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INTEGRATED STUDY MASTER'S THESIS

Innovations in refractive surgery

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1. Abbreviations

AI - Artificial Intelligence

AIDS - Acquired immunodeficiency syndrome

CDVA - Corrected distance visual acuity

CLEAR - Corneal Lenticule Extraction for Advanced Refractive Correction

D - Diopter

Epi-LASIK - Epithelial Laser In Situ Keratomileusis

FDA - Food and Drug Administration

Hz - Number of hertz

KLEx - Keratorefractive lenticular extraction

LASIK - Laser-assisted in situ keratomileusis

MM - Millimetr

MMC - Mitomycin C

NJ - Nanojoules

OCT - Optical coherence tomography

PIOL - Phakic intraocular lenses

PRK - Photorefractive keratectomy

PTK - Phototherapeutic keratectomy

PVD - Posterior vitreous detachment

RA - Rheumatoid arthritis

RLE - Pseudophakic refractive lens exchange

SILK - Smooth Incision Lenticular Keratomileusis

SLE - Systemic lupus erythematous

SMILE - Small Incision Lenticular Extraction

UDVA - Uncorrected distance visual acuity

2. Summary

Theme:

Innovations in refractive surgery

Refractive abnormalities of vision - myopia, hypertropia and astigmatism remain one of the most significant problems in ophthalmological field, directly affecting the quality of life and working capacity of patients. With rapid technological progress and increasing incidence of refractive abnormalities, there is an objective need to improve not only surgical treatment methods but also diagnostic systems, forecasting and individual planning of surgical interventions.

The aim of the study:

To analyse modern innovative technologies in the field of refractive surgery, compare approaches, assess their clinical effectiveness, safety and potential integration with digital systems and artificial intelligence. Special attention is given to evaluating the improvement of the quality of diagnosis of refractive errors in the eye based on modern algorithms for visualization and data processing.

Research objectives:

1. Research and comparison of innovative technologies in refractive laser surgery, with particular consideration of functional characteristics and clinical applications of new-generation high-precision laser systems, including femtosecond lasers, excimer lasers, and microkeratome-assisted platforms.
2. Consideration of the development of modern surgical correction methods for laser vision correction, including LASIK (Laser-Assisted in Situ Keratomileusis), SMILE (Small Incision Lenticule Extraction), SmartSight, SILK (Smooth Incision Lenticule Keratomileusis), and CLEAR (Corneal Lenticule Extraction for Advanced Refractive correction) and compare their effectiveness, safety profiles, and biomechanical influence on the cornea.
3. Analysis of individualised approaches to laser vision correction, including wavefront-guided LASIK and topography-guided LASIK for the correction of both lower- and higher-order aberrations.
4. Exploration of using artificial intelligence (AI) and mechanical technologies in ophthalmological field for enhancing the accuracy of diagnosis, precision of operative process, and predictability of treatment results.
5. Analysis of future directions in the advancement of high-precision, minimally invasive ophthalmic surgical techniques.

Methodology:

A systematic review of the current scientific literature, analysis of the latest meta-studies results, clinical trials and evaluation of diagnostic platforms using corneal topography, wave front and OCT were used. Software solutions with AI support and machine learning were considered.

Results:

The latest ophthalmo-surgical techniques, including CLEAR, SMILE, SmartSight, SILK and LASIK-controlled technologies provide a high level of clinical efficacy, stable and predictable postoperative outcomes and reduced rehabilitation period as well as damage of the cornea. The use of AI and digital platforms allows to achieve significantly higher accuracy in the diagnosis of refractive disorders, customize surgical interventions and improve functional outcomes predictably.

Conclusion:

1. Innovative technologies in field of ophthalmic surgery confirms plays a central role in correction of refractive impairments through the introduction of next-generation, high-precision laser systems such as femtosecond and microkeratome technologies.
2. The evolution of surgical methods of refractive surgery, including LASIK, SMILE, SmartSight, SILK, and CLEAR demonstrates a clear tendency toward minimally invasive interventions and personalised plan of approach that enhance surgical accuracy, preserve corneal biomechanics, reduce complications, and expedite postoperative recovery.
3. The development and application of methods for customised corneal ablation profiles creation. such as wavefront-guided and topography-guided LASIK, upgrade the process of the correction of both higher- and lower-order visual aberrations, significantly improving the quality and predictability of visual outcomes.
4. The integration of artificial intelligence (AI) into laser vision correction dramatically enhances precision of the individualized ablation profiles, provides accurate real-time intraoperative guideline, as a result establishes a greater standard of precision and safety.
5. Innovations in refractive surgery not only contribute to improving the quality of medical ophthalmological care but also shape the strategic direction of high-tech medicine development with a wider range of applications and a more personalized approach to treatment.

3. Keywords

Refractive surgery, refractive errors, Small Incision Lenticular Extraction, Laser assisted in situ keratomileusis, Photoretractive keratotomy, Laser subepithelial kertomileusis, Keratorefractive Lenticular Extraction, Smartsight, Corneal Lenticule Extraction for Advanced Refractive Correction, Topography-guided LASIK, Wavefront-guided LASIK, OCT, laser vision correction, literature review, meta-analysis, myopia, astigmatism, higher-order aberrations, lower-order aberrations, ophthalmology, artificial intelligence, corneal ablation, personalised corneal ablation profile, femtosecond laser, microkeratome laser, innovations.

4. Introduction

Various forms of refractive errors of vision function widely persist in all populations around the world. According to medical literature and research, the prevalence of myopic refractive impairment has significantly increased over the past 30 years with a rise from 24% cases in the global population to 36%, as it was reported in the British Journal of Ophthalmology. Ophthalmological experts suggest that this visual disturbance pattern is expected to persist continuously, with estimates indicating by 2050, around 50% of people will be affected by myopia. (1)

The highest frequency of myopic cases is being observed across the countries in the South Asia region. Notably, in Japan, the myopic refractive impairment was observed in 86% of the population. (2)

Based on the information provided above, the leading aim of modern ophthalmology is the development of new innovative methods for the correction of anomalies of refraction.

All corrective methods for refractive errors are divided into two groups: non-surgical approaches and surgical approaches. The non-surgical techniques, including contact lenses and glasses, are simple and have high safety rate. Despite the significant advantages of simplicity, safety and, accessibility and affordability, these variants for correction of refractive impairments, there is a wide range of optical conditions, remarkably limiting the possibilities for treatment, such as myopic impairment of the higher degree (> -8.00 D), combined with astigmatism or anisometry; narrowed vision fields of patient’s eye. In addition to this, the patient’s satisfaction is lowered due to the persistent inconvenience caused by wearing glasses. Working in several professional specialties and sports and high risks of eye traumatization are the main factors contributing to the discomfort and impracticability of using eyeglasses.

The second non-surgical correction method of refractive eye errors is contact lenses. The modern form of contact lenses was introduced in 1960 when the Czech chemist Otto Vikterle was able to synthesize an elastic material called hydrogel. The development of soft contact lenses was a breakthrough moment in refractive treatment, as well as in common ophthalmological history. Because of convenience and high availability, this method rapidly became popular worldwide. However, this corrective investigation has certain disadvantages that could negatively influence the health of the eye, including corneal trauma by foreign body, contact lens-associated acute eye response, dry eye syndrome, neovascularisation of the cornea, several infectious-inflammatory conditions of the eye, including conjunctivitis, keratococonjunctivitis, keratitis, corneal infiltrates. (3). Different studies across the world explored the risks of complications due to contact lens wearing. Statistical research from the United Kingdom confirmed that the frequency of infectious keratitis associated with the use of daily contact lenses is 22-45 cases per 100000 individuals annually and 92-209 cases per 100000 due to wearing lenses during the night. (4).

Around 20% of lens users experienced allergic reactions due to wearing contact lenses and approximately 60% had ocular symptoms, such as ocular pain, photosensitivity and photophobia, itchiness, redness, excessive tearing, and evidence of corneal epithelium disruption. (5).

Today, in ophthalmological specialty, surgical investigation for correction of refractive impairments of the human eye become an increasingly prevalent approach, despite the extensive usage of non-surgical optical methods to manage visual disturbances. Modern ophthalmo-surgical techniques provide a high degree of safety, ensuring effective visual correction, minimised risks of potential complications, and overall enhancement of patient's quality of life by providing excellent vision acuity. (6)

The aim of my literature review is to represent the state-of-the-art innovations in field of refractive surgery, directed at improving precision of diagnostic, accuracy of surgical procedure, stability of post-operative outcomes in a long term, and convenience and satisfaction rates not only for patients but also for ophthalmological professionals.

4.1 Definition of refractive surgery

Refractive impairment is considered to be a huge part of the ophthalmological surgical field, presenting procedures that aimed at vision function correction. At the consequence of increasing number of clinical cases of vision impairments during the last several decades, the ophthalmological area has developed significantly into a specialized field with ongoing advancements in techniques and approaches.

Ophthalmo-surgical refractive correction dates back to 1953 when the Japanese ophthalmologist T. Sato proposed to perform corneal incisions on the epithelium of the cornea for myopic impairment treatment. The technique keratomileusis was created by the Spanish scientist J. Barraguer in 1964, which was the next step in refractive eye surgery. J. Barraguer also proposed a method for the removal of the corneal flap by using a microkeratome laser and subsequent treatment. This innovation became a basis for modern Laser-assisted in situ Keratomileusis. (7) Another success in the refractive surgery progression is related to the development of Rayev A.M. the excimer laser with a wavelength of 193 nm. This type of laser was introduced in 1976 for use in ophthalmo-surgical procedures. Researches Trokel S. and Srinivasan R. Studied the effect of excimer laser on the cornea in 1986. (8)

Since then, scientists and ophthalmologists around the world have continued to improve and modernize techniques of refractive error correction using an excimer laser, which has led to improved safety, effectiveness rates, and postoperative treatment results in the field of vision correction surgery.

