A REVIEW ON THE LASIK LASER EYE SURGERY MEDICAL DEVICES

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ABSTRACT

There are several types of lasers that are used for various treatments in the body. In this article we discussed about current health authority regulations for laser eye treatment Laser-Assisted in Situ Keratomileusis (LASIK) Lasers. The LASIK is done by various methods like the topography guided treatment and the wave front guided treatment which is mostly suggested by an ophthalmologist. We also discussed about FDA approved LASIK medical devices and their contraindications associated with each laser device according to topography and wave front including the procedure, wavelength range, and advantages of each device.

KEYWORDS

1.Lasik
2.Laser
3.Myopia
4.Astigmatism
5.Dryeye
6.Roboticsassisted

INTRODUCTION

A surgical procedure called laser surgery uses the cutting force of a laser beam to remove a superficial lesion, such as a skin tumor, by making bloodless incisions in the tissues. The interest in minimally invasive surgery has grown recently. Lasers can seal lymphatic veins to reduce swelling and the growth of tumors cells, as well as close nerve terminals to lessen postoperative discomfort. Every year in the United States, some 600,000 people, mostly in their 30s and with disposable cash, get LASIK or similar operations. Although millions of people globally, notably in Asia, still opt for refractive surgery, its popularity in our country has declined from a peak of 1,400,000 treatments in 2006 for reasons that are not totally clear.[1]

The first excimer laser refractive error correction surgery was named photorefractive keratectomy (PRK), and several years down the line, laser assisted in situ keratomileusis (LASIK) was introduced.[2] Dr. Gholam Peyman first received a patent for LASIK in 1989.Dr. Ioannis Pallikaris and colleagues published the first LASIK study that employed inpatient care in the early 1990s. Due to shorter recovery times and fewer postoperative problems, this method gained popularity quickly without sacrificing effectiveness. LASIK is one of the surgical techniques that has undergone FDA inspection that has received the most scrutiny and research. When compared to wearing glasses or contact lenses, LASIK continues to produce effective, predictable, and safe results, according to patients.[3]

WAVE-FRONT GUIDED LASIK FOR TREATMENT OF LOW-LEVEL MYOPIA AND ASTIGMATISM

Technique:

The standard LASIK treatment and WFG LASIK are nearly identical. Before the flap is restored, a precise amount of stromal tissue is removed using an excimer laser. The patient is first prepared for the procedure using a microkeratome or femtosecond laser. There are multiple aspects for an original approach that are addressed. The aberrometer's reading of the eye's alignment and the alignment at the moment of operation must match. Torsional misalignment during surgery, whether it be cyclotorsion or head tilt, might result in under correcting the aberration or even inducing aberrations. As a result, precise alignment is essential in the surgical management. When a patient transitions from a seated posture measured on the aberrometer to lying beneath the excimer laser, it has been demonstrated that their eyes can experience up to 9.5° of cyclol rotation.[4]

Swami et al. found that the average deviation from vertical to supine position in their study of 240 eyes was 13.7°; 8% of the eyes had a departure of more than 10°. According to the authors, under correcting astigmatism by 14% and 35%, respectively, would be necessary for this degree of misalignment.[5]

The alignment process has been automated due to the most current technological development, iris registration. The aberrometer collects distinct iris information and transmits it to the laser. The laser's camera and computer system capture and compare iris detail to the aberrometer prior to the process. Cyclotorsional correction is provided to precisely coordinate the ablation at the start of the laser therapy. To get positive results, an ablation must be well centered. A mathematical model predicts that significant visual complaints could result from decentrations as little as 0.5 mm. As the pupil expands or contracts, the pupil centroid can move up to 0.7

mm. Even with proper initial centration and alignment, eye movement during surgery can still have a negative impact on the outcome. All specialized excimer laser systems use sophisticated eye trackers. Both techniques can be used by laser systems, which can direct the beam if eye movements are modest yet pause it if they are strong. This is crucial since active eye trackers do not take into account the parallax error between the corneal and iris planes or the change in effective laser energy when the cornea's curvature changes as the user rotates their head.[6]

Star S4 IR Excimer Laser System & IDESIGN Advanced WAVESCAN STUDIO SYSTEM

The CDRH (Center for Device and Radiological Health) of FDA conducted the review on the premarket approval application and the device was brought to the market in June 30, 2017.The device is used for LASIK in patients with hyperopia with or without astigmatism of the range **+4.00D** in spherical equivalent and **+2.00D** in cylinder. Components of the device system include:

- Excimer laser
- Gas Management system
- Laser bean Delivery system
- Patient management system
- Computer control
- Treatment card

Procedure: After all the patient inclusion criteria are made and the patient has been proved fit for the treatment then the following steps are followed by the ophthalmologist. A flap is created on the cornea using either a laser or automatic cutting device. An eye suction ring is applied. After flap is cut it is lifted and then folded. After the laser treatment is done the doctor repositions the flap. **Risks:** Even after undergoing the treatment the patient has to wear glasses. **Warning:** Certain group of patients cannot undergo the treatment. They are: Diabetic patients, Glaucoma patients with severe allergic conditions cannot undergo this treatment. **After surgery**: After undergoing the surgery for the first few days there may be pain, discomfort, blurred vision and sensitive to bright light. For about 6 months there may be fluctuation in eye vision and dryness in the eye.[7]

Kremer Excimer Laser System

Company: Laser light Technologies, Inc**.** Approval date: July 30, 1998. Kremer excimer laser system was the firstly approved LASIK medical device by the USFDA. This device is used for the treatment for myopia and astigmatism patients. Excimer laser: This is an argon-fluorine excimer laser. The wavelength of this laser: 193nm**.**Laser pulse duration: 8-30 ns (FWHM)**.** Composition of gases: Argon, Fluorine, Helium**.**

Patient selection: The following criteria is necessary for undergoing the treatment:

- Above 18 years of age
- Myopia between -1.0D and -15.0D with astigmatism and without astigmatism up to 5.0D. Patients between 18 to 20 should not show a refraction change of more than 0.5D and patients more than 21 should not show a refractive shift of more than 1.0D.[7]

TOPOGRAPHIC GUIDED LASIK TREATMENT

Cornea is the eye's primary refractive surface corneal aberrations lead to less-than-ideal vision. Wavefront-optimized treatment and topography-guided treatment are both diverse in a plethora of ways. In topography treatment a corneal curvature is created.] Corneal curvature is not dependent on pupil size as in case of wavefront treatment hence it makes topography treatment free from pupil errors. In strongly aberrated eyes or those with corneal opacities, where erroneous measurements could be made using an aberrometer, topography-guided therapy is used. Hence topography treatment measured data is acceptable.[8] The disadvantage is that it does not take into consideration about the eyes components which leads to corneal aberrations which may affect the visual activity.

Correction of irregular corneas: Lasik complications causing irregular astigmatism and other irregular corneal conditions is generally cleared by the topographic method.[9] For instance in a study which involved 17 eyes that are shown to have Lasik complications 9 of the eyes failed to get recovery by following the wavefront guided treatment. All the eyes which were seen to have normal eyesight was shown to have visual activity of 20/40 and around 64.7% of the eyes was said to have a vision improvement. Topography is generally recommended as it shows an improvement in the diopter range from **7-8.5 D.**

In recent findings it is shown that topography along with CXL (collagen cross link) would treat corneal ectasia thus it gives a better visual activity. In many cases where wavefront guided treatment is applicable the topographic treatment has a superior choice and better activity.

Nidek EC-5000 Eximer laser system:

The CDRH (Center for Device and Radiological Health) and FDA have conducted the review of the Premarket approval application and have approved the device in the year 2013. It is used for topography assisted Lasik treatment. It makes use of the **Final Fit^{TM} custom ablation treatment planning software.** It treats myopic errors from **-1.0 to around –4.0D.** In the case of astigmatic refractive errors from **-0.5 to -2.0D.** It is used in patients of the age 21 or older. The sale and distribution of the device is under **21 CFR 801.109**. The Final fit simulation software has three simulation modes for EC-5000 laser system which include **spherical ablation, optimized aspheric treatment zone ablation (OATz) and customized aspherical treatment zone ablation (CATz)**.[7]

Allegretto wave eye-Q 400Hz excimer laser system;The allegretto wave 400Hz system is used in combination with wavelight allegro topolyzer **and T-CAT treatment planning software** is indicated for topography guided Lasik treatment. It is used for the treatment **of myopia up to -9.0D and for myopia with astigmatism up to -8.0D and up to -3.0D in case of only astigmatism**. The system uses an infrared high-speed camera working at 400Hz to watch the patient's eye movements. If the eye wanders outside of a predetermined range, the system either stops the therapy or compensates for the change in eye position. In order to retain a more natural corneal shape, the Wavelight Allegretto Eye-Q laser delivery programme accounts for the cornea's asphericity based on anterior curvature data and reduces the amount of spherical aberration brought on by surgery.[7]

TECHNIQUES FOLLOWED FOR LASIK TREATEMENT BY AN OPTHALMOLOGIST

The patient is given the choice of taking an oral sedative (Valium 5 mg). The patient will be prepared for surgery after the sedative has had time to take effect. One-minute separate injections of topical anesthetic (BNX, Benoxinate Minims), antibiotic (ciprofloxacin, Ciloxan), and anti-inflammatory (dexamethasone, Maxidex) drops are made. In order to prepare the operated eye(s) for the femtosecond laser process, betadine swabs are applied soon after the operation.

While the surgeon positions the laser, the patient is lying on the bed. The patient's eye is covered with a suction ring, which is carefully placed over the pupil. Depending on the surgeon's preference and anatomy of the patient, a speculum may or may not be used. The patient interface is inserted into the laser arm and lowered to connect with the suction ring to make a whole set. The surgeon will now verify the laser's settings and where the intended ablation will occur. Once satisfied, the surgeon will activate the footswitch to begin the ablation. Patient interface will be withdrawn after suction ring has been taken off. Once at the excimer laser, the patient is transferred. Another drop of anesthesia is given before placing the surgical drapes over the lids. After that, the speculum is put in. With the use of a disposable LASIK cannula the hinged flap formed by the laser is raised. Just before the laser, the stromal bed may be cleaned of any extra moisture or debris using a sterile swab. The flap is replaced and the interface is irrigated with balanced salt solution following excimer ablation. (Alcon Laboratories Inc.). Ciprofloxacin and dexamethasone are administered after surgeon validates the position of the flap before the speculum and drapes are taken off. Before being released, the patient is next examined under a slit-lamp microscope.[10]

FDA APPROVED LASIK MEDICAL DEVICES

DEVICE NAME	COMPANY	APPROVAL DATE	USE
Wave light Allegretto Wave Excimer laser	Wave light AG	April 19, 2006	Mixed Astigmatism
LADAR Vision 4000 Excimer Laser system	Alcon Laboratories, Inc	May 1, 2006	Hyperopia
LADAR Vision 4000 Excimer Laser system and the LADAR 6000 Excimer system	Alcon Laboratories, Inc	May 2, 2006	Mixed Astigmatism
MEL 80 Excimer Laser System	Carl Zeiss, Inc	August 11, 2006	Myopia

Nidek EC-5000 Excimer Laser System	Nidek, Inc	October 11, 2006	Hyperopia
Star S4 IR Excimer Laser system with Wave scan system	VISX, Inc	July 11, 2007	Myopic Astigmatism
MEDITEC MEL 80 Excimer Laser System	Carl Zeiss, Inc	March 28, 2011	Hyperopia with or without refractive astigmatism
Allegretto WAVE Eye-Q Excimer Laser System	Alcon Laboratories, Inc	September 27, 2013	Myopia/ Myopia with astigmatism
STAR S4 IR Excimer Laser System and iDesign Advanced WaveScan Studio System	AMO Manufacturing USA, LLC	May 6, 2015	Hyperopia
STAR S4 IR Excimer Laser System and iDesign Advanced Wave scan Studio system	AMO Manufacturing USA, LLC	June 30, 2017	Hyperopia
I design Refractive Studio Star Excimer Laser System	AMO Manufacturing USA, LLC	June 15, 2018	Myopia

LASER SURGERY IN INDIA

The name of the Lasik surgery in India that is mostly used is the **blade-less laser** procedure. This is the most advanced and safest treatment that is available in India after being approved in USFDA in the year 2016. In this treatment not only treating the refractive power error it also keeps a tract of corneal imperfection and optical system resulting in a better focusing surface and vision improvement. The other alternative methods include Contoura vision and SMILE.[11]

The Comparison of the three treatments SMILE, CONTOURA Vision and Bladeless Lasik

COMPARING TOPICS	CONTOURA VISION	BADELESS LASIK	SMILE
Visual recovery	Fast	Fast	Slow
USFDA Approved	Yes	Yes	Yes
Refractive error treatment	All myopia, hyperopia, and astigmatism spectra	All specs powers inclusive in myopia, Hyperopia, Astigmatism	Limited specs range in myopia, hyperopia, Astigmatism
Treatment area	Visual axis-superior vision	Pupil axis	Pupil axis
Re-treatments	Possible	Possible	Impossible

Advantages of Bladeless Lasik Surgery:

- No fear of the blades working on the eye.
- Precise cutting gives excellent visual result and speed up recovery.
- Better quality, smaller flap which is safer than blade LASIK.
- More personalized care for patients
- Tissue saving.
- Quicker recovery.

CONTOURA VISION:

The most recent development in laser vision correction for eyeglasses removal is Contoura Vision. The world's most cutting-edge and secure technology for removing glasses is now accessible in India following the completion of multicenter clinical studies and receipt of US - FDA approval in the United States of America in 2016. Because Contoura Vision is a topography-guided laser system, it can record and fix flaws in individual corneas and optical systems in in addition to improving spectacle power, creating a better focusing surface.

With the use of the fastest tracker in the world, the treatment is also focused on the eye's visual axis, producing superior results to LASIK & SMILE. According to studies, people who have Contoura treatment for vision correction have a 40% probability of experiencing vision that is better than 6/6 (6/6 vision is typically regarded as the normal range for vision). Comparatively to other laser vision correction techniques, the treatment also produces fewer glares. Contoura is a favorite option for patients and physicians worldwide due to its total blade-free experience.[11][12]

SMILE:

Smile technique was the recent findings for eye related refractive surgery. It is used as an alternative treatment for LASIK surgery for myopia and myopic astigmatism. It was first used in Germany. Unlike other surgeries it is a flapless refractive surgery. SMILE works by using a single femtosecond laser. It is shown that around 2 million people have undergone the surgery all over the world. The laser system mostly used and is appropriate is theVisuMax 500-kHz femtosecond laser. The treatment strategy as of SMILE for myopia is up to -10.0D and for myopic astigmatism up to around -3.0D and not more than -10.0D. [11]

Tear proteomics and neuromediator profile changes in SMILE and LASIK:

A study included 70 patients who would be undergoing SMILE surgery on one eye and LASIK surgery on the other. A comparative study was conducted for a term of one year and the various proteomic ratio of various protein at every stage was studied.

Post-SMILE UP regulated proteins:

1 week	3 months	12 months
Apolipoprotein C3	Ig lambda variable 2-11	Mucin-like protein 1
Glutamate/proline-tRNA	Cystatin D	Chitinase domain containing 1
Apolipoprotein E	Mucin-like protein 1	Cystatin D
Serum paraoxonase		Interleukin 19
Complement C1r		Adhesion G protein coupled receptor VI
Fibronectin 1		Peptidylglycine alpha amidating monooxygenase
Mucin-like protein 1		Annexin A11
Ig lambda variable 2-18		
Alpha 2-antiplasmin		
C4b binding protein alpha chain		

***Post SMILE DOWN regulated proteins*:**

1 week	3 months	12 months
Peptidyl-prolyl cis-trans isomerase C	Submaxillary gland androgen regulated protein 3A	Tubulin alpha 4a
Superoxidase dismutase 3	Inter-alpha-trypsin inhibitor heavy chain 2	N-Acylsphingosine amidohydrolase-1
Myeloblastin	Thymine phosphorylase	Eukaryotic translation initiation factor 5A
Src substrate cortactin		Lymphocyte cytosolic protein 1
Tryptophan- tRNA ligase		Proteinase 3

Proteasome subunit alpha 2		Apolipoprotein B editing enzyme catalytic subunit 3A
Plasminogen activator inhibitor 2		Proteasome subunit beta9
Transitional endoplasmic reticulum ATPase		Phosphoglycerate kinase 1
Glutathione S-transferase omega-1		

LASIK CONTRAINDICATIONS

The contraindications are of two types absolute and relative contraindications. These are the reasons that prevent patients from receiving the LASIK treatment since it may be harmful.

Absolute Contraindications:

- Refractive abnormality
- Corneal conditions
- Uncontrolled diseases

Relative contraindications:

- Age
- Pupil size
- Cataract
- Glaucoma

Refractive abnormality: The changes in the eye greater than 0.5 D (diopter) the LASIK surgery is not recommended and cannot correct the defect and may lead to a new condition called ectasia. According to FDA LASIK is not recommended to the pregnant women and patients with uncontrolled diabetes mellitus.[13]

Corneal conditions*:* Normal corneal thickness is about 540-550 microns. In such condition LASIK can be performed. If it is less than 500 microns and if surgery is performed it may lead to a new condition Keratectasia.[14]

Uncontrolled diseases*:* Rheumatoid arthritis, graves' disease, in case of such diseased condition if surgery is done it may keratoconjunctivitis sicca.[15]

Age*:* LASIK is not advised to be performed in children as the power may keep changing in their stage and is advisable to be used in the age of above 18.

Pupil size*:* People with large pupil size may risk of postsurgical visual complication.[16]

Cataract*:* Patients with mild level of cataract may undergo the treatment but with the case of higher level it may further affect the visual activity.

Glaucoma: Patients with glaucoma who undergo the surgery may develop a false decrease in the intraocular pressure due to the decrease in corneal thickness. Further it may also cause damage to the optic nerve.[17]

POST LASIK DRY EYE:

After undergoing the Lasik treatment, the most common outcome that has occurred in most of the patients is the dry eye. It occurs in about 1 month after the surgery has been conducted and is termed as the post Lasik dry eye. The symptoms include dryness, irritation and red eyes. It usually lasts for a period of 1 month. Only in certain cases the chronic dry eye symptoms last for about 1 year.

Mechanism of post Lasik dry eye:

The mechanism for the occurrence of dry eye is not known in a correct manner but the source or the causative subjects are known. After the surgery there may be disruption in the intracorneal nerves which may lead to the decrease in corneal sensitivity, blink rate, tear secretion. In such a way the tear evaporation is increased. This leads to the ocular surface damage and may lead to the dry eye.[18] It may also occur if there is a damage to the goblet cells which leads to the mucin rate alteration which causes a decrease in the tear stability and it ultimately causes dry eye. During the surgery the corneal shape may be altered which is also a factor for the dry eye. To overcome the dry eye certain precaution steps are to be taken and followed to completely overcome dry eye. All possible surgeries are to be done prior to the Lasik surgery in a way to overcome the symptoms of dry eyes. If still the conditions to overcome are not met then the treatment method is changed to SMILE. The precaution steps are to be taken at the very early stage of the occurrence of symptoms.[19]

ROBOTICS ASSISTED TREATMENT IN EYE SURGERY

The use of robotic assistance in retinal surgery is notable for enabling tremor-free, steady instrument manipulation for extremely delicate procedures. The frequency of age-related macular neovascularization damage to the outer retina due to degeneration (AMD)in the USA population aged 40 and older is predicted to be1:47 %. According to projections, its prevalence will rise due to an ageing population, 288 million by 2040. Another Retinal vein occlusion (RVC), a frequent retinal condition, from a blood clot occluding a retinal vein, which can cause an unnoticeable loss of vision. According to a recent survey, 0:77% of adults aged 30-89 worldwide had any form of RVO in 2015. Neither of these illnesses currently has a standard of care that includes surgery. To sustain vision, both, however, implicitly rely on the management of the underlying condition's side effects. Overcoming the physiological tremor limits of humans is necessary for the targeted subretinal injection and retinal vein cannulation direct treatment of choroidal neovascularization. The diameter of the implicated retinal and choroidal vessels (i.e., between 50 and 150 m) is equivalent to the root mean squared (RMS) value for an eye surgeon's hand tremor, which is 182 m. Furthermore, when the amount of hand tremor is taken into account, a healthy human retina has an average thickness of 212 m at the fovea, making the accurate targeting of freehand sub retinal injections unpredictable and potentially dangerous.

Operation method:

The passive mode and the active mode are the two ways that this device can be used. The surgeon drags the endoscope to the target position in the passive mode, which is primarily thought of before and after the surgery, puts it into the eyeball through a trocar hole, and

positions the endoscope so that it points in the direction of the surgical site. In this mode, the surgeon's hands control every movement. The electromagnetic breaks in the arm unit are removed, and the translation drive unit (XYZ stage) is locked in the passive mode, signifying that the surgeon has free movement of the arm unit. The endoscope may be easily manually positioned thanks to the arm unit's design.[20]

After introducing the endoscope into the eyeball and adjusting the view region, the surgeon will start performing surgery on the patient's eye. The active mode allows the surgeon to change the endoscope's vision while performing surgery. The arm unit is rigid as a result of the electromagnetic breaks being locked. Only the XYZ stage's translation motion determines the posture and position of the passive endoscope holder unit. Allow the surgeon to instinctively change the endoscopic vision by foot because they utilize both hands to operate. A potentiometer that measures the motion direction is attached to the moveable black square on the left side. As a result, the direction in which the surgeon moves the black square will be where the endoscopic camera, which displays the picture on a screen, moves. The zooming of the endoscopic vision is controlled by the joystick on the right side. As a result, it is possible to change the endoscopic view without stopping the hand operation.

Furthermore, by moving to passive mode, the surgeon can manually modify the perspective if necessary. A different footswitch is used to switch between the two modes; if the surgeon constantly presses the footswitch, the device will remain in passive mode. As a result, switching modes is simple and only requires a modest elevation of one foot.[21]

Working range:

The Eye Explorer is fixed to a mobile platform (whose wheels can be braked) that is placed adjacent to the operating table. The mobile stand's height can be altered to match that of the operating table. The objective eye can be accessed by the endoscope at a 45° angle. The endoscope's field of view and the necessary field of view for surgical cases, where the endoscope holder and objective eye are on the same side of the patient's nose when both the vertical and horizontal perspectives are taken into account. The endoscope's visible ranges are 118° and 97° in the vertical and horizontal viewpoints, respectively. [22]

The needed and actual observation range, taking into account both views, is 118° and 85° of the holder unit relative to the horizontal plane, or 45° in circumstances when the endoscope holder and objective eye are on different sides of the patient's nose. Furthermore, regardless of the access method, the viewable ranges taking into account both views are larger than those necessary (90° and 80°). The red areas depict the required working space for the surgeon's hands when facing the top of the patient's forehead during the majority of eye procedures. Additionally, the endoscope holder can only be in one of two positions above the patient's eye, which is 155 or 171 mm.[23]

CONCLUSION

As the LASIK surgery is generally used for myopia, hyperopia and astigmatism treatment it has been used worldwide in all the countries in the past decade in an increased rate. Though it is a high-risk manner as it comes under the class III of the medical device classification according to USFDA it is been widely useful for the elimination of the eye focus burden

directly from not wearing glasses. Among topography and wavefront guided it is said that the topography guided treatment has a far accurate way of treatment and benefit in comparison with the other method. Various devices have been approved by the USFDA and has been used in various countries. Robotic assistance kind of LASIK treatment has been known to be the newest update or invention concerned with the LASIK eye treatment. It is expected that in the near future the LASIK surgery will be used all over with a corneal correction of 20/20 and reduced contraindications.

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