

UPDATES OF REFRACTIVE SURGERY

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١٤/٣/٢٠١٥

Basic knowledge

Refraction

Refraction is the bending of light rays as they pass from one transparent medium to another of a different density. It is measured in diopters (D). The refractive power at the central cornea is about +43D, providing about 2/3 of the total refractive power of the eye (+58D). The ideal refractive procedure would be simple, effective, minimally invasive, safe, and applicable in all patients desiring vision correction.

Taken together, the cornea is supposed to be the main target for laser application in refractive surgery.

Radial Keratotomy, or RK, changes the shape of the cornea by making incisions with a surgical knife to flatten, steepen, or alter the contour of the front of the eye.

Radial Keratotomy was developed in the Soviet Union, and became a common surgery worldwide in the 1970's.

Corneal incisions are very effective at changing the shape of the eye, but because these **incisions** go almost all the way through the cornea, and because the **healing process** varies greatly among individuals, complications are substantially more common with RK than with laser refractive surgery.

The great majority of patients who have had RK have obtained markedly improved vision. However, it is quite common for RK patients to notice variable vision through the course of each day, due to **weakening of the cornea** and resultant **fluctuation** in its shape in an ongoing basis. Some people who have had RK have also experienced progressive changes in their vision over years after their surgery, so that the initial improvement fades with time. Even more serious complications, including severe **scarring** requiring further corneal surgery, or constant blurring not treatable with contact lenses or glasses, have occurred on an infrequent basis.

Most surgeons feel that while RK was a valuable step in the development and evolution of vision correction surgery, it will likely no longer be used as laser surgery continues to improve and expand its horizons.

