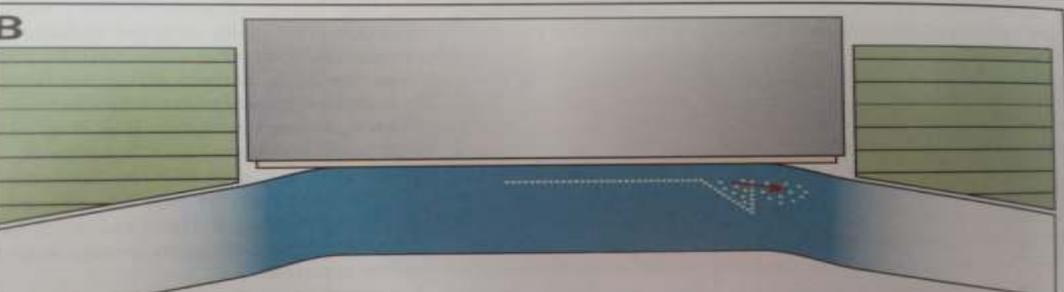
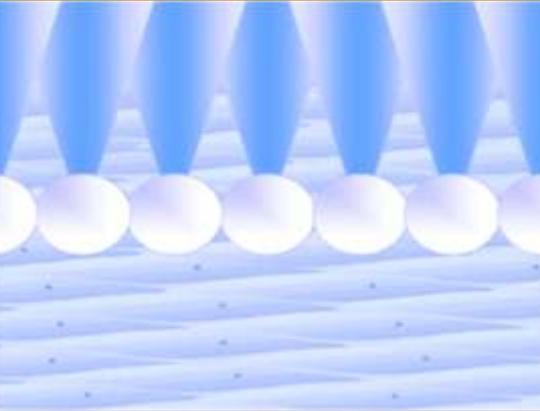




AIOS, CME SERIES (No. 31)

FEMTO IN OPHTHALMOLOGY



ALL INDIA OPHTHALMOLOGICAL SOCIETY

This CME Material has been supported by the funds of the AIOS, but the views expressed therein do not reflect the official opinion of the AIOS.

(As part of the AIOS CME Programme)
Published February 2016

Published by:

ALL INDIA OPHTHALMOLOGICAL SOCIETY

For any suggestion, please write to:

Dr. Barun K. Nayak

(HOD – Dept of Ophthalmology)

Honorary General Secretary, AIOS

AIOS Secretariat : P.D. Hinduja National Hospital & MRC, Veer Savarkar Marg, Mahim, Mumbai - 400 016
Tel.: 022-24447165 • Email: aiosoffice@yahoo.com, secretary@aios.org • Website: www.aios.org

AIOS Headquarters : AIOS, 8A, Karkardooma Institutional Area, Karkardooma, Delhi - 110092 (India)
Tel.: 011-22373701-05 • Email: aiosoffice@yahoo.com, secretary@aios.org • Website: www.aios.org



Femto in Ophthalmology

ALL INDIA OPHTHALMOLOGICAL SOCIETY
OFFICE BEARERS (2015-16)

President Dr Debasish Bhattacharya

President Elect Dr D Ramamurthy

Vice President Dr Santhan Gopal

Hon. General Secretary Dr Barun Kr. Nayak

Joint Secretary Dr Sambasiva Rao

Hon. Treasurer Dr Yogesh C. Shah

Joint Treasurer Dr Rajesh Sinha

Editor IJO Dr S Natarajan

Editor Proceedings Dr Samar Kr. Basak

Chairman Scientific Committee Dr Lalit Verma

Chairman ARC Dr Partha Biswas

Immediate Past President Dr Quresh B Maskati

FOREWORD

Femtosecond Laser is the new 'High- tech Precision Knife'. I thank our Chairman ARC, Dr. Partha Biswas for incising this current topic so precisely on the CME series for us.

This Laser first relieved us of our apprehensions while using microkeratome in 2000's by making "designer software corneal flaps" for us in Lasik and then went on to be used in Lamellar and Penetrating corneal surgery (AK, LK, PKP, ICRS, etc). Dr. Chitra Ramamurthy brings us this whole gamut in a very lucid writing.

It was then used to remove a lenticule (ReLex) from the cornea and correct refractive errors without a flap or reshaping the cornea with an eximer laser. Dr. Rupal Shah, one of the pioneers in this field educates us with her huge and invaluable experience in this field.

Its current attraction, Femto Laser Assisted Cataract Surgery (FLACS) is discussed in pros and cons by the doyens in this field, Dr.D Ramamurthy and Dr.Sri Ganesh. I thank them all for their valuable contribution.

Today at Rs1 crore for the equipment, 6 thousand for the disposable patient interface (PI), corneal flaps in LASIK have become quite relieving compared to microkeratome flaps. But Rs 4 crore for an equipment with Rs 20 thousand for disposable PI's for a round, central and prettier looking rhexis, nucleolysis and corneal incisions sounds alarmingly expensive.

Innovation is Invention + Commercialization and we are all committed to it.

Think of a solution when competition between manufacturers gives us Rs 1 crore equipment with an interface cost of Rs 5000 which can make flaps, corneal incisions for keratoplasty, remove lenticule for corneal refractive surgery and do precise rhexis and corneal incisions, LRI, nucleolysis and do some refractive touch ups after Cataract surgery, even perform some lens based presbyopic solutions or defer cataract by photolysis.

Well it makes a lot of sense for all of us.

When Thomas Alva Edison said "I will make electric bulb so simple that candles will be something that only the rich can afford", how true he was. So read on. We all maybe using this precision knife in many more procedures a decade from now.



Dr. Debasish Bhattacharya
President, AIOS
(2015-16)



Dr. Barun K. Nayak
Hony. General Secretary
AIOS

ACADEMIC RESEARCH COMMITTEE

(2014-17)

Chairman : Dr Partha Biswas
chairmanarc@aios.org
(M) 09830531457

Members

North Zone : Dr. Namrata Sharma
namrata103@hotmail.com
(M) 0-9810856988

East Zone : Dr Ashis K Bhattacharya
ashis.bhattacharya@gmail.com
(M)09831019779, 09331016045

West Zone : Dr Parikshit Gogate
parikshitgogate@hotmail.com
(M) 09850086491

South Zone : Dr Rishi Pukhraj
docrishi@yahoo.co.in
(M) 0944401 5160

Central Zone : Dr Virendra Agarwal
drvirendra@yahoo.com
(M) 09829017147

PREFACE

“Process lies not in enhancing what is.....but in advancing towards what will be” – Khalil Gibran

With the introduction of femtosecond laser in 2001 there has been a revolution in the field of ophthalmology. The word “Femto” is derived from the Danish word ‘Femten’ which means fifteen. By generating microplasms inside corneal stroma with Femtosecond pulses, it is possible to achieve a cutting effect inside tissue while leaving the anterior layer intact. The Femtosecond Laser employs near infrared pulses to cut tissue with minimal collateral tissue damage.

Femtosecond lasers have revolutionized Lamellar Corneal Surgery having re-invigorated LASIK, simplified insertion of intracorneal ring segments, re-invented corneal transplantation and taken cataract surgery to the level of refractive surgery.

Both patients and surgeons alike are demanding more from a procedure which was initially designed to restore vision. Modern cataract surgery is now cataract refractive surgery with very little scope for refractive surprises. LASIK has gone through a revolutionary change from blade to blade-less procedure with the evolution of femtolaser.

Femtosecond laser assisted cataract surgery is best summed up as one that represents a potential paradigm shift in cataract and refractive surgery. Just as phacoemulsification has become more of a refractive surgery, FLACS may allow to obtain better results, and may demonstrate a significant improvement for cataract surgeons implanting premium intraocular lenses. ReLEx Smile is the latest advancement in the field of refractive surgery, bringing smile on the faces of patients and surgeons equally. The precision, minimal collateral damage and versatility make these lasers unique. Today they are imperative to a refractive surgeon’s armamentarium.

Our renowned expert team have put together this CME series on “Femto In Ophthalmology” to try and answer some of these questions and have offered their insights on how these new laser systems can be used.

Good knowledge of advancements in cataract surgical techniques is vital. While going through the chapters, one will understand very well about it. I am sure you will enjoy the practical approach that many of the authors have taken in their chapters, and the “surgical tips” that are offered that can be used in your operating room right away.

Enjoy the CME Series!



Dr Partha Biswas

Chairman Academic and Research Committee,
AII India Ophthalmological Society

FROM DARKNESS TO LIGHT



Contents

AIOS CME Series: 'Femto in Ophthalmology'

1. **Femtosecond Lasers In Refractive Surgery** **1**
Dr. R. Chitra, Dr. Yachana Prakash
 - Femtosecond Lasers
 - Mechanism Of Corneal Femtodissection
 - Principles Of Femtodynamics
 - Postoperative Findings-
 - Laser Settings
 - Pocket Specifications
 - Hinge Parameters
 - Procedure Technique
 - Troubleshooting
 - Intrastromal Corneal Ring Segment Implantation
 - Astigmatic Keratotomy
 - Presbyopia Treatment
 - Femtosecond Laser Enabled Keratoplasty
 - Lamellar Keratoplasty
 - Femtosecond Laser And Corneal Collagen Crosslinking
 - Future

2. **Flapless Refractive Surgery** **20**
Dr. Rupal Shah M.S.
 - Surgical Technique
 - Advantages of ReLEx® over Femto-LASIK
 - Complications

3. **Femto Laser Assisted Cataract Surgery (FLACS)** **29**
Dr. D. Ramamurthy
 - Historical Perspective — The Evolution of Cataract Surgery
 - Lasers in Cataract Surgery
 - Femtosecond lasers: Mechanism of action
 - Preoperative Planning for FLACS Surgery

- Docking the Eye
- Intraoperative Anterior Segment Imaging
- The Treatment Stage
- The major platforms
- Applications and Potential Benefits
- Anterior Capsulotomy
- Corneal Wound Construction
- Lens Liquefaction and Fragmentation
- Limbal Relaxing Incisions
- FLACS & CSME
- Complex Cataract Cases
- Practicalities and Limitations
- Capsular Complications
- Surgical Time
- Training Implications and the Learning Curve
- Economics and Financial Considerations
- Future applications
- Conclusion:

4. Femtosecond Laser - Assisted Cataract Surgery 48

Dr. Sri Ganesh

- Machines
- CATALYS Precision Laser System
- Disadvantages and contraindications
- Conclusion

5. Laser Cataract Surgery 56

Abbott write up

- Introduction
- How The Femtosecond Laser Works?
- Benefits of Laser Cataract Surgery
- Capsulotomy
- Lens Fragmentation
- Corneal Incisions
- Conclusion
- Image bank

CHAPTER 1

FEMTOSECOND LASERS IN REFRACTIVE SURGERY

Dr. R. Chitra
Dr. Yachana Prakash
THE EYE FOUNDATION

Femtosecond lasers have revolutionized lamellar corneal surgery having re-invigorated LASIK, simplified insertion of intracorneal ring segments, re-invented corneal transplantation and much more. The precision, minimal collateral damage and versatility make these lasers unique. Today they are imperative to a refractive surgeon's armamentarium. A thorough understanding of the femtodynamics, its applications and knowledge of troubleshooting some challenging situations will help refractive surgeons in creating consistent corneal resection planes regardless of corneal specifications like shape, size etc.

History

Intelligence Surgical Laser (ISL) approached Arturo S. Chayet M.D. (Mexico) in 1994 with the idea of using a picosecond laser as an alternative to the excimer laser for the correction of refractive errors. Soon enough, Chayet concluded that the picosecond laser was better suited for the creation of corneal flaps, which at that time were created with the mechanical microkeratomers. Researchers at the University of Michigan, however, realized that the picosecond lasers were inadequate for Chayet's idea and discovered that the femtosecond laser would work more effectively. In 2000, a corneal flap created by the femtosecond laser along with a refractive error corrected by the excimer laser was conducted on a patient for the first time.^{1,2}

Femtosecond lasers

The femtosecond laser is a focused infrared laser with a wavelength of 1053nm that uses ultrafast pulses with duration of 100 fs (100 X 10⁻¹⁵seconds). It is a solid state Nd:Glass laser which operates on the principle of photoionisation i.e. laser induced optical breakdown. In this process the collateral damage seen is 106 times less than the Nd:YAG laser which makes it ideal for use in corneal surgeries due to the precision and safety.²⁹ The latest femtosecond lasers have a higher laser firing speed of as much as 500 kHz as compared to the 6kHz in the first femtosecond laser machine.