Currently, two primary groups of surgical procedures are used to treat impairments of the eye's refraction: refractive corneal surgery and refractive intraocular lens surgery. The first group involves the application of the excimer laser to proceed with incisions and ablation of the corneal surface, including modern the LASIK and the, the SMILE, the PRK, the PTK and other innovative technologies that allow to proceed minimally invasive surgical interventions. Refractive lens surgery includes phakic intraocular lenses (PIOL) and pseudophakic refractive lens exchange (RLE). Both refractive surgery groups: corneal and intraocular surgical methods are verified and conform to standard requirements for safety, effectiveness rate, efficacy and predictability in achieving the desired vision acuity correction through changing eye’s structures.

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Location of surgical investigation	Type of procedure	Specific procedure	Refractive error treated
Inraocular	Phakic	Anterior chamber, iris fixated ans posterior chamber phakic intraocular lens	Myopia
	Pseudophakic	Refractive lens exchange (multifocal/accommodative, toric)	Myopia, hyperopia, astigmatism, presbyopia
Corneal	Incisional	Radial keratotomy	Myopia (historical)
		Astigmatic keratotomy • Arcuate keratotomy • Limbal relaxing incisions	Astigmatism
		Hexagonal keratotony	Hyperopia (historical)
	Excimer laser	Surface ablation • Photoretractive keratotomy (PRK) • Laser subepithelial kertomileusis (LASEK) • Epipolis LASIK (EpiLASIK)	Myopia, astigmatism and hyperopia (+6.00D- -14.00 D)
		Lamellar • Laser in situ keratomileusis (LASIK)	
		Lenticular • Keratorefractive Lenticular Extraction (KLEx)	
	Nonlaser lamellar	Epikeratophakia, epikeratoplasty Intrasomal corneal ring segments	Myopia, astigmatism and hyperopia (Historical)
		Intrasomal corneal ring segments	Myopia, keratoconus
	Collagen shrinkage	Conductive keratoplasty	Hyperopia, astigmatism

Table 1: Overview of refractive surgeries (9)

4.2. Refractive eye errors

The disorders affecting the eye's refractive function are called refractive errors and based on the eye's failure to collect and direct the light rays onto the retina, leading to altered eye function. Myopia (short-sightedness), hyperopia (long-sightedness), and astigmatism are recognized as the most prevalent refractive abnormalities globally. These conditions are measured using diopters (D) and can be categorised as axially symmetrical, astigmatic, or the most frequent mixed type.

Short-sightedness and long-sightedness are examples of axially symmetrical impairments. Myopia occurs due to the eye's elongated shape, causing the light waves to sample before the retinal layer, provoking, as a result, a blurred-distance vision. The prevalence of nearsightedness is growing continuously and has become frequent and widespread globally. According to the estimated research and global prevalence, the incidence of myopic error cases will increase from 28% (2.000.000 in 2010) to 50% (5 billion people) by 2050. (10)

Nearsightedness is classified on severity: mild myopia (-0.50 to -4.00 D), moderate (-4.00 to 8.00 D) and severe (> -8.00 D). According to these parameters, a suitable ophthalmo-surgical procedure could be selected to correct vision disturbances.

In hyperopia, also known as farsightedness, the key determinants are short axillar length, increased lens thickness, insufficient lens power, and flattened corneal curvature, which could be the reason for blurred vision because of light focusing behind the surface of the retina. Along with nearsightedness, farsightedness is divided into 3 stages: low hyperopia (< +2.00 D), moderate (+2.25 to +5.00 D) , and high (> +5.00 D).

Astigmatism is a type of refractive impairment resulting from irregular corneal or lens curvature shape, leading to unequal light rays refraction.

A meta-analysis revealed that the astigmatic abnormality is the most prevalent vision impairment, affecting 40% of individuals older than 18 years. (10)

This condition is determined by the alignment to the most potent power meridian and differentiated as regular astigmatic error (with the rule) and irregular astigmatic error (against the rule). The last be treated by using the cylindrical lens correction.

Nowadays, innovations in the ophthalmological surgical field are mostly focusing on correcting complicated astigmatic errors by using wavefront-guided technologies and artificial intelligence to create personalised corneal curvature or/and lens correction profiles.

In conjunction with this, refractive anomalies can be compounded under certain conditions by higher-order aberrations, including coma, spherical aberration, trefoil, trefoil, and secondary astigmatism. These aberrations affect negatively the acuity and quality of vision and worsen the quality of life.

5. Laser-assisted in situ keratomileusis (LASIK) and LASIK-modifications

5.1 Definition of the LASIK

LASIK (laser in situ keratomileusis) is a highly popular surgical technique in the ophthalmological specialty aimed at correcting refractive errors. This surgical technology is among the most commonly chosen types of laser eye correction procedures, owing to the faster recovery time after investigation, effectiveness rate in treating a great wide range of impairments of refractive function, safety, low risks of complications, unpredicted post-operative outcomes, and high patients' subjective satisfaction rates. The most common indications for LASIK are myopic refractive error of different degrees with or without accompanying astigmatic failure. The primary aim of LASIK surgery is to alter the corneal surface in order to improve its ability to cumulate beams of light directly onto the retinal layer and, consequently, improve vision function capacity and to minimise the dependence on corrective lenses. (11)

The term "keratomileusis in situ" means that the laser treatment is performed directly on the corneal surface without any tissue removal or transplantation, making the procedure minimally invasive. The surgical process includes two parts: the creation of a thin, hinged flap of the superficial corneal layer and the reshaping of of underlying corneal tissue by using a microkeratome or femtosecond laser. After elevating the flap, the excimer laser modifies the corneal curvature. The corneal flap approach affords the possibility of restoring the corneal structure after surgery without sutures.

5.2 Development of the LASIK innovation and differences from photoretractive keratotomy (PRK)

Before performance the keratomileusis in situ the photoretractive keratotomy (PRK) was first-based procedure successfully applied for myopic refractive abnormality correction by incising and removing the part of epithelial layer of the cornea and ablation Bowman's membrane and the anterior corneal stroma. Indications for PRK were the same as for LASIK: myopia and hyperopia of different degrees with or without astigmatic condition. However, due to keratotomy outcomes, including post-operative discomfort and prolonged recovery, LASIK enhanced technique was introduced as an alternative for treatment, providing faster recovery and effective results.

A major factor limiting PRK performances was the post-operative risk of corneal haze. Nevertheless, this concern has been significantly reduced by the introduction of 0.2% mitomycin C (MMC)—a chemotherapy DNA-cross-linking agent targeted at DNA-synthesis inhibition and apoptosis induction in myofibroblasts. To elevate the influence of mitomycin C during corneal ablation for nearsightedness, the met-analysis examined the post-operative outcomes after PRK with and without intraoperative injection of MCC. Results revealed a substantial decrease in haze after photoretractive keratotomy who underwent mitomycin treatment. (12)

Today, PRK is mainly used to treat axially symmetrical refraction abnormalities complicated by several conditions, such as irregular astigmatism, keratoconus, eye dryness, a decreased depth of the corneal tissue and predisposing factors of injury.

The key distinction of LASIK lies in creating a flap within corneal surface using a laser system. Usually, the width of the corneal incision extends below the Bowman membrane layer to the middle of the corneal stroma, where the thickness ranges from 130 nm to 160 nm. After completing flap-creation, this incised structure is lifted and laser reshapes the stromal curvature. Afterwards, the corneal flap structure is repositioned and stabilised through natural adhesion, facilitated by the dehydration process of the corneal fluid regulation system. In opposition the decline of vision acuity after LASIK can occur, similar to post-operative consequences of PRK, but it is less frequently observed. (13)

In myopic impairments of refraction , the main approach is to reshape the corneal optical center and flatten it, reducing optic power and achieving emmetropia (normal vision). For hyperopic conditions, it is essential to increase refractive power by flattering the paracentral curvature of the corneal surface.

5.3 Investigation approach

The initial preparatory stage of the keratomileusis in situ procedure includes the application of local drop anaesthesia, the operated eye’s eyelid fixation with eyelid speculum insertion, and the opposite eye cover with a sterile bandage is necessary for the prevention of any possible infectious contamination.

The beginning of the LASIK performance includes an incisional procedure to make a flap body within the corneal surface. Advanced refractive impairment correction methods could customize this process by using aberrometer or topography scan measures. Incision depth usually ranges from 100 to 120 μm and depends on laser features. (14)

The second stage of the LASIK investigation is to ablate the corneal layer with excimer laser. After carefully lifting and folding back the previously created flap, the laser reshapes and exposes the corneal tissue to correct impairment of the refraction. Several additional functions improve modern excimer laser machines. These enhancing innovations reduce risks of laser position shifting, improve the accuracy of the vision acuity corrections, and positively influence post-operative outcomes. For example, the tracking systems of movement of the operated eye help to align the laser with the eye's position throughout the surgical procedure. The other feature is cyclotorsion control, which prevents eye transposition in case the patient's position is shifting.

For myopia correction, the excimer laser flatters the anterior eye layer curvature by vaporising the central part of the cornea. In other cases of hyperopia, the peripheral corneal part is targeted to create a more spherical shape. (15)

The LASIK duration time ranges approximately one minute and depends on thickness, the volume of tissue that needs to be ablated, and the degree of refractive error.

The third part includes returning the flap structure to its previously position on the cornea and ensuring the finished adhesion within the managed area. By adjusting the edges with a spatula, the operator reaches the required alignment and promotes proper closure of corneal cut. As a result, it eliminates the requirements of the sutures on the corneal surface.

