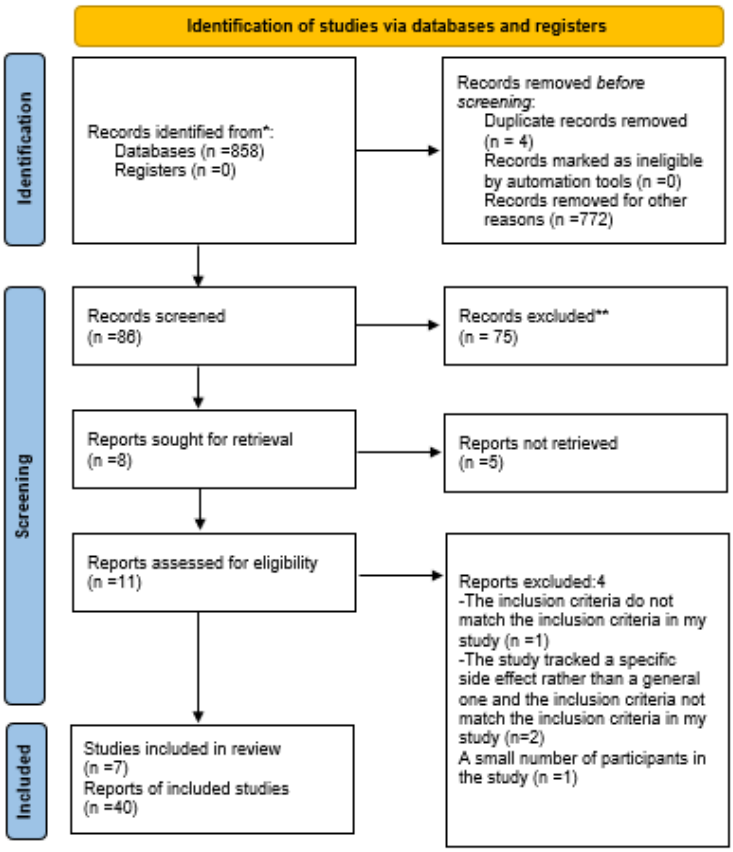
The total number of articles obtained with this database search was 858. In all the studies included there were patients that had myopia of 5.50 diopters or above, age 18 and above and stable refraction at follow-up for at least 3 months or more.

Studies which examined LASIK for low myopia were removed (less than -5.50 diopters), apart from one research of Kojima et al. (2008) that assesses the outcomes in high myopia compared to the low myopia group.

After applying the inclusion and exclusion criteria, the number of articles obtained was 11. Thus, this study is based on 7 articles from the last two decades that examine the long-term effects on vision from patients with high myopia that undergo LASIK refractive surgery. Of these 11 studies 4 were not included because they either examined too few participants, the study examined only one specific side effect, or the age range was too narrow.

The duration of follow-up, age, gender, and number of participants, number of eyes operated, type of laser device and degree of refractive error varied between studies.

Table 1. *PRISMA 2020 flow diagram*



RESULTS

From the articles that follow-up from 3 months until 10 years there have been few side effects and most of the patients were satisfied with their outcomes.

The side effects that were observed were myopic regression, loss of BSCVA, the need of retreatment with LASIK, over/under correct, difficulty in night-time driving, myopic shift, increase in HOA, interface debris and peripheral epithelial ingrowth.

The percentage of 0.50± that was achieved was the lowest in the research of Gazieva et al. (2011): 17% of 326 (group A) and 34% of 358 (group B) after three months compared with 56.90% at the research of Kojima et al. (2008) after three months, 72% at the research of Wallerstein et al. (2020) after two years, 62% at the research of Vega-Estrada et al. (2019) after five years. The relatively low results can be attributed to the fact that in Gazieva's study, there was an unreliable amount of treatment with a tendency to undercorrect. We could explain that this is because perhaps the surgeons were afraid to over-correct and therefore preferred not to remove enough corneal tissue.

However, in the research of Gazieva et al. (2011), during the first 3 months SE ±2.00 higher was achieved (75% from group A and 89% from group B) compared to the research of Orucoğlu et al. (2012) were only 46.50% achieved SE ±2.00 during the first year. Also, only four out of thirty-nine (10.3%) were within ±2.00 at the final 12.50 years follow up. This can be explained by the fact that Orucoğlu et al., (2012) used in his research higher numbers of refractive errors. Therefore, the surgery was less successful.