Currently five femtosecond laser systems are commercially available:¹⁸

| Comparison of Commercially Available Femtosecond Lasers | | | | | |
|---|--|----------------------|---------------------------|----------------------------|----------------------|
| Parameter | IntraLase iFS 150 | Femto LDV | Zeiss VisuMax | Femtec 2010 | WaveLight FS200 |
| Laser type | Amplifier | Oscillator | Fiber optic amplifier | Amplifier | Oscillator-amplifier |
| Wavelength (nm) | 1053 | 1045 | 1043 | 1053 | 1045 |
| Laser pattern | Raster | Segmental | Spiral | Spiral | Raster |
| Centration | Computer | Mechanical | Mechanical | Mechanical | Computer |
| Visualization of surgery | Visual and virtual | Virtual | Visual | Visual | Visual and virtual |
| Mobile | No | Yes | No | No | No |
| Suction | Single syringe | Single built in | Single built in on limbus | Single built in | Dual built in |
| Application surface | Planar | Planar | Curved | Curved | Modified planar |
| Additional procedures | AK, Wedge, LK, PVP, ICRS, Biopsy, Pocket | LK, PKP Pocket, ICRS | FLEX, SMILE | AK, LK, PKP ICRS, INTRACOR | AK, LK, PKP ICRS |

AK = astigmatic keratotomy, LK = lamellar keratoplasty, PVP = penetrating keratoplasty, ICRS = intracorneal ring segments, FLEX = femtosecond lenticule extraction, SMILE = small-incision lenticule extraction

Table 1: Comparison of Commercially Available Femtosecond Lasers

Mechanism of Corneal Femtodissection

A multiphoton ionization of corneal tissue is initiated at a depth at which the laser beam is focused and applied, which creates a small microplasma bubble of 1-5 μ (water and carbon dioxide).^{3,4} The gas inside the microplasma bubble expands and a cavitation bubble, several sizes larger, is formed.^{4,5,6} Several cavitation bubbles either coalesce or come very close to each other, with very thin bridges of tissue separating them.^{5,6} The cavitation bubbles, then implode, releasing water and carbon dioxide which are absorbed via the endothelial pump action. The remaining tissue bridges are to be broken over the course of the surgery with a spatula, ring segments or dissecting instruments.

To facilitate tissue separation and reduce tissue bridges, the laser pulse pattern can be “overlapping pulse pattern” wherein pulses are placed closely together and each new pulse overlaps the previous one or “double pass” where laser pulses are applied over a previously femtodissected area.⁶ If the distance between pulses is decreased, the pulse energy may also need to be decreased to prevent oncoming pulse from entering the cavitation bubble. Also, enough time needs to elapse between closely spaced pulses to prevent increase in the size of cavitation bubble rather than vaporize the adjacent tissue.

Successful femtodissection is, therefore, a process that coordinates laser pulse energy, distance between the pulses and the time delivery of the laser pulses.

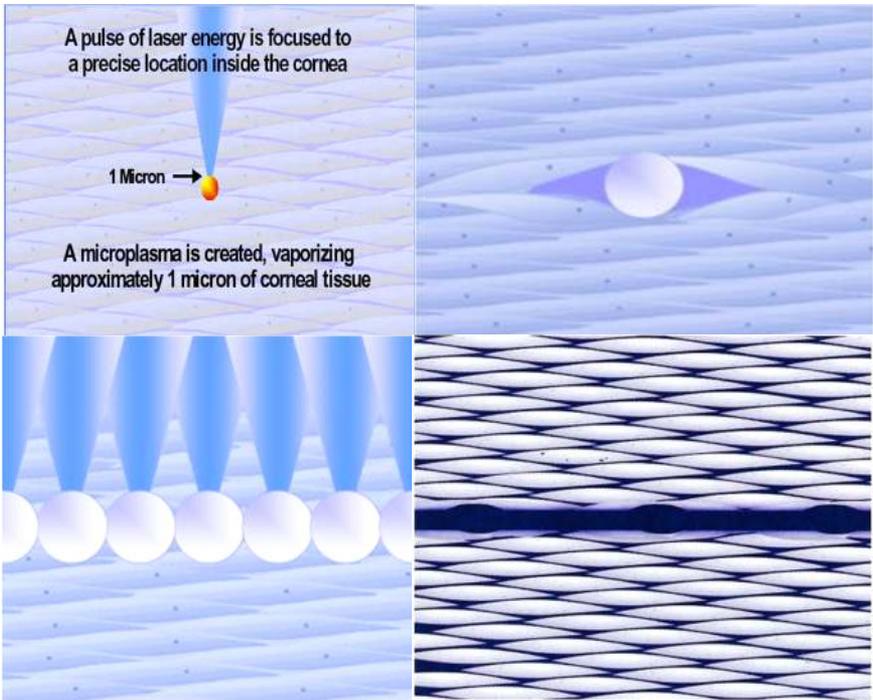


Fig :1. (Clockwise from top left) Focus and application of laser beam; Formation of microplasma bubble; Cavitation bubbles lying close together and Gas bubbles forming a contiguous layer.

PRINCIPLES OF FEMTODYNAMICS

To be able to customize laser settings and procedure techniques based on the individual eye and corneal characteristics is not only an important feature but an advantage with femtosecond lasers. For the process of optimisation, the following components serve as a guide:

1. Centration:

In LASIK flap creation, the resection can be centered either on the center of the undilated pupil or on the line of sight (**Fig :2**). All laser systems use a suction ring to couple the laser's applanation interface with the cornea. While in some, a suction ring is placed around the limbus first and then the applanation cone is docked into it (AMO), in others the suction ring is coupled to the applanation cone (VisuMax). Suction ring and eye landmarks can be used for alignment.¹²

In AMO lasers, the centration can be altered, albeit slightly, after the suction ring is applied. It is advisable to avoid excessive shift of the intended area of dissection after applanation because it may result in decreased diameter of dissection. At this stage one has to recognize parallax effect and corneal apex shift (in keratoconus patients) and take steps to avoid it. Some lasers like the FEMTEC lasers and VisuMax lasers have a curved applanation interface where the risk of shift of corneal apex is unlikely.¹²



Fig :2 Flap Centration

2. Quality of dissection :

Quality of dissection, the ease or difficulty of flap lift may be used to gauge whether the energy applied to the cornea is too high or too low. The energy delivered to the cornea during femtodissection depends on laser pulse energy, the distance between the pulses, the duration of each pulse and the laser repetition rate. For any given laser, the repetition rate and pulse duration are typically fixed. The distance between the pulses and the laser pulse energy can be adjusted accordingly.¹²

| <i>The Effect of Laser Pulse Separation and Pulse Energy on Energy Delivered to the Cornea and the Quality and Speed of Dissection</i> | |
|--|--|
| <i>Decreased distance between the pulses</i> | Increased energy delivered to the cornea Decreased difficulty of tissue separation Increased smoothness of dissected surface Decreased speed of dissection |
| <i>Increased distance between the pulses</i> | Decreased energy delivered to the cornea Increased difficulty of tissue separation Decreased smoothness of dissected surface Increased speed of dissection |
| <i>Increased pulse energy</i> | Increased energy delivered to the cornea Decreased difficulty of tissue separation Increased smoothness of dissected surface No change in speed of dissection |
| <i>Decreased pulse energy</i> | Decreased energy delivered to the cornea Increased difficulty of tissue separation Decreased smoothness of dissected surface No change in speed of dissection |

Table 2: The Effect of Laser Pulse Separation and Pulse Energy on Energy Delivered to the Cornea and the Quality and Speed of Dissection

3. Opaque bubble layer (OBL):

Opaque bubble layer is a collection of gas bubbles in the intralamellar spaces of the cornea (**Fig :3**). It is an undesirable intraoperative occurrence. It does eventually clear spontaneously but may take as long as 30 to 45 minutes. Sometimes it appears as long as 20-30 seconds after the laser beam has been passed. Therefore, it may represent a secondary rather than primary effect on the corneal tissue by laser beam. OBL, typically, does not affect refractive outcomes.

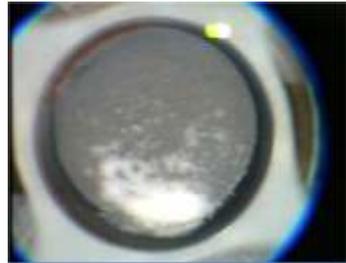


Fig 3: Opaque Bubble Layer

OBL, due to high energy, results because of forceful spread of shock waves and cavitation bubbles. It, typically, “shoots out” ahead of where the laser beam interacts with the cornea. It spreads more readily in the lightly or the unapplanated area. OBL can also appear when the energy is too low. Here, it is less dense, more patchy, multifocal and tends to develop late. Given the above differences,

the OBL can serve as a potent guide for optimising laser settings (*Fig:4*).

It is of importance to have the laser serviced in a timely manner which may be a cause for persistent OBLs. Besides these, one should be mindful of certain patient factors that may predispose to OBL like older patients, smaller corneas and steeper corneas.

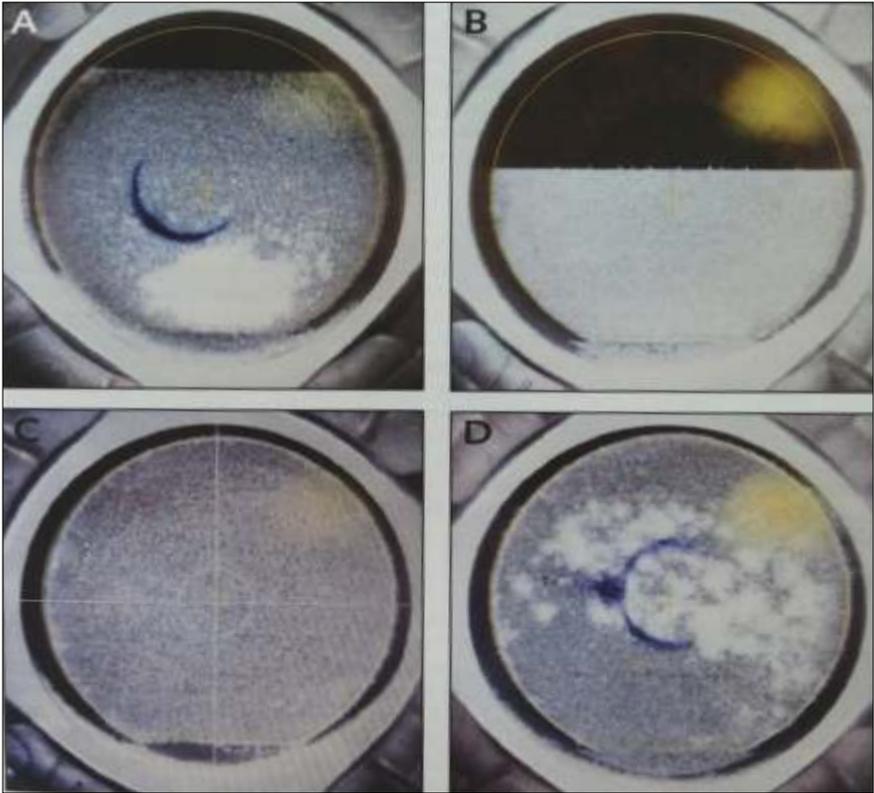


Fig 4: Opaque Bubble Layer at Different Stages of Raster Pattern

Postoperative findings-

Postoperative corneal appearance, the speed of visual recovery, the incidence of peripheral lamellar keratitis and transient light sensitivity syndrome can be used to gauge the energy delivered and amends can be made by carefully analysing the parameters.

LASER SETTINGS

The pattern of laser pulse placement during LASIK corneal flap creation is the “Raster Pattern” wherein the direction of flap dissection depends on the location of the hinge e.g. For a superior hinge, the dissection proceeds from superior towards inferior. Another pattern of laser pulse placement is the “Spiral Pattern” where the resection starts at the center of the cornea and proceeds outwards in the pattern of expanding concentric rings, a pattern typically used for anterior lamellar keratoplasty (*Fig :5*).

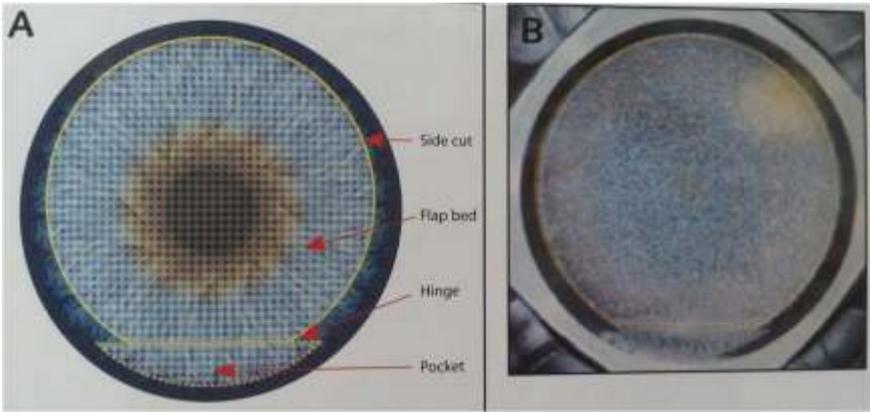


Fig 5: Four Categories of Laser Settings for Flap Creation.