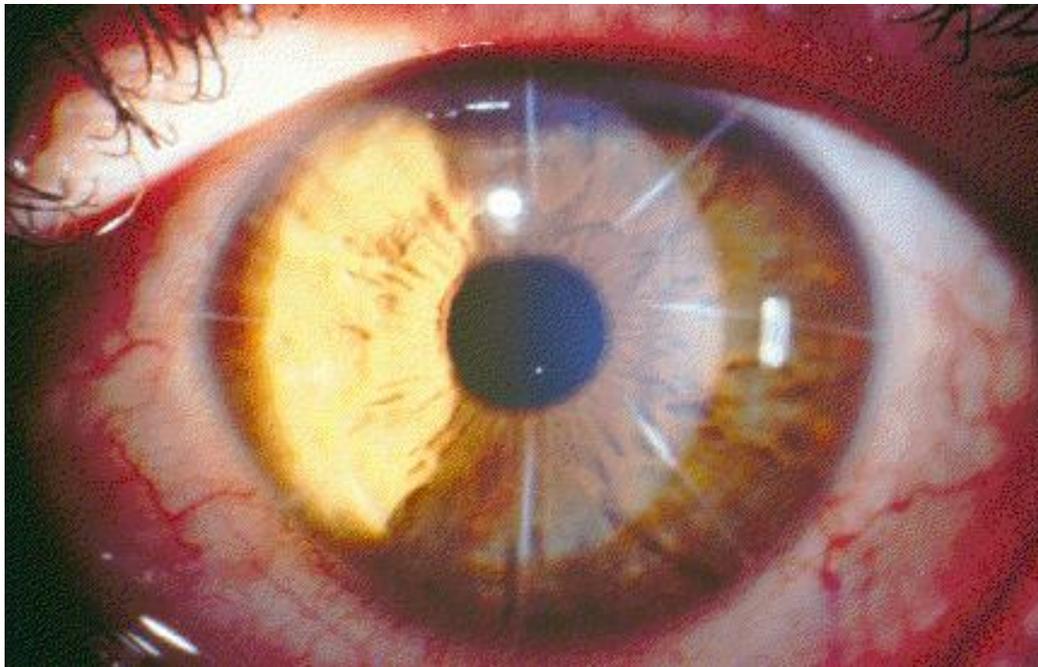


Figure 2: Staff illustrations

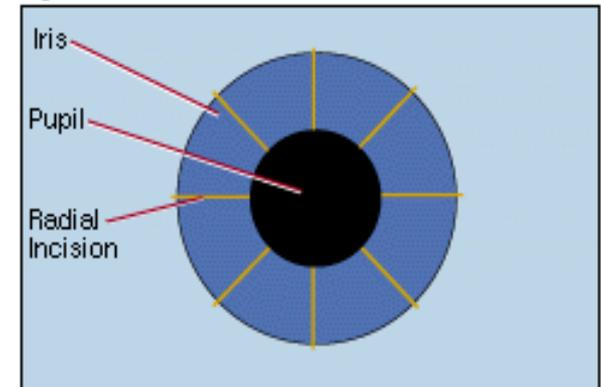


Figure 2. With radial keratotomy (RK), a thin diamond knife is used to make cuts directly into the cornea to about 90% to 95% of its thickness. Myopia is corrected with radial incisions, as shown.

The excimer laser

The excimer laser is used to reshape the surface of the cornea by removing anterior stromal tissue.

The excimer laser was introduced by Trokel et al in 1983 and first used on a human subject by McDonald et al in 1991.

The 193 nm ultraviolet light from the argon fluoride laser, which has the least corneal transmission, causes:

1- less adjacent tissue damage

2- creates a smoother ablation than longer wavelength lasers. At a wavelength of 193 nm, high-energy photons break organic molecular bonds of the superficial corneal tissue in a process called ablative photodecomposition.

Ejection of material from the cornea begins on a time scale of nanoseconds and continues for 5 to 15 microseconds following the excimer pulse.

Other important properties of the laser,
including:

1- optimum irradiance levels and

2- optimum repetition rates, and optical principles for the laser correction of ametropia were also explored and developed. Thereafter, the U.S Food and Drug Administration (F.D.A) first approved the excimer laser in **October 1995** for correcting mild to moderate nearsightedness. Currently, the excimer laser has been approved for use in PRK, and, since November 1998, for LASIK.

For an optimal excimer laser beam the fundamental information needed is the corneal ablation behavior, i.e. the relationship between the per-pulse tissue ablation depth and the fluence (energy per area) of the incident laser radiation.

The ablation efficiency is the amount of tissue vaporized per unit of laser pulse energy , which maximizes for a peak fluence between 380 and 600 mJ/cm² (the absolute maximum occurs at approximately 440 mJ/cm²).

PHOTOREFRACTIVE KERATEECTOMY : With PRK, the outer layer or **epithelium is first removed** with special medicine and then the laser removes tissue from the underneath layer called the stroma. During the healing process, the epithelium returns to become the outer layer and the nearsightedness is reduced.

Most surgeons prefer the use of a therapeutic soft contact lens to promote reepithelialization, decrease pain, and increase mobility. The lens should be kept in place until complete reepithelialization occurs; however, sterile infiltrates and an increased risk of infectious keratitis must be kept in mind and treated meticulously. Medications and treatments vary in different laser refractive surgeries .

Refractive stabilization may require up to 3 months in myopia and is usually longer for hyperopia, depending on the amount of treatment.

Repeat surgery, which is often called enhancement, can be performed once the refraction is stable for at least 1 month, but is generally not performed until 3 months after the first surgery.

A bandage contact lens maybe placed after surgery to stabilize the flap. It can be removed within 2-3 days.

It is important to ensure that a residual bed thickness of 250 microns is maintained after enhancement also. Surface ablation or **PRK maybe performed in patients who have inadequate corneal thickness for an enhancement procedure. Mitomycin C is applied at the end of the laser to reduce corneal haze. Post-operatively, the patient is examined to ascertain the refractive correction and flap placement the day after surgery, a week and 2 weeks later.**

Antibiotic and steroid drops are administered along with lubricants as for any laser procedure and tapered gradually.

LASIK: LASIK is a lamellar laser refractive surgery in which excimer laser ablation is done under a partial-thickness lamellar corneal flap. After a suction ring has been properly positioned, suction is activated. Intraocular pressure should be raised to over 65 mmHg. A microkeratome, is used to create a corneal flap about the size of a contact lens. Hinge positions, nasal or superior, depend on the design of the microkeratome, and are at the surgeon's discretion. There are no differences in refractive outcome; however, it should be noted that loss of corneal sensation and dry eye syndrome occur more often with a superior hinge flap than with a nasal-hinge flap. The flap thickness, which averages **130 μm to 160 μm** , is folded back to expose the underlying stroma.