In the research of Orucoğlu et al. (2012), 14% achieved ±1.00 in one year (it can be explained by the reason described above). After this, according to Wallerstein et al. (2020), 94% achieved ±1.00 in the two years. And according Vega- Estrada et al., (2019), 77% achieved ±1.00 in the first five years.

The manifest spherical equivalent (MSE) remained more or less stable. According to Wallerstein et al., (2020) the SEQ was -0.19±0.46 after two years. The MSE was -0.51±0.64 after three years according to Kojima et al., (2008). The MSE was -0.30±0.54 after three years and -0.24±0.57 after five years according to Vega-Estrada et al. (2019). The MSE was -2.88±2.15 after one year and -6.09±3.35 at the last examination (12.50 years follow up), according to Orucoğlu et al. (2012).

According to Wallerstein et al. (2020), the mean amount of regression was 0.51±0.38 during two years, while 25.40% had a myopic regression or equal to 0.50D, and 52.60% did not have a SEQ change greater than ±0.25D. According to Mingna et al., (2019) the mean regression was -1.13±0.51D during five years. (17 out of the 35 eyes that were treated with LASIK suffered refractive regression). The incidence of high myopia regression rate was 2.20%. Similar results were observed in the research of Vega-Estrada et al., (2019), in which less than 4% of the group had regression larger than 0.50D and a large reduction of more than 7.50D was observed with a minimal regression of less 0.25D in SE between the three months to five years.

However, in the research by Oruçoğlu et al. (2012), from one month to 10 years there was observed a big regression of myopia (>1.00D). The regression was -6.10±2.20D (months) and -3.07±1.80D (years). This can be attributed to the fact that the spherical equivalent was bigger than in the rest of studies and not attributed to the time of follow-up.

After three years, according to Gazieva et al. (2011), the safety index was 1.07±0.21 in group A and 1.00±0.18 in group B. A similar result was found after five years in the study by Vega-Estrada et al. (2019), (1.02). Wallerstein et al., (2020) found 1.05±0.12. However, Oruçoğlu et al., (2012) found a slightly higher result (1.37) after one year and 1.56±0.95 after ten years.

According to Wallerstein et al. (2020), 21.9% gain lines of vision and 73.7% did not change after two years. Good results observed also at the research of Kojima et al. (2008), 19.5% achieved one line or more of BSCVA and 66.7% no loss BSCVA. However, 13.89% lost one line or more of BSCVA at the research of Kojima et al., (2008) after 3 months but only lost one line at the research of Wallerstein et al., (2020) after two years. At the research of Gazieva et al. (2011), 1.2% loss on line or more of two lines after 3 months. A relative reduction was observed in the others compared to him.

At the research of Vega-Estrada et al. (2019), the efficacy index was 0.91 after five years. Also, at the research of Wallerstein et al. (2020), after two years similar results were observed -0.93±0.20. However, worse results were seen after one year, -0.56 according to Oruçoğlu et al. (2012), and 0.29 after ten years. It occurred the same in the results after three months. According to Gazieva et al. (2011), the results were similar, -0.54±0.36 in group A and 0.67±0.33 in group B.

There were observed little side effects. According to Wallerstein et al. (2020), the amount of postoperative HOAs spherical aberration and coma aberration was 0.67± 0.25, 0.70± 0.40 micron, respectively.

According to Vega-Estrada et al. (2019), significant induction of primary spherical aberration and coma aberration was also found at 3 months with levels of 0.61 and 0.47 micron respectively, with no further changes at 5 years. The amount of HOA at 3 months postoperatively was significantly correlated with the changes in the keratometry throughout the 5 years.

According to Gazieva et al. (2011), after primary treatment, interface debris occurred in 57 eyes (17%) in group A and 4 eyes (1%) in group B.

Peripheral epithelial ingrowths were seen in 11 eyes (3%) in group A, but none in group B.

According to Charles et al., (2000), two patients (4.30%) reported a significant deterioration. Many patients (19.10%) noted difficulty in reading with uncorrected vision in artificial light. Most patients noted significant improvement in their UCVA for distance. However, 3 patients (8.80%) noted significant visual difficulties with night-time driving.

DISCUSSION

Nowadays, there is not enough knowledge about the influence of LASIK procedure for high myopia. This research aimed to look primarily at the side effects that were caused by LASIK refractive surgery for high myopia and see if they occur more during the first year after the surgery or after a longer period of time.