Pocket Specifications

Laser-tissue interaction begins at the pocket which is initiated peripherally and posterior to the flap hinge. The position of the pocket is posterior to the position of the hinge. The purpose of the pocket is to create a path of least resistance to facilitate the egress of gas bubbles outside the flap and a thin area of cornea is left unapplanated posterior to the pocket (*Fig :6*). This crescent of unapplanated cornea is called a meniscus (*Fig :7*). In a situation where meniscus is absent, if the pocket is surrounded by cornea, the bubbles will still exit through the pocket. If the meniscus is absent, the likelihood of

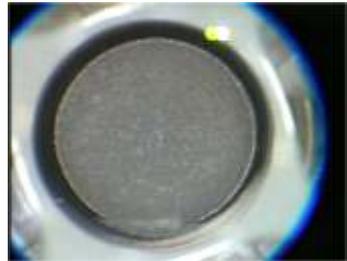


Fig 6: Pocket OBL

OBL formation increases if the pocket is located adjacent to the sclera due to the resistance of the tough sclera collagen.¹³

A desired pocket depth can be optimized bearing in mind that it should always be less than 50% of the corneal thickness. A typical starting point is 220μ . If the OBL remains a problem, it can be increased in 10μ intervals until it reaches 250μ . A typical pocket width is 25μ .

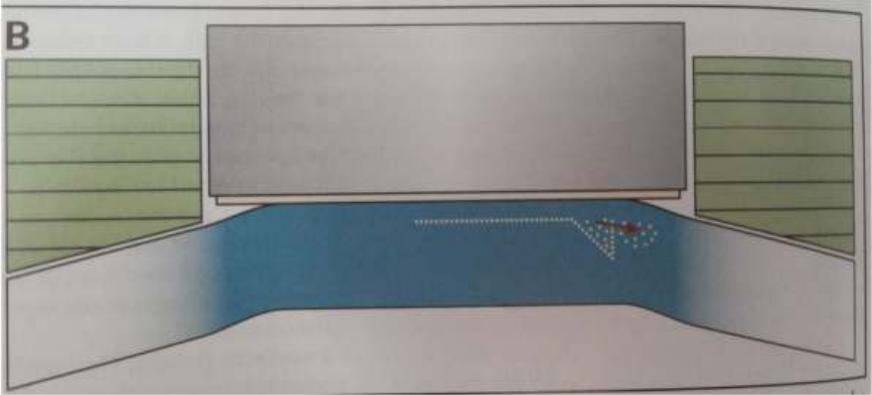


Fig 7: Pocket OBL Adjacent to Meniscus

Hinge parameters

The hinge angle (or width) and position can be varied. A flap hinge created with a femtosecond laser is narrower than that created with a microkeratome, which means that a smaller flap diameter can be planned with a femtosecond laser. A hinge angle of 55 degrees is considered adequate.^{8,12} Too wide a hinge angle will result in inadequate bed exposure whereas too narrow a hinge angle will give a good bed exposure but result in difficulty in accurate flap repositioning. However, a narrow hinge angle may be considered in patients with decentred line of sight or those requiring large ablation zones.

The position of the hinge can be superior or nasal. Occasionally, it may be positioned temporally, in patients with large angle kappa who need ablation over the line of sight which is displaced nasally. The hinge can also be placed over a pterygium in cases required.

Flap bed parameters

Optimised laser pulse energy (raster energy) or the distance between the pulses allow for a flap that can be lifted with minimal stretch. In case of flap lifts that require more tension and cause flap stretch the energy of the laser pulses can be increased or the distance between laser pulses can be decreased. The reverse can be done if the energy needs to be decreased. Small changes in energy can impact the ease or difficulty of flap lift and OBL formation.^{12,13}

Flap diameter

Flap diameter can be customized based on the size of the planned ablation zone and the corneal diameter. When the flap outline is moved on the video display in an attempt to position the flap over the intended area of dissection, the flap diameter will decrease, especially when the flap is moved horizontally. Therefore, it is best to center the suction ring on the eye in the position of the intended flap.^{12,13}

Flap thickness

The flap thickness can be customised based on individual corneal thickness. The goal is to create a flap that is thin enough to preserve as much of the residual stromal bed as possible to reduce the risk of ectasia, but not too thin to result in gas bubbles escape through the bowman's membrane into the space between the epithelium and applanation lens causing “vertical gas breakthrough”. Thinner flaps (100 μ or less) have more OBL formation possibly due to the more compact superficial collagen.^{12,13} In vertical gas breakthrough, the gas escapes through the bowman's membrane breaks that may be present in corneas with scars or EBMD. Such eyes may require deeper flaps of 120-130 μ .

Flap side cut parameters

The side cut angle in femtosecond lasers is between 45 and 75 degrees as against the mechanical microkeratome where the side cut angle ranges between 15 to 30 degrees. A steeper side cut angle allows for an easier flap repositioning and possibly a decreased likelihood of epithelial ingrowth than a shallower side cut angle. The angle may be adjusted in increments of 5 degrees.^{12,13}

When the side cut energy is normal, the peripheral gutter of the flap is narrow and the edge of the flap is smooth and even. A low side cut energy is a possible cause of peripheral tags apart from a faulty flap lifting technique. A high side cut energy leaves a wide gap between the edge of the flap and the edge of the bed. Such gaps can result in peripheral lamellar keratitis and/or more pronounced scar.^{12,13}

Some salient features of flaps made by a microkeratome and femtosecond laser are:⁷⁻¹¹

| Comparison of Microkeratomes and Femtosecond Lasers for LASIK Flap Creation | | |
|--|--|---|
| Parameter | Microkeratome | Femtosecond Laser |
| Flap shape | Meniscus | Planar |
| Flap/hinge diameter | Keratometry dependent | Computer control |
| Flap thickness | Dependent on pachymetry, keratometry, IOP, blade quality and translational speed | Computer control |
| Thickness predictability | Moderate | High |
| Side cut | Shallow angled | Computer control |
| Epithelial ingrowth | More than femtosecond laser flaps | Less |
| Unique complications | Flap buttonhole | Opaque bubble layer, vertical gas breakthrough, transient light sensitivity syndrome, rainbow glare |

IOP = intraocular pressure

Table 3: Comparison of Microkeratome and Femtosecond Lasers for LASIK Flap Creation

PROCEDURE TECHNIQUE

Positioning the suction ring

The suction ring needs to be placed symmetrically around the intended suction area. Asymmetric positioning will necessitate excessive movement of the flap outline on the console which will decrease the flap diameter. The planned ablation zone is centred on the line of sight or the pupil and in most patients the line of sight is centered within the pupil. In cases where line of sight is not centred on the pupil like in eyes with positive angle kappa, different method of flap creation may be utilized to maximise stromal bed exposure. We can select a large flap size in these patients, place the hinge location temporally, decrease the hinge angle, turn off the pocket or decrease the width of the pocket.

Docking the Applanation Cone

The head should be tilted slightly nasally, allowing for the nose to move away from the applanation cone to facilitate full contact (**Fig :8**). The iris should be parallel to the floor and aligning the chin, cheekbone, forehead parallel to the floor helps achieve this. In patients with narrow lid apertures, lateral tilt of the head should be minimised to avoid pressure of medial and lateral canthus on the suction ring. A lid speculum may interfere with suction ring placement and the lid speculum can be done away with in such patients.



Fig 8: Docking the Applanation Cone

Once the applanation plate is lowered onto the cornea, there should be symmetrical expansion from centre to the periphery. A meniscus, ideally, a thin symmetric peripheral one is achieved when the applanation cone is lowered symmetrically onto the cornea. The meniscus may completely surround the periphery of the resection area or may be localised just posterior to the pocket. To achieve the meniscus, an applanation cone may be lowered onto the cornea until a thin sliver of unapplanated cornea remains peripherally or a full applanation is done first followed by raising the cone slightly to achieve meniscus.

False Meniscus is one that occurs between the fluid over the cornea and applanation cone, therefore placement of lubricants, BSS and antibiotic drops should be avoided prior to femtodissection.

Fine tuning flap centration

The vertical axis of the applanation cone needs to be perpendicular to the iris surface to avoid parallax error. Fine adjustments can be made to bring pocket close to the meniscus and the flap outline can also be moved to fine-tune the centration. Excessive shifting should be avoided since it decreases the flap diameter and it is best to center the flap by centering the suction ring over the intended flap area.

Lifting the flap

The general principles of a flap lift are:

- Stabilizing the eye by holding on to the limbus with toothed forceps
- Two step technique: the side cut is opened first using a hook like instrument (ie, Sinsky hook) by holding it parallel to the side cut angle to avoid flap tags. The entire side cut may be opened first or a section of it followed by insertion of the dissecting spatula in the interface and exiting through the contra lateral sidecut and then dissecting the remaining flap.
- One step technique: the side cut and the flap bed are dissected simultaneously.
- In both the above techniques the dissection can be started near the hinge first. If the dissection is easy, the spatula can be advanced within the interface using a single sweeping motion. When a difficult dissection is encountered, especially when the flap is thin (less than 100μ), a gentle back-and-forth “windshield wiper” motion of the spatula can help ease the dissection. Slight downward pressure of the spatula can also help facilitate dissection.

Repositioning the flap

When the flap is kept retracted during the ablation, a drop of BSS is placed at the hinge and once the ablation is complete, irrigating cannula is positioned under the flap to flip it back over the stromal bed and the flap is floated back into place. The peripheral gutter will need to be examined to make sure that it is symmetrical.

For repositioning the flap, when flap striae are present, which may occur due to a difficult flap lift, typically radiating from the hinge, two dry weck Merocel sponges can be used to stretch the flap in the direction perpendicular to the striae while the flap is retracted. The flap can then be floated back in place and its surface smoothed.

TROUBLESHOOTING

OBL

Pocket OBL:

Positioning the flap a little away from the limbus, having an adequately wide meniscus, a pocket OBL is typically a sign of too much energy in the pocket. A lucent pocket indicates too much energy. Patient factors such as an older age and tougher collagen should also be kept in mind.¹⁵

Bed OBL:

Pocket collapse during flap resection is a common reason for bed OBL. Too much or too little energy delivered to the bed are also possible reasons. Identification of the same is mentioned above in the femtodynamics section. Uneven corneal applanation may result in OBL localized in the excessively applanated area. A difficult flap lift due to an OBL could be due to low bed energy, raster spots too far apart and not holding the eye while dissecting the flap.¹⁵

Peripheral tags

A low side cut energy or gas escaping peripherally during femtodissection and blocking the oncoming laser pulses can cause peripheral tags. In this case, the tags will be scattered throughout the circumference of the flap. Not holding the tip of the side cut dissecting instrument parallel to the side cut angle can also cause peripheral tags that are typically localised to the area of instrumentation.^{12,13}

Interface keratitis (DLK):

Interface haze could rarely develop and could be graded based on the intensity of the inflammatory response (Fig :9). Early DLK can be treated with frequent topical steroids, more severe would need interface wash with complete recovery



Fig 9: Interface Keratitis

Loss of suction

Inadequate initial suction, excessive patient movement, excessive eye rotation, excessive head tilt or not enough head tilt may result in loss of suction during either raster pass or side cut dissection. If the suction is lost before flap bed dissection the suction ring can be repositioned overlying the previous area of dissection. If suction is lost during the flap bed dissection, the dissection can be repeated without activating the pocket. If the suction is lost during the side cut creation then only the side cut needs to be repeated. Since the exact alignment of the new dissection diameter with the one previously created may not be possible, a slightly smaller flap diameter is selected.^{12,13}

If complete dissection is unsuccessful after several attempts of applying the suction, the flap lift should not be attempted. Flap dissection can be attempted after three months by setting a flap thickness deeper than the original cut. Alternatively a surface ablation can be performed.^{12,13}

Vertical gas breakthrough

If a flap lift is attempted, button hole is likely. A very small buttonhole doesn't interfere with the excimer ablation. When the break is large, a flap lift should not be attempted. In patients in whom a Bowman membrane defect is suspected like in case of scars or EBMD, a deeper flap can be planned.^{16,17}

Horizontal gas breakthrough

It results in the “wash board” appearance of the raster pattern associated with excessive eye movement especially when the cornea is lightly applanated. The patient should be properly instructed to avoid eye movements, a mild oral sedative can be used too. If the problem persists in several patients, the laser energy should be decreased.^{16,17}

Others

Other complications that can be seen with a femtosecond laser procedure are bubbles in the anterior chamber which resolve spontaneously and do not interfere with the procedure.