The excimer laser system is then focused and centered over the pupil and the patient is asked to look at the fixation light. After the ablation is complete, the flap is replaced onto the stromal bed. If a significant epithelial defect is present, a bandage contact lens should be placed. Most surgeons place a drop of antibiotics and steroids over the eye at the conclusion of the procedure followed by placement of a clear shield. remained in proper The flap is optionally rechecked at one day later to be sure it has alignment.

Postoperative management

Patients are placed on topical prophylactic antibiotics and topical steroids four times per day for 4 to 10 days, and they are generally seen 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months post-operatively. Preservative-free lubricating drops are helpful for most patients for the first month and frequent use should be encouraged.

On the first post-operative day, careful inspection of the corneal flap of **LASIK patients should be performed with a slit lamp. The patient may resume most activities if the postoperative evaluation is normal. Patients are particularly instructed not to rub their eyes or swim during the first month to prevent flap displacement or infectious keratitis.**

EPILASIK

Epilasik uses an instrument called an epikeratome (Fig. 19) to create a flap at the level of the basement membrane maintaining its integrity and sparing the stroma.

It is especially useful in patients with thinner corneas. The excimer ablation is performed after which the thin flap may either be repositioned or removed and a bandage contact lens is placed to allow a smoother epithelial healing . Use of Mitomycin C drops 0.02% have been recommended to reduce the chances of post-operative corneal haze. Retaining the epithelial flap has also been known to protect the bare stromal surface and prevent influx of inflammatory cells from tears thereby reducing the incidence of corneal haze. Epilasik is associated with faster healing and less pain than other surface ablation procedures.

Clinical outcomes *Safety and efficacy*

Safety is defined as the number and percentage of eyes losing two or more lines of best spectacle corrected visual acuity (BSCVA). Efficacy is defined as the percentage of eyes with an uncorrected visual acuity (UCVA) of 20/20, or 20/40 or better. We will review randomized controlled trials, comparative case series and prospective, noncomparative cases series, focusing on safety and efficacy in PRK and LASIK.

1- PRK: For low to moderate myopia (-1 to -6 diopters), studies showed that safety ranged from 0% to 7%, while efficacy ranged from 97% to 100% for a UCVA of 20/40 and from 36% to 70% for a UCVA ,of 20/20.

2- LASIK: for moderate to high myopia (-6 to-15 diopters)

safety ranged from 0% to 11.8%, while efficacy ranged from 59% to 93% for a UCVA of 20/40 and from 19% to 47% for a UCVA

For moderate to high myopia (−6 to −12 diopters), safety ranged from 0% to 3.2%, while efficacy ranged from 55% to 94% for a UCVA of 20/40 and from 10% to 36% for a UCVA of 20/20.

LASIK or PRK after previous refractive surgery

According to the Prospective Evaluation of Radial Keratotomy, 25-43% of patients who had undergone incisional RK became hyperopic. Secondary myopia was also not uncommon because surgeons had a tendency to undercorrect myopia for fear of a possible hyperopic shift.

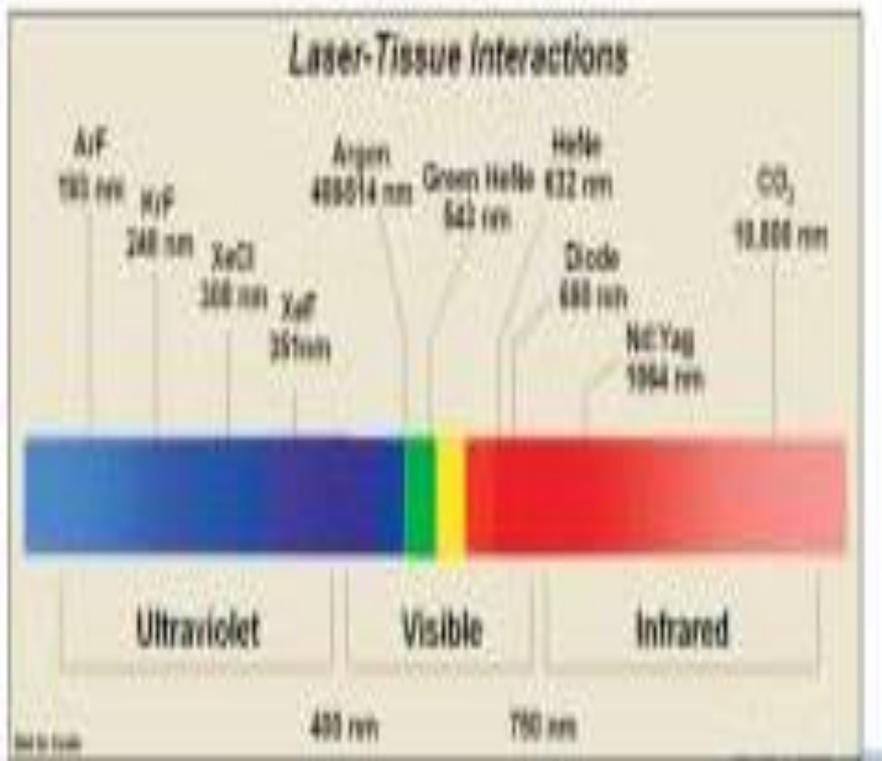
CONCLUSIONS

PRK, including the surface ablation procedures LASEK and epi-LASIK, and LASIK are relatively effective and predictable surgical procedures for the correction of myopia and hyperopia with or without low-to-moderate astigmatism. However, data from prospective clinical trials directly comparing LASIK with PRK are insufficient. For low-to-moderate myopia (– 6.0 diopters) with astigmatism, surface ablation procedures remain good alternatives to LASIK and have similar long-term results.

FEMTOSECOND LASER

A femto-second laser represents a breakthrough in ultrafast laser science. The laser uses an **infrared beam** of light to precisely separate tissue through a process called **photo-disruption** by generating pulses as short as one-quadrillionth of a second (10^{-15} = femto-second).

The Intralase Femtosecond laser (Fig 30) is a 60Khz diode pumped Nd:glass oscillator with a wavelength of 1053 nm (Fig 31) based upon the technology whereby focused laser pulses divide material at the molecular level without transfer of heat or impact to the surrounding tissue.



Wavelength spectrum



Fig. 30: The IntraLase femtosecond lase.

New Refractive Approach

Ronald R. Krueger, MD, medical director of refractive surgery at Cleveland Clinic's Cole Eye Institute, noted that the success of LASIK flap creation via IntraLase has spurred the development of several new femtosecond laser-based technologies. Systems. Zeiss and Technolas, in particular, are preparing to roll out platforms with innovative applications.

One laser, many uses. Carl Zeiss Meditec, for example, has a femtosecond laser with a curved appplanation plate that allows precise placement of pulses without significantly compressing the cornea. The company has developed a procedure called **femtosecond lenticule extraction**, or FLEx. FLEx involves making two cuts that intersect in the periphery, creating a lenticule that can be removed from the cornea without requiring an excimer laser for the refractive procedure. “The company is hopeful that FLEx will be a way of refining refractive procedures so that one laser technology can do it all,” Dr. Krueger noted. “Investigators are beginning some early trials with a modification of FLEx called small-incision lenticular extraction, **or SMILE**.”

SMILE attempts to make corneal lenticule extraction less invasive by enabling the lenticule to be removed through the small incisions without having to lift up the flap."

SMILE procedure

Each SMILE procedure will be performed using an established, described technique . After application of topical anesthesia, standard sterile draping, and insertion of the speculum, the patient's eye will be centered and docked with the curved interface cone before application of suction fixation. The laser will then be activated for photo-dissection in the following sequence: first the posterior surface of the refractive lenticule (spiral in), then the lenticule border is created.

The anterior surface of the refractive lenticule (spiral out) is then formed which extended beyond the posterior lenticule diameter by 0.5 mm to form the anterior flap and is followed by a rim cut.

We will use the following :

1-FS laser parameters: 120 μm flap thickness,

2-7.5 mm flap diameter,

3- 6.5 mm optical zone of lenticule,

4-145 nj of power with side cut angles at 90°.

5- A superior hinge, 50° in cordal length, طول حبلي will be made in all cases.

6-The spot distance and tracking spacing are 3/3 μm for the lenticule,

7- 2.5/2.5 μm for the lenticule side cut,

After the suction is released, a Siebel spatula is inserted under the flap near the hinge before the flap is separated and reflected. The edge of the refractive lenticule is separated from the stromal bed with ainsky hook and the posterior border of the lenticule gently separated with the Siebel spatula. The lenticule is then grasped with non-toothed serrated forceps through the small incision.

Outcomes

We plan to use standard primary and secondary outcomes measures at 3 months postoperatively, which are reported in any assessment refractive surgical technique and standard outcomes in refractive studies. Measurements and outcomes are based on :

1-Visual acuity (VA) and

2- Refraction that are performed by trained refractive optometrists and are repeatedly tested to ensure accuracy and stability.

Our primary outcome measure is refractive predictability, which is defined as the proportion number of eyes achieving a postoperative spherical equivalent (SE) within ± 0.50 D of the intended target.

Secondary outcome measures include:

(1) Efficacy: defined as the proportion number of eyes achieving an unaided visual acuity (UAVA) of 20/20 or better postoperatively.

(2) Safety: defined as the proportion number of eyes that lost or gained one or more lines of postoperative best-corrected visual acuity (BCVA) relative to the preoperative BCVA;

(3) Higher-order aberrations (HOAs): measured using the Bausch and Lomb Technolas Zywave aberrometer .

Intracor

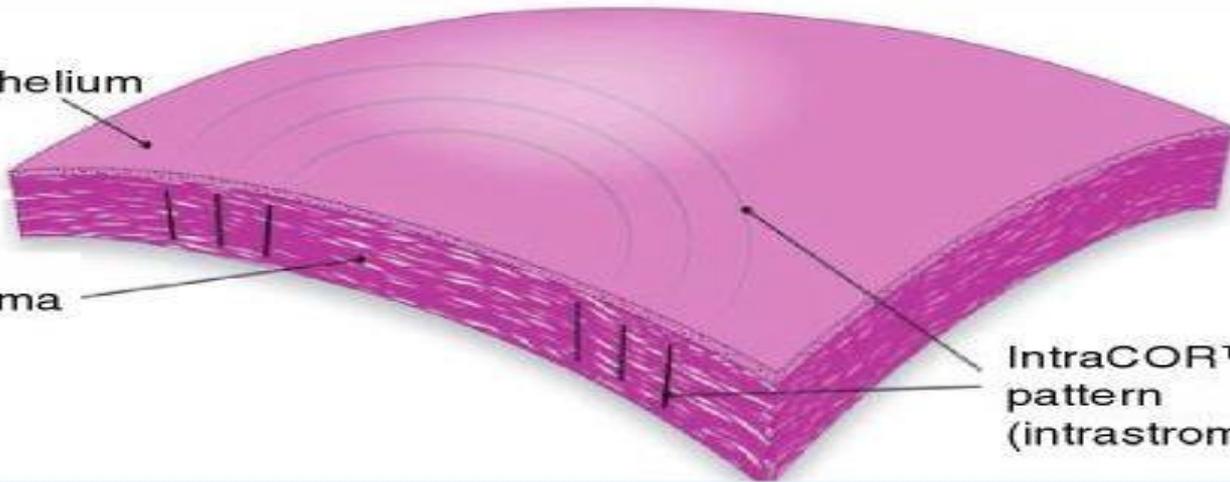
Tissue not removed, just reoriented. Technolas Perfect Vision (a company created from an initial joint venture between Bausch & Lomb and 20/10 Perfect Vision) has fashioned an intrastromal procedure called **Intracor. Intracor applies femtosecond laser energy inside the cornea without bringing it to the surface. The pulses are placed as concentric intrastromal circles centered about the visual axis and extending no closer than 100 μm from the surface. The Intracor concept is novel because the procedure removes no tissue, instead applying a concentric pattern of cut fibers to shift the center of the cornea slightly anteriorly and create a hyperprolate shape.**

A

Epithelium

Stroma

IntraCOR™
pattern
(intrastromal)



B



The Intracor causes a biomechanical change in the cornea that shifts the center slightly forward, creating a pattern of hyperprolate asphericity that gives the person some near vision while still maintaining distance vision,” Dr. Krueger said. “So this is a procedure for correcting presbyopia in emmetropic patients with normal distance vision.”

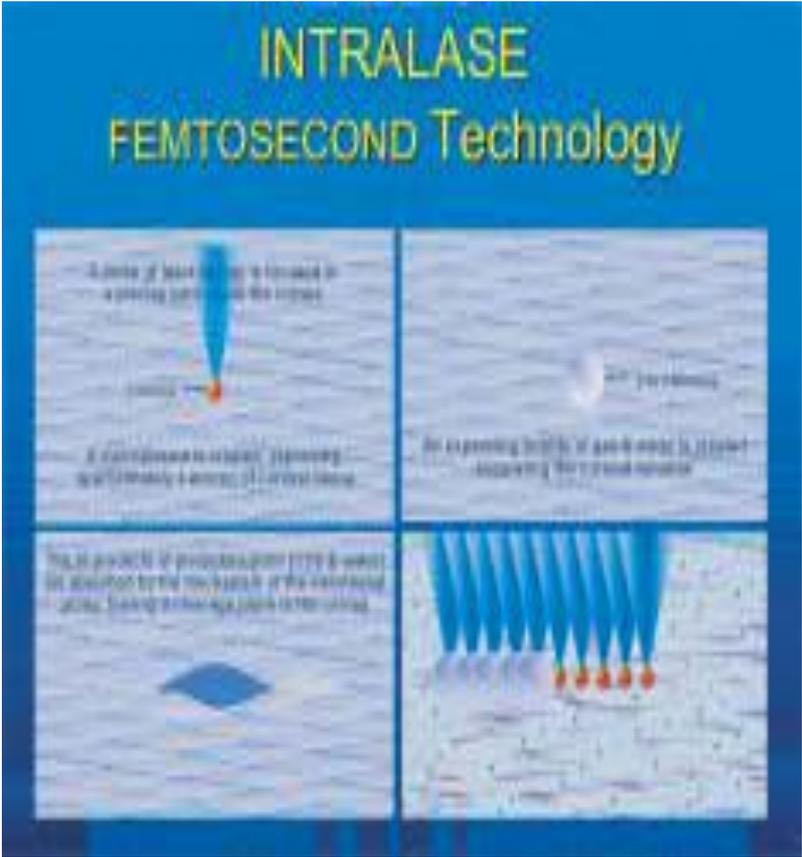
The surgeon also can expand the circle diameters or add radial intra-stromal incisions, depending on whether a small amount of hyperopia or myopia is involved. The radial intra-stromal incisions are similar to those created in radial keratotomy and are effective in biomechanically correcting a small degree of myopia.

Intracor is attractive because it provides a way of correcting low refractive errors and presbyopia with an entirely biomechanical method that never breaks the surface epithelium," Dr. Krueger said. "As a result, there is no migration of white blood cells coming in from the tear film and no aggressive healing response. No real pain is involved because you are not breaking the surface and exposing nerve fibers. In addition, the little bubbles that form from the femtosecond pulses in the cornea all dissolve within the "first day or evening, and patients see well within hours.

Intralase Femtosecond laser is used to create the corneal flap in a lasik procedure eliminating the use and risk of a micro-keratome and blade and increasing the overall safety, precision and accuracy. The laser beam is focused on a pre-programmed depth and position within the cornea with each pulse forming a **microscopic bubble**(Fig 31 & 32). As the Intralase laser moves painlessly back and forth, the bubbles connect to form a flap with no trauma to adjacent tissue, the entire process taking around 20-30 seconds. The surgeon then lifts the flap to allow treatment by excimer laser . Laser specifications which can be modified to meet individual patient's needs include flap diameter, depth, hinge location and width and side-cut architecture.

Intralase laser creates a corneal flap of precise size, shape and depth to micron-level accuracy 100% greater than that of blade-keratome and markedly reduces the risk of blade-related flap complications such as free caps, button holes, incomplete or decentered flaps .

Not only is the visual acuity after femtosecond laser better but the incidence of *postoperative* dry eye symptoms is reduced. It also creates fewer high and low-order aberrations which may cause glare and haloes at night. The precision of the flap also reduces the incidence of induced *postoperative* astigmatism as compared with microkeratome created flap



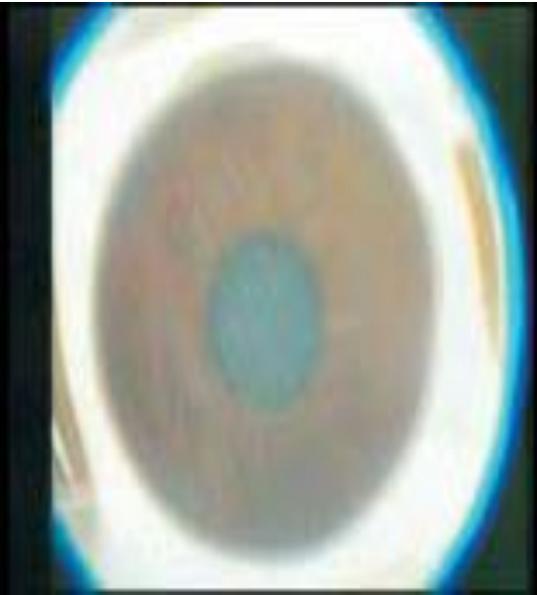


Fig. 35: *Applanation of the corneal surface*

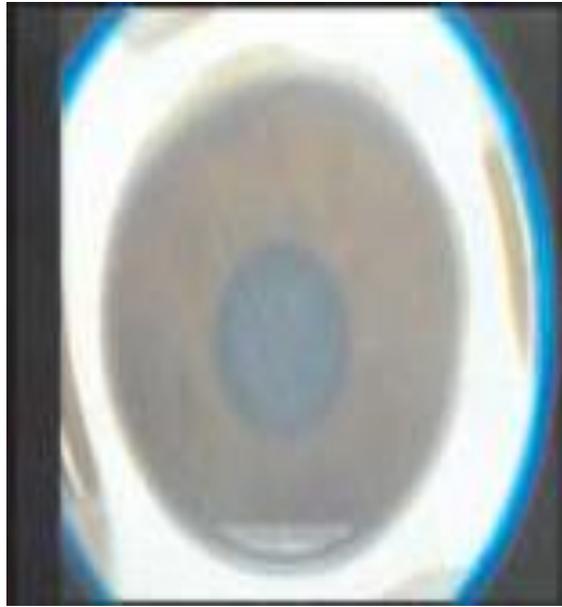


Fig. 36: *Creation of laser pocket at a predetermined depth*

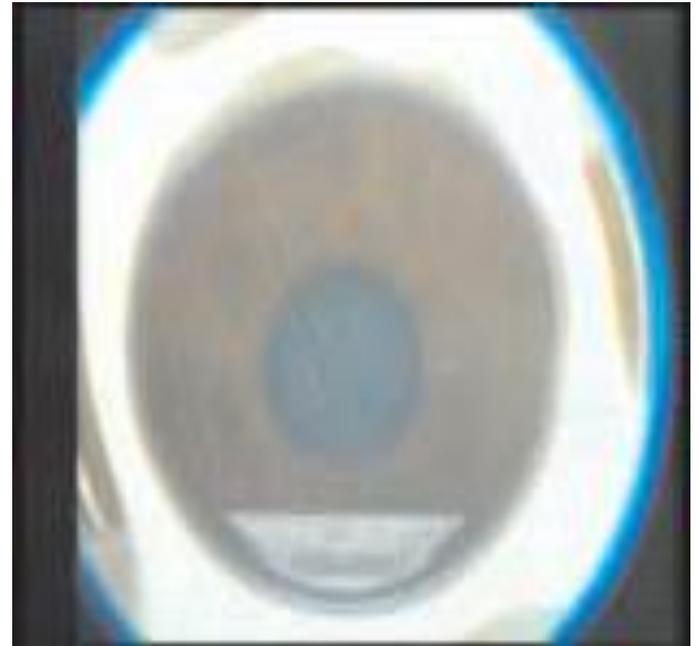


Fig. 37: *Progression of the femtolasar procedure*



Fig. 38: Laser beam traveling forward creating a tissue plane



Fig. 39: Femtolaser assisted flap more than 50% complete



Fig. 40: Femtolaser assisted flap almost 80% complete



Fig. 41: Flap complete, side cut being delivered

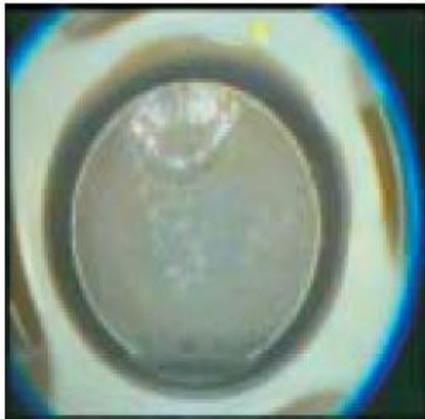


Fig. 42: 'Burp' where a condensed water bubble appears at the cleavage plane

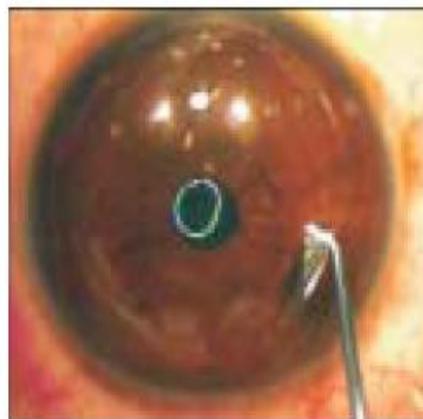


Fig. 43: Lifting the flap by delineating the edge



Fig. 44: Flap lifted up from the stromal bed

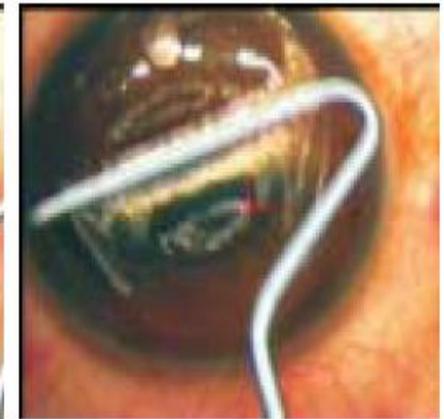


Fig. 45: Flap completely separated

Post-operative complications these include :

1-displaced or dislocated flaps.

A careful alignment of the flap edge should be done and a slit lamp examination performed before the patient is sent home after the laser procedure. If any displacement is noted, the flap should be immediately repositioned and smoothed out in the correct orientation. The patient is asked to not rub the eyes at all in the immediate *postoperative* period.

2-Flap striae or flap folds may be noted in the immediate *postoperative* period. While macrofolds depict full thickness flap tenting in a linear fashion, microfolds are wrinkles in the Bowman's membrane or epithelial basement membrane seen most clearly as negative lines on fluorescein staining. They are more common in patients with thin flaps and high errors where greater tissue ablation is performed. Visually significant flap striae need to be removed by re-lifting the flap and stroking it back to smoothen out the striae. Severe cases as seen with *fixed folds* or late in the *postoperative* period may need epithelial debridement and thermal ironing followed by bandage contact lens placement.

3-Epithelial ingrowth:

It is usually rare, occurring in < 1-2% cases with an extent of not more than 1 mm from the flap edge. Rarely epithelial nests or sheets may grow into the visual axis, induce irregular astigmatism and cause blurring and haloes.

Treatment involves early identification and removal of the epithelial cells. Scraping both the stromal bed and the undersurface of the flap is essential to prevent recurrence.

4-Diffuse lamellar keratitis:

Also known as Sands of Sahara, diffuse lamellar keratitis is a sterile inflammatory reaction with ported incidence of around 1.8% . The exact etiology is unknown but is believed to be caused by foreign cells introduced at the time of surgery . These include gram negative bacterial endotoxins, residue from the micro- keratome head, glove powder etc. It is characterized by pain , blurred vision, foreign body sensation and light sensitivity and occurs usually 1-6 days after surgery but can occur months to years later as well.