The final stage of the investigation contains the preventing inflammatory processes and reducing post-operative risks of infections, by using anti-inflammatory, as well as antibacterial ocular drops. At the end, the eyelid speculum is removed, and managed eye is bandaged. (16)

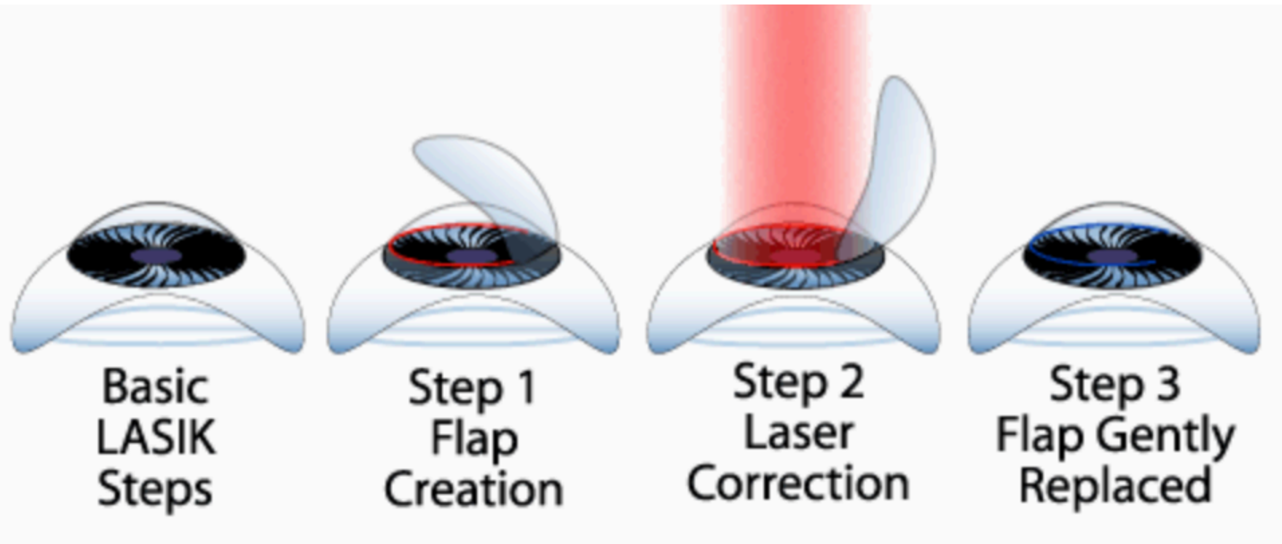

Image 1: Steps of the LASIK procedure (17)

5.4 Microkeratome and femtosecond laser

Two main laser-options of the LASIK application are used: microkeratome and femtosecond laser. The femtosecond laser, which is gaining popularity, offers a significant advantage in terms of safety. In 2018, approximately 53.1% of LASIK procedures worldwide were performed using femtosecond lasers, compared to 28.7% using blade-based microkeratomes (18). The crucial divergence between these two technologies is in how they create a corneal flap. The mechanical microkeratome forms a corneal flap through a single mechanical incision made by a blade. On the other hand, the femtosecond laser uses the microphotodisruption technique to expand and separate the stromal tissue by vaporizing the small intrastromal tissue area. This method ensures that the corneal flap is not separated from the stromal bed, significantly reducing the risk of a cut mistake.

In the case of microkeratome variation of the LASIK surgery, the usage of a mechanical device is applied. This device includes two parts: the first one is aimed at fixating the patient's eye by using the vacuum ring mechanism, and the second is for precise corneal cut and includes a disposable blade. As a consequence of this, it's possible to create a corneal flap of different suitable thicknesses, as the ophthalmological surgeon's treatment plan is predetermined. It is significant to point out that the vacuum ring for a patient's eye can cause an elevation of intraocular pressure up to 60 mm (19)

Despite the fact, that this condition is transient, it can lead to postoperative complications, including posterior vitreous detachment (PVD). Moreover the presence of preexisting retinal dystrophies could also lead to retinal detachment. Due to this possibility, preoperative retinal laser coagulation is strongly recommended for patients with such conditions to lower the risks of possible complications. (16)

In more advanced femtosecond laser-assisted surgical methods, the femtosecond-flap is created with more precise laser incision control in comparison to micro-keratome technique.

Several medical studies analyzed refractive results and long-term vision changes after 2 LASIK surgery. Dr. Jose Garcia-Gonzales presented a statistical evaluation of 3826 eyes of individuals in age over 40 after the nearsightedness correction (1,725 eyes underwent microkeratome LASIK and 2,101 underwent femtosecond LASIK treatment). During the results, analysis was confirmed that the effectiveness, as well as reliability rates of the femtosecond performance were higher in contrast to microkeratome technique outcomes. This conclusion could be explained by age-associated alterations of collagen fibrils in stromal tissue of the cornea and reduced lesion-repair mechanism. (20).

A faster recovery can be achieved by using a femtosecond method by compassion to microkeratome. It results in more precise flap creation and corneal incision. However, several confirming conclusions from multiple ophthalmological META analyses proved that both LASIK surgery methods provide high effectiveness, reliability, and consistency. (21)

5.5 Indications and contraindications for LASIK surgery

The success of the correction of refractive impairment is influenced by multiple factors, with the most significant aspects: patient's age, thickness of the corneal layer, and corneal parameters. For instance, the excimer laser that have received approval by the United States Food and Drug Administration (FDA) for LASIK procedures are capable of correction myopia up to -12.00 D, hyperopia up to +6.00 D and astigmatism up to 6.00 D simultaneously. (22)

Contraindications for LASIK surgery can be divided in several groups as absolute, comparative and further co-conditions categorised as general diseases or ocular-specific circumstances.

An absolute contraindications for keratomileusis in situ is keratoconus at any stage. Additionally, ocular conditions such as cataracts, glaucoma, dry eye syndrome could impose several limitations of the procedure's effectiveness. A critical surgical consideration is that the residual stromal thickness limit for corneal flap investigation must be no less than 300 microns. It's important to mention, that this limitation factor was defined during observation and still remains under the discussion. (23)

Comparative contraindications of LASIK are associated with previously ophthalmological conditions as herpetic keratitis, acute ocular infections, retinal dystrophies, and retinal detachment. These conditions may worsen post-operative outcomes. (24)

In case of general health conditions, decision of the LASIK procedure opportunity is based on the stage, progression and severity of underlying diseases. These include systemic lupus erythematous (SLE), rheumatoid arthritis (RA), acute bronchial asthma, diabetes mellitus type 1 and type 2, epilepsy, acquired immunodeficiency syndrome (AIDS), tendency of keloid scars' development, psychiatric disorders, substance abuse addictions. It's important to evaluate health condition properly to distinguish it as definitive or relative restriction.

In addition to this, pregnancy and lactation are also considered as contraindications for refractive errors laser correction. LASIK surgery is not recommended during pregnancy, lactation period and for 6 months postpartum minimum.

Age is critical determinant of the acceptance for LASIK performance. Patients under the age of 18 can't be imposed as candidates for keratomileusis procedure, due to the fact that their eyes may still be undergoing developmental changes and growth. In addition to this refractive stability is also a crucial factor for keratomileusis in situ. Eyes' conditions with progressive myopia are also excluded from LASIK treatment cases, as their refractive error continues to worsen over the time and could lead to post-operative progression of visual deterioration.

Certain professions and occupations with high-risks impose restrictions on laser vision correction that involve the corneal flap creations, such as LASIK or Femto-LASIK, due to the elevated risk of ocular trauma associated with these fields. Occupations such as aviation, military, security involve severe physical activity and potential direct eye injuries. In this situation, the choice for refractive error correction are flap-free surgical alternatives, such as SMILE or photoretractive keratectomy (PRK). (16)

5.6 Wavefront-guided and wavefront-optimised LASIK

The newest innovation course in LASIK surgery aims to prevent postoperative vision adverse effects and higher order aberrations caused by decreased eye sensitivity to contrast and light. Topography-guided LASIK and wavefront-guided LASIK are upgraded approaches that provide lower risk of aberrations after corneal ablation and corneal flap cutting comparing to standard LASIK. (25)

The aim of wavefront-guided LASIK is to generate the most suitable custom excimer laser ablation profile by measuring the curvature of the eye with wavefront aberrometer, when the topography-guided LASIK procedure is based on parameters from corneal topography. In compassion with retinoscopy the main advantage of aberrometer is detection of both lower and higher-order aberrations.

Today the wavefront-guided excimer laser ablation is being indispensable part of customised plans of vision impairment treatments. By using wavefront aberrometry, a precise map of defocus, astigmatism an high-order aberrations is generated. This data is integrated into the laser system refractive error to be treated. As a result, not only correction of sphere and cylinder could be possible, but reduction and induction of high-order aberrations as well. It reduces risks of vision quality degradations, particularly in low-light conditions.

To achieve required results in wavefront-customised LASIK surgery, the following technological components are essential for imaging wavefront-personalised ablation profile:

1. Wavefront-guided analysing aberrometry
2. Beam laser eye adjustment
3. Eye movement tracking
4. Effective wavefront-laser interface.

Several companies on the market provide wavefront-based refractive treatments' interfaces under proprietary names such as "CustomVue" and "CustomCornea".

Foundational technology in wave-front analyser utilises Tscherning's aberroscope and Hartmann-Schack sensors to measure wavefront deviations. A directed laser beam passes through a mask which contains a regular matrix of pin holes, generating parallel rays group. These rays produce a retinal spot pattern, that could be distorted by various degrees of eye's aberrations. This pattern can be projected onto the sensor system of a low-light CCD camera through indirect ophthalmoloscopy method. After individual model is analysed and compared with optimal corneal parameters and the optical aberrations are calculated by using Zernike polynomials. (26).

These conclusions are used to determine the necessary refractive corrections and future plan of corneal ablation. As it was mentioned, the primary object of this procedure is to correct spherocylindrical refractive errors and at the same time reduce underlying higher-order aberrations. The most significant benefits of wavefront-guided ablations could be showed on patients with preexisting higher-order aberrations, who often report enhanced night vision after refractive surgery compared to their experience with glasses or contact lenses. On the other hand some other factor are still remaining, that could provoke introduction of new aberrations or relapse of preexisting. It is also necessary to evaluate factors that could influence on the wavefront-analyse results, such as pharmacologically induced pupil dilation, laser ablation plan mismatches, limits of eye-tracking precisions. Moreover due to either microkeratome or femtosecond laser impact during the LASIK corneal ablation and flap creation, some biomechanical collagen fibres' structure and mechanisms of cornea are disrupted and could cause irregular modifications of the corneal curvature. As a result, in most cases the high-order aberrations can still remain on minor values after surgical procedure. (27)

Despite the fact that this refractive surgical method enhance the conventional treatment outcomes, it may not achieve the same level of post-operative vision function as a completely customised wavefront-guided LASIK surgery that take into consideration every individual ocular aberrations of the patient's eye.