Subconjunctival hemorrhage may occur occasionally which need to be prevented by slow and controlled application of suction. Peripheral lamellar keratitis and transient light sensitivity syndrome may need the laser energy to be reduced for subsequent cases but do resolve over the course of time without hampering the visual acuity.¹⁸

INTRASTROMAL CORNEAL RING SEGMENT IMPLANTATION

Intrastromal corneal ring segments are being currently used to treat postoperative LASIK corneal ectasia, pellucid marginal degeneration, and keratoconus. Intrastromal corneal ring segments are inserted in intrastromal channels (created either manually or using a femtosecond laser) at 75% depth of the thinnest pachymetry. Compared to the manual technique, a femtosecond laser makes tunnel creation faster, easier, and more reproducible and offers accurate tunnel dimensions (width, diameter, and depth).¹⁹ Depth is consistent throughout when using a femtosecond laser. However, similar visual and refractive outcomes with both procedures were reported over short-term follow-up in eyes with keratoconus and postoperative LASIK ectasia.¹⁸

ASTIGMATIC KERATOTOMY

Astigmatic keratotomy is a simple, safe, and minimally invasive technique. Therefore, it is the most commonly used method for the reduction of high amounts of astigmatism in postoperative penetrating keratoplasty patients.^{20,21} The technique is similar to limbal relaxing incisions, with incisions placed inside the donor-recipient junction as it behaves like a new limbus due to a fibrotic ring formed as part of the healing response. Astigmatic keratotomy may be performed manually with a diamond knife as well as with a femtosecond laser. Compared with the mechanical method, the use of a femtosecond laser offers the advantages of higher precision and stability as well as more accurate planning of the length, depth, and optical zone of the cuts. Femtosecond laser AK has been reported to be effective in reducing astigmatism and improving uncorrected and corrected distance visual acuity in patients.²²

PRESBYOPIA TREATMENT

Femtosecond lasers are now also used for the creation of intrastromal

pockets to insert biocompatible intracorneal inlays for the treatment of presbyopia.²³ Intracorneal inlays are inserted in the nondominant eye either under a LASIK flap or into a stromal pocket created by a femtosecond laser. Implantation of intracorneal inlays has been described for the treatment of presbyopia and hyperopia using corneal flaps created by mechanical microkeratomers or femtosecond lasers or corneal pockets created by femtosecond lasers.²⁴ Femtosecond laser–assisted intracorneal pocket creation could increase the precision of the inlay position by customization of depth and length of the tunnel, which could enhance the predictability, resulting in better final outcomes and improving the safety of the procedure. In addition to pocket creation for inlay implantation, femtosecond lasers are being used in INTRACOR.²⁵ The INTRACOR procedure is a femtosecond laser–based incisional method for intrastromal correction of presbyopia using the Technolas 520FS, where two to four cylindrical ring incisions are created in the corneal stroma aiming to change its biomechanical properties and induce a central hyperprolate region for the treatment of presbyopia.²⁵

FEMTOSECOND LASER ENABLED KERATOPLASTY

PENETRATING KERATOPLASTY

In penetrating keratoplasty the goal of femtosecond laser is to improve certain crucial factors like obtaining precisely same shape and size of host and donor incisions, precise alignment of radial marks, possible stronger incision healing due to tissue rupture of photodisruption. The previously popular “top hat” shape of incisions has given to the currently popular “zig zag” incision pattern.^{26,27} (Fig :10).

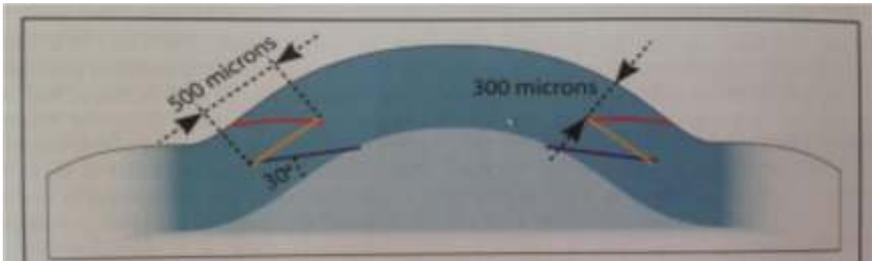


Fig 10: Zig Zag Pattern of PK

LAMELLAR KERATOPLASTY

The femtosecond laser offers precise, repeatable parameters of diameter and depth in donor and host, a marked improvement over variables in microkeratome preparation of tissue. Surgeons are now employing femtosecond laser to create precisely matched donor lenticules to replace scarred anterior corneal stroma, where the dimension match is tight enough for the lenticule to stay in position aided only by a bandage contact lens with no sutures placed. Deeper lamellar femtosecond laser beds are not yet established to be superior to microkeratome incisions.¹²

FEMTOSECOND LASER AND CORNEAL COLLAGEN CROSSLINKING

In patients with borderline thin corneas, high refractive errors or suspicious topographies, LASIK is combined with the Corneal Collagen Crosslinking procedure. It aims to strengthen the cornea at the time of the surgery to prevent its distortion in the future. Here femtosecond laser are preferred due to its ability to form thin and reliable flap and leave behind an even corneal bed.²⁸

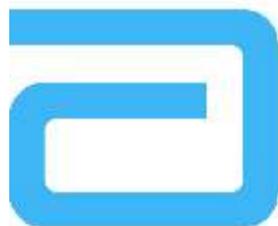
FUTURE

Keeping in mind, the ever expanding horizon of possibilities that femtosecond lasers offer, it wouldn't be imprudent to expect femtosecond lasers playing a very crucial role in not only refractive and cataract surgeries but slowly taking on glaucoma surgeries too to a new level of precision and possibilities. Several aspects of limbal stem cell harvesting, high resolution tissue imaging and biopsy techniques are already being experimented and dealt with. The full potential of femtosecond lasers is slowly being unfolded and is definitely one of the most promising technologies to look forward to in the future.

References:

1. Ratkay-Traub I, Ferincz IE, Juhasz T, Kurtz RM, Krueger RR. First clinical results with the femtosecond neodymium-glass laser in refractive surgery. *J Refract Surg.* 2003;19(2):94–103.
2. Slade SG. The use of the femtosecond laser in the customization of corneal flaps in laser in situ keratomileusis. *Curr Opin Ophthalmol.* 2007;18(4):314–317. doi:10.1097/ICU.0b013e3281bd88a0
3. Kurtz RM, Elnor V, Liu X, et al. Plasma-mediated ablation of biological tissue with picosecond and femtosecond laser pulses. In: Jacques SL, Editor, *Laser- Tissue Interaction VIII. Proceedings SPIE 2975*, SPIE, Bellington, WA. 1997:192-200.
4. Juhasz T, Kastis, GA, Suarez C, et al. Time-resolved observations of shock waves and cavitation bubbles generated by femtosecond laser pulses in corneal tissue and water. *Lasers Surg Med.* 1996;19:23-31.
5. Binder PS, Sarayaba M, Ignacio T, et al. Characteristic of submicrojoule femtosecond laser corneal tissue dessection. *J Cataract Refract Surg.* 2008;43(1):146-152.
6. Lubatschowski H. Overview of commercially available femtosecond lasers in refractive surgery. *J Refract Surg.* 2008;24(1S):102-107.
7. Talamo JH, Meltzer J, Gardner J. Reproducibility of flap thickness with IntraLase FS and Moria LSK-1 and M2 microkeratomes. *J Refract Surg.* 2006;22(6):556-561.
8. Slade SG. The use of the femtosecond laser in the customization of corneal flaps in laser in situ keratomileusis. *Curr Opin Ophthalmol.* 2007;18(4):314-317.
9. Rocha KM, Randleman JB, Stulting RD. Analysis of microkeratome thin flap architecture using Fourier-domain optical coherence tomography. *J Refract Surg.* 2011;27(10):759-763.
10. Sutton G, Hodge C. Accuracy and precision of LASIK flap thickness using the IntraLase femtosecond laser in 1000 consecutive cases. *J Refract Surg.* 2008; 24(8):802-806.
11. Stahl JE, Durrie DS, Schwendeman FJ, Boghossian AJ. Anterior segment OCT analysis of thin IntraLase femtosecond flaps. *J Refract Surg.* 2007;23(6):555-558.
12. Faktorovich Ella. *Femtodynamics: a guide to laser settings and procedure techniques to optimize outcomes with femtosecond lasers.* SLACK Incorporated 2009; 3; 17-200.
13. *The IntraLase FS Laser Training Manual.* 2006 IntraLase Corp; Irvine, CA.
14. Binder PS. Femtosecond lasers: How do you select a system? *Cataract and Refractive Surgery Today.* 2008 October.

15. Kaiserman I, Maresky HS, Bahar I, Rootman DS. Incidence, possible risk factors, and potential effects of an opaque bubble layer created by a femtosecond laser. *J Cataract Refract Surg.* 2008;34(3):417-423.
16. Srinivasan S, Herzig S. Sub-epithelial gas breakthrough during femtosecond laser flap creation for LASIK. *Br J Ophthalmol.* 2007;91(10):1373.
17. Seider MI, Ide T, Kymionis GD, Culbertson WW, O'Brien TP, Yoo SH. Epithelial breakthrough during IntraLase flap creation for laser in situ keratomileusis. *J Cataract Refract Surg.* 2008;34(5):859-863.
18. George D, Kymionis, Vardhaman P, Kankariya, Argyro D, Plaka, Dan Z, Reinstein. Femtosecond Laser Technology in Corneal Refractive Surgery: A Review [J Refract Surg. 2012;28(12):912-920.]
19. Rabinowitz YS, Li X, Ignacio TS, Maguen E. Intacs inserts using the femtosecond laser compared to the mechanical spreader in the treatment of keratoconus. *J Refract Surg.* 2006;22(8):764-771.
20. Bochmann F, Schipper I. Correction of post-keratoplasty astigmatism with keratotomies in the host cornea. *J Cataract Refract Surg.* 2006;32(6):923-928.
21. Wilkins MR, Mehta JS, Larkin DF. Standardized arcuate keratotomy for postkeratoplasty astigmatism. *J Cataract Refract Surg.* 2005;31(2):297-301.
22. Nubile M, Carpineto P, Lanzini M, et al. Femtosecond laser arcuate keratotomy for the correction of high astigmatism after keratoplasty. *Ophthalmology.* 2009;116(6):1083-1092.
23. Mulet ME, Alio JL, Knorz MC. Hydrogel intracorneal inlays for the correction of hyperopia: outcomes and complications after 5 years of follow-up. *Ophthalmology.* 2009;116(8):1455-1460.
24. Kymionis GD, Bouzoukis DI, Pallikaris IG. Corneal inlays: a surgical correction of presbyopia. *J Cataract Refract Surg Today Europe.* 2007;3:48-50.
25. Ruiz LA, Cepeda LM, Fuentes VC. Intrastromal correction of presbyopia using a femtosecond laser system. *J Refract Surg.* 2009;25(10):847-854.
26. Busin M. A new lamellar wound configuration for penetrating keratoplasty surgery. *Arch Ophthalmol.* 2003;121:260-265.
27. Farid M, Kim M, Steinert RF. Results of penetrating keratoplasty performed with femtosecond laser zig-zag shaped incisions. *Ophthalmology.* 2007;114:2208-2212.
28. Stephenson, Michelle. "LASIK Xtra: Is It for Everyone?". *Review of Ophthalmology*
29. Chung SH, Mazur E. Surgical applications of femtosecond laser. *J Biophotonics.* 2009;2(10):557-572.



High Definition iLASIK. Everything is Clearer in HD.

Powered by
iDesign



- ▶ The **iLASIK** procedure is completely customized
- ▶ Wavefront guided treatment plan
- ▶ **95%** patients are with 20/20 vision*
- ▶ The iDesign system captures **5 times** more data
- ▶ Over **11 million** procedure done worldwide with iLASIK technologies.
- ▶ Higher-Definition provides outstanding accuracy and ability to measure complex wavefronts.

© 2011 Abbott Medical Optics. All rights reserved. iLASIK is a registered trademark of Abbott Medical Optics. iDesign is a registered trademark of Abbott Medical Optics. All other trademarks are the property of their respective owners.