The secondary aim of this research was to check what percentage of patients will suffer from new visual disturbances due to surgery.

Because of the minority of studies that examine the long side effects among patients with high myopia from LASIK surgery, and also because this surgery appears to be less predictable in high myopia (more than -5.50D), this research tries to acknowledge if this surgery is recommended in high myopia, and if and when there will be side effects (if any).

There are observed little side effects after the procedure. According to Gazieva et al., (2011), after primary treatment, peripheral epithelial ingrowths were seen in 11 eyes (3%) in group A, but none in group B. Similar results were observed according to Yin (2021), that did not present postoperative complications, such as corneal epithelial ingrowth in the fs-lasik group.

It is seen that ±0.50 obtained among most of the patients and saved over time. A total of 62% of patients achieved ±0.50 at the research of Vega-Estrada et al. (2019) after five years. Also, according to Yin (2021), after 12 months, 65% of eyes achieved SE within ±0.50 and 73% achieved ±0.50 according to Zhang et al., (2020).

The safety index was saved stable over the time. At the follow-up visit of 6 months of the research of Zhao et al., (2021), the safety index was 1.10. According to Zhang et al. (2020), it was 1.08 at postoperative 12 months, similarly to the research of Vega-Estrada et al., (2019), in which the safety index was 1.02 after five years.

It seen that the percentage of SE intended ±1.00D were achieved in good way throughout different follow up times in the cases. It can be seen in the research of Zhao et al. (2021), that 65% (24/37) of eyes achieved ±1.00D within six months, and 92% according to Zhang et al. (2020). A total of 85.71% achieved SE within +/- 1.00 according to Mounir et al. (2020) after 12 months, compared to 77% eyes that achieved this result after five years, according to Vega-Estrada et al. (2019).

After one year, according to Yin et al. (2021), the Logmar UDVA was 0.032±0.176. Similar results were observed at the research of Zhang et al., (2020) -0.01± 0.08. Nevertheless, according to Vega-Estrada et al., (2019) the UDVA (Logmar) was 0.13±0.23 after five years. So, it is seen that the results start low and get better after the years.

A total of 74% (36/49) had a postoperative Snellen visual acuity of 20/20 or better after one year according to Yin et al., (2021), and according to Zhang et al., (2020), at postoperative 12 months, 90% of eyes achieved 20/20 or better Snellen UDVA. Similar results were observed at the research of Wallerstein after two years. A total of 79.50% of patients

achieved a bilateral UDVA of 20/20 after two years.

According to Zhang et al. (2020), the spherical aberration was 0.63 ± 0.22 after 12 months. Also, according to Wallerstein et al., (2020) the spherical aberration was 0.67± 0.25 after two years. Similar results were observed to according to Vega-Estrada et al. (2019), that significant induction of primary spherical aberration was also found at 3 months with levels of 0.61 micron with no further changes at 5 years.

The results obtained are consistent. Lasik surgery for high myopia over -5.50D has been found to give good visual results.

In conclusion, it can be seen that the results obtained partially support the research hypothesis. Results from LASIK surgery are maintained well throughout the years of follow-up but there is no significant difference between the period of time that has passed less than a year since surgery versus several years since surgery. On the other hand, additional studies should be examined in the future that will examine side effects for a longer period of time.

Due to the fact that in these studies, the machinery used, the follow of time, the number of eyes studies, etc. were not uniform, there is a need for further research to examine the long side effects of LASIK refractive surgery.

In general, the results of refractive surgery LASIK for high myopia were good and the satisfaction of the patients was high. In addition, the side effects observed were small.

However, there is a need for future studies to examine this procedure and to have a larger follow up time to better analyze the effects of LASIK on high myopia over the long term.

CONCLUSION

As the world population increases, and as myopia and high myopia increases, more and more people will want to undergo LASIK surgery to improve their quality of life, and will not need to be dependent on glasses or contact lenses.

Thus, I believe more studies have to be performed to understand the risk and complications of LASIK for high myopia.

LASIK surgery in high myopia patients above -5.50D is a challenge due to insufficient corneal tissue that can constitute a risk of ectasia and leading to halos, photophobia and more.

This report provides a comparative data set from patients who underwent LASIK surgery for high myopia and tracks their rate of side effects over different follow-up times.

As examined in this article, good and stable results were observed for visual needs for long period of times, from three months until ten years.

Also, the results were found to be similar despite the difference in the various research protocols.

The results include percentage of myopic regression, SE ±0.50, ±1.00, ±2.00 intended, safety and efficacy indexes and gain or lose of BSCVA.

The side effects that were observed were myopic regression, peripheral epithelial ingrowths and increase in spherical aberration.

Nevertheless, it is possible that these will be more serious side effect in the long-term post surgery, and then need to be further investigated.

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ANNEX

Table 2. Summary of results

Author	Number of participants	Gender	Mean age	Number of eyes operated	Follow up time	Results
Charles et al. (2000)	48 patients	28 men 20 women	40.2± 9.9 years (range 21 to 57 years)	76 eyes	Range 2 to 21 month	The mean residual refractive error was -1.1± 2.5D in the first eyes and -0.6± 1.3D in the second eyes. 83.0% with the preoperative potential to obtain a UCVA of 6/12 or better achieved this level in at least 1 eye. Postoperative UCVA>6/12 or better (n=34, 70.8%) compared with <6/12 (n=14, 29.2%).
Kojima et al. (2008)	227 patients	131 males 96 females	37.9 years	320 eyes	3 months	SE -0.51± 0.64 UCVA 0.13± 0.16 BSCVA 0.01± 0.06 56.9% eyes were within ±0.50D. 86.1% eyes were within ±1.00D.
Gazieva et al. (2011)	-	-	In group B the age of the patient was slightly higher	680 eyes: Group 1- 326 eyes Group 2- 354 eyes	3 months	SE within ± 0.50 D % eyes: A-17% B-34%. SE within± 1.00 D % eyes: A-39% B-60%. SE within± 2.00 D % eyes: A-75% B-89%. 3 months after surgery the percentage of patients with UCVA>/=0.5 was reduced to 50% (108 eyes) in group A and to 73% (123 eyes) in group B. Efficacy index was 0.54± 0.36 for group A and 0.67± 0.33 for group B. Safety

						index was 1.07±0.21 for group A and 1.00± 0.18 for group B.
Orucoglu et al. (2012)	23 patients	12 males 8 females	-	39 eyes	10 years	The mean SE was -6.09± 3.35D. UCVA 0.06± 0.13. BCVA 0.31± 0.16. 10.3% were within ±2.00D. The regression was -6.1± 2.2D (months) and -3.07±1.8D (years). All eyes showed a significant regression (>1.00D) from 1 month to 10 years.
Mingna et al. (2019)	-	7/5 ratio male/female	29.17± 6.04 years (range 21-41 years)	837 eyes	5 years	The mean amount of regression (MSE) was -1.13± 0.51D. 35 eyes in 25 individuals (17 eyes treated with Lasik) suffered refractive regression The incidence of high myopia regression rate was 2.2%.
Vega-Estrada et al. (2019)	40 patients	29 males 41 females	35.55± 8.44 years (Range from 24 to 56 years)	70 eyes	3 years (In addition, 34 eyes had a follow-up period of 5 years)	SE after 3 years was -0.30± 0.54 and after 5 years was -0.24± 0.57. Logmar UDVA after 3 years was 0.07±0.12 and 0.13±0.23 after 5 years, respectively. Logmar CDVA after 3 years was 0.01±0.03 and after 5 years was 0.00±0.04,respectively. Less than 4% of the cases have regression larger than 0.50D between the 3 months and the 5 years. At 5 years 62% and 77% of the patients were within ±0.50 and ±1D, respectively. At 5 years mean efficacy and safety index were 0.91 and 1.02, respectively.
Wallerstein et al. (2020)	78 patients	37.2% male 62.8% female	34.2± 8.9 years (range 19 to 55 years)	114 eyes	2 years	The SEQ was stable at the 1 month, 3 -6 ,-and 24-month time points with non-significant trend toward a decrease in SEQ at the last follow-up. 86.5% were within 1 line of CDVA. 79.5% of patients achieved a bilateral UDVA of 20/20. Safety index 1.05± 0.12. The final SEQ was -0.19±0.46D. The average myopic regression was 0.51± 0.38D. A total of 52, 72, 84 and 94% of eyes were within ±0.25, ±0.50, ±0.75, and ±1.00. Efficacy index 0.93± 0.20.