The effectivity rate of wavefront-guided LASIK corneal ablation during the treatment of refractive impairments strongly depends on the adjusted parameters of the scanning laser, including size and diameter of the laser spot, shape of the operated ray and frequency of the laser flash. These adjustments significantly impact the results and accuracy of the corneal tissue removal and reshaping in treatment of both high and low-order aberration of the human eye.

The width and configuration of the laser spot are key determinants of the precisions the efficacy of the personalised laser ablation profile.

Some empirical researches of the small diameter constant intensity spot laser scanning have revealed that 2 mm uniform-intensity beam laser leads to reduced effectiveness of correction in cases of high and low-order refractive errors. (28)

This negative decline in post-operative consequences is linked to the impact of flat-top laser spot and the development of the sharp ablation boundaries and unexpected gradients, which may cause uneven tissue removal and increased risks of the optical aberrations' progression. Otherwise, 1 millimetre width spot that corresponds to the Gaussian laser beam parameters has been presented better outcomes due to the smoother and uniformer ablation results in corneal tissue layer. The Gaussian beam profile is a followed the Gaussian function laser bell-shaped spot with the highest intensity in the center and symmetrical intensity decrease towards the edges. It allows to keeps frequency of laser flash pulses stable. This investigation variant effectively completes all degrees of refractive aberrations by proving precise remodelling of corneal shape. Ophthalmological studies confirmed that the larger that 1 mm laser spot could lead to deficient correction of high-order optical aberrations and potential of the vision quality reduction. (29)

Apart from the size and shape of the laser sport, frequency of laser production influences the consequences of refractive surgery. This parameter affects both the correctness of the corneal ablation process, as well as the biochemical response of the tissue-corneal hydration. Overexposure of the excimer laser could lead to condition, called dehydration and as a consequence cause undesired refractive outcomes after surgical perfomance. The most of small-spot Gaussian profile lasers provide frequency 100-1000 Hz, based on balance between effective treatment and stability of corneal response.

During eye fixation for refractive ablation process, human's eye could proceed frequent random movements, approximately 5 times per second. This factor could destroy programmed wavefront-ablation profile. For lowering risks of mistakes during vision correction surgery, there is a surgical requirement to follow eye movement. Nowadays 2 variants of eye trackers are useful in refractive surgery: closed-loop (laser radar-based) tracking and open-loop (video-based) tracking. The first method captures several images of eye's position at set intervals and calculates changes to adjust laser accordingly. based on real-time optical screening of the eye's position and sending feedbacks to control system to adjust laser. The second approach is based on real-time optical screening of the eye's position and sending feedbacks to control system to adjust laser. This constant eye's movements checking provide ensures precise tracking and minimises latency during corneal reshaping. (30)

Other wavefront-method for excimer laser corneal ablation is called "wavefront-optimised laser profiles". This software includes pre-programmed corrections without a fully-customised wavefront ablation profile. The main goal is to address the most common complication after refractive surgery- induction of positive spherical aberrations that could cause reduction of sharpness of vision and glare especially in low-light conditions specifically in situation when patients' eye has it already. Wavefront-optimised treatments are designed to maintain the eye's preexisting spherical aberration levels while minimising the inductions new distortions. Rather than measuring individual eye's aberration and treating it by using personalised plan, the aim of wavefront-optimised approach is to keep natural shape of cornea in post-surgical period by adding an empirically determined correction plan for spherical aberration based on averages. Some these treatments could be called as "aspheric" or "Q-factor-adjusted" ablation and used to elevate vision function by improving the spherical corneal shape. The Q-factor is a measure unit of corneal sphericity. The normal value is around 0.25 in common population, indicating a slightly prolate shape. The goal of the treatment is to reach the optimal Q-factor value by changing corneal shape and, as a result, a better vision, regardless of the overall spherical aberrations and spherocylyndrical retraction. Some studies suggest that an ideal Q-factor value for improved cornea could be between 0.4 and -0.5. (31)

In 2019 in United States a randomised, controlled clinical research was conducted to compare post-operative visual outcomes of 100 patients after wavefront-guided LASIK performed on one eye and wavefront-optimised LASIK on the opposite eye. Results on the follow-up control after one year of surgical investigation revealed that eyes treated with wavefront-guided technique became more sensitive to contrast, showed greater degrees of supervision and markedly better improvement in corrected distance visual acuity in comparing to wavefront-optimised group. Furthermore, based on the findings observed at the postoperative follow-up in 12 months it can be concluded that wavefront-guided LASIK method results in refractive outcome closer to emmetropia, as it was confirmed by sphere and spherical measurements. Additionally, this approach can reduce evidence of trefoil aberration and provide the high level accuracy of the corneal ablation with using of high-definition aberrometry. However, both groups wavefront-guided LASIK as well as wavefront-optimised LASIK achieved safely the same excellent goal of uncorrected sharpness of vision. (32)

5.7 The topography-guided LASIK

The topography-guided LASIK is another keratomileusis in situ approach to recognise high-order aberrations and create personalised ablation profile plan. Also topography-guided LASIK procedure is aimed to prevent future refractive errors and to maintain the corneal surface structure in post-operative time period.

The main superiority of topography-guided method is the most suitable indication of different corneal irregularities, which are localised on anterior eye layer. This kind of condition appears often after ocular trauma, corneal scarring due to infection or contact lenses, previous laser ablations, corneal transplantation or other surgical interventions. In comparison to wavefront aberrometer, which measurements are bordered by the pupil width, topographic eye scanning provides fully-structured and detailed image of the entire corneal surface. After topographic scanning digitalisation, the customised corneal ablation profile is calculated by analysing radial parameters of the corneal curvature. (29)

In these days the most innovative topographic ablation profile customiser is presented by Alcon and called “Contoura Vision”. It creates several pictures of 20000 points of corneal surface and presents perfect post-operative visual outcomes. In 2016 U.S. Food and Drug Administration confirmed the effectiveness of the Contoura Vision topography-guided LASIK with 93% eyes with myopia achieved 20/20 and better vision results and 65% eyes astigmatic myopic refractive error reached eyes 20/16 and more visual acuity in 12 months after ophthalmological procedure. (33)

In 35 patients randomised research compared the visual outcomes of topography-guided versus wavefront-guided LASIK. Both keratomileusis in situ techniques provided high rate in the surgical outcomes predictability and post-operative visual function. After comparing clinical results of wavefront-guided and topography-guided LASIK was confirmed that despite the technological differences between the two types of LASIK performances, they both offer identical refractive visual outcomes with safety and efficiency in different optical parameters, such as residual spherical equivalent refractive error, uncorrected distance visual acuity (UDVA) and astigmatism. (34)

In 2024 retrospective research was held to compare post-operative visual outcomes of topography-guided LASIK and waterfront-optimised LASIK methods. A topography-guided LASIK procedure was performed with the Contoura Vision and combined with the Phorcides Analytic Software to accurately identification and characterisation of the all corneal surface abnormalities. This analytical technology is targeted to develop a customised corneal ablation strategy by using personalised topographical profile of the eye. The main observation was post-operative condition after Contoura Vision LASIK and wavefront-optimised LASIK intervention for myopia correction either or without astigmatic refractive error. Wavefront-optimised LASIK treatment plan was performed with the EX 500 laser. The study criteria required medical data of 3 months follow-up after corneal surgery, including measured parameters such as uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), and manifest refraction. Patients cases were excluded, if they had pre-operative corneal injuries that could worse surgical outcomes: severe dry eye, keratoconus, dystrophy of corneal tissue, corneal ectasia, as well as severe complications during operation and in post-operative time period.

In this retrospective study participated 227 eyes after topography-guided LASIK surgery and 121 eyes after wavefront-optimised. All these cases were satisfied the eligibility requirements. Despite the fact, that some notable differences in preoperative visual measurements were observed, there was no clinical significance.

Baseline factor	Contoura Vision with Phorcides Analytic Software LASIK M±m (Range)	Wavefront-optimised LASIK M±m (Range)	P-value
Eyes quantity	227	121	-
Patients' sex			
Female (n)	111 (49%)	74 (61%)	>0.05
Male (n)	116 (51%)	47 (38%)	>0.05
Age (years)	33.0±6.9 (20-54)	32.1±7.8 (19-54)	>0.05

Baseline factor	Contoura Vision with Phorcides Analytic Software LASIK M±m (Range)	Wavefront-optimised LASIK M±m (Range)	P-value
Corrected distance visual acuity, CDVA	-0.01±0.03	-0.02±0.04	0.03
Spherical refractive component (D)	-3.48±2.56 (-9.00 - 0.50)	-3,89±2,24 (-9.5 - 0.00)	0.04
Cylindrical refractive component (D)	-1.02±0.75 (-3.25 - 0.00)	-0.91±0.82 (-3.75 - 0.00)	0.04
Manifest refraction spherical equivalent, MRSE (D)	-3.96±2.58 (-9.88 - -0.50)	-4.35±2.33 (-10.38 - -0.63)	0.05

Table 2: Preoperative and Demographic Data (35)

After analysing 3 months follow-ups vision results, it was concluded, that 57% of eyes after Contoura Vision LASIK procedure achieved 20/16 or better vision acuity in comparison with 17% of the eyes from waterfront-optimised group, that became the same visual outcome. Other evidence was also found, that uncorrected distance visual acuity parameter became equal to or even better than preoperative corrected distance visual acuity after topography-assisted corneal ablation among 95% of Contoura Vision group cases as opposed to 81% from wavefront LASIK.

Post-operative outcome parameter	Contoura Vision with Phorcides Analytic Software LASIK M±m (Range)	Wavefront-optimised LASIK M±m (Range)	P-value
Uncorrected distance visual acuity, UDVA	-0.05±0.06	-0.01±0.06	<0.001

Post-operative outcome parameter	Contoura Vision with Phorcides Analytic Software LASIK M±m (Range)	Wavefront-optimised LASIK M±m (Range)	P-value
Corrected distance visual acuity, CDVA	-0.03±0.05	-0.04±0.05	>0.05
Spherical refractive component (D)	0.13±0.25 (-0.50 - 1.25)	0,03±0,28 (-0.75 - 1.00)	0.003
Cylindrical refractive component (D)	-0.26±0.25 (-1.00 - 0.00)	-0.27±0.27 (-1.25 - 0.00)	>0.05
Manifest refraction spherical equivalent, MRSE (D)	0.00±0.24 (-0.75 - 0.88)	-0.01±0.24 (-0.88 - 0.38)	0.002

Table 3: Postoperative outcomes of Contoura Vision topography-guided LASIK surgery (n=22) and wavefront-optimised LASIK surgery (n=121) (35)

To summarise, both keratomileusis in situ methods topography-guided and wavefront-optimised performed great outcomes after corneal refractive errors correction. However, due to greater rates in uncorrected distance visual acuity correction after Contoura Vision technique, it could highlight some advantages in this LASIK variant over wavefront-optimised implemented with EX 500 laser tool. (35)

6. The modern approaches of the keratorefractive lenticular extraction (KLEx)

6.1 Innovative approaches of the keratorefractive lenticular extraction

As a result of significant femtosecond-laser performances in LASIK, new innovative approaches in field laser refractive surgery were developed. In 2007 Femtosecond keratorefractive lenticule extraction (KLEx) was introduced, which forms corneal flap without ablation, reduce damaging impact on corneal tissue structure and consequently lowers risks of postoperative vision errors. After the presentation of VisuMax femtosecond laser, produced in Germany, Small Manual Incision Lenticule Extraction started to gain popularity worldwide. By the Food and Drug Administration (FDA) verification, the main indications for this refractive error correction method are: myopia -10.00 D and less with our without astigmatism no more that -5.00 The main goal during the SMILE surgical procedure is to sculpt a lens-shaped optical structure - lenticule inside the deeper layers of the cornea by using femtosecond laser and extract it within small corneal incision between 3 and 6 mm. This technique excludes the requirements of the creation of corneal flap, as it performed during laser-assisted keratomileusis in situ (LASIK), which reduces intraoperative in addition to postoperative undesired complications. Today several advanced methodologies of femtosecond keratorefractive lenticular extractions have been intoduced to enrich the spectrum of refractive impairment treatment and enhance post-operative outcomes of visual acuity. Besides the Small Incision Lenticular Extraction these innovations include: the Corneal Lenticule Extraction for Enhanced Refractive Correction (CLEAR), the SmartSight SCHWIND ATOS lenticular extraction, the Smooth Incision Lenticule Keratomileusis (SILK). These KLEx modifications are based on the surgical fundament of lenticular extraction, but with enhanced laser cutting technology, optimised operative investigations and elevated possibility to maintain corneal structure. (36)

6.2 Innovation advances of the SMILE method in comparison to the LASIK surgery

Due to the no-flap approach and minimally invasive characteristics of surgical investigation the Small Incision Lenticule Extraction has rapidly gained popularity for the myopic refractive impairment with or without astigmatism. Based on the finding of various ophthalmological researches was confirmed, that lenticular extraction offers better post-operative outcomes in comparison to the Laser-assisted in situ Keratomileusis.

The significant advantage of the Small Incision Lenticular Extraction is the protection of biochemical mechanism undergoing in the corneal stromal tissue. As apposed to Laser-assisted in situ Keratomileusis, which can impair the corneal structure and its stability due to the flap creation technique, the SMILE method features the preservation of the corneal structural integrity and reduces influence on the corneal nerves during procedure. (37)

These innovations in refractive surgery result in lowered post-operative complications, including incidences of dry eye syndrome. (38)

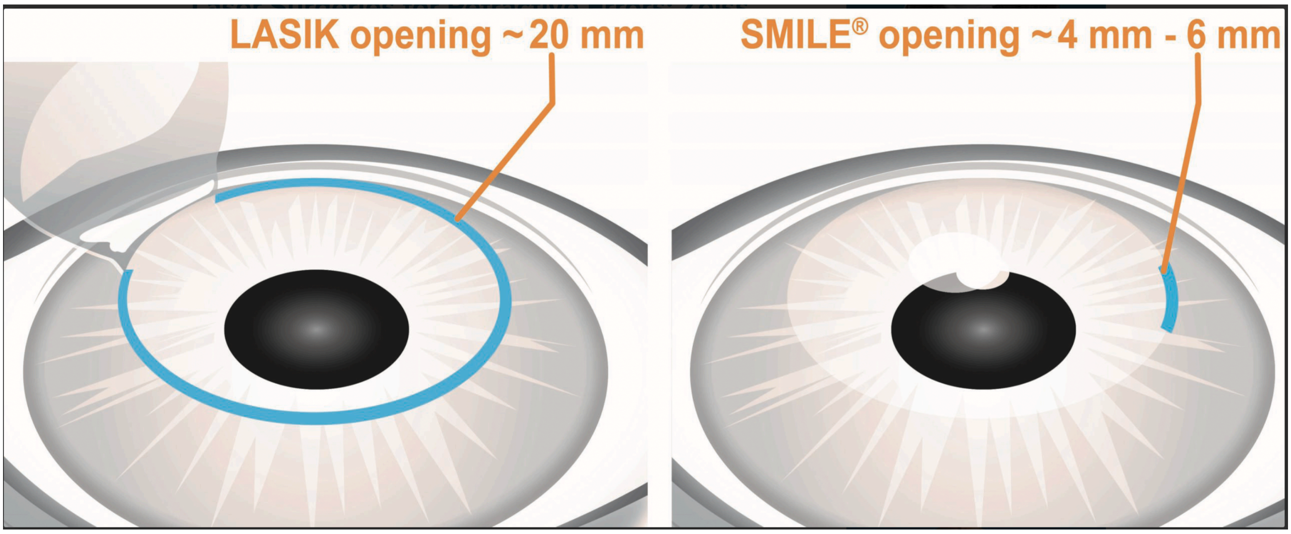

Image 2: Difference between corneal incision during the LASIK and the SMILE procedure (39)

In 2016 the ophthalmological surgical research was performed to compare clinical outcomes of vision functions between to groups of patients with moderate myopia (-4.00 to -8.00 D) and high myopia (more than -8.00 D). The first group of 38 patients underwent refractive error correction with Small Incision Lenticule Extraction (SMILE). It consisted of 76 eyes of 10 men and 28 women in age 18-36 years. The second group included 60 eyes of 30 individuals, 20 women and 10 men in their age between 19 and 30 years. These patients were treated with laser-assisted keratomileusis in situ (LASIK) procedure.

For assessment the effectiveness of both laser vision correction methods, all patients from both groups were evaluated before operation and after during follow-up after 24 hours, 1 and 3 months, according to all ophthalmological guidelines. The examination of corneal condition was performed by using topographic Pentacam scanner, which provides highly accurate detailed imaging of all corneal surface, anterior segment visualisation, corneal thickness measurements and corneal map in three-dimensional image. Other subjective evaluation results after questionnaires were also taken into account. The main task was to assess the quality of life after surgical procedure through 5-point scale This evaluation focused on various situations, including working at the computer, driving under low-light conditions, subjective perception of vision function at different distances.

In both groups before laser corneal correction the parameters of uncorrected distance visual acuity, corrected distance visual acuity, spherical and refractive components of refraction were comparable. The collected data were analysed using variance statistical methods to understand correlation between physical and subjective surgical outcomes, that helps to determine the effectiveness of LASIK and SMILE surgical methods.

Baseline factor	SMILE group M±m	LASIK group M±m
Uncorrected distance visual acuity (UDVA)	0.07±0.02	0.04±0.03
Corrected distance visual acuity (CDVA)	0.84±0.02	0.78±0.03
Spherical refractive component, D	-6.60±0.08	-6.40±0.27
Cylindrical refractive component, D	-0.70±0.06	-0.57±0.11

Table 4: Preoperative visual parameters of both group's eyes: SMILE and LASIK group (40)

On the next day after laser refractive error correction, patients from the first group after SMILE surgery revealed the significantly improvement (19%) in uncorrected distance visual acuity (UDVA) in comparison to LASIK group. This evidence could be explained by surgical technique of the lenticular extraction, which requires smaller corneal incision and damage than in keratomileusis in situ during the corneal flap creation. This method offers quicker post-operative recovery and reduces injuries of corneal surface. The data of monocular and binocular uncorrected distance visual acuity were collected after 1 day, 1 month and 3 months post-operative follow-ups. The difference between monocular and binocular results was statistically valuable.

Uncorrected distance visual acuity (UDVA)	SMILE group M±m	LASIK group M±m
1 day post-operative follow-up		
Monocular vision acuity	0.88±0.05	0.71±0.03
Binocular vision acuity	0.95±0.06	0.08±0.03
1 month post-operative follow-up		
Monocular vision acuity	0.94±0.07	0.82±0.02
Binocular vision acuity	0.96±0.09	0.92±0.04
3 month post-operative follow-up		
Monocular vision acuity	0.97±0.03	0.89±0.04
Binocular vision acuity	1.13±0.02	0.97±0.02

Table 5: Visual parameters results at postoperative follow-ups on the 1st day, on 1st and 3rd month after surgery of both group's eyes: SMILE and LASIK group (40)

Concerning the subjective outcomes in both groups after SMILE and LASIK surgical methods for laser correction of vision function, patients' evaluation from the first group reported a markedly high level of satisfaction with quality of vision compared to results from LASIK group. The possible reason of increased contentment after lenticular extraction is a surgical technique with no need of corneal flap creation. It allows to achieve faster post-operative recovery time, lower risks of vision impairment and development of high order aberrations, that could be seen more frequently after LASIK performance. These unexpected optic outcomes could lead to incidence of glare and halos.

Subjective evaluation outcomes	SMILE group M±m	LASIK group M±m
Points on a 5-point scale (n)	4.90±0.10	4.10±0.10

Table 6: Results of questionnaire of patient’s satisfaction rate with visual acuity and postoperative outcomes of both group’s eyes: SMILE and LASIK group (40)

It is important to mention, that in both groups during follow-up period no major post-operative complications that could lead to vision impairment were observed.

During follow-ups optical coherence tomography (OCT) was also performed for all patients from both group. Comprehensive comparing imaging outcomes after SMILE and LASIK surgery revealed that femtosecond laser, which was used in lenticular extraction, produced more structurally consistent and uniform corneal surface. Due to the fact, that SMILE technique performs more precise cut, it minimises post-operative irregularities in corneal structure, providing easier healing and more predictable vision outcomes.

Today femtosecond laser also could be used during LASIK procedure. However, the greater part of SMILE advantages are based on lenticule extraction technique, which makes procedure minimal invasive and preserves corneal structure.

On the other hand, LASIK is still excellent reliable option for refractive errors treatment, which allows to correct severe degree of myopia. Several studies were perform in past 10, confirming the effectiveness of keratomileusis in situ for high myopic error correction. In 2020 post-operative LASIK outcomes of 114 eyes were analysed. These patients had myopia of severe dergee (-10.00 D - 13.50D) and myopia with astigmatism. Results after 2 year post-operative follow-up were sampled and compared. LASIK technique provided excellent visual outcomes and a subjective enhancement among the patients. 72% of eyes achieved ±0.50 D of the targeted visual correction, 84% within ±0.75 D and 94% of patients ±1.00D. The study verified the efficacy of LASIK method in case of high myopia. 80% of operated eyes achieved binocular uncorrected distance visual acuity 20/20. (40)

The high degree myopia is still remaining a limiting factor for SMILE performance. In case of severe myopic refractive errors, complicated astigmatism and high-order aberrations the LASIK surgery with wavefront-guided technology continues to be the choice for treatment correction. (41)

6.3 The SMILE Femtosecond laser application

The SMILE surgery method is based on effect of femtosecond laser, high-focused pulses of which target specific area of the corneal stroma and ionise molecules there with high light energy. Because of this influence, atomic bonds in these place are starting to break and free ions, as well as positively charged ions are being expanded. This formation is called photo-disruption and it initiates the release of thermal energy and forces the separation of corneal layers' tissue. This space within stroma between layers is becoming filled with the gas-filled bubble, what is called the lenticule creation. (42)

The key aspects of the efficiency of the femtosecond laser application are duration and energy of the laser pulse. New innovative SMILE machines offer the opportunity of highly-precise laser application with low energy and high rate of the laser pulses. This femtosecond usage prevents post-operative complicated outcomes, including inflammation of the cornea, formation of the lenticular body, elevated photosensitivity, corneal tissue distraction due to photo-disruption process. Because of small diameter of laser rays the energy, required for cuts of the corneal surface, is minimising. It helps to create more accurate corneal incision with wide range of customised parameters as special shape or unordinary depth. (43)

These corneal incision plan are also influenced by optical parameter, called numeric aperture. Numeric aperture shows the capacity of eye lens for collection and focusing light rays. The higher aperture lenses have ability to focus light ray in more concentrated spot, comparing to lower aperture eyes. This circumstance allows to achieve more correct separation of corneal layers and to decrease unexpected tissue injury, while laser energy is concentrated in smaller dot diameters. The lenticular body corresponds to the Munnerlyn formula, which calculates the depth of the corneal ablation for refractive error correction. (44)

After the complete development of intrastromal lenticule the next step is to create small incision (<6 mm) and to extract carefully the lenticular body. This method reduce the need of corneal flap performance and, as a consequence, intra-operative and post-operative complications. The depth of femtosecond laser injection must be adjusted for every eye.

6.4 Investigation approach

The key objective of the Small Incision Lenticule extraction is the creation and the removal of lenticular body. In preoperative period the investigation plan is being customised by analysing the imaging scanning of the corneal surface, measuring thickness and refractive error degree and adjusting femtosecond laser parameters. After applying local anaesthesia, positioning the operated eye either lid speculum and covering the opposite with bandage, the surgical process can be started.

The surgical performance could be divided into three parts: laser phase and lenticule development , microscopic phase with lenticular separation and surgical extraction of lenticular body. (43)

At the beginning of the first laser stage, it is necessary to centralise the eye accurate and to fixate it. For the better performance of the upcoming corneal ablation, patient is being asked to focus on flashing light to align the center of the cornea. After precise fixation the docking system connects ablation area of eye's cornea and laser lens and keeps eye fixated by using vacuum. The innovative docking systems provide opportunity to stabilise eye of different parameter by choosing sizes of laser lens. After ocular placement, the femtosecond laser with adjusted rate and pulse energy creates highly-controlled incisions on the corneal surface. The performance of femtosecond laser VisuMax is programmed before surgical procedure and cut parameters depends on eye's measurements, corneal thickness, shape and condition. Laser pulse creates through photoablation incisions the lower cut within the corneal stroma, side lenticular margins, superior cup and 2 small incisions for future extraction of the lenticule. During the lenticular creation, gas-filled bubbles are forming within stromal tissue. Within bubble 2 circle are noticeable and help to define lenticular margins.

After lenticular formation the lenticular body is being separated upper and lower surface of lenticule from the surrounding corneal tissue with spatula or dissector. The last stage includes the lenticule extraction by using microsurgical tweezer. Surgeon uses the marginal corneal incision to enter the cavity with and removes the lenticular layer through microscope-controlled circular movements. (42)

Various techniques are used for the dissection and extraction of lenticular layer, which could be problematic. The more innovative separation method, called lenticuloschisis allows to peel away the lenticular body from the stroma and exclude need of surgical dissection. As a consequence of reducing surgical investigation approach and minimising corneal structure disruption, better surgical vision outcomes could be seen after surgery, as well as faster recovery period. It also lowers risks of high-order aberrations' development. (45)

6.5 Indications and contraindications of the SMILE procedure

The Food and Drug Administration (FDA) in the United States concluded the refractive errors' range, that could be corrected through Small Incision Lenticule Extraction procedure. The main indications for SMILE surgery in the USA are: myopic condition of mild and moderate severity (from -1.00 D to -8.00 D) not or complicated astigmatism (< -0.50 D). The age of the patient must be more, than 22 years. (46)

It is essential to bring up, that European Ophthalmological Communities established a wider range of indicative refractive conditions, suitable for SMILE surgical method. In comparison to the United States, in Europe mild, moderate and severe myopia (from -1.00 D to -12.00 D) among the patients older than 18 years, are subjects to lenticular extraction. Moreover, the myopic astigmatic condition up to -5.00 D could be also treated with SMILE technique in European Union. The other corneal parameters, that suitable for SMILE procedure were concluded practically and include mesopic pupil size, thickness of the corneal central optical zone, time of no changes of refractive error degree, width of the residual stromal bed.

Optical parameters	Values
Patient's age	>18 years
Residual stromal bed	>250 nm
Central corneal thickness	>475 nm
Stability of refractive error's degree	>1 year
Myopic refractive error	-0.50 D - -12.00 D With astigmatic error <-5.00D

Table 7: Indications for SMILE procedure (47)

As it was discussed in LASIK indications and contraindications chapter, there are contraindications, that are divided in 2 groups: absolute and relative, according to the influence on the general health condition. According to the updated guidelines for refractive error surgical treatment, the absolute contraindications for SMILE procedure are: uncontrolled glaucoma, uncontrolled uveitis, thickness of the corneal surface, cataract with corrected distance visual acuity <6/6, keratoconus, pregnancy, lactation, dry eye of the severe degree, allergic reaction, corneal injury, active inflammative/ infectious process.

Other general health conditions, such as diabetes mellitus, autoimmune disorders, immunodeficiency, herpetic keratitis, dry eye of the mild degree, irregular astigmatism, epithelial basement membrane dystrophy, age less than 18 years belong to relative contraindications and should be clarified according to severity, stage, progression to exclude or include individuals into SMILE surgery candidates' group. (47)

6.6 The SmartSight as the SMILE enhancement

Since the Small Incision Lenticule Extraction became highly used ophthalmo-surgical procedure for refractive error correction worldwide, new innovative approaches in this field were introduced to broad the possibilities of lenticular extraction performance.

As it was mention, the main limiting factor of the SMILE method was the central corneal thickness. This parameter is required to be no less than 475 nm. (47) However, this aspect was eliminated after development the new improved the SCHWIND ATOS excimer laser systems, that operate on the SmartSight surgical technique. (48)

The SmartSight technology represents an impressive progression of lenticular extraction investigation and enhances the accuracy and safety of laser vision correction, predictability and stability of post-operative outcomes, what influence on patients' satisfaction and quality of life. New machines for SmartSight surgical variant, designed in Germany and called the SCHWIND, include upgraded laser scanning, precise control of eye's movement, extended laser adjustment parameters, incorporated in treatment profile gradual transition zone. (49)

The last one is used to reduce sharp change between treated and untreated corneal areas. This abrupt transition could cause corneal structure instability and, eventually, regressive optical outcomes, commonly appearing after refractive surgery. This technology of progressive transition zone strives for maximal uninterrupted shift, which keeps cornea structurally stable, reduces undesired post-operative refractive complications (high order aberration progression). (50)

The transition zone improvement could broader indication parameters of corneal thickness for effective lenticular extraction.

Another innovative feature of ATOS laser machine is the prioritising the central optical area by using centrifugal scanning pattern and treating the central zone first. The key advantages of this method is reduction of ablation failures during the procedure and higher cut accuracy in the most important for vision part of the corneal surface.

For astigmatism treatment during SmartSight procedure fully-controlled cyclotorsion compensation is applied, used for detection and modification eye's rotation in real time, which helping to minimise post-operative risks of irregular or residual astigmatism, halos and glare. (51)

The SCHWAND diagnostic device provides the highly precise tracking of movements and recognition of pupil position. In addition to this, the SmartSight technique protects from lenticular decentration by creating the corneal thickening from the center to the periphery. Confirmation of the the proper alignment of the visual astigmatic axis elevates the predictability of the achievements after vision correction.

In contrast to laser characteristics of traditional SMILE method, ATOS femtosecond laser provides new technological modifications of corneal ablation. In SmartSight technique the frequency of laser pulses is high, but energy is low (usually 80 nJ). This energy are focused on plasma-mediated process, which is less damaging than conventional photo-disruption effect of femtosecond laser application. As a result, laser impact on corneal surface is minimised, that can prevent unexpected post-operative complications and help to achieve desired goals after refractive impairment correction. (52) This factor also utilises limits of corneal width parameters.

The retrospective, observational study was performed in Nepal to compare the first day post-operative outcomes after low-energy asymmetric spacing Schwind ATOS laser (energy range: 80-115 nJ) and high-energy symmetric spacing laser Schwind ATOS (energy range: 110-120 nJ) refractive treatment of myopia with and without astigmatism. 224 eyes of individuals in average age 28 years (18-40 years) with stable refractive error parameters undertook SmartSight lenticular extraction. The first group consisted of 112 eyes of 33 male and 23 female patients with the average range of preoperative spherical equivalent: -1.63D - -9.88D. The average range of preoperative astigmatic error of the first group patients was between 0.00D and 4.00D. The second group with 112 eyes of 30 males and 26 females had average ranges of preoperative spherical equivalent: from -1.25D to -12.75D and preoperative astigmatism: 0.00D-5.25D. P-values for these optical parameters were 0.1 and 0.2 retrospectively. The range of preoperative corrected distance visual acuity (preop CDVA) was -0.10 to +0.20 logMar of the first group patients and 0.00 to 0.00 of the second with p-Value (preop CDVA) 0.40.

The laser energy difference of the first group lenticular extraction with asymmetric pulse distance and the second with symmetric conventional spacing was 25±1 nJ (p-Value <0.0001). In addition to this, during low-energy asymmetrical spacing SmartSight procedure the spot distance was increased, while the track distance was reduced in comparison to the high-energy symmetrical spacing lenticular extraction with 0.70±0.10 nm (p-Value<0.0001) and 0.80±0.10 nm (p-value<0.0001) retrospectively. Due to these laser parameter changes, the incision length of the corneal surface was lowered to 0.50±0.10 mm in the first group (p-Value <0.0001). These aspects provide opportunity for lenticular extraction improvement and saving the corneal structure unmodified as much as it possible.

The uncorrected distance visual acuity was measured on the first day after the SmartSight performance it two groups. Summarily, 89% of all patients' eyes from both group achieved 20/20 after small incision lenticule extraction and 14% of eyes 20/16 of the uncorrected distance visual acuity and better. Comparing the uncorrected distance visual acuity (UDVA) of the first and second group results, in the first group 27% of eyes reached 20/16 UDVA, while only 1% of the second patients' group attained this post-operative visual acuity level. The result 20/20 of the uncorrected distance visual acuity was achieved by 92% of eyes in group 1 and 86% of eyes in group 2.

On the 1 day after the surgical procedures was confirmed that 96% of the eyes of the all participants reached their preoperative corrected visual acuity, including 72% eyes from the fisrt group and 85% from the another. A notable difference of the postoperative uncorrected distance visual acuity and preoperative corrected distance visual acuity is seen in group 1, in which 21% of the eyes gained the improvement at least one Snellen line, in contrast to group 2 with only 1%.

The decline of visual acuity in post-operative period was also noticed with 3% of the patients' eyes in the first group and 9% in the second, losing one Snellen line.

Accordingly to these SmartSight post-operative outcomes, completed in 2 variants of laser parameters, it is possible to conclude, that both group achieved rapidly excellent vision function results, confirming the efficacy level of SCHWAND ATOS technique. However, the low-energy asymmetrical spacing method shows slightly better effects, by performing smoother corneal incision and more precise lenticular extraction. As a consequence, the cornea stabilises faster, avoiding development unpredictable structural degradation during post-operative period. After laser-assisted Lenticule extraction. This study verifies the advantages of the SmartSight SCHWIND ATOS surgical approach over conventional SMILE technique, providing high performance of safety, effectiveness, efficacy and patients' satisfaction after procedure. (53)

6.7 The SILK: Smooth Incision Lenticular Keratomileusis

The American development company Johnson&Johnson produced new femtosecond-laser system, called the ELITA and aimed to proceed the completely new innovative technique in field of ophthalmological surgery the Smooth Incision Keratomileusis (SILK). This surgical device combines the greatest advantages from both well-established refractive errors' correction methods: the Laser-assisted in situ Keratomileusis and the Small Incision Lenticular Extraction. The key goal of the SILK is to achieve superior post-operative results of the vision acuity and to preserve corneal structure and its biomechanical processes. The Smooth Incision Lenticular Keratomileusis uses the low-energy femtosecond laser technology for the highly-precise lenticular creation, minimisation of the corneal tissue damage and promotion of the safety rate. Other modernised laser reformations, produced during the Smooth Incision Lenticular Keratomileusis, include the shorter pulse duration, the higher pulse frequency and the upgraded laser scanning technology, performing minimal spot-to-spot separation within 1 nm to elevate the precision rate during lenticular creation and minimise corneal tissue disruption. The SILK femtosecond laser delivers a great number of laser pulses in the short period of time and promotes highly-effective cutting of corneal tissue and accurate lenticular creation. In addition to this, The ELITA laser system provides uninterrupted laser cut pattern for smoother corneal incision, as well as modern sub-micron precision for highly-controlled cutting trajectory. This features enhance the lenticular extraction, maintain corneal structure and corneal stability and reduce undesired post-operative complications, that could cause blurred vision, making this platform one of the most advanced refractive surgery techniques. (54)

The main distinguishing characteristic of the Smooth Incision Lenticular Keratomileusis is the creation of the lenticular body in new, firstly-introduced biconvex shape. As a conventional lenticular incision form, biconvex lenticule follows the Munnerlyn formula, providing the same amount of the corneal tissue, that is needed for removing to correct eye's refractive impairment. The main difference is the that new biconvex incision begins in a deeper depth within cornea, where the concentration of the corneal fibrils and corneal nerves is lower. (55) It results in reduced formation of the opaque bubble layer and accelerated regeneration. New biconvex shape provides the great variety of optical benefits, such as complete symmetry of anterior and posterior surfaces after lenticular extraction. This structural adjustment reduces Bowman's membrane formation within corneal tissue, which can lead to post-operative vision disturbances and reduced contrast sensitivity. (54)

Lenticular formation	SMILE	SILK
Lenticule incision shape	 Plano-convex	 Biconvex
Laser pulse energy	± 125 nJ	± 45 nJ
Laser scanning technology	Standard galvo scanning	Digital encoder guided scanning with submicron accuracy
Laser scanning pattern	Discrete spots with 3-4.5 nm distance	Contiguous spots within 1 nm center-to-center distance
Postoperative recovery	< than after the LASIK procedure	< than after the SMILE procedure
High-order aberration induction rate	Low	Very low

Table 8: Comparison the SMILE and SILK lenticular creation technology (56)

The regeneration of intracorneal nerve fibres is an critical component of the healing process after refractive impairment correction. The severity of fibril structure disruption, as well as the sub-basal nerve regeneration success depends on the chosen ophthalmo-surgical method.

By comparing the Small Incision Lenticule Extraction to the Laser-assisted in situ Keratomileusis, the SMILE procedure is associated with reduced nerve plexus damage due to minimal invasive no-flap surgical technique and smaller corneal incision requirements. (57)

Owing to modernised biconvex incision shape during the Smooth Incision Lenticule Keratomileusis the number of disrupted nerve fibrils is significantly reduced. The ELITA laser platform creates a larger residual cap thickness especially among the peripheral part of the lenticular body in contrast to other methods, involving lenticular establishments.

The clinical study was conducted in India to compare the process and its consequences of corneal nerve structure recovery after the SILK and the LASIK refractive surgeries. During the post-operative follow up at 1, 3 and 6 months after procedures, the imaging evaluations with in vivo confocal microscopy were performed. After results analysing it was confirmed: in eyes, that underwent the SILK operation, the first signs of nerve regeneration has appeared during the first month after the surgical investigation and continued progressively through all follow-up periods. By the 6-months post-operative follow-up after the ELITA laser vision correction the regeneration of the sub-basal nerve plexus was almost completed. In contrast to the eyes' results after the LASIK procedure, the degree of the nerve healing process was significantly higher among the SILK-treated corneas.

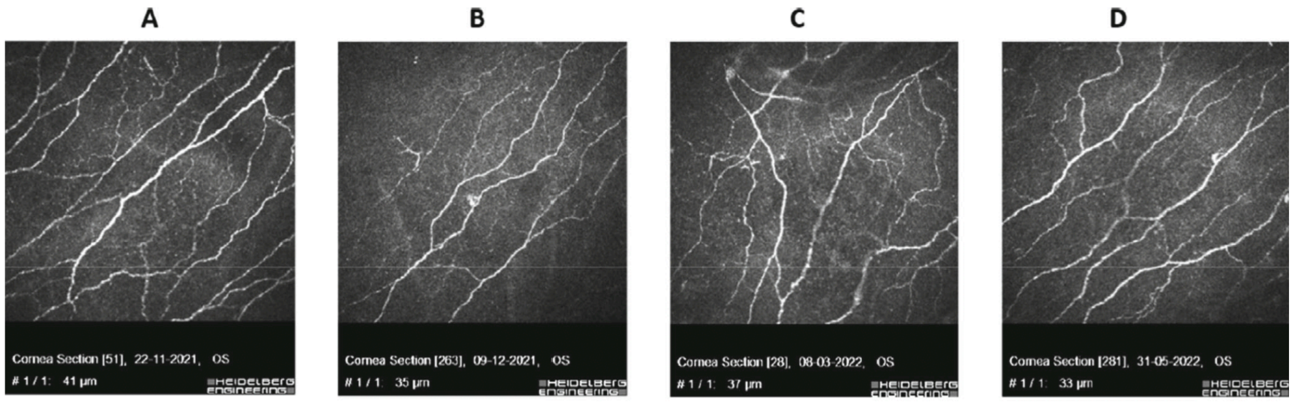

Image 3: In vivo confocal microscopic corneal nerve plexus imaging after the SILK procedure. Image A: preoperative sub-basal nerve plexus imaging. Image B: sub-basal nerve plexus imaging during 1-month post-operative follow-up. Image C: sub-basal nerve plexus imaging during 3-months post-operative follow-up. Image D: sub-basal nerve plexus imaging during 6-months post-operative follow-up. (58)

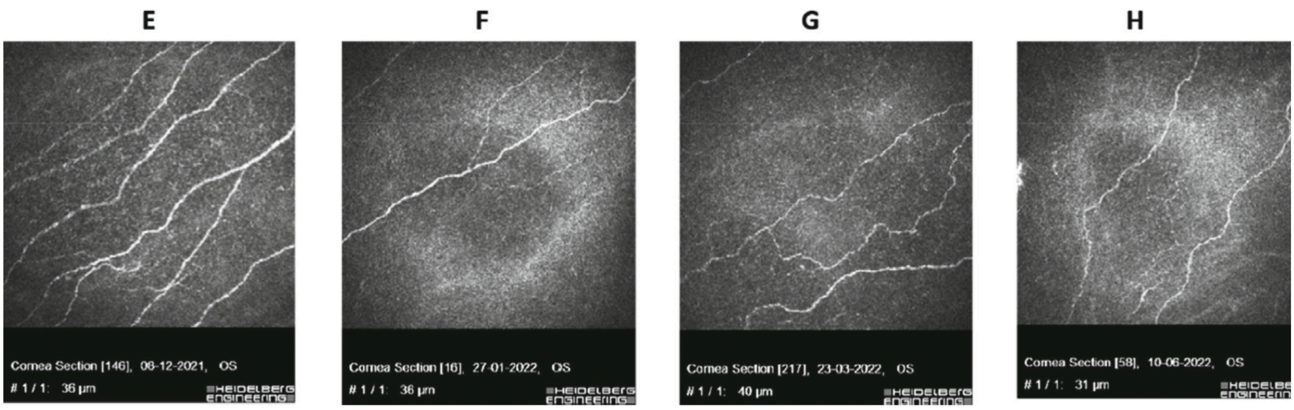

Image 4: In vivo confocal microscopic corneal nerve plexus imaging after the LASIK procedure. Image E: preoperative sub-basal nerve plexus imaging. Image F: sub-basal nerve plexus imaging during 1-month post-operative follow-up. Image G: sub-basal nerve plexus imaging during 3-months post-operative follow-up. Image H: sub-basal nerve plexus imaging during 6-months post-operative follow-up. (58)

The importance of the effective regeneration of corneal nerves is one of the major aspect of the post-operative healing process and the condition of the ocular surface. The promoting factor of one of the most common post-surgical complications, including dry eye syndrome, inflammation and discomfort feeling, is corneal nerve destruction.

In conclusion, this study can confirm advantages of the Smooth Incision Lenticule Keratomileusis in the nerve recovery maintenance and the corneal healing improvement in comparison to the Laser-assisted in situ Keratomileusis. (58)

6.8 The CLEAR: Corneal Lenticule Extraction for Advanced Refractive Correction

The CLEAR technology is based on the performance of the Ziemer FEMTO Z8 laser system, produced in Switzerland. This machine implies the low-energy overlapped femtosecond laser pulses (below 50 nJ) with elevated pulse frequency rate to promote plasma-mediated ablation process. The main innovation of the CLEAR method is decreased production of gas-filled bubbles into corneal tissue during the lenticular creation, resulting in reduced damaging impact on the cornea. Another advantage of FEMTO Z8 laser adjustments is the prevention of epithelial uncut bridges development during lenticule formation and corneal tissue separation by producing overlapped laser pulses. In addition to this, this method of femtosecond-laser vision correction requires a minor corneal incision (1.5mm) while during the SMILE procedure, the incision is approximately 2.5 mm. (59)

The lenticular extraction technique requires superior surgical skill compared to the LASIK method. Ophthalmo-surgeons should be able to accurately identify the shape and margins of the lenticular body and the proper placement of surgical instruments. The CLEAR procedure is beneficial in this question due to the specific configuration of the corneal cut, looking like a “keyhole”. This variant allows the formation of two small guiding tunnels, that help to guide surgical instruments above and under the lenticule. The diameter of the tunnel can be adjusted under 1,5 mm. This surgical approach reduces the development of the bubble layer during the lenticular creation, while gas can be extracted through tunnels. (60)

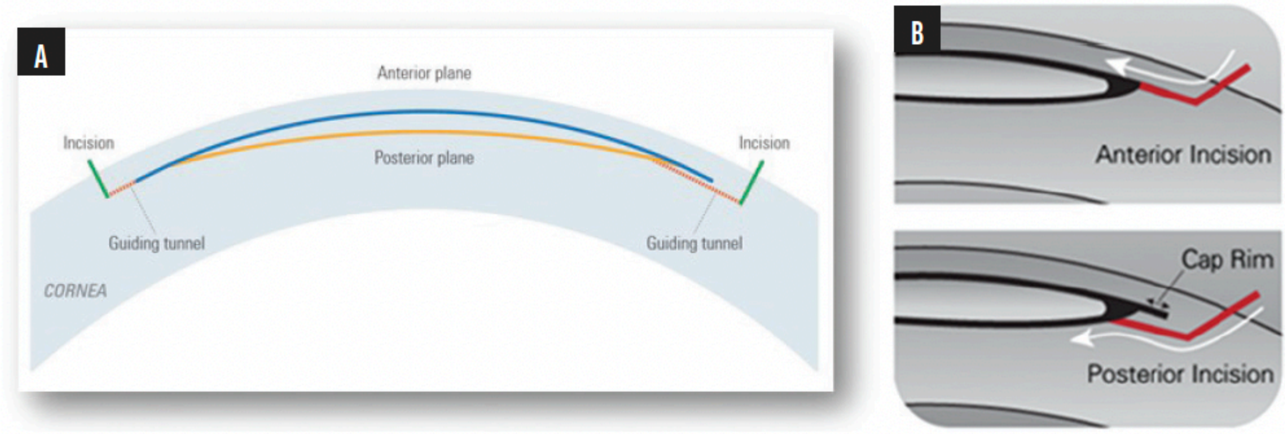

Image 5: Guiding tunnels scheme on the anterior and posterior lenticular surfaces A and B. (61)

Ocular outcomes after this technique are beneficial, because of reduction the number of manipulations within the corneal stroma, which minimises risks of inflammation, ruptures and improves postoperative results, enhanced restoration of visual function, faster optical nerve regeneration and corneal stability in a long-term. By applying minimised mechanical effect and inducing minor biomechanical stress on the corneal stroma, the anatomical and structural constitution of the cornea are preserved. This process avoids risks of post-operative complications, including inflammation, eye's dryness, ocular irritation and patients' discomfort.

The enhanced docking system in the Ziemer FEMTO Z8 laser system, with adapting imaging technology, that allows to modify cyclotorsion during the surgical procedure. The system recognises before surgery the main eye's features, including positioning of pupil and corneal marking, and aligns with patient's visual axis. It offers the ability to reposition and correct the eye rotation even after performing the corneal cut, improving, as a consequence, the treatment accuracy.

Furthermore, the Ziemer FEMTO Z8 laser system is integrated with real-time optical coherence tomography (OCT) performance. This feature remarkably improves the visualisation of the anterior eye segment, which enables the evaluation of the corneal condition during the CLEAR procedure faster and precise. Moreover the OCT system provides an opportunity to detect foreign body, corneal injuries and further abnormalities during the preoperative period, resulting to advance postoperative outcome and customise treatment process correctly. (62)

7. Conclusion

1. The analysis of innovative directions in refractive surgery confirms its key role in transforming modern approaches to ophthalmo-surgical treatment.
The development of new-generation high-precision laser systems, including femtosecond and microkeratome, can significantly increase the accuracy and safety of surgical interventions, minimize corneal tissue trauma, reduce the duration of operation and post-operative rehabilitation, and guarantee better outcomes.
2. Modern refractive surgery methods aimed at correction vision abnormalities have acquired special importance in developing laser technologies. Among the most significant is LASIK (Laser-Assisted in Situ Keratomileusis), which is recognized as the "gold standard" in refractive surgery and is based on creating a corneal flap with subsequent excimer ablation. The less invasive SMILE (Small Incision Lenticule Extraction) method eliminates the need for flap formation, reducing the risk of complications and accelerating recovery. More advanced technologies such as SmartSight and SILK (Smooth Incision Lenticule Keratomileusis) use advanced femtosecond lasers to accurately remove lenticule, ensuring minimal intervention and increased biomechanical stability of the cornea. CLEAR (Corneal Lenticule Extraction for Advanced Refractive correction) further develops these approaches, providing wide possibilities for customized correction at the expense of high accuracy and safety of action.
3. Personalized methods such as wavefront-guided LASIK and topography-guided LASIK are also valuable. Wavefront-guided correction allows to consider the optical aberrations of the entire optical system of the eye, including higher orders, which is especially important for patients with special visual requirements. Topography-guided LASIK is based on a detailed corneal map and is effective when the cornea is irregular in shape or with micro-defects. These technologies significantly increase the accuracy of ablation and allow us to achieve the highest-quality visual result.
4. The expectations for the development of laser ophthalmo-surgery are directly related to the introduction of artificial intelligence. Modern algorithms are already being used to create personalized ablation models, predict clinical outcomes, and automate surgical planning. Integrating AI with intraoperative visualization and robotic laser systems paves the way for a new generation of precision, safe, and personalized surgery.
5. In summary, innovations in refractive surgery not only contribute to improving the quality of medical ophthalmological care but also shape the strategic direction of high-tech medicine

development. Given the rapid advances in science and technology, it is safe to say that laser systems will continue to improve, with a wider range of applications and a more personalized approach to treatment.

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