 **Abbott**
Medical Optics

For more information please contact : Tel. No. 0124-4618065, 080-49426666 / 49426608
E mail: amoindinfomarketing@abbott.com • Website: www.amo-inc.com

CHAPTER 2

Flapless Refractive Surgery (Femtosecond Lenticule Extraction)

Dr. Rupal Shah M.S.

Corneal Refractive Surgery involves reshaping of the cornea to change its focusing power and eliminate the need to wear contact lenses and spectacles to see clearly. Typically, corneal refractive surgery is excisional—a small amount of corneal tissue is excised in a precise amount and shape. Most commonly, an excimer laser is used to ablate (remove) corneal tissue from the cornea. Since an excimer laser can only ablate a small volume of corneal tissue with one laser shot, several thousand laser shots are fired on the cornea in a precise way to remove a precise lenticule of the cornea, corresponding to the refractive error.

Excimer Lasers can be used to perform refractive surgery using three techniques. The first involves surface ablation, where the corneal epithelium is first removed, excimer laser ablation is carried out, and the epithelium is allowed to grow back. Two other techniques, LASIK and Femto-LASIK involve the creation of a hinged flap of the cornea. The hinged flap is reflected back to expose the corneal stroma, excimer laser ablation carried out, and the hinged flap replaced. LASIK uses a mechanical microkeratome to create the flap, while Femto-LASIK uses a femtosecond laser to create the flap.

In recent years, a new paradigm for corneal refractive surgery has developed, known as ReLEx Smile. This new technique of performing refractive surgery, uses a femtosecond laser for all steps of the keratomileusis procedure. The VisuMax (Carl Zeiss Meditec AG) femtosecond laser keratome is used to cut a refractive lenticule

within the corneal stroma. The lenticule is then extracted from the cornea using a small incision, to provide a refractive correction. No excimer laser is needed for the whole procedure. No flap is necessary for the procedure either. So flapless refractive surgery, which involves only the femtosecond laser, is now possible.

ReLEx was first described by Sekundo et al² in 2008. Subsequently, over a 100000 eyes have been treated worldwide using the ReLEx[®] technique. Since 2008, we have treated over 5000 patients with the ReLEx Smile technique at our center.

Currently, ReLEx Smile is available to treat myopic errors upto -10 Diopters spherical equivalent, with or without astigmatism of upto -5 Diopters. Clinical trials are underway for the treatment of hyperopia or hyperopic astigmatism of upto +8 D spherical equivalent. Efforts are also on to extend the treatment range to myopia upto -14 D. Patient selection criteria are similar to LASIK.

The VisuMax femtosecond laser (Fig1) is used for performing the ReLEx[®] procedure. The VisuMax is capable of creating refractive lenticules within the cornea with a high degree of accuracy. The VisuMax[®] software allows the calculation of the refractive lenticule needed to correct for a particular refractive error, and it also automates all stages of the procedure.



Figure 1: VisuMax Femtosecond Laser used for performing ReLEx

Surgical Technique

Patients are treated under aseptic conditions and topical anaesthesia, in a manner similar to LASIK. A standard speculum is used to keep the eye open. In the VisuMax[®] Laser System, the laser system remains fixed, while the patient position can be aligned by adjustment of the position of the patient bed with a joystick. The

patient's eye is positioned under a curved contact glass interface during the operation of the femtosecond laser, and it is positioned under a surgical microscope integrated into the system during the phase of surgical manipulation. The eye view is relayed to the surgical microscope eye pieces in both cases to allow for full visual control during the entire procedure.

Once a sterile curved contact glass is attached onto the laser system optical aperture, and the patient positioned some distance below it, the patient is then asked to look at a blinking fixation light, and the patient's eye is adjusted in relation to the contact glass interface. The surgeon must ensure that the centration is appropriate. After the surgeon is convinced that the centration is within acceptable limits, suction is initiated to hold the cornea against the contact glass interface.

Once the contact interface is fixed, delivery of the femtosecond laser pulses is initiated. Femtosecond laser pulses with typical pulse energy of less than 200 nJ are delivered with a pulse repetition rate of 500 kHz.

Four different tissue disruption planes are created for the ReLEx Smile procedure (Fig.2). These four tissue disruption planes include a) the posterior surface of the refractive lenticule, with a pre-

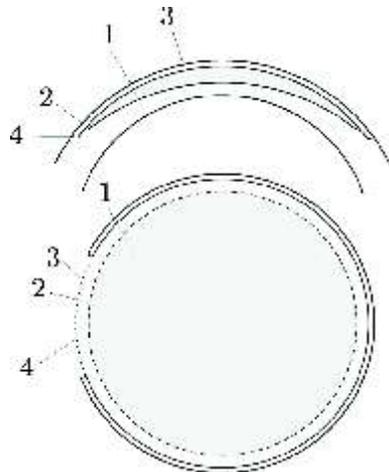


Figure 2: Schematic View of the ReLEx Smile procedure showing the different tissue disruption planes

programmed diameter based on the optical zone selected b) the 360° cordal length vertical edge of the refractive lenticule, with a depth equivalent to the thickness of the edge of the lenticule c) the anterior surface of the refractive lenticule, which is extended by about 0.5 mm beyond the optical zone desired and finally d) a small 45-110 degree inclination incision of 40-50 (2-5 mm) degrees in cordal length from the surface of the cornea with a depth up to the edge of the anterior part of the lenticule. The entire procedure takes 20-35 seconds, practically independent of the refractive error to be corrected. The sphero-cylindrical shape of the lenticule generated thus is designed to correct for refractive errors. The anterior surface of the lenticule (which is also the undersurface of the “cap”) can be programmed to be 90 microns or more below the corneal surface, similar to the flap thickness in LASIK. The lenticule diameter can be 5.00 to 7.00 mm, while treating myopia and myopic astigmatism. The minimum thickness of the lenticule edge is 10-15 μm to support easier manual manipulation of the lenticule edge. The side cut incision can be 2-5 mm in cordal length, depending on the dexterity of the surgeon.

The parameters mentioned above represent our current clinical experience. All parameters are computer controlled and can be adjusted in the treatment planning step.

Once the femtosecond laser cutting procedure (treatment mode) is finished, the suction is switched off automatically, and the patient's eye is released from the contact glass and moved under the microscope (observation mode, Fig 3A).



Figure 3: Surgical Steps of the ReLEx Smile procedure

The side cut incision is generally created superiorly or superior-temporally, in order to preserve the nasal and temporal nerve arcades, and to provide surgical convenience. A small sharp tipped instrument is used to open a small portion of the side cut incision. A small blunt spatula is inserted into the side cut incision, and the anterior surface of the lenticule separated from the overlying cornea (Fig 3B). A small sharp instrument is then used to enter into the tissue disruption plane on the posterior side of the lenticule to separate the edge of the lenticule (Fig 3C). A blunt spatula is then inserted through this edge below the lenticule and used to separate the posterior part of the lenticule from the underlying stroma (Fig 3D). Once the lenticule is free from both surfaces, a small microforceps (Shah Forceps for Lenticule Extraction, Segal Optics) is inserted to grasp the lenticule and extract it from the corneal stroma (Fig 3E). The speculum is then removed. Both eyes can be treated sequentially at the same sitting.

Post-operatively patients are prescribed mild steroids and antibiotics for a week and artificial tear supplements for a period of 4-8 weeks after the procedure.

Advantages of ReLEx[®] over Femto-LASIK

There are economic, clinical and work flow advantages of an only femtosecond laser procedure like ReLEx Smile over performing Femto-LASIK or conventional LASIK or PRK.

The economic advantages of using an all Femto procedure over femto-LASIK are obvious. You require only one laser to perform the entire refractive surgery procedure, instead of two. This means saving on capital costs, maintenance costs and consumable costs.

The clinical benefits are critical too. An excimer laser ablates the lenticule required to correct the refractive error. In ReLEx Smile, the lenticule is carved out within the cornea by a cutting action. This difference between cutting with the femtosecond laser, as opposed to ablation with the excimer laser is significant. Excimer laser ablation

rates are dependent on corneal hydration levels, environmental conditions like humidity and temperature, and also on the depth in the stroma at which ablation occurs. The scatter in ablation rates is particularly high, when the ablation depth is large, which explains the greater scatter in the results of treatment of larger refractive errors. The femtosecond laser's cutting action is not dependent on any of the above factors. So the scatter in the thickness of the lenticule is minimized, and it is also independent of the refractive error being treated. For all these reasons, the refractive predictability with the ReLEx Smile procedure is higher than with an excimer laser, particularly for higher amounts of refractive errors.

Furthermore, there is the well known loss of fluence in the periphery of the treatment zone with the excimer laser, which induces spherical aberration. While most modern excimer lasers compensate for this peripheral energy loss, such compensation does increase the overall ablation depth. With the femtosecond laser, such peripheral energy loss is not a factor at all, and no compensation needs to be carried out, and thus the amount of tissue required per diopter of treatment is smaller than that required with an excimer laser which compensates for the peripheral energy loss.

The total amount of energy laid down into the cornea is also much less (orders of magnitude less) than with an excimer laser. Since there is some evidence that the heat generated by fast excimer lasers has an adverse impact on the healing reaction after LASIK, the low amount of energy used by the ReLEx[®] procedure is a welcome clinical benefit.

There are also clinical advantages of having no flap, and a very small incision. The small incision heals relatively quickly, leading to less patient discomfort after the procedure. There is little risk of the flap getting displaced, and this could be a benefit for all patients who are at risk for flap shearing or displacement (for example, those patients who play contact sports). There could be other advantages-the small "flap" diameter and the small side cut incision means that there is a

smaller likelihood of cutting corneal nerves, perhaps leading to less problems of dry eye after the procedure, as opposed to Femto-LASIK or standard LASIK.

Finally, the procedure saves working time, as there is no time required for switching from one laser to another.

Complications

There are two intraoperative complications which can occur. There could be a suction loss, wherein the contact glass and cornea become detached during the procedure. This could happen because of several reasons. The most common reason is a sudden movement by the patient. Occasionally, we have also observed this happening when there is fluid ingress between the suction ports of the contact glass and the cornea. Sometimes, the suction loss could also occur due to gas bubble migration and subsequent compressive forces against the contact glass. In the event of suction loss, the VisuMax® laser automatically goes into a “Restart Mode”, based on the stage of the procedure at which the suction loss occurred. The general challenge in this situation is re-docking of the contact glass interface to the eye, with the same centration as with the earlier cut. Sometimes, the pupil is obscured by the gas bubbles, making this difficult. Depending on the stage at which the suction loss occurs, the Restart Mode repeats both femtosecond passes, only the “cap” pass or only the side cut incision. In our experience, repeating the treatment immediately is convenient, and does not seem to affect the results of the procedure.

The second intraoperative complication generally observed is that while trying to separate the anterior lenticule surface from the overlying cornea, the wrong plane is selected by the surgeon, and the posterior part of the lenticule is separated instead. In this case, the lenticule is stuck on the undersurface of the flap, rather than on the stromal bed. In our experience, we have generally observed that the initial separation between the flap and the lenticule in this situation is easiest near the hinge. Once a small separation is observed or created,

it is not difficult to grasp the lenticule with a micro-forceps and carefully peel it away from the flap, while using a PVA spear or another similar instrument to stabilize the flap. In our experience, it is still possible, with some surgical dexterity, to separate the lenticule from the overlying cornea.

In our experience, there are no other serious intra-operative or post-operative complications. We have not observed complications like vertical gas breakthrough²¹, transient light sensitivity syndrome²², or rainbow glare²³. In many cases, a fine scarring is observed at the flap edge or the lenticule edge. However, this is outside the pupillary zone and is visually non-significant. Some patients, especially chronic contact lens users before the procedure, experience dry eyes after the procedure. We have observed a few cases of a fine interface haze several months after the procedure. However, this was never visually significant.

Like any other refractive surgery procedure, there is likely to be need for enhancements after the procedure. This can be because of a myopic drift several years after the procedure, or because of a primary over or under correction. Currently, enhancements after FLEx and SMILE must either be completed using excimer laser PRK or by using special software to convert the “cap” into a flap, and then lifting the flap and performing excimer laser corneal reshaping.

To conclude, Flapless Refractive Surgery or ReLEx Smile is an emerging modality to treat refractive errors using only a femtosecond laser. In our experience³, the results for treating myopia or myopic astigmatism with ReLEx Smile are similar to, or superior to, the results obtained with Femto-LASIK. Since ReLEx Smile has several advantages over Femto-LASIK, it is a technique with a high potential to be the refractive surgery technique of the future.

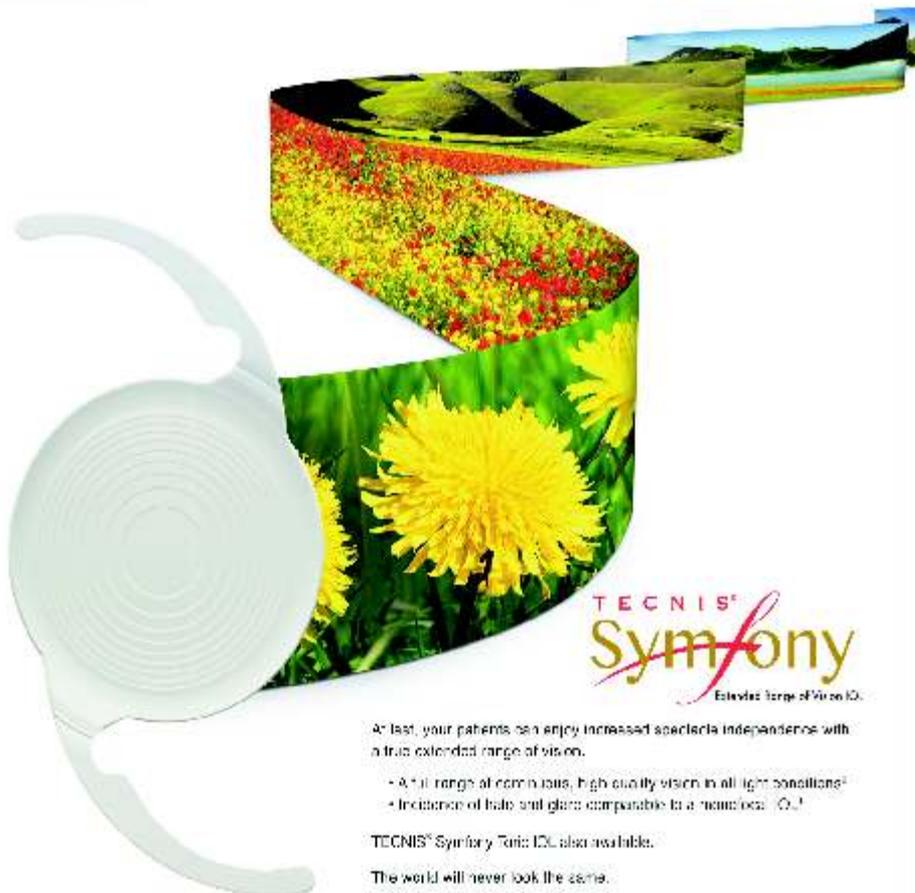
References:

1. Shah R, Shah S, Vogelsang H. All in One Femtosecond Laser Refractive Surgery. *Techniques Ophthal* 2010;8(1): 35-42
2. Sekundo W, Kunert K, Russmann C, Gille A, Bissmann W, Stobrawa G, Sticker M, Bischoff M, Blum M. First Efficacy and Safety Study of Femtosecond lenticule extraction for the correction of myopia Six Month Results. *J Cataract Refract Surg* 2008;34:1513-1520
3. Shah R, Shah S, Sengupta S. Results of Small Incision Lenticule Extraction- All in One femtosecond laser refractive surgery. *J Cataract Refract Surg* 2011;37:127-137



A NEW ERA HAS BEGUN, AND IT LOOKS AMAZING.

Introducing **TECNIS[®] Symphony IOL**, the first and only
presbyopia-correcting Extended Range of Vision IOL.



**TECNIS[®]
Symphony**
Extended Range of Vision IOL

At last, your patients can enjoy increased spectacle independence with
a true extended range of vision.

- A full range of comfortable, high quality vision in all light conditions¹
- Incidence of halo and glare comparable to a monofocal IOL²

TECNIS[®] Symphony Toric IOL also available.

The world will never look the same.

For more information please contact : Tel. No. 0124-4618065, 080-49426668 / 49426608
E-mail: ami@india.marketing@abbott.com Website: www.ami-inc.com

¹ See also article on extended range of vision IOLs in the study results PDF
2. TECNIS[®] Symphony IOL

TECNIS[®] Symphony Extended Range of Vision IOLs were indicated for presbyopia patients. For the full range of vision, including visual acuity under mesopic conditions without wearing spectacles, in whom a monofocal IOLs had been removed by cataract extraction and space filling refractive technology. In postoperative study, who demonstrated a true extended range of vision including far, intermediate and near, a visual acuity level of 20/40 or better, and increased spectacle independence. Results are presented below in the available PDF on extended range of vision IOLs, which you can also visit to the following link.

TEC 6 and TECNIS MP20 are trademarks owned by Abbott and used herein for identification purposes only.

©2015 Abbott Medical Devices Inc.
www.AbbottMedicalDevices.com
49426608

Abbott
A Division of Janssen

CHAPTER 3

Femto Laser Assisted Cataract Surgery (FLACS)

Dr. D. Ramamurthy
*The Eye Foundation,
DB Road, Coimbatore.*

Femtosecond lasers have been used successfully in ophthalmic surgery since 2001. The technology has been applied widely, most notably in LASIK (Laser In-Situ Keratomileusis) refractive surgery. Once a laser enters the surgical arena the opportunities to optimize are endless. We are just in the beginning of this refractive laser-assisted cataract surgery journey, and precision improvements will arrive quickly.

Historical Perspective — The Evolution of Cataract Surgery

The first references to cataract surgery were made by the scholar Aulus Celcius in 29 AD. From Susrutha's couching in 200AD to Harold Ridley's IOLs in 1948 & Charles Kelman's concept of phacoemulsification in 1967 it has been a long & interesting journey in the evolution of Cataract surgery.

Since its inception, phacoemulsification surgery has accelerated through improved instruments, lens technology, fluidics, and energy delivery. Nevertheless, the basic series of steps involved have remained largely unchanged over the past 20 years. Today, cataract surgery is the most commonly performed surgical procedure in the world, with an estimated 22 million operations performed annually.

Lasers in Cataract Surgery

During the 1970s, lasers began to be investigated and developed for a variety of different applications within the arena of cataract surgery. The most widely adopted is the neodymium-doped yttrium-

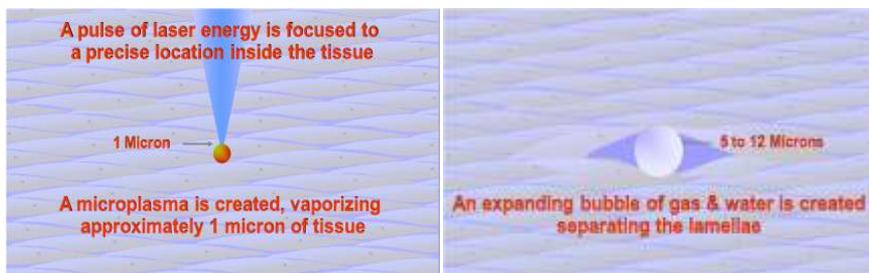
aluminium-garnet (Nd: YAG) laser for posterior capsulotomy in pseudophakic patients with posterior capsular opacification, a technique first described in 1980, Lasers have also been employed for phacopuncture, anterior capsulotomy before cataract extraction and photolysis of the cataractous lens. However, owing to either undesirable complications or simply a preference for other non-laser-based techniques, these applications are not in common usage.

Ultrafast femtosecond laser (FSL) technology was introduced in 2001, revolutionizing corneal flap creation in laser in situ keratomileusis (LASIK). This has resulted in more predictable and accurate flaps with a lower frequency of complications. The number of corneal refractive procedures performed so far using FSL is estimated at over two million and newer generation FSL systems continue to evolve in terms of both precision and versatility. It is postulated that FSL technology can produce the same gains in cataract surgery as it promises to improve accuracy, reproducibility, and safety beyond what is currently possible. It has even been stated that FLACS may herald, the most important evolution since the transition to phacoemulsification.

Femtosecond lasers: Mechanism of action

The FSL causes tissue disruption with its near-infrared scanning pulse focused to 3 μm with an accuracy of 1 μm .¹ Photodisruption is essentially induced by vaporization of target tissues, which occurs through the following steps: the focused laser energy increases to a level where a plasma is generated; the plasma expands and causes a shock wave, cavitation, and bubble formation; and then the bubble expands and collapses, leading to separation of the tissue.^{1,2} Because FSLs function nearly at an infrared wavelength, they are not absorbed by optically clear tissues.¹¹ This makes FSL-assisted surgery amenable to anterior chamber targeting at various depths, as the anterior chamber provides an optically clear tissue space.² The near-infrared wavelength is not absorbed by the cornea, and the waves are known to dissipate approximately 100 μm from the lens tissue target.

PHOTODISRUPTION



Preoperative Planning for FLACS Surgery

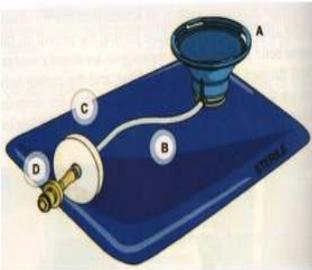
First, detailed planning of each stage of the operation is required. This involves assessing the anatomy of the patient's eye, pupil diameter, anterior chamber depth, and thickness of the lens and cornea. Size, shape, and centration of the capsulotomy are then calculated, with the choice of IOL in mind. The type of lens fragmentation or liquefaction is chosen and customized by the surgeon, as this will have a bearing on the amount of phaco time and power, which is required subsequently. Parameters for the location, structure, and depth of the clear corneal incisions (CCIs) are subsequently fed in. If astigmatic keratotomies are to be performed, their depth, length, and axis are currently determined by making adjustments to the traditional LRI nomograms. However, as femtosecond technology develops, these nomograms will require modification and this is currently being worked on.

Docking the Eye

After the planning stage is complete, the patient's eye is docked into the laser platform, using a patient interface (PI), in a method similar to laser refractive surgery. Docking of the eye into the LASIK interface is known to cause a significant rise in intraocular pressure, in the order of ≥ 80 mm Hg. Although this has been linked to complications such as LASIK-induced optic neuropathy, it is generally well tolerated by the younger refractive surgery population. However, this rise in intraocular pressure is likely to be more

problematic in elderly cataract patients, with the risk of ischaemic retinal and optic nerve injury. In particular, patients with advanced glaucoma may be at risk of 'snuff-out'. For this reason, the developers of FLACS platforms have been compelled to devise alternative methods of stabilizing the patient's eye within the optical system, while reducing intraocular pressure rise and anatomical distortion. LenSx(Alcon) was earlier uses contact lens, which applanates the cornea and used to produce an IOP rise of up to 40 mm Hg. Presently they have a soft hydrogel contact lens placed on the patient interface which ensures the pressure raise is only around 16 mm & causes minimal corneal distortion. OptiMedica's Liquid Optics interface has been found to generate an intraocular pressure rise of 15 mm Hg.

Both OptiMedica and LensAR have developed no-touch, non - applanating systems, which employ a liquid interface between the laser system and the eye. This prevents the formation of corneal folds, which can interfere with laser delivery. Maintaining a highly focused laser in this way allows lower energy levels to be used, with less collateral damage and consequently better results.



Patient Interface

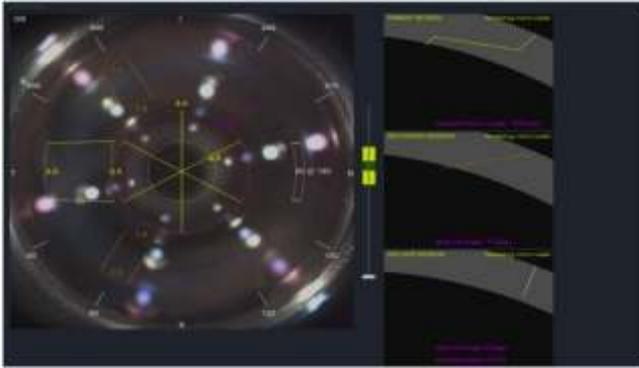


Eye Being Docked

Intraoperative Anterior Segment Imaging

The third step in the procedure involves high-resolution, three-dimensional, wide-field imaging of the anterior segment. Detailed visualisation of the cornea, iris, iridocorneal angle, and lens

(including anterior and posterior capsule) is the key to success and safety. Two systems have been developed for this purpose, with LenSx (Alcon), Catalys (Optimedica - AMO), and VICTUS (Technolas Perfect Vision) utilizing Fourier-domain optical coherence tomography and LensAR employing a confocal structured illumination-scanning transmitter system similar to the Scheimpflug imaging systems developed for corneal topography.



Spectral Domain OCT Picture after docking and before laser. On the left is seen a good dock showing the planned template for incisions, rhexis, nucleus fragmentation and astigmatic keratotomy on the right is profile of Triplanar main incision, side port & astigmatic keratotomy.

The Treatment Stage

Subsequent to docking the treatment stage is initiated. Each laser incision is made from the posterior to anterior plane a principle that elegantly employs the posterior microcavitation bubbles to scatter the laser beam and reduce the amount of energy reaching the retina. Also by keeping the bubbles posterior to the laser target, the focus of the laser beam is maintained and this avoids scatter before the target tissue. The sequence of incision creation varies between the various machines and although theoretical differences exist, there is currently insufficient evidence to suggest which order has superiority. After the laser incisions have been created, lens removal and IOL implantation are performed under sterile conditions. This usually involves moving the patient from the laser room to a sterile operation theatre.

The major platforms:

Currently there are four lasers at or near the point of commercial release. These include Alcon LenSx (Alcon Laboratories, Ft Worth, TX, USA), OptiMedica Catalys (Optimedica Corp, CA, USA), LensAR (LensAR Inc, FL, USA) and Technolas (Technolas Perfect Vision GmbH, Germany). All laser systems share a common platform which includes an anterior segment imaging system, patient interface and femtosecond laser to image, calculate and deliver the laser pulses. The specific technology to achieve these steps differs between the individual lasers with notable differences in imaging and docking systems and laser treatment algorithms. There appears to be little, if no data to assert the enhanced ability of a single unit over the others at this time. The choice for surgeons in 2012 was related to availability, technical support and cost. By mid-2013 over 120,000 eyes have been operated upon in 67 countries.



LenSx



Catalys



LensAR



Technolas

Applications and Potential Benefits



Under Microscope before commencing surgery: Cavitation bubbles in AC, Rhexis margin, Nucleus chop & cylinder pattern, the temporal, side port & AK Incisions

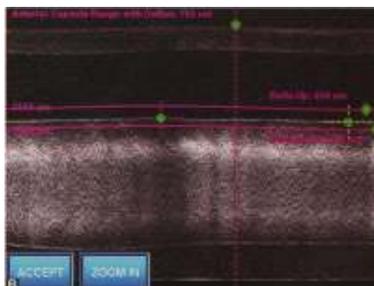
Femtosecond laser currently has four applications in cataract surgery:

- a) Corneal wound construction
- b) Anterior capsulotomy
- c) Lens fragmentation
- d) Arcuate keratotomy (AK) to address corneal astigmatism

Anterior Capsulotomy

Several studies have increased the understanding of the importance of the anterior capsulotomy. Its size and circularity is one of the key determinants of the positioning and performance of the IOL. An anterior capsule that completely overlaps the optic of the IOL is known to reduce the risk of posterior capsular opacification, improve IOL centration and reduce myopic shift. If the capsulotomy is too small, fibrosis and hyperopic shift may ensue. Conversely, if too large or asymmetric, the IOL may be adversely affected by tilt, rotation, decentration, myopic shift, and posterior capsular opacification. The capsulotomy is also closely related to the effective lens position (ELP) and it has been found that imprecise estimation of the ELP is the single biggest cause of inaccurate IOL power calculation. Tilt, rotation, decentration, and changes in ELP may have even more profound effects with toric, accommodating and multifocal IOLs. All of these factors have implications for the final refractive outcome, while also increasing the risk of aberrations such as astigmatism, halo and coma. Ideally, the capsulotomy should be perfectly circular and overlapping the IOL optic by 0.5 mm for 360 degrees.

These factors are of great significance when considering the newest IOL designs. One example is the dual-optic accommodating IOL, though not widely in use, whose accommodative ability depends on movement of the anterior optic with ciliary contraction and relaxation. This relies on the IOL being fully overlapped by the anterior capsule, without which the anterior optic may prolapse out of the capsular bag. Moving forward we may be in a



Deltas 300 Microns
anterior and posterior to
the capsule for Rhexis

position to make a small precise rhexis, empty the capsular bag, fill it with a pliable material which can accommodate. Obviously this kind of precision will be assisted by the availability of laser technology.

Constructing the anterior capsulorhexis manually is technically challenging and recognized as one of the more difficult aspects of cataract surgery to learn. Despite this, it remains unenhanced by advances in technology and is still dependent on freehand, circular tearing by the surgeon. It is estimated that the manual capsulorhexis is complicated by capsular tears in 1% cases and its complexity increases in cases involving shallow anterior chambers, paediatric /mature cataracts, fibrosed capsules, weak zonules or poor visibility. Although cataract surgeons may previously have been satisfied by completing the capsulorhexis safely, the emphasis is now shifting towards completing the procedure with greater accuracy in terms of shape, centration and diameter. Most surgeons currently use anatomical landmarks such as the pupillary margin to guide the placement of the capsulorhexis. Owing to factors such as irregular pupillary dilation, differences in corneal magnification and other anatomical variants, these landmarks are not always reliable. Studies have shown that even in the hands of an experienced cataract surgeon, there is considerable variability in the construction of the manual capsulorhexis. In their landmark study from 2009, which evaluated the LenSx platform, Nagy et al demonstrated FSL capsulotomies to be significantly more accurate and reproducible in terms of size, circularity and centration than manual capsulorhexis. Similar conclusions have since been reached by several other studies.

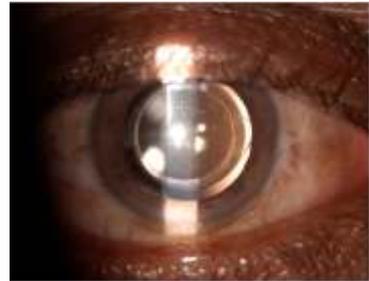


Free Floating Rhexis

Nagy's team have produced statistically significantly lower rates of incomplete capsulotomy-IOL overlap with FLACS (6/54; 11%) when compared with conventional cataract surgery (16/57; 28%), although this study was limited by short follow-up of 1 week and a

lack of blinding for the postoperative measurements. Another conclusion from this study was that the diameter of manual capsulorhexis varied with differences in pupil size, axial length, and magnification from the corneal curvature. Conversely, capsulotomies performed with femtosecond laser were not influenced by these variables. No significant difference in capsulotomy circularity between the laser and manual groups was found in this particular study.

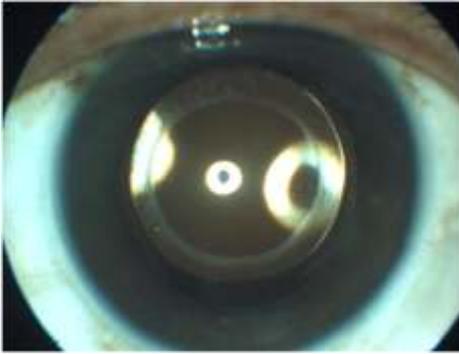
Although there are variations between the LenSx, LensAR and Catalys systems in their capsulotomy results, they are united by increased precision and circularity relative to manual capsulorhexis. The LenSx and Catalys systems have also been reported to give improved results for IOL centration when compared with the manual technique. Using LenSx, Kranitz et al found the improved IOL centration to remain statistically significant at 1 year postoperatively. In this study, horizontal and vertical IOL centration was found to worsen more over the first year with manual capsulorhexis than with femtosecond capsulotomy (anteroposterior IOL position was not evaluated). This was presumed to be a result of asymmetric capsular contraction, although interestingly the study found no significant difference in circularity between femtosecond capsulotomy and manual CCC after 1 month. The authors concluded that the risk of IOL decentration was six times higher with manual capsulorhexis. This is particularly important with accommodating and multifocal IOLs, in which it has been found that even slight decentration (>0.4 mm) can adversely affect optical performance.



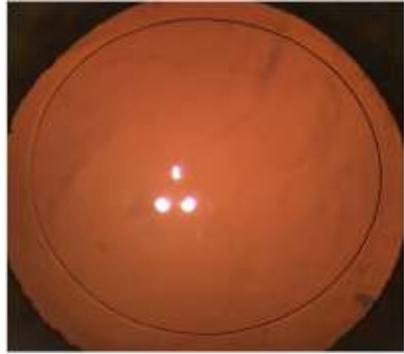
360 Degree Overlap of
Rhesis Margin

New intraocular lenses designed specifically to take advantage of the increased precision of femtosecond technology are already in development. **However, there is currently no long-term data to prove the more precise laser capsulotomy ultimately leads to significantly better visual and refractive outcomes than a manual**

capsulorhexis performed by an experienced surgeon. Particularly with simple, monofocal IOLs, the differences may be unnoticeable.



3 Months post FLACS



PRISTINE RHEXIS WITH FLACS

Corneal Wound Construction

The self-sealing clear corneal incision (CCI), used by the majority of cataract surgeons to gain access to the anterior chamber, is another aspect of cataract surgery which femtosecond technology aims to improve. The length and shape of the incisions are important factors in corneal wound safety, with square surface architecture being associated with less wound leakage and consequently a lower risk of hypotony, iris prolapse, and endophthalmitis. A well-constructed three-step CCI reduces the risk of 'wound slippage', which can result in induced astigmatism. Damage to Descemet's membrane and gapping at the internal aspect of the corneal wound are also commonly found with manual CCIs. This can lead to delayed healing and an increased risk of corneal decompensation.

Masket et al demonstrated greater architectural stability and reproducibility with corneal incisions in cadaveric eyes created with the femtosecond laser. Using indentation with ophthalmodynamometry, FSL incisions measuring 3.0×2.0 mm were found not to leak at any level of external pressure. More rectangular incisions (3.0×1.0 mm) leaked with all levels of external pressure. However, conclusions from this pilot study were limited by the small sample size and the fact that cadaveric eyes were used. In a

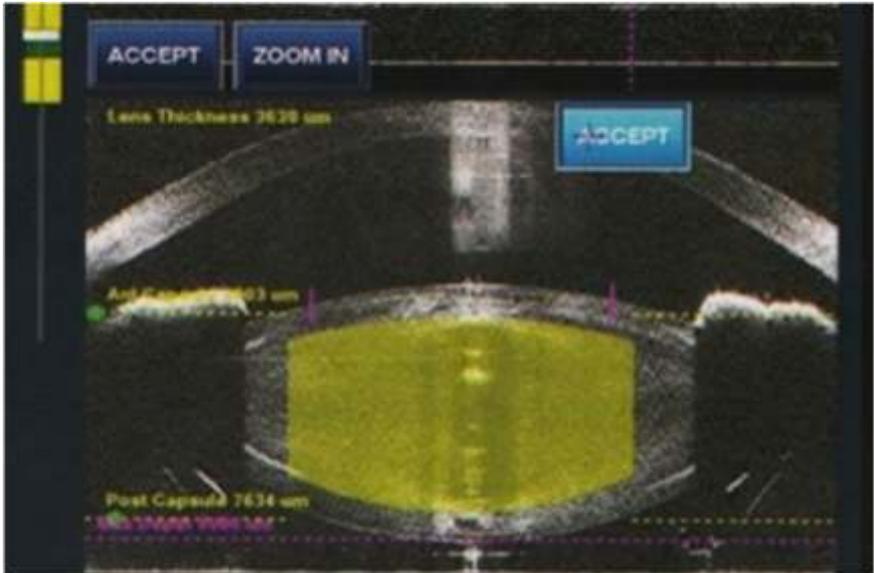
subsequent in vivo study of 50 human eyes, Palanker et al employed multiplanar corneal incisions, which were self-sealing and resistant to leakage under physiological intraocular pressure. It is thought that this, combined with a reduction in the mechanical stress exerted on the eye during the FLACS procedure, will lead to faster healing and fewer CCI-related complications. Longer follow-up data are required to add evidence to these hypotheses. From a technical viewpoint, some debate exists regarding the benefits of laser corneal incisions. Masket's cadaver study certainly highlighted improved structural stability, but current practice involves a partial thickness incision, which is then completed manually once the patient is sterile. Although this avoids breaching the anterior chamber before the patient is sterile, it may impact on the perceived advantages of the laser incisions.

Lens Liquefaction and Fragmentation

Complications in cataract surgery most frequently occur during or because of phacoemulsification itself. Intraocular manipulation of the rapidly oscillating ultrasound probe at this stage increases the risk of injury to the capsule, iris, and cornea. Thermal injury to the corneal wound may also occur. Furthermore, the risk of endophthalmitis is thought to increase every time an instrument is introduced into the eye. Laboratory and animal studies have shown that ultrasound power within the anterior chamber causes oxidative stress and cellular injury, with the production of free radicals that are toxic to the corneal endothelium. However, the magnitude of this cellular damage in vivo with modern phacoemulsification techniques is uncertain, so its clinical relevance remains unclear.

FLACS has been designed to pretreat the lens, by using liquefaction or fragmentation patterns to segment the nucleus and soften harder cataracts, thus decreasing the amount of intraocular instrumentation and movement. Liquefaction has been suggested for refractive lens exchange and softer cataracts (up to LOCS grade 2.0), whereas fragmentation is recommended for harder lenses up to LOCS grade 4.0). In porcine studies with the LenSx system, lens fragmentation allowed the surgeon to reduce ultrasound power by 43%, and

phacoemulsification time by 51%. The authors of this study employed a 'divide and conquer' technique for manual phacoemulsification. Whether such significant contrasts in ultrasound power and phaco time exist with other techniques (eg 'phaco chop') remains to be elucidated. Palanker et al's randomized case-controlled study of 59 human eyes in vivo found that phacoemulsification energy was reduced by 39% in eyes treated with FLACS compared with standard cataract surgery. However, the technique used for manual surgery was not specified in this study.



Profile for Nucleus Fragmentation: Yellow area is the area of nucleus fragmentation with an offset of 500 microns from Anterior & Posterior Capsule

Similar results have been achieved with alternative fragmentation algorithms on different laser platforms. One study demonstrated significantly less corneal swelling on the first postoperative day with FLACS, compared with conventional surgery. Although differences between the two groups did not remain statistically significant at 1 week and 1 month postoperatively, the authors concluded that FLACS may be less traumatic to the corneal endothelium. This seems promising, but long-term studies are required to determine whether

or not laser lens fragmentation significantly improves the safety profile and outcomes of cataract surgery. Efforts are ongoing to determine which fragmentation patterns have superiority in terms of reducing effective phacoemulsification time. The ultimate objective may be to develop a fragmentation and liquefaction algorithm, which allows the lens to be simply aspirated, obviating the need for ultrasound energy at all.

Enhanced ability in lens fragmentation would minimize the need for additional ultrasound energy, even for the densest cataracts, but the improved outcomes may not be sufficient to justify the extra expense.

Limbal Relaxing Incisions

A potential application of FLACS is in the creation of highly accurate, reliable astigmatic LRIs. Manual LRIs can be technically challenging, with many surgeons reluctant to perform them due to concerns related to inaccuracy and the small risk of corneal perforation. Therefore, only a small proportion of patients who could benefit from LRIs are actually receiving them. Femtosecond laser-assisted LRIs may allow for optimum correction of low astigmatism, rendering conventional and somewhat unpredictable, manual LRIs obsolete. For higher degrees of astigmatism, however, it is likely that toric IOLs will continue to represent the best treatment modality.

FLACS & CSME:

Subclinical macular oedema is a common complication of conventional phacoemulsification. In a study comparing the macular effects of FLACS vs conventional surgery with a 'divide and conquer' technique, significantly less thickening of the inner macular ring was found in the FLACS group at 1 week postoperatively (mean difference of 21.68 μm , $P < 0.001$). This difference between the FLACS and control groups reduced after 1 month and no longer attained statistical significance, but the authors suggested that reduced subclinical oedema in the early postoperative phase could be beneficial for patients at risk of developing clinically significant cystoid macular oedema later on. No statistically significant

differences between the two groups were found in terms of foveal thickness, total macular volume, or outer macular ring thickness.

These findings may be relevant when considering patients deemed to be at high risk of developing postoperative inflammation, cystoid macular oedema, and diabetic maculopathy. However, both of the aforementioned studies were limited by small numbers and short follow-up periods of 1 month and 4–8 weeks, respectively, so larger, longer-term studies are required to fully investigate this potential benefit. Little is known about the effects of FLACS on age-related macular degeneration (ARMD), although one could infer that a reduced inflammatory response in the eye may decrease the risk of ARMD progression.

Complex Cataract Cases

FLACS is possible, and may even help improve outcomes, in trauma cases with white cataract formation or anterior capsule rupture. Anterior capsular lacerations complicate the construction of the manual capsulorhexis, but the increased delicacy and accuracy of femtosecond lasers may be able to overcome this. However, the high precision of FLACS does currently depend on a stable lens and so lens fragmentation may not be an option if phacodonesis has occurred as a consequence of trauma. Similarly, unstable lenses in the context of pseudoexfoliation or zonular dialysis may also be a relative contraindication.

Although the majority of studies to date have focused on improving refractive outcomes in relatively low-risk patients, as the technology develops and limitations are addressed, it could be found that FLACS is the method of choice for dealing with difficult cataracts at high risk of corneal, capsular, zonular, or retinal problems.

The use of femtosecond lasers in cataract surgery continues to evolve and with that, its potential applications extend. A case series of eight patients has reported success using FLACS with 25-gauge phacovitrectomy, which paves the way for combining the technology with other procedures.

Practicalities and Limitations

The Docking Process

The FLACS platforms are strongly reliant upon the compliance and other characteristics of patients. Poor mobility, tremor, an inability to lie flat, deep set eyes, and narrow palpebral apertures may impair the docking process and therefore are relative contraindications. Indeed, in a study of 200 eyes undergoing FLACS, the mean number of docking attempts was 1.5, although this decreased as the surgeons' experience increased. Occasionally, a loss of suction can occur after the eye has been docked. Bali et al encountered this in 5 of 200 eyes, but in each case the footswitch was released and the laser was not initiated. It has been suggested that movement of redundant conjunctiva, or the appearance of a meniscus, may alert the operating surgeon to an impending loss of suction.

Corneal Limitations

Corneal incisions are currently designed to be incomplete, so the anterior chamber is not breached before the patient enters the operating theatre and the ocular surface and adnexae are sterilized. Although no cases of endophthalmitis have so far been reported following FLACS, protocols regarding ocular surface sterilization have yet to be established. Conceivably, microorganism entrapment could occur within the corneal incision, which is then opened with a blunt spatula.

Corneal opacification may hamper absorption of the laser, and therefore affect the quality of corneal incisions. Similarly, it may result in dispersion of laser energy, although the extent of corneal opacification and oedema through which FSL can pass without significant scatter is not yet known. Although the corneal incisions aim to be self-sealing, stromal hydration is invariably required to seal the incisions. Since all the incisions have to be corneal rather than limbal there is a potential for the incisions to be weaker than the limbal incisions created manually.

Capsular Complications

FSL capsulotomy requires pupillary dilatation in the order of 7–8 mm, and therefore marked corectopia, poor dilatation, and posterior synechiae are relative contraindications. In addition, FLACS has been associated with an increased risk of capsular block syndrome (CBS), in which posterior capsule rupture (PCR) and lens dislocation occurs following hydrodissection. In Roberts et al's series of the first 50 patients undergoing FLACS at their facility, two eyes were complicated by intraoperative CBS. The theory behind this is that FSL lens fragmentation results in intralenticular gas, which expands the nuclear volume. The near-perfect edge of the FSL capsulotomy is then thought to form a seal around the expanded nucleus. This restricts the flow of fluid around the lens, resulting in posterior pressure on the capsule and posterior capsular rupture. It should be noted that, with adjustments to the technique and increased awareness of the risk of CBS, no further cases have occurred at this particular facility. So it is important to be aware of the pneumodissection that occurs with FLACS & decompress the bag before performing hydrodissection & to do this gently with limited amount of fluid injection.

Surgical Time

Because of the two stages of treatment involved there is a potential, especially in the initial cases, for greater time being taken compared to the conventional phacoemulsification. But once the surgeon & his team get conversant with the procedure it is possible to make the process more efficient. It is possible to complete the laser step in multiple cases & then subsequently do the surgical steps. There is no specific time limit that has been recommended between the two steps but ideally it should be less than 60 minutes. One model has been proposed, whereby a single laser suite, operated by one surgeon, feeds into several operating theatres with other surgeons completing the manual parts of the procedure.

Training Implications and the Learning Curve

FLACS will certainly require a period of training under supervision, just as with phacoemulsification. Surgeons will need to learn to dock the eye to the laser, as well as understand how to interpret the anatomical images, adjust the laser parameters and deliver energy safely. As demonstrated by Bali et al and as was the case with phacoemulsification, the FLACS technique will involve a significant learning curve even for experienced cataract surgeons. Each machine is likely to have specific alterations that will require a period of learning by the attending surgeon.

One suggested concern with the development of FLACS is that of a 'loss' of surgical skills, particularly in view of the limitations of the technology. It should be emphasized that FLACS was designed to improve safety and efficacy, but not to replace highly trained surgeons with lesser skilled technicians. A competent surgeon would still be essential in managing potential complications or irregularities with the laser system. It has also been highlighted that the critical factor of surgical judgement and experience simply cannot be coded into the laser software.

Overall, FLACS may allow less experienced surgeons to obtain better results, but may fail to demonstrate a significant improvement for experienced cataract surgeons not implanting premium intraocular lenses. It is therefore likely to 'flatten the curve', with surgeons attaining similar outcomes across the board.

Economics and Financial Considerations

Despite its perceived benefits, FLACS is not yet widespread, even in high-volume cataract centres. This is largely due to the significant financial costs involved in its implementation. Although costs are likely to reduce with competition and more entrants to the market, it is probable that the initial cost of the FLACS platform itself will be between US\$400 000 and \$500 000. Furthermore, a usage fee is likely to be \$150 to \$400 per eye and maintenance costs are estimated

to be around \$40–50 000 per year. If surgeons are confident in their own microsurgical skills and outcomes, it could be difficult to justify the additional expense, except perhaps in a very high-volume refractive cataract practice.

However, with time and marketing, it is likely that the public perception will change. As with all branches of medicine and surgery, the expectations and demands of patients are changing. With rapidly advancing IOL technology and an increasing emphasis on achieving near emmetropia, tolerance of less than perfect visual and refractive outcomes is decreasing among patients and surgeons alike. Cataract surgery is being transformed into a refractive operation, and is now the most common procedure to correct refractive errors, being performed five times more frequently than corneal refractive treatments. As awareness of femtosecond technology increases, we will start to experience more and more patients asking about or demanding FLACS. This may necessitate a change in the state funded healthcare system & insurance reimbursements to allow co payment, where patients are given the option of paying extra for the premium IOL and laser technology. Another method of improving economic viability may be through 'bundled discounts', whereby companies reduce the cost of their laser machines in return for a supply contract for other surgical instruments and IOLs.

With rapidly advancing IOL technology and an increasing emphasis on achieving near emmetropia, tolerance of less than perfect visual and refractive outcomes is decreasing among patients and surgeons alike. Cataract surgery is being transformed into a refractive operation, and is now the most common procedure to correct refractive errors, being performed five times more frequently than corneal refractive treatments. Unfortunately, the limitations of currently available biometry and surgical techniques mean that the full potential of toric, multifocal, and accommodating IOLs may not reliably be achieved. Several authors have suggested that FLACS may provide the solution to this dilemma, as well as improving the results of standard cataract surgery, which are highly dependent on the skill and experience of the surgeon. If significantly improved

outcomes and safety can be demonstrated, it is possible that FLACS may become the gold standard in years to come.

Future applications:

Currently, there is no known way of preventing cataract formation. Similarly, although attempts have been made, no non-surgical treatment modalities exist in a clinically useful form. However, femtosecond lasers have been demonstrated to 'bleach' the human lens through photolysis, decreasing the amount of yellow pigment and resulting in optical rejuvenation of between 3 and 7 years. It has been postulated that this may delay the need for cataract surgery by 5 years, leading to a 35% reduction in surgical volume.

Photodisruption with femtosecond laser has been shown not to cause cataractogenesis or loss of lens function. This opens up the possibility of using FSL technology in lenticular refractive surgery. It has been suggested, through the creation of lenticular incisions acting as gliding planes across collagen fibrils, that an element of accommodation to presbyopic lenses could be restored.

Conclusion:

Femtosecond laser-assisted cataract surgery (FLACS) represents a potential paradigm shift in cataract surgery, but it is not without controversy. Advocates of the technology herald FLACS as a revolution that promises superior outcomes and an improved safety profile for patients. Conversely, detractors point to the large financial costs involved and claim that similar results are achievable with conventional small-incision phacoemulsification. While in its infancy, FLACS sets out the exciting possibility of a new level of precision in cataract surgery. However, further work in the form of large scale, phase 3 randomized controlled trials are required to demonstrate whether its theoretical benefits are significant in practice and worthy of the necessary huge financial investment and system overhaul. Whether it gains widespread acceptance is likely to be influenced by a complex interplay of scientific and socio-economic factors in years to come.



Control. Confidence. Performance.

Achieve perfect balance with smooth, efficient cutting and the flexibility of venturi and peristaltic capabilities in one system.

Only the **WHITESTAR Signature** high performance system combines proprietary **ELLIPS FX** Technology and the exclusive **FUSION** Pump for controlled, effective lens removