

Recent Advancements in Refractive Surgery.

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INTRODUCTION

Refractive surgery has seen extensive advancements in recent years and has evolved from a rudimentary science a few decades ago to an extremely sophisticated and hi-tech branch of Ophthalmology. Major innovations and breakthroughs have helped to make refractive surgery safe, precise, predictable and stable and improved not only the vision but the quality of life of millions of patients who have benefited from it. At the same time complications remind us to be extremely cautious and careful before we advise any refractive procedure and to be meticulous and methodical at every step of examination, surgery and follow up.

Cornea is the chief refractive surface of the eye and is of approximately 550 microns thick in the centre going up to 700 microns in the periphery with an average power of +44D. It is composed of 5 layers: epithelium which is made up of basal columnar cells, wing cells and surface cells; Bowman's membrane which is not a true membrane but a condensation of the superficial stroma, stroma which constitutes 90% of corneal thickness and is made of parallel arrangement of collagen fibrils, Descemet membrane which is a true membrane and endothelium made of hexagonal cells¹.

Laser refractive surgery essentially consists of a spectrum of procedures aimed at modifying the refractive power of the eye by changing the corneal curvature using lasers (LASIK- Laser-Assisted In Situ Keratomileusis, PRK - photorefractive keratectomy, LASEK - laser assisted sub-epithelial keratomileusis), and intra-corneal insertion of rings or gels or changing the lenticular power using phakic lenses in the anterior or posterior chamber or clear lens extraction as for high myopia. A combination of techniques maybe used to correct higher refractive errors such as phakic IOL implantation along with LASIK etc which is broadly termed as *bioptics*.

CLASSIFICATION OF REFRACTIVE SURGERY

Changing the corneal curvature

- Incisions(RK, AK)
- Lasers

A) Surface treatment techniques

- PRK (Photo-refractive keratectomy)
- LASEK (laser-subepithelial keratomileusis)
- Epi-LASIK

B) Lamellar treatment techniques

- LASIK using the micro-keratome
- LASIK using the femtosecond laser
- Intra-corneal inserts (segments/ gels)

Changing the lens

- Phakic IOLs (Anterior/ posterior chamber)
- CLE (clear lens extraction)
- Lens exchange (Multifocal/ accommodative IOLs)

Lasers for presbyopia

- CK (conductive keratoplasty)

- Corneal inlays and onlays
- Intra-stromal femtosecond laser

Combination of techniques

- Bioptics
- Trioptics

An intensive examination is done to assess the status and suitability of the eye for any procedure and decide the best technique possible to produce an optimum vision correction.

PRE-OPERATIVE WORK UP IN LASER REFRACTIVE SURGERY

History: Thorough history taking is an extremely important part of the refractive surgery workup. Stability of refraction must be ensured for the last one year. Contact lenses must be removed prior to the pre-op examination for a minimum of 7-14 days for soft contact lenses and 3 weeks for rigid gas permeable lenses. Any other past significant ocular or systemic history must be ruled out. Systemic contraindications for Lasik include auto-immune disorders, collagen vascular disorders, diabetes mellitus and immuno-compromised states, predisposition to hypertrophic scar or keloid formation^{2,3,4,5}. Pregnant and nursing women should also defer surgery due to fluctuation of refractive error during pregnancy, unstable tear film status and avoiding exposure of the foetus or neonate to medicines that maybe required after the Lasik procedure⁶. Patients on medications such as Amiodarone, Isotretinoin & Sumatriptan should be treated with caution as these medications may interfere with the wound healing response^{7,8}.

PRE-OP EXAMINATION

Ophthalmic examination

A complete and detailed ophthalmic examination is mandatory before a patient is taken up for laser refractive surgery. Both Uncorrected visual acuity and best corrected visual acuity must be recorded. A dry and cycloplegic refraction is performed. A cover test should be done to rule out any form of phoria or tropia. A detailed slit lamp examination of the ocular adenexa and anterior segment should be carried out to look for any lid abnormalities, corneal scarring or opacities or conjunctival disease. Any blepharitis or meibomitis must be treated to improve tear function and prevent trapping of any secretions at the flap interface. Intraocular pressure by applanation tonometry should be measured Careful evaluation of the cornea to rule out corneal opacities, thinning, vascularisation and punctate erosions should be done. Ophthalmic contraindications include active ocular disease or inflammation such as conjunctivitis, scleritis, iritis or corneal ulcer. Severe dry eye associated with kerato-conjunctivitis sicca or exposure keratitis is an absolute contraindication. Herpes zoster ophthalmicus or herpetic keratitis especially if active in the previous 6 months is at risk for re-activation after exposure to ultraviolet radiation⁹. Corneal ectasias seen in keratoconus, pellucid marginal degeneration and keratoglobus also preclude Lasik surgery¹⁰. Indirect ophthalmoscopy is carried out to look for any significant

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treatable peripheral retinal lesions. Schirmers test should be done in every patient to rule out dry eyes.

A corneal topography and wavescan measurement is performed. The corneal curvature, thickness, anterior and posterior floats are measured. Any corneal thinning or ectasia or early keratoconus (keratoconus form fruste) is ruled out.

Ocular dominance is tested in patients undergoing monovision refractive surgery. It can be tested using sighting tests e.g (hole in the card test), sensory tests (binocular rivalry tests) or by assessing asymmetry in visual acuity and contrast sensitivity. In patients undergoing monovision refractive surgery, the dominant eye is corrected for distance vision, and the non-dominant eye undercorrected to less than 2 diopters of myopia for near vision.

CORNEAL WAVEFRONT ABERROMETRY

Refractive errors are traditionally described as a spherical error (plus or minus) with or without astigmatism. Optical defects which significantly affect the retinal image quality beyond the spherical and cylindrical component are called aberration derived from the Latin word ‘ab-erratio’, which means going off-track or deviating. Aberration is the difference that exists between an ideal image formed by in a perfect optical system (Snell’s law) and what is actually achieved (Fig. 1). These differences vary from simple defocus to highly aberrated wavefronts. The Dutch mathematician and astronomer, Frits Zernike described these aberrations first using mathematical models known as Zernike’s polynomials to explain the wavefront measurements of the eye (Fig.2). The shape of the wavefront is described in the x, y and z coordinates^{11,12} (Fig.3). The final figure is obtained from the sum of the Zernike polynomials describing all types of deformation (Fig. 4). The French mathematician and physicist Jean Baptise Fourier used sine waves to describe the wavefront pattern¹³. By adding sine waves of appropriate amplitude and frequency, the exact wavefront analysis is obtained to identify and measure imperfections of the eye (Fig. 4). A Hartmann Shack pattern is used to identify 255 spots and wavefront map is obtained (Fig. 5).

Aberrations can be divided into two groups: chromatic and monochromatic. Chromatic aberrations are caused by the difference in distribution of incident polychromatic radiation throughout a medium and depend on the wavelength of the light that penetrates the eye. This type of aberration cannot be corrected, because it depends on the composition of the ocular structures and not their shape. Monochromatic aberrations are related to a specific wavelength and include spherical refractive error (defocus), cylindrical refractive errors (astigmatism), and high-order aberrations (HAO) such as spherical aberrations and coma.

Optical aberrations produced by each person’s eye are as distinct as each person’s fingerprint. They have been classified as below:

Low-order aberrations include the following:

- Order-zero (no order). These aberrations are characterized by axial symmetry and a flat wavefront.
- First-order. These linear aberrations correspond to tilting around a horizontal (x) or vertical (y) axis. They describe the tilt or prismatic error of the eye.
- Second-order. Spherical defocus and astigmatism describe the spherical error and astigmatic component and its orientation or axis. These components are similar to measurements found with basic refraction.

High-order aberrations are as follows:

- Third-order aberrations correspond to horizontal and vertical

coma and triangular astigmatism with the base along the x- or y-axis (trefoil).

- Fourth-order aberrations include spherical aberration, tetrafoil, and secondary astigmatism.
- Fifth-tenth order aberrations are important only when the pupil is greatly dilated.

Wavefront devices

The wavefront device or aberrometer is the instrument used to study of the refractive errors and total aberrations of the eye. The analysis of the emerging wavefront can be based on different principles and may be done using the Hartmann Shack wavefront sensing device, Tscherning aberrosopy, Optical path difference scan and Ray tracing refractometry.

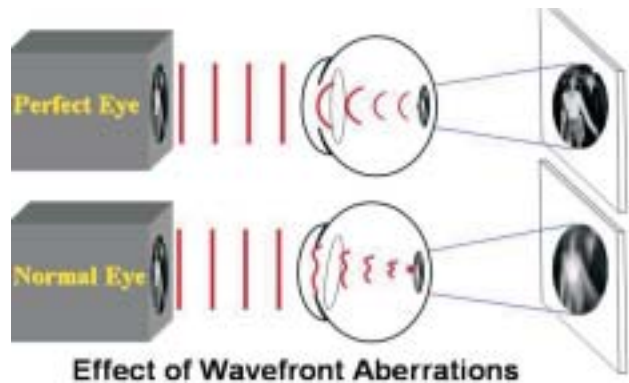


Fig. 1: Effect of aberrations on the image produced in the eye.



Fig. 2: Zernike’s polynomials to show various aberrations

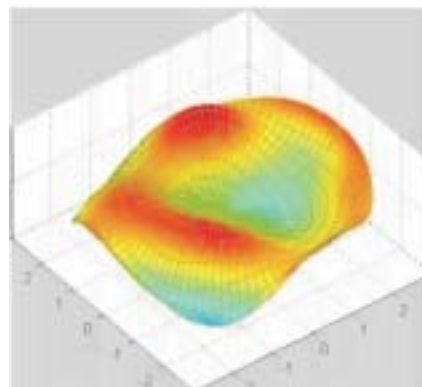


Fig. 3: A wavefront pattern described in x, y and z co-ordinates showing how light is moving through the visual system. The colors indicate how light is progressing with areas moving ahead ‘faster’ are shown in red and ‘slower’ areas shown in blue. A perfect wavefront with no visual defects would appear.

Data Resolution Summary

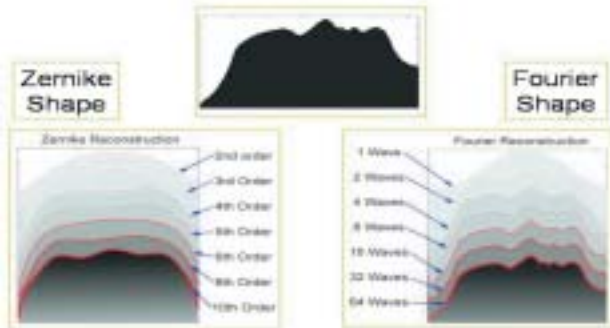


Fig. 4: Comparison of Zernike's analysis and Fourier analysis.

WaveScan™ Fourier Software

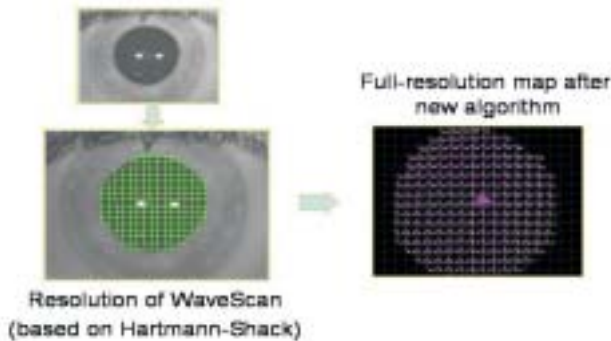


Fig. 5: A Hartmann Shack analysis of the wavefront pattern

HARTMANN-SHACK SYSTEM

Hartmann-Shack aberrometer uses a laser light source to measure and visualize ocular aberrations. The light reflected by the retina is divided into several light points by a lenslet array^{14, 15, 16}. The location of each spot is captured by the video sensor and compared with its theoretical location in an aberration-free system. The combined relative offsets of the points provide a wavefront aberration map (Fig. 6).

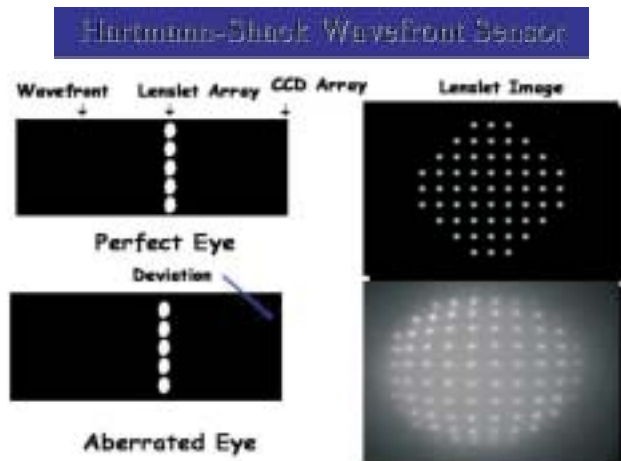


Fig. 6: Hartmann Shack wavefront sensor

TSCHERNING SYSTEM

The Tscherning system uses a frequency-doubled neodymium:yttrium-aluminium-garnet (Nd:YAG) laser emitting light at 532 nm. The incident light beam passes through a perforated lens and a video recorder registers the deformation of the reflected pattern, analyzes it, and returns the image to a reticulum¹⁷. Analyzing the image and comparing the aberrated retinal grid pattern with the ideal grid positioning quantifies the optical aberrations at the level of the entrance of the pupil. The distortion of the grid pattern enables calculation of the aberrations of the optical system of the eye.

TRACEY SYSTEM

This device measures an ingoing light that passes through the optical system of the eye and forms an image on the retina, measuring one ray at a time in the entrance pupil rather than measuring all of the rays at the same time¹⁸. This design decreases the chance of crossing the rays in highly aberrated eyes with a total scanning time of 10 to 40 ms. It processes a complete refractive map of the eye and a distortion map of the wavefront.

Scanning system or optical path difference scans

This system scans a large number of points and examines the relationship between the light source and the reflected component¹⁹. This diagnostic instrument combines autorefractometry, corneal topography, and analysis of the wavefront to create a single map of the corneal surface's refractive power. After analysis, all the systems produce aberrometric maps or topographical maps which describe the difference in microns between a light wavefront and a reference wavefront.

Wavefront images can be used for diagnostic and therapeutic reasons

- 1) They are used to localize aberrations
- 2) They are used to measure all aberrations of the eye including 2nd order (sphere and cylinder), 3rd order (coma like), 4th order (spherical aberrations) and others.
- 3) Combined with corneal topography systems, they are used to plan customized ablations. Clinically, correction of the spherocylindrical error alone in some eyes is insufficient to produce an optimal result, because some of the aberrations present can cause irregular astigmatism. The integration of the wavefront analysis and corneal topography with the laser treatment plan helps to perform an ideal ablation which can treat almost all significant aberrations of the eye.

Summary: Wavefront technology allows measurement of the sphere, cylinder, and axis of a patient and HOA such as coma and spherical aberration. The aberrations measured are not just corneal but aberrations of the entire optical system. Treating these aberrations with personalized laser ablation plans helps to provide better quality vision.

CORNEAL TOPOGRAPHY

Accurate mapping of the corneal structure, contour, surface and thickness has become increasingly important as refractive procedures are gaining popularity for elective vision correction. Advancements in technology have allowed us to move beyond traditional keratometry by using sophisticated imaging systems which analyze multiple data points at both the anterior and posterior surface of the cornea. The commonly used corneal topography systems include

- three dimensional topography (Astramax, LaserSight technologies Inc., Winter Park, Florida)

- slit scanning (Orbscan, Bausch & Lomb, Rochester, New York).
- scheinpflug imaging (Pentacam, Oculus Inc, Dutenhofen, Germany).
- very high frequency (VHF) ultrasound (Artemis, Ultralink LLC, St. Petersburg, Florida).
- high speed anterior segment optical coherence tomography (Visante, Carl Zeiss Meditech, Jena, Germany).

Standard keratometry measures the corneal curvature on two principal meridians at points 3 & 4 mm apart at the centre of the cornea and assumes that the remainder of the central and peripheral cornea is a perfect sphero-cylinder. However as corneal irregularities increase, these two measurements do not suffice. In such cases placido disc measurement of the corneal surface helps to highlight the irregularities in shape²⁰. The placido disc mires appear widely separated in flat areas while steeper portions show closely placed mires. Topographers use computerized keratoscopic imaging to digitally reconstruct the corneal surface and represent it as a color coded map. As a general rule, cooler colors such as blue represent flat areas while warm colors such as red indicate steep areas. These maps portray not only the central region of the cornea but also the peripheral and mid-peripheral areas where surface abnormalities may lie.

Corneal tomography (fig. 7) is creation of three dimensional images from two dimensional cross sections. The Orbscan II is a hybrid system which combines a projective slit scanning device with a reflective placido technique²¹. The images are represented as color maps including a curvature map, anterior & posterior elevation map and pachymetric map. Though Orbscan has been found to be accurate for corneal topography in normal population, myopes and keratoconus patients, its posterior elevation data is unreliable in patients after refractive surgery. This is possibly related to loss of transparency and increased scattering of light by edema²².

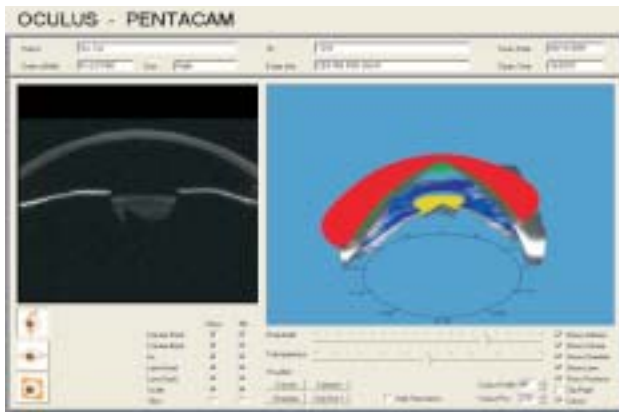


Fig.7: Corneal tomography image obtained with a pentacam 3-D reconstruction of the anterior segment of the eye with red and green denoting the anterior and posterior corneal surface, blue depicting the iris tissue and the lens shown in yellow.



Fig. 8.: Pentacam

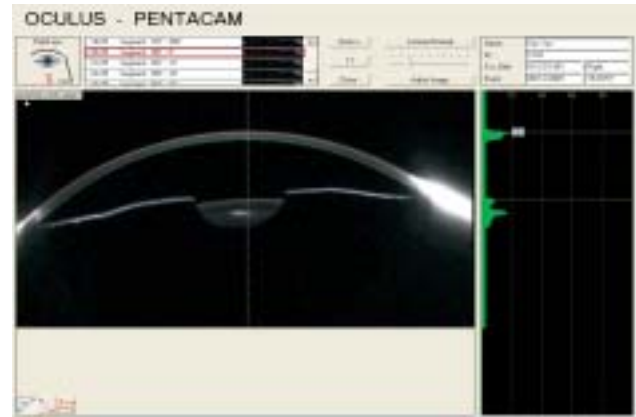


Fig. 9: Scheimpflug image obtained with a pentacam. The lens densitometry is shown on the right.

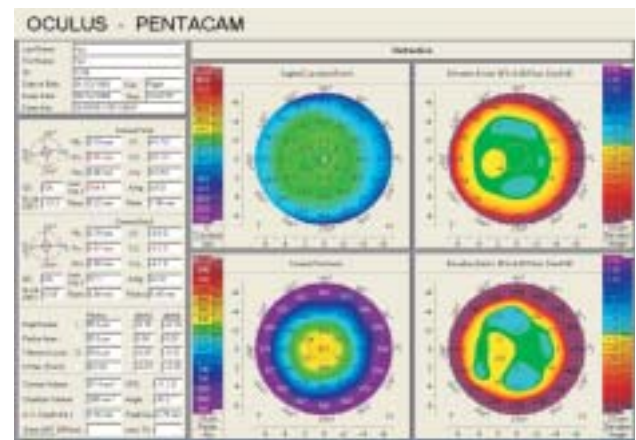


Fig. 10: Pentacam generated image of the corneal topography showing 4 refractive maps (clockwise from top left) the saggital curvature, the front elevation, the back elevation and corneal thickness maps. The data on the left provides information regarding the keratometry and astigmatism and corneal thickness at the centre of the pupil and the thinnest pachymetry values.

The Pentacam (fig. 8) uses rotating Scheimpflug imaging (fig. 9) technology to generate a complete image of the anterior segment of the eye within 2 seconds. Topography and pachymetry of the entire anterior and posterior surface of the cornea from limbus to limbus is calculated and displayed (fig. 10). Along with this, it measures the anterior chamber angle, depth and volume. It also images the iris, anterior and posterior surface of the lens and quantifies the lens densitometry.

Posterior elevation mapping has been found to be more accurate with Pentacam than with Orbscan as the Pentacam views the cornea directly. In evaluation of keratoconus, the anterior elevation map differences between the best fit sphere (BFS) and the corneal contour are studied:

- less than +12 μm are considered normal
- between +12 μm and +15 μm are suspicious
- more than +15 μm are typically indicative of keratoconus

Similar numbers about 5 μm higher apply to the posterior elevation maps. These are especially useful for Lasik/PRK screening and to detect post surgery ectasia.

The Pentacam also allows calculation of 'Equivalent K-Readings' based on the "Holladay Report" to improve the calculation of IOL

power for patients who have undergone prior refractive surgery. Normal keratometry measurement in post-refractive surgery patients leads to erroneous IOL calculation due to^{23, 24}:

- following myopic Lasik, overestimation of keratometry reading causes under-estimation of IOL power resulting in a hyperopic outcome
- following hyperopic Lasik, underestimation of keratometry reading causes overestimation of IOL power resulting in myopic outcome.

This happens because most keratometers measure four paracentral points on the corneal surface ignoring adjacent steeper or flatter areas which have been modified by ablation during refractive surgery. Also most keratometers are calibrated for a corneal index of 1.3375 which assumes that the corneal thickness and the relationship between the anterior and posterior corneal surface is constant. None of these may be true following excimer ablation leading to inaccurate calculation. Methods which may be used to calculate the IOL power after refractive surgery include^{25, 26, 27, 28}:

- clinical history method
- contact lens over refraction
- vertexed IOL power method
- double keratometry adjustment
- intra-operative autorefraction
- effective refractive power calculation using the Holladay Diagnostic Summary

Optical coherence tomography is an optical method of cross-sectional scanning based on reflection and scattering of light from structures within the cornea achieving an axial resolution of 3 to 20 μ m using a non-contact technique²⁹. It allows a precise calculation of thickness of different corneal layers and is especially useful in measuring Lasik flaps, corneal epithelium, intra-corneal ring segments etc.

Ultrasound bio-microscopy allows measurement of individual corneal layers including the epithelium, corneal flaps, stroma and can be used as a guide for free cap replacement according to the pattern of flap irregularities³⁰. VHF (Very High Frequency) ultrasound scans a series of meridians in an arc motion matched to the curvature of the cornea.

Pachymetry or measurement of corneal thickness is crucial for refractive surgery planning. While ultrasonic pachymetry has been the standard in past years, it suffers from the following disadvantages:

- need to use anesthetic
- contact method, may cause spread of infection or epithelial abrasion
- differences in pressure applied during measurement
- lack of precision

Optical pachymetry is considered more useful as it produces detailed thickness maps at multiple locations on the cornea giving the exact position on the cornea using a co-ordinate system³¹. Peripheral corneal measurements and early changes as in form fruste keratoconus are better identified on these maps. The Pentacam also gives a Relative Pachymetry map which gives a comparative difference from a normal eye pachymetry map with the thinnest point being normalized to zero.

Orbscan measurements have been found to be more than those seen by ultrasonic pachymetry and this may create an impression that the maximum safe ablation depth for a LASIK procedure is greater than acceptable. Therefore, the manufacturers of the Orbscan devices

introduced a correction factor to more closely match the results from Orbscan and US pachymetry. The value of this correction factor, known as the acoustic factor is 0.92³². Consequently, studies show a close agreement between mean central pachymetry values for Orbscan II and US when assessing central pachymetry in normal corneas. Light scatter from stromal haze and flap interface interferes with precise calculations in the Orbscan after refractive surgery. Leung et al found that scanning slit topography tends to underestimate corneal thickness in corneas measuring less than 500 μ m and over-estimate it in corneas more than 500 μ m in thickness³³. Most studies have found a good correlation between pachymetry values as measured with Pentacam scheimpflug imaging, optical coherence tomography and ultrasonic pachymetry³⁴.

PUPIL MEASUREMENTS

An accurate measurement of the pupil is necessary in both dim light (scotopic) and room light (photopic). Pupil diameters more than 6mm usually are associated with greater night vision problems and haloes and though not a contra-indication to surgery, may need a modification of the surgical plan. Pupillometry may be performed using a Rosenbaum card or a hand-held infrared pupillometer³⁵. Most wavefront sensing devices measure pupil diameters along with aberrations to plan customized ablation profiles (fig. 11). In a pupil less than 3mm in size, HOA's are greatly reduced. In eyes with larger pupils and dim light conditions such as night driving, HOA's may become significant. Customized ablations reduce the incidence of HOA's.

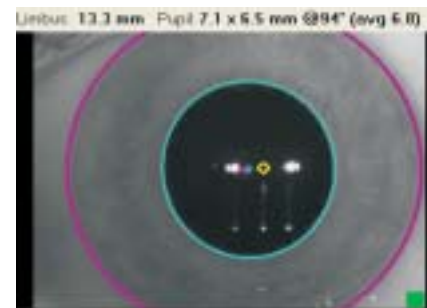


Fig.11: Pupil measurements using a wavefront analysis. Note elliptical shape of pupil (7.1 x 6.6 mm)

CORNEAL HYSTERESIS

Hysteresis is a term coined by Sir James A Ewing in 1890 denoting a property of physical systems to not instantly follow the forces applied to them but react slowly³⁶. Corneal hysteresis is the 'energy absorption capability' of the cornea and is a measure of the viscous damping of the corneal tissue. The Corneal Response Analyzer from Reichert utilizes a rapid air impulse and an advanced electro-optical system to measure two applanation pressure measurements; one while the cornea moves inwards and the other as the cornea returns^{37, 38}. Due to its biomechanical properties, the cornea resists the dynamic air puff causing delay in inward and outward applanation events resulting in two different pressure values. The difference between these 2 pressure values is Corneal Hysteresis (CH).

Measuring the corneal hysteresis has helped clinicians study the biomechanical properties of the cornea. Low CH means that the cornea is less capable of absorbing the energy of the air pulse and normal eyes exhibiting significantly lower CH values maybe at risk for developing corneal disorders in the future. Such people may be more at greater risk for developing post-LASIK ectasia. As such pre-op estimation of the CH has not yet become universal but may soon be incorporated in LASIK work up schedules as its utility

becomes clearly identified.

CONTRAST SENSITIVITY

Contrast sensitivity: Contrast sensitivity is the reciprocal value of the contrast threshold which is the smallest amount of contrast required to be able to see a target. Tests used to measure contrast sensitivity include the following^{39,40,41}:

- a) Grating tests: Vistech, CSV 1000, FACT chart
- b) Optotype tests: Pelli-Robson Chart

Grating tests define contrast sensitivity in different sizes of targets in terms of several different cycles per degree (cpd). Contrast sensitivity measurements with grating tests usually start at 1.5 cpd and go up to 18.0 cpd (or even higher with computer-based equipment). The range of the contrast levels can be from 3 to 0.004. The CSV-100 (Vector Vision) is a grating based chart which has an internal retro-illumination system mounted on the wall or a stand (fig.12). This test provides four rows of sine-wave gratings. At the recommended test distance of 8 ft (2.5 meters), these gratings test the spatial frequencies of 3, 6, 12 and 18 cycles/degree.

Another example of grating test is the Vistech Contrast Sensitivity chart which was first introduced in 1984. It contains circular photographic plates of sine wave gratings arranged in five rows (spatial frequencies 1.5, 3, 6, 12 and 18 cycles per degree (cpd)) and nine columns (contrast levels).

The Functional Acuity Contrast Test (FACT™): The FACT sine-wave grating chart tests five spatial frequencies (sizes) and nine levels of contrast. The patient determines the last grating seen for each row (A, B, C, D and E) and reports the orientation of the grating: right, up or left. The last correct grating seen for each spatial frequency is plotted on a contrast sensitivity curve.

Optotype tests: Pelli-Robson contrast sensitivity chart. Each letter subtends an angle of 3 degrees at a distance of 1 meter. Letters are organized in triplets with two triplets in each line. The contrast decreases from one triplet to the next. The log contrast sensitivity varies from 0.00-2.25. The Pelli-Robson test with optotypes (letters) only measures 1 cpd region at a recommended distance, and the examination must be done at different distances if more cycles per degree are needed. The lowest contrast level of the Pelli-Robson test (0.006) is adequate.



Fig. 12: CSV 1000. Contrast sensitivity testing is an important estimate of the complete visual system function. Measured under varying conditions of luminance and glare, it denotes the relationship between the optical efficiency of the eye and the minimum retinal threshold for pattern detection. Spherical and cylindrical refractive errors as well as higher order optical aberrations such as spherical aberrations and coma have an impact on the contrast sensitivity function of the eye⁴². Wavefront guided ablations provide greater contrast sensitivity than standard lasik^{43,44}.

EQUIPMENTS/ INSTRUMENTS USED IN LASER REFRACTIVE SURGERY

LASIK or Laser assisted in situ keratomileusis was originally conceived by Dr Jose I. Barraquer in Bogota, Columbia in 1949 where he created a free corneal cap, froze it, sculpted the undersurface on a cryolathe and sutured it back on the cornea⁴⁵. This was followed by automated lamellar keratoplasty in which after making a corneal flap, a microkeratome was used to excise a disc of stromal tissue and the flap was replaced without sutures⁴⁶. Burrato and Pallikaris first combined excimer laser with microkeratome technology⁴⁷. Subsequent modification in technique led to the current form of Lasik wherein an Excimer Laser is used to ablate the stromal bed after creating a hinged corneal flap with a very fine microkeratome blade, followed by accurate placement of the flap on the ablated stromal surface making it an extremely safe, precise & predictable procedure. Lasik has become increasingly popular since 1995 and is now the most commonly performed refractive procedure to correct myopia, hyperopia and astigmatism. Errors ranging from -0.5D to -12D of myopia, +0.5 to +4D of hyperopia and upto 8D of astigmatism can be treated^{48,49}. Lasik can also be used to treat residual refractive errors after PRK, RK, after cataract surgery with IOL implantation and penetrating keratoplasty and combined with other refractive surgery (bioptics & trioptics) etc.^{50,51,52,53}.

The basic instruments required for a Lasik procedure are the microkeratome and the excimer laser unit. A wide variety of microkeratomers are available including the conventional mechanical keratome, disposable keratome, water jets and laser keratomers.

A micro-keratome essentially consists of a fine oscillating blade which can penetrate the cornea at pre-determined depths to slice a smooth layer of corneal tissue. The adjustable parameters allow the surgeon to decide the depth and diameter of the corneal flap with an accuracy of 5-10 microns. The assembly, operation and maintenance of the microkeratome system are crucial to ensure accurate and predictable resections of corneal tissue.

The microkeratome set up includes a pneumatic suction ring which fixates the globe and elevates the intraocular pressure upto 65mm Hg to create an even and smooth corneal flap. On the surface of the suction ring, there are dove-tailed grooves over which the microkeratome head is placed and the motor allows the blade to advance to create a hinged corneal flap. A surgeon controlled foot pedal ensures movement of the blade forward till the hinge is reached after which it is reversed and the microkeratome removed from the eye.

The Excimer Laser system works on the principle of ablative photodecomposition using Argon Fluoride as the essential gas mixture. It is a Class IV laser with a wavelength of 193 nm. At this wavelength it causes selective ablation of corneal tissue according to preset parameters. For myopia greater ablation is done in the centre of the cornea to flatten the corneal shape while in hyperopia, the peripheral tissue is ablated to cause steepening of the cornea. The ablation protocol is determined specifically for each individual patient's refractive error and calculated accordingly by a software program in the laser system. The lasers may be delivered through an either large beam diameters of 5-7 mm or using the scanning technique to deliver a small spot or slit in a controlled manner on the stromal bed.

The depth of tissue ablation is calculated by Munnerlyn's equation which in a simplified way states that

$$\text{Depth of ablation } (\mu\text{m}) = [\text{diameter of optical zone (mm)}]^2 \times \text{I/3 power (D)}$$

Hence the amount of tissue that must be removed depends not only on the amount of refractive error but also on the optical zone. Both the diameter and depth of ablation need to be optimized to attain best results. Smaller optical zones cause greater degree of regression and haloes while larger zones are beneficial in reducing night vision problems.⁵⁴

All laser systems come with their recommended list of safety precautions. All operating room personnel should avoid direct exposure to skin or eye with the primary laser beam. The area of potential hazard for production of photochemical keratitis is less than 40 cm. Safety glasses should be worn within this range. Odors and fumes interfere with laser function and should not be allowed inside the laser room. The gas cylinders used in the laser have Fluorine, Argon, and Helium & Neon. Fluorine is a highly toxic gas with a sharp odor that causes irritation to nose, eyes and throat at extremely low concentrations. Excimer lasers use < 0.25% concentration of Fluorine. Argon, Helium & Neon are inert non-toxic gases with no color, odor or taste.

Strict environmental conditions need to be maintained in the laser suite for proper functioning of the laser system. Temperature range should not fluctuate beyond 60°-80° F (15.5-27°C) and relative humidity should be between 35%-65%.

LASIK IN MYOPIA

Lasik is most commonly performed the world over for correction of myopia. The pre-requisites for Lasik include a minimum age of 18 years and refractive stability (no more than a $\pm 0.5D$ change in refraction in the last 6 months).

LASER PROCEDURES

Laser refractive surgery is based on the principle of modifying the refractive power of the cornea by ablating the stromal tissue. Laser procedures performed using excimer lasers to correct refractive errors are of two types:

Surface treatment techniques^{55,56,57,58}

- PRK (Photo-refractive keratectomy)
- LASEK (laser-subepithelial keratomileusis)
- Epi-LASIK
- Surface ablation

Lamellar treatment techniques

- LASIK using the micro-keratome
- LASIK using the femtosecond laser

In the surface treatment techniques, corneal tissue is ablated with an excimer laser just below the corneal epithelium. The various techniques refer to how the corneal epithelium is removed.

- In trans-PRK epithelium is removed using a laser
- In LASEK an alcohol solution is used to abrade the epithelium
- In epi-LASIK, a microkeratome is used to remove a uniform sheet of epithelium
- In surface ablation, a mechanical instrument is used to scrape off the epithelium

The excimer laser procedure is performed. The corneal epithelium usually grows back in a couple of days.

In lamellar laser techniques, a microkeratome or a femtosecond laser is used to create a flap. The flap is everted on its hinge and the stroma is exposed for laser ablation. After ablation, the flap is reflected back in its original place where adhesions form within a few hours.

Performing the laser procedure

Based on the refraction, corneal topography and wavescan

measurements, the laser treatment plan is made. The information is complied together and the ablation profile is created keeping a residual bed thickness of atleast 250 microns. The laser technique is adopted depending on the amount of refractive error, the corneal thickness and the ablation depth required while maintaining the minimum bed thickness.

The ablation profile of an excimer laser corrects the spherical and cylindrical portions of the refractive error with lasers for myopia removing tissue from the center of the cornea to make the cornea flatter while hyperopic ablations are performed in the corneal periphery to make the central cornea steeper. Aspheric and wavefront-guided ablation profiles treat higher-order aberrations (HOA) of the eye and thus improve the patient's quality of vision^{59,60,61}.

Eye trackers monitor the centre of the pupil and the iris pattern to prevent de-centered ablations and compensate for normal saccadic eye movements. The ablation procedure stops if the eye tracker cannot locate the pupil so that incorrect or poorly centered ablations are not performed⁶².

Standard lasik ablation parameters are available, which have the recommended ablation depth calculated based on the refractive error and treat the spherical and cylindrical components. However they do not treat the higher order aberrations (HOA's) and may even induce them especially during correction of high refractive errors. To avoid this, customized LASIK or C-Lasik is performed which integrates wavefront technology with the laser treatment.

CUSTOMIZED LASIK

Various laser machines and wavescan devices are available. We describe the system we've used most often in our clinical practice. The VISX WaveScan WaveFront system based on Fourier Technology and the VISX STAR S4™ Excimer Laser System (Fig 1) are combined together to perform Customized Lasik or C-Lasik (Fig 2). Data from the wavescan is analysed and transferred to the Excimer Laser System as the two systems are integrated together. Using Iris Registration Technology and Variable Spot Scanning, the smoothest ablation profiles are created for accurate correction of refractive errors.



Fig 13 a & b: STAR Visx WaveScan & CustomVue Excimer Laser system

The shape factor or asphericity of the cornea is numerically described by the Q factor⁶³. The Q factor value in normal population has been found to be -0.25 but the ideal Q factor value has been calculated to be around -0.4⁶⁴. The normal cornea has a prolate shape with the refractive power progressively decreasing from the centre to the periphery. Modifications in laser ablation profiles have been aimed at maintaining the asphericity of the cornea to obtain optimum results. Mochren et al have divided laser treatment profiles according to those based on the total optical system and those based on the cornea⁶⁵.

These can be described as follows:

Treatment based on total optical system

- Classic Munnerlyn's formula
- Wavefront guided profiles
- Wavefront optimized profiles

Treatment based on the cornea

- Topography guided profiles
- Aspheric / Q-factor adjusted profiles

In Classic laser ablation procedure, the Munnerlyn's formula is used to calculate the amount of tissue to be removed, based on the objective and subjective refraction and the resultant sphero-cylindrical correction required⁶⁶.

In Wavefront-guided ablation procedures, Zernike's polynomials or Fourier analysis is used (as described above) to measure the wavefront pattern of the eye. This offers the advantage of not only correcting the refractive error but also reduces aberrations and minimizes induction of HOA's⁶⁷.

Wavefront-optimized laser procedures preserve the eye's pre-existing optical aberrations without introducing newer aberrations and hence maintain the normal physiological state of the eye.

Topography-Guided Ablation is based upon the calculated difference between the pre-existing corneal surface and the desired surface and is aimed at correcting the refractive error and corneal HOA's. It is also known as Corneal wavefront ablation⁶⁸.

Aspheric or Q factor adjusted laser treatment is aimed at achieving the ideal shape or Q factor of the cornea independent of the overall spherical aberration of the eye⁶⁹.

Customized Lasik can correct errors ranging from -0.5 to -12D of myopia, +0.5 to +4D of hyperopia and upto 8D of astigmatism^{70,71}.

The basic instruments required for a Lasik procedure are the microkeratome and the excimer laser unit. A micro-keratome essentially consists of a fine oscillating blade which can penetrate the cornea at pre-determined depths to slice a smooth layer of corneal tissue. The adjustable parameters allow the surgeon to decide the depth and diameter of the corneal flap with an accuracy of 5-10 microns. The assembly, operation and maintenance of the microkeratome system is crucial to ensure accurate and predictable resections of corneal tissue.

The microkeratome set up includes a pneumatic suction ring which fixates the globe and elevates the intraocular pressure upto 65mm Hg to create an even and smooth corneal flap. On the surface of the suction ring, there are dove-tailed grooves over which the microkeratome head is placed and the motor allows the blade to advance to create a hinged corneal flap (fig. 2). A surgeon controlled foot pedal ensures movement of the blade forward till the hinge is reached after which it is reversed and the microkeratome removed from the eye. The corneal flap is then gently lifted and everted to allow laser ablation on the stromal bed (fig. 3-6). The interface is irrigated, and the flap is replaced on the stromal bed after ensuring accurate placement. Visual recovery is almost immediate with a stable and precise refractive outcome.



Fig. 14: The microkeratome head placed on the suction ring



Fig. 15: The corneal flap being lifted up

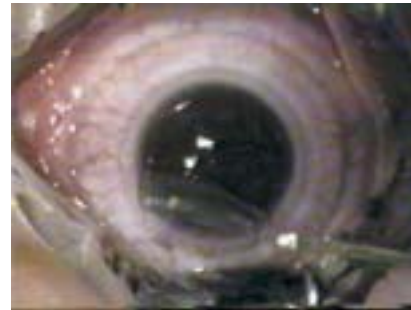


Fig. 16: Corneal flap placed on its hinge



Fig. 17: Laser ablation being performed on the stromal bed

COMPLICATIONS OF LASER REFRACTIVE SURGERY

As with any procedure, complications can occur during or after laser refractive surgery. A complete pre-op evaluation, an experienced refractive surgeon and meticulous post-op care can pre-empt the occurrence of such events. In the event of a complication, a prompt and appropriate intervention may prevent any long-standing visual or structural damage to the eye.

Complications following laser refractive surgery include the following:

- 1) **Flap related complications:** These include thin, irregular or button-holed flaps with average reported incidence of <0.2%⁷². *Thin or button-holed* are seen more commonly in patients with steep corneas (>46 D) or with poor suction. Treatment consists of replacement of the flap and applying a bandage contact lens to avoid further displacement. The laser procedure should be deferred till the flap heals smoothly. The patient can be taken up for re-cutting the flap after 3 months if the BSCVA is obtained. Alternatively, a surface ablation procedure maybe performed. *Irregular flaps* occur with jamming or jerky movement of the micro-keratome and indicate poor assembly or maintenance of

the motor system. Pre-op inspection and careful alignment and insertion of the microkeratome is essential to avoid such complications. A *free cap* occurs usually occurs in flat corneas (<41D) or with de-centered placement of the suction ring. The laser ablation should be completed, and the flap carefully removed and replaced in the correct orientation on the stromal bed^{73,74,75}.

- 2) **Laser related complications:** These include *decentration and irregular astigmatism*. Patients with high refractive error may find it difficult to fixate on the fixation light leading to de-centered ablations. Switching off external light sources helps the patient to fixate on the target light. Lasers using iris registration to recognize and match the eye position relative to the pre-op wavescan have lesser incidence of decentrations. Post-op, patients with decentered ablations complain of glare, haloes and ghosting of images due to light scattering at the edge of the ablation zone. Irregular astigmatism may occur due to decentered ablations and uneven flap healing. *Central islands* may occur when specific tissue areas are not ablated resulting in central elevated areas. Patients complain of poor vision and undercorrection. Customized lasers prevent such complications and provide better quality vision⁷⁶.
- 3) **Post-op complications:** These include *displaced or dislocated flaps*^{77,78}. 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 re-positioned and smoothed out in the correct orientation. The patient is asked to not rub the eyes at all in the immediate post-op period. *Flap striae or flap folds* may be noted in the immediate post-op 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 post-op period may need epithelial debridement and thermal ironing followed by bandage contact lens placement to keep the flap stretched in place⁷⁹.
- 4) **Epithelial ingrowth:** It is usually rare, occurring in < 1-2% cases with an extent of not more than 1 mm from the flap edge^{80,81}. 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.
- 5) **Diffuse lamellar keratitis:** Also known as Sands of Sahara, diffuse lamellar keratitis is a sterile inflammatory reaction with a reported incidence of around 1.8%^{82,83}. 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.
- Grade I:** This is a mild keratitis which is localized at the periphery with minimal to no symptoms. Frequent topical steroids

(prednisolone 1-2 hourly) should be started and patient reviewed in 1-2 days.

- Grade II:** Moderate infiltrates extending to the central cornea causing decreased vision and photophobia occur. Treatment includes frequent topical steroids along with oral steroids to control the inflammation.
- Grade III:** Clumping of inflammatory cells which obscure the iris details and central infiltrates with a significant decrease in vision is seen. Along with topical and oral steroids, lifting the flap to brush the stromal bed and the flap underface and irrigation to remove all the inflammatory cells and debris is important to prevent permanent damage.
- Grade IV:** Dense white central infiltrates maybe associated with corneal melting and loss of vision. The flap should be immediately lifted to scrape and remove all the interface debris and irrigated thoroughly. The infiltrate should be cultured to rule out an infective agent. A drop of steroid maybe placed on the stromal bed to prevent further inflammation along with topical and oral steroids. Complete and meticulous removal of infiltrates may help to prevent significant visual loss. Attention to prevention is the key, with emphasis on cleaning and sterilization of the microkeratome, avoiding build up of residue, using disposable canulas, wearing powder-free gloves etc.
- 6) **Infectious keratitis:** Though infectious keratitis after laser surgery is rare, it can be caused by *Streptococcus pneumoniae*, *Staphylococcus aureus*, *Mycobacterium chelonae*, and *Nocardia asteroides*. Atypical mycobacteria have a predilection for the anoxic environment at the flap interface and may present 2-4 weeks after surgery with multiple dense infiltrates with feathery margins. Patients will complain of pain, redness and decreased vision. Early diagnosis and prompt intervention with aggressive antibiotics should be started. Fourth generation fluoroquinolones and cephalosporins are recommended. Cultures should be performed and flap amputation or penetrating keratoplasty maybe needed in unresponsive cases^{84,85,86,87,88}.
 - 7) **Ectasia:** Thinning and bulging of the cornea may occur due to bio-mechanical weakening of the corneal tissue following laser ablation (Fig. 18). Patients with pre-op abnormal topography, keratoconus forme fruste cases which are missed but which progress, thin corneas and high refractive errors, residual corneal bed thickness < 250 microns are the risk factors. Patients will complain of decrease vision while topography will demonstrate irregular astigmatism with a myopic shift. Corneal cross linking with Riboflavin 0.1% and ultraviolet radiation helps to increase

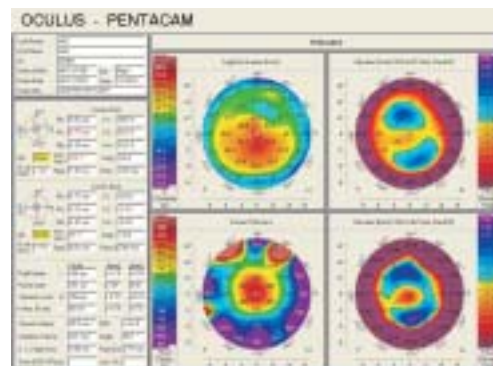


Fig. 18: Pentacam showing post lasik ectasia right eye.

the tissue rigidity and improve the bio-mechanical strength. Advanced cases may need corneal transplantation^{89,90,91}.

ENHANCEMENT AFTER REFRACTIVE SURGERY

Under or over-corrections after refractive surgery may need enhancement procedures to optimize the vision. These should only be performed after the refractive error is stable which is usually 3 -6 months post-operatively. Over-corrections usually regress over time, so it may be prudent to wait longer in such patients.

Enhancement procedures^{92,93,94} :

1. **Relift:** a) Wavefront-guided; b) Standard lasik
2. **Recut:** a) Wavefront-guided ; b) Standard lasik

3. Surface ablation

The corneal flap can be lifted easily after several years of refractive surgery, no cut-off limit is specified beyond which re-lifts are not possible. However, re-cutting a flap with a micro-keratome always remains an option.

To perform an enhancement procedure, the cornea is indented slightly with a merocel sponge to identify the edge of the flap which is then delineated with a Sinsky hook. A spatula is used gently lift the edge of the flap in the original plane between the flap and the stromal bed. The flap is gradually lifted and peeled back to be placed on its hinge. The corrective laser ablation is performed and the flap is replaced back. Careful attention is paid to irrigating the interface, wiping the stroma with sponges and aspirating the irrigating fluid and debris which maybe trapped beneath the flap. It is important to ensure accurate apposition of the flap at the edge to prevent flap displacement and epithelial in-growth which are more common after re-surgeries. 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 procedure⁹⁵. Mitomycin C is applied at the 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.

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 (Fig. 20-29). Use of Mitomycin C drops 0.02% have been recommended to reduce the chances of post-op 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.

Role of Mitomycin C in refractive surgery

Mitomycin C, an alkylating agent with cytotoxic and anti-proliferative properties has been used to reduce corneal haze after laser refractive surgery^{96,97}. It inhibits sub-epithelial fibrosis and abnormal activation and proliferation of stromal keratocytes after laser ablation⁹⁶. Dose and duration of Mitomycin C application is variable ranging from

0.002 to 0.02 % for 12 to 120 seconds but most surgeons use a concentration of 0.02% for 12-30 seconds. Use of Mitomycin C has not been associated with any significant epithelial toxicity but endothelial cell depletion has been reported by some authors. In refractive surgery, Mitomycin C has been used in primary surface ablation, to treat corneal haze and scars after refractive procedures and in re-surgeries after previous refractive procedures^{98,99}.

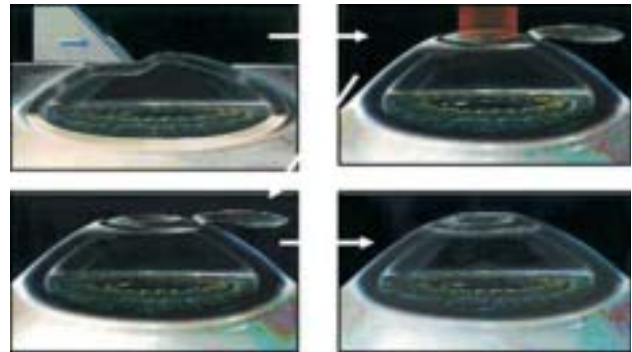


Fig. 19: The Epilasik procedure



Fig. 20: The epikeratome is placed on the eye



Fig. 21: The epikeratome is smoothly glided forward



Fig. 22: The epithelial flap is created.

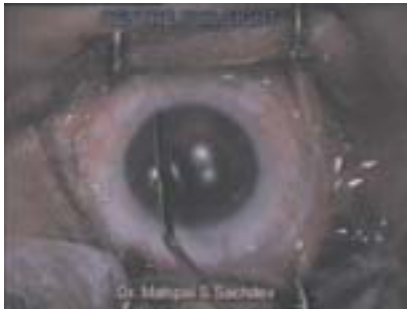


Fig. 23: The epithelial flap is lifted up gently



Fig. 24: The epithelial flap is everted on its hinge



Fig.25: The excimer laser ablation is performed



Fig. 26: The bed is irrigated with balanced salt solution



Fig. 27: A bandage contact lens is placed



Fig. 28: Post-op day 1, bandage contact lens in situ

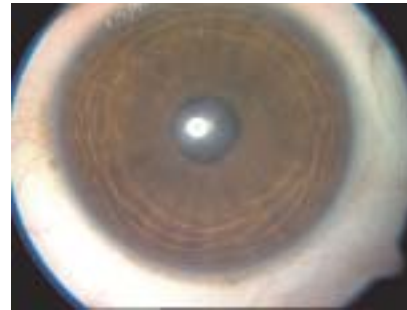


Fig. 29: Post op 1 week, note clear cornea with no stromal haze

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.



Fig. 30: The IntraLase femtosecond laser

The 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. The Intralase laser also creates a distinctive beveled edge flap which allows for precise re-positioning and alignment after Lasik is completed.

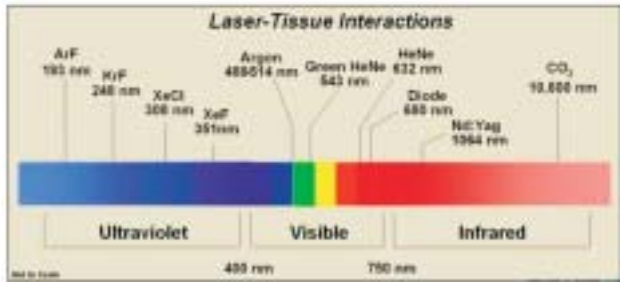


Fig. 31 Wavelength spectrum

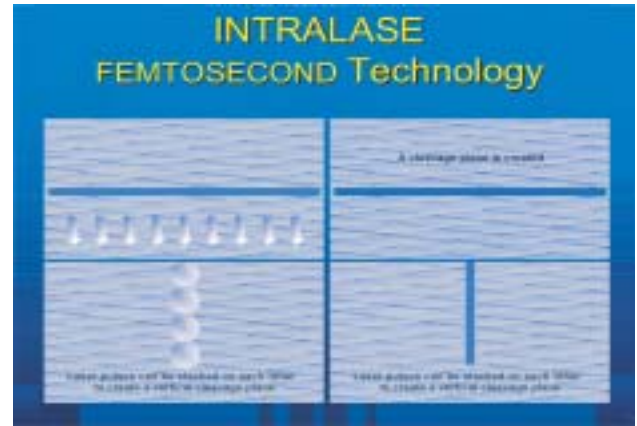


Fig. 33: Creation of a cleavage plane

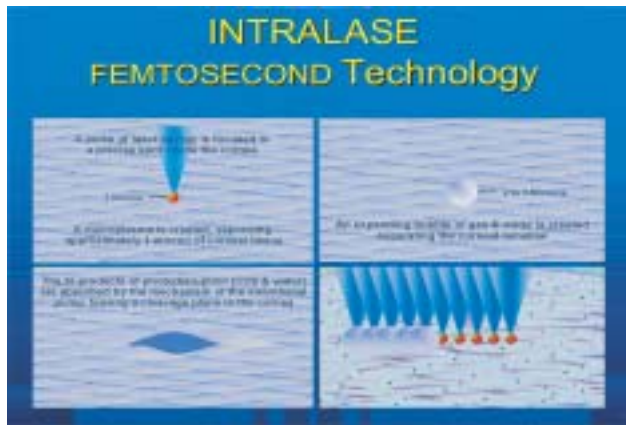


Fig. 32: Separation of corneal lamellae by focused laser energy

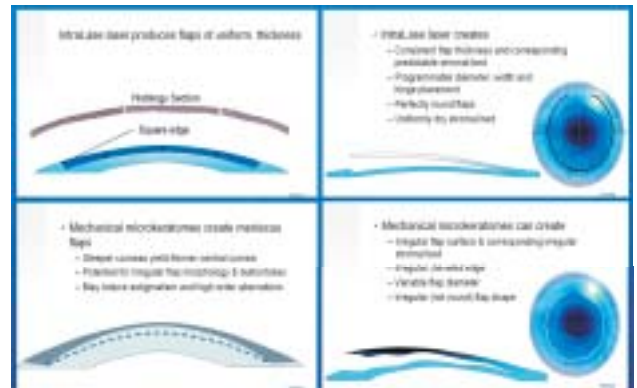


Fig. 34: Difference between IntraLase and microkeratome flaps

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^{100,101}. Not only is the visual acuity after femtosecond laser better but the incidence of post-op 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 post-op astigmatism as compared with microkeratome created flap (Fig. 33). The surgical steps are highlighted below (Fig. 34-45).

The Intralase femtosecond laser has also revolutionized other forms of corneal surgery such as corneal transplantation and Intra-stromal ring implantation. The femtosecond laser enables surgeons to create straight, angled and arcuate incisions which allow faster healing and improved visual recovery in penetrating keratoplasty. The mushroom-

shaped incision preserves more host endothelium than the traditional trephine approach while the top-hat incision allows for transplantation of large endothelial surfaces (Fig. 46). The zig-zag incision approach provides a smooth transition between host and donor tissue and allows for a hermetic wound seal. Intralase enabled keratoplasty (IEK) establishes secure grafts requiring less suture tension and reduced incidence of astigmatism leading to a faster and better visual recovery. The Femtosecond laser is also now being used to create intrastromal pocket for insertion of ICRS in the treatment of keratoconus¹⁰² (Fig. 47). Instead of using a mechanical spreader, the femtosecond laser is used to create channels at a pre-determined depth with a high degree of accuracy. The laser parameters which need to be specified include channel depth, entry incision length and width and channel size inner

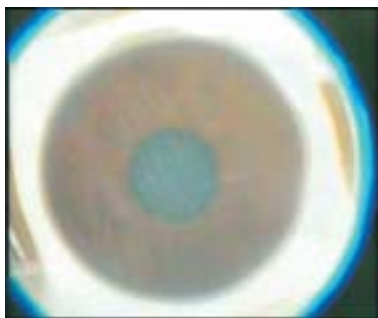


Fig. 35: Applanation of the corneal surface



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



Fig. 37: Progression of the femtolaser procedure

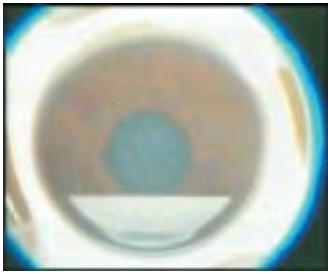


Fig. 38: Laser beam traveling forward creating a tissue plane

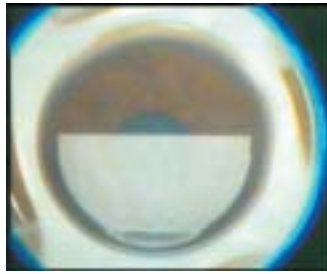


Fig. 39: Femtolaser assisted flap more than 50% complete

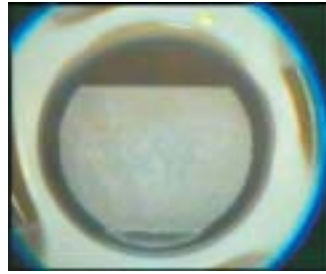


Fig. 40: Femtolaser assisted flap almost 80% complete



Fig. 41: Flap complete, side cut being delivered

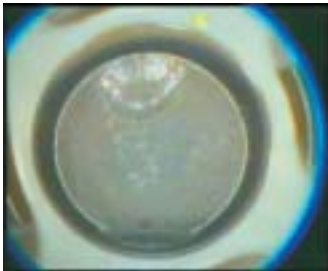


Fig. 42: 'Burp' where a condensed water bubble appears at the cleavage plane



Fig. 43: Lifting the flap by delineating the edge

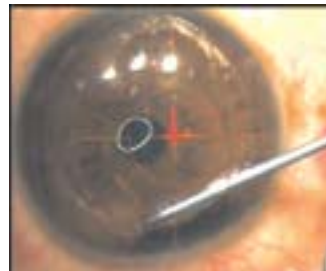


Fig. 44: Flap lifted up from the stromal bed



Fig. 45: Flap completely separated

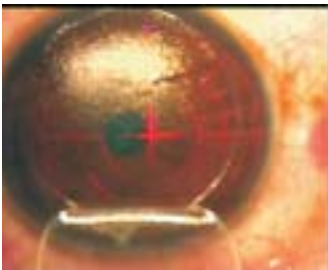


Fig. 46: Excimer ablation being performed on the stromal bed



Fig. 47: Femto-laser assisted penetrating keratoplasty

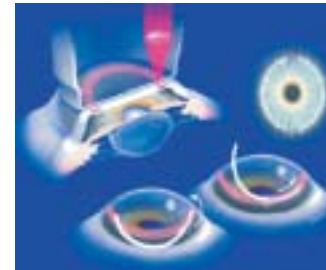


Fig. 48: Intacs placement using the femtosecond laser



Fig. 49: Intra-stromal ring implants (INTACS)



Fig 50a: TICL calculation software

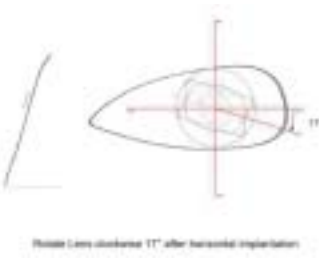


Fig 50b: TICL implantation diagram



Fig 51: Measuring the white-to-white diameter with pentacam (Schiempflug image)



Fig 52: Introducing the injector into the eye



Fig 53: ICL being slowly implanted in the eye



Fig 54: ICL placed behind the iris and in front of the lens



Fig 55: Post operative Slit lamp view of ICL

and outer diameter. The narrower the channel the greater the effect, however a narrower channel also results in increased difficulty in inserting ICRS. A compromise between maximal outcome and ease of insertion is achieved. The entry wound and channel creation takes 12 seconds after which the entry wound is opened with a Sinsky hook and the ICRS segment is carefully pushed forward into the channel with the forceps till the edge lies within 1-2 mm from the entry wound. Various studies have reported equally effective results with femtosecond laser and the mechanical dissector with a significant reduction in average keratometry, spherical equivalent refraction and surface asymmetry index and improvement in BSCVA, UCVA and spectacle and contact lens tolerance^{103,104,105}.

INTRA-STROMAL CORNEAL RING SEGMENTS (ICRS)

ICRS are corneal implants which are used to change the shape of the cornea and correct the refractive error in patients with myopia, keratoconus and ectasia. Approved by the US FDA, they consist of two, tiny clear crescent shapes pieces of PMMA which can be inserted into the cornea (Fig. 48). For myopia, ICRS work by flattening the cornea to re-focus light rays and improve vision while in keratoconus patients, ICRS flatten the steep part of the cone and reduce vision distortions. Based on the principle of the 'hammock effect', they redistribute the bio-mechanical stress exerted on the cornea by the aqueous and prevent further steepening of the cornea. Intacs (Additions Technology Inc) are available in various sizes from 0.250 to 0.450mm which are chosen according to the refractive error and the corneal thickness of the patient and offer a correction ranging from +1.00D to -8.00 D and higher.

A clear central cornea with a minimum corneal thickness of 450 microns at the incision site and a mesopic pupil size of less than 6 mm are preferred. After performing the corneal topography and the refraction, the size of the ICRS and placement is planned. The incision may be made mechanically with a diamond knife and a tunnel created by a dissector into which the ring segments are placed. Alternatively, the femtosecond laser can be used for the same using pre-programmed parameters. The segment is placed in the tunnel and advanced slowly with the distal end being placed at least 1 to 2 mm beyond the incision site to prevent extrusion. If any resistance or wave like appearance of the corneal tissue is noted, stop insertion and ensure that the segment is being placed in the right plane. At the end of the procedure, the incision is closed with a 10-'0' nylon suture and removed after 6 weeks- 3 months depending on the result attained. Contact lens fitting maybe started as soon as 6 weeks after surgery but vision may fluctuate till 6 months.

Intacs offer the advantages of leaving the central cornea undisturbed. The results are rapid and predictable and if required, the INTACS can be removed or exchanged. The corneal asphericity is maintained with minimal adverse effects. Possible complications include epithelial defects, channel haze, under/ over correction, sterile infiltrates/epithelial cysts, infectious keratitis and ring extrusion^{106,107}.

PHAKIC IOLS

Patients who have high refractive errors and/or thin corneas, are unsuitable for corneal refractive surgery. For such patients, lenticular refractive surgery is an option. This is available in the form of phakic IOLs which are implanted between the cornea and lens. Also termed 'duophakia' or 'artiphakia', the normal crystalline lens is retained and an additional intraocular lens is placed to correct the refractive error. The lens maybe fixated in the angle or enclavated to the mid-peripheral iris with a claw or placed in the posterior chamber.

The advantages of phakic IOLs are the following:

- Allow the crystalline lens to retain its function;
- Predictable;
- Immediately stable, because the refractive outcome depends less on healing processes;
- Excellent vision even in dim light conditions;
- Removable and exchangeable;
- Easily adjustable with complementary fine-tuning corneal surgeries;

Angle supported lenses include the Vivarte/GBR lens (Zeiss-Meditec), I-CARE (Corneal, Pringy, France) and Kelman Duet Implant (Tekia, Irvine, CA, USA).

The prototype iris fixated lens is the Artisan lens (Verisyse) which is a one-piece PMMA IOL. Available in two meniscus-shaped optic diameters of 5.0 and 6.0 mm, it has a fixed overall diameter of 8.5mm and an average vaulting of 0.9 mm. Potential complications include progressive endothelial cell loss, chronic uveal inflammation, chafing of the iris stroma at the sites of enclavement, lens displacement/decentration, pigmentary dispersion syndrome and irregular pupil. The other phakic IOLs include the Artiflex and Veriflex foldable iris supported lenses with a polysiloxane optic and rigid PMMA haptics and the Nikai lens (Fig.) which is a one-piece silicone lens with a 3.2-mm concave optic and a frontal surface that projected anteriorly through the pupil. It is fixated behind the iris plane by two haptics and has a total length of 8.0 mm.

IMPLANTABLE CONTACT LENS

The Implantable Contact lens (ICL) is a posterior chamber phakic IOL made of collamer which has become a preferred modality for correction of high myopia and for patients with thin corneas. It was first developed in the late 1980's in Russia by Dr. S. Fyodorov and the first implant was placed in Europe in 1993. Fyodorov introduced the concept of a soft phakic lens in the space between the iris and the anterior surface of the crystalline lens¹⁰⁸.

INDICATIONS AND PRE-REQUISITES

- When residual bed after LASIK is likely to be less than 250µ
- When the initial corneal thickness is less than 480µ
- Refractive error between the ages of 21-45
- Anterior chamber depth greater than 2.8 mm
- Stable refraction (<0.5D change in previous 12 months)
- No ocular pathology (NSC, glaucoma, lid pathology, etc)
- Mesopic pupil <6.0mm

Implantable contact lens is indicated for placement in the posterior chamber of the phakic eye for correction of moderate to high myopia ranging -3.0 D to -20.0 D. Toric ICL (TICL) can correct upto -3 to -23 D of sphere and + 1.0 to + 6.0 D of cyl. The toric ICL has the same overall design as the spherical ICL with the addition of a toric optic. The toricity is manufactured in the plus cylinder axis, within 22 degrees. The STAAR® Visian ICL™ is made from a combination of copolymer and collagen called Collamer®. This Collamer® implantable contact lens reduces reflections and glare, and the collagen makes it extremely biocompatible. It is made-up of 60% poly-HEMA, Water (36%), Benzophenone (3.8%) and Collagen (0.2%), it attracts the deposition of fibronectin on the lens surface, inhibits aqueous protein binding and makes the lens invisible to the immune system. Overall lengths available for myopic lenses are 11.5, 12.0, 12.5 and 13.0 mm and hyperopic lenses are 11.0, 11.5, 12.0, and 12.5 mm. Optic diameter of myopic lenses range from 4.65 to 5.5 mm and hyperopic lenses is 5.5 mm. Myopic lenses are plano-

concave (concave front surface) and hyperopic lens are meniscus-shaped (convex front surface).

PREOPERATIVE WORKUP

Preoperative evaluation includes dry and cycloplegic refraction, corneal topography, assessment of anterior chamber depth and white to white diameter calculation, specular microscopy, intra-ocular pressure measurement by applanation tonometry and detailed retina examination to rule out any treatable retinal pathology and peripheral retinal degeneration.

Calculation of power: ICL/TICL calculation and implantation software (Fig. 49) allows calculation of spherical and cylindrical power, length and generates the ICL/TICL implantation diagram (Fig. 50).

Measurement of white to white diameter: In the pre-operative planning, the critical parameter in sizing the ICL is the white-to-white (WW) measurement which can be measured with a Pentacam, OrbScan, UBM or using calipers (Fig. 51). In myopic eyes, to determine the overall length (in mm) of the ICL, add 0.5 mm to the horizontal WW measurement. If the ICL is too short for the sulcus, the lens vault may be insufficient to clear the crystalline lens, exposing it to the risk of an anterior capsular cataract. If it is too long, the lens will vault excessively, crowding the angle and possibly causing closed angle glaucoma.

Vault: Ideal ICL vault is approximately 500 μ m, which is roughly one corneal thickness. There are concerns about high vault (1000 μ m) leading to angle crowding and resulting in angle closure or synechiae formation. High vault may also increase iris chaffing and pigment dispersion, resulting in pigmentary glaucoma. Furthermore, low vault (125 μ m) may also cause ICL contact with the crystalline lens and increase the risk of cataract formation over time^{109,110}.

Peripheral iridotomy: A peripheral iridotomy is performed 1-2 weeks before the surgery to provide an outlet for the aqueous flow around the lens. Alternatively it may be performed intra-operatively after ICL implantation with a Vannas scissors or a vitrectomy cutter. It should be sufficiently wide (at least 500 μ m), positioned superiorly (from 11 to 1 o'clock) and well away from the haptics placement.

PROCEDURE: The procedure is performed under topical anaesthesia. After making a 0.6mm side port, a 3.2-mm clear corneal incision is made on the steep meridian. The lens is introduced with the injector and positioned behind the iris on a horizontal axis with a cyclodialysis spatula (Fig 52-55). To control for potential cyclotorsion in a supine position, the zero horizontal axis is marked preoperatively on the slitlamp. The lens is implanted temporally and gently rotated to align the axis with the cylindrical axis of the patient. Complete removal of viscoelastic material is essential. Presence of residual viscoelastic material behind the implant may cause opacification of the crystalline lens. A miotic agent is injected and the aspiration is completed. The incision is closed by hydrating the corneal incision.

DISCUSSION

Various studies have reported that phakic TICL implantation is a good option for the correction of moderate to high myopia,¹¹¹ hyperopia,¹¹² high myopic astigmatism, in eyes with keratoconus^{113,114}, correction of hyperopia post radial keratotomyl^{115, 116} and post penetrating keratoplasty¹¹⁷.

Kamiya et al¹¹⁸ studied long-term clinical outcomes of implantation of Visian implantable lens for moderate to high myopia in 56 eyes of 34 patients with myopic refractive errors of -4.00 to -15.25 diopters (D). They concluded that implantation of ICLs is safe and effective and provides predictable and stable refractive results in the treatment of moderate to high myopia during a 4-year observation period.

Pesando et al¹¹² evaluated ICL in 49 hyperopic eyes of 34 patients. Preoperatively, the spherical equivalent (SE) was between +2.75 D and +11.75 D and astigmatism was between +0.50 D and +1.00 D. The mean postoperative SE of the manifest refraction was +0.07 \pm 0.54 D; refraction stabilized quickly and remained stable throughout the follow-up period. The results confirmed the long-term safety, efficacy, accuracy, and predictability of ICL for hyperopia. Alfonso et al¹¹³ evaluated the efficacy, predictability and safety of myopic phakic posterior chamber ICL to correct myopia associated with keratoconus. They showed that spherical equivalent refraction was within \pm 1.00 D of the desired refraction in all cases and 84% of cases were within \pm 0.50 D. Alfonso et al suggested that phakic intraocular lens implantation is a viable treatment for myopia and astigmatism after PKP in patients for whom glasses, contact lenses, or corneal refractive surgery is contraindicated. Studies comparing ICL implantation with wavefront guided lasik by Igarashi et al have shown that ICL implantation induces significantly fewer ocular HOAs than wave front guided LASIK¹¹⁸. Kamiya et al compared Collamer toric ICL implantation and wavefront-guided laser in situ keratomileusis for high myopic astigmatism and found that all eyes in the ICL group and 71% of eyes in the LASIK group were within \pm 1.00 D of the targeted SE correction at 6 months¹¹⁹. They suggested that Toric ICL implantation was better than wavefront-guided LASIK in eyes with high myopic astigmatism in almost all measures of safety, efficacy, predictability, and stability. The overall complication rate with ICL is low and most patients have a good visual recovery. The incidence of glare, haloes and night driving problems is also minimal. Sanders et al¹²⁰ studied incidence of anterior subcapsular opacities and cataracts 5 years after surgery in the Visian implantable collamer lens FDA trial. Approximately 6% to 7% of eyes developed anterior subcapsular opacities over 7 years following ICL implantation but only 1% to 2% progressed to clinically significant cataract during the same period, especially very high myopes and older patients. Visual outcome following cataract extraction was good. Other reported complications of ICL are pigment dispersion¹²¹ and lens deposits, acute angle closure glaucoma¹²², late subluxation of ICL¹²³, endophthalmitis¹²⁴ and retinal detachment¹²⁵. ICL is a safe and effective modality for correction of high myopia and for patients with thin corneas, with excellent and stable post operative results. Advancements in anterior segment imaging and measurement technologies such as ultrasonic biomicroscopy, optical coherence tomography and Scheimpflug imaging are now providing valuable information about anterior segment anatomy for custom-designed phakic intraocular lenses for correction of moderate to high refractive errors.

BIOPTICS

For eyes with large refractive errors, one refractive procedure alone may not be sufficient to correct the entire refractive error. Combining two or 3 procedures together is called bioptics or trioptics respectively¹²⁶. Lenticular options are available in the form of phakic IOLs, toric IOLs and piggy back IOLs while corneal options for bioptics include Corneal relaxing incisions (CRIs), anterior limbal relaxing incisions (ALRI), laser-assisted epithelial keratomileusis (LASEK), photorefractive keratectomy (PRK), conductive keratoplasty (CK) and Intrastromal ring implants. Combinations for bioptics or trioptics include

- clear lens extraction with a monofocal or multifocal implant combined with limbal relaxing incisions to correct concomitant astigmatism;
- phakic IOL followed by LASIK to fine tune the residual refractive

error if any;

- toric IOL in the bag, multifocal IOL in the sulcus followed by LASIK can be used for trioptics;

Refractive surgery is of the most evolved aspects of ophthalmic science and is undergoing rapid advancements each day in the endeavor to provide crystal clear vision without the aid of glasses and contact lenses. Sophisticated equipments and technological breakthroughs have greatly contributed but at the base of all these innovations is the restless human mind searching for perfection. As this spirit continues, so will the quality of vision that we can provide to our patients with minimal complications.

REFRACTIVE SURGERY FOR PRESBYOPIA

Treatment of presbyopia is a challenge for the refractive surgeon as the mechanisms of accommodation are complex and the causes of presbyopia are not fully understood. More importantly, it progressively increases with age. Most widely used standard protocol has been the use of progressively hyperopic spectacles which take over the near focus of the crystalline lens.

Apart from near vision glasses the following is the list of treatment options for correction of presbyopia

- Monovision correction (using contact lenses/ monofocal intra-ocular lenses);
- Multifocal IOLs;
- Accomodative IOLs;
- Phakic multifocal IOL;
- Conductive keratoplasty (CK);
- Intracorneal inlays;
- Multifocal LASIK;
- Monovision LASIK
- Anterior ciliary sclerotomy;
- Laser anterior ciliary sclerotomy;
- Scleral expansion bands;

Monovision correction means correcting one eye for distance and the other eye for near so that the patient may be able to perform all activities at near and far distance without the aid of glasses. Ideally the dominant eye is corrected for distance vision and the non-dominant eye for near vision¹²⁵.

Monovision maybe obtained using contact lenses, monofocal IOLs, LASIK or in combination with CK.

CONTACT LENSES

Various types and combinations of contact lenses are available for people with presbyopia including distance CLs with glasses for near reading, CLs for near vision with spectacles for distance vision, monovision CLs, RGP bifocal CLs, soft bifocal CLs, and modified monovision CLs¹²⁷. The simplest option for patients already on contact lenses would be to wear near glasses concomitantly for near work. To obtain monovision with contact lenses, one eye could be given a contact lens for distance correction and the other eye a contact lens with the near add incorporated. Distance CLs with the use of glasses for near reading provide the patient with the best binocularity at all distances. The disadvantages include the need for the patient to put on glasses for reading. Modified monovision involves either the combination of a bifocal CL on one eye and a single vision CL on the other eye or the use of two bifocal CLs with one CL correcting for distance and intermediate vision and the other CL correcting for

intermediate and near vision.

Bifocal lenses are available which can be classified as a) alternating vision and b) simultaneous vision types. In alternate vision lenses, the wearer sees an object through either the distant or near vision part by moving the visual axis upward or downward. In simultaneous vision bifocal CL, which are of refractive and diffractive types, both distant and near images are formed on the retina simultaneously^{128,129}

MONOVISION WITH MONOFOCAL IOLS

For patients who are well-adapted to monovision contact lenses, surgical removal of the crystalline lens with monofocal IOL replacement may be performed correcting one eye for distance and the other eye for near. Since the patient may take a while to adapt to monovision correction, a trial with monovision contact lenses must be performed to gauge patient acceptance and comfort before surgery¹²⁷.

MULTIFOCAL IOL IMPLANTATION

A refractive or presbyopic lens exchange with multifocal IOL implantation may be considered for patients who want reduced dependence on glasses both for distance and near. Multifocal lenses are available as diffractive and refractive types. The diffractive type provide better near vision and contrast sensitivity and are less dependent on the pupil while the refractive type are pupil dependent but provide better light transmission and better intermediate range vision^{130,131}. A combination of a diffractive and refractive type offers best results and provides good vision at all ranges¹³². Gunenc et al have found bilateral implantation with a diffractive multifocal IOL in one eye and a refractive multifocal IOL in the fellow eye is safe and could provide patients with better intermediate vision, increased depth of focus and contrast sensitivity, and also less dependence on spectacles¹³³. The best candidates are hyperopes and high myopes who accept multifocal correction most readily. Haloes and glare are the most common complaints which gradually reduce over time¹³⁴.

ACCOMODATIVE IOLS

The Crystallens, the Accomodative 1CU lens and the Synchrony are some of the IOLs which work on the principle of restoring accommodation based on the optic-shift principle. The Crystallens is a multi-piece silicone lens with a movable optic-haptic junction that works like a hinge. When placed in the capsular bag, the ciliary body and the vitreous body pressure causes a forward shift of the optic resulting in about 0.5 to 1.5 D of accommodation which allows the patient a better range of intermediate and near vision as compared to a monofocal lens¹³⁵. The 1CU lens is a hydrophilic acrylic lens with a biconvex optic of 5.5 mm and overall diameter of 9.8mm. Post-operative lens position shifts, capsular opacification and fibrosis are issues that may influence the long term effectivity of these lenses.

Conductive keratoplasty (CK) is a relatively new corneal steepening procedure wherein radiofrequency (RF) waves are used to cause collagen shrinkage. Shrinkage of the fibrous protein in the collagen lamellae decreases the chord length of the cornea in the meridian of application. Using a Keratoplast tip, RF waves are delivered to discrete spots in the corneal stroma in a ring pattern to create a purse-string effect. The 450 micron long tip has a diameter of 90 microns and produces heat to a temperature of 65° C upto 80% depth in the corneal stroma. This causes steepening of the corneal surface and reduction of presbyopic symptoms by inducing myopia of 1-2 D. It has been approved by the FDA for treatment of presbyopia in emmetropic and hyperopic patients beyond the age of 40 years.

Rings of eight evenly spaced spots of 0.6mm diameter can be placed at 6 mm, 7 mm, and 8 mm with an additional second ring of eight

spots at 7 mm. Thus treatments consist of eight, 16, 24, or 32 spots. Using a single ring of eight spots at a 7-mm diameter gives an expected correction of 0.75 to 0.875 D. Adding a second ring at a 6-mm diameter gives a correction of 1.0 to 1.625 D. Adding a third ring at 8 mm gives 1.75 to 2.25 D. Finally, adding eight spots at the 7-mm diameter gives an expected correction of 2.375 to 3.00 D. A one-year follow-up of the clinical trials showed that all CK patients experienced some improvement in near vision. Possible after-effects are temporary and include tearing, vision fluctuation and foreign body sensation^{136,137,138}

ANTERIOR CILIARY SCLEROTOMY (ACS)

Multiple incisions are made in the sclera over the ciliary muscle to increase the distance between the lens equator and the ciliary muscle¹³⁹. The incisions produced accommodative amplitude of +1.25 D in young presbyopes but the effect regressed over time. While some studies have shown minor improvements in presbyopic vision others found no improvement, but concluded that this procedure weakens the sclera significantly so that it may rupture more easily.

A variation of the procedure has been tested in Japan, called **ACS-SEP**, for Anterior Ciliary Sclerotomy with Silicone Expansion Plugs¹⁴⁰. This study was done on 12 people with presbyopia. The same incisions were made in the sclera but this time they were filled with silicone plugs. The plugs were sutured in position to the exact same depth as the incision was made (95% of scleral thickness). Results showed 1.5D of improvement over 18 months. The plugs prevent the sclera from weakening

Laser Presbyopia Reversal (LAPR) This is similar to ACS, but uses a erbium YAG laser instead of a surgical knife. The laser vaporizes the tissue in eight radial lines on the sclera. This removal of tissue thins the sclera and increases the amount of space for the ciliary muscle beneath it.

SURGICAL REVERSAL OF PRESBYOPIA (SRP) WITH SCLERAL EXPANSION BANDS

The effects of the scleral expansion band are based on the theory of Schachar that states that the crystalline lens is under increased equatorial zonular tension during accommodation^{141, 142}. In 1992, the first scleral expansion band procedure was performed using a plastic polymethyl methacrylate (PMMA) circular band sutured to the sclera. Now a separate PMMA segment is placed in each of the 4 oblique quadrants of the eye. With a worldwide experience with the scleral expansion band procedure for the SRP involving more than 500 eyes, mean amplitude of accommodation of 3.25 D has been obtained. The overall response has been favorable with no change in distance refraction, best-corrected visual acuity, or axial length. Common adverse effects include subconjunctival hemorrhage, transient astigmatism, fluctuating near vision, and dry eyes which usually resolve in 6-8 weeks¹⁴³. Safety concerns about the procedure include the possibility of infection, degradation of the implants over time, and compromised blood circulation in the eye.

Presbyopic lasik or Monovision LASIK corrects one eye for near vision and the other eye for distance vision. Patients who respond well to a trial of monovision contact lenses can undergo presbyopic lasik¹⁴⁴. The patients must learn cortical adaptation and suppression to be comfortable with the quality of vision attained with monovision LASIK as at any point of time only one eye is focusing clearly.

CORNEAL INLAYS

Corneal inlays are another option for the treatment of presbyopia¹⁴⁵. They're based on the principle of 'small-aperture optics'. In a

presbyopic person, light rays from a near object form a blurred retinal image. If the peripheral rays are cut-off and only the central rays are allowed to pass, the size of the blur circle is reduced and depth of focus is increased. Corneal inlays are opaque implants with a small central aperture which are placed intra-stromally in the cornea. They are centered over the pupil in the non-dominant eye and provide improvement in near and intermediate vision.

The design of the inlays has undergone various modifications in the last few years. The AcuFocus Corneal Inlay 7000 (ACI 7000) has a thickness of 10.0 μ m, an outer diameter of 3.8 mm, and a central aperture or inner diameter of 1.6 mm¹⁴⁶. It is made of polyvinylidene fluoride (PVDF) and carbon. Polyvinylidene fluoride with nano particles of carbon to make it opaque. It is placed on the stromal bed after making a corneal flap using a microkeratome or femtosecond laser. Clinical trials have demonstrated good bio-compatibility, maintenance of corneal metabolism and significant improvement in intermediate and near visual acuity. The INTRACOR and the InVue inlays are other commercially available inlays.

Treatment of presbyopia is still far from perfect but with continued research and innovation, the day is not far when ageing changes in the eye will not only be reversed but may never occur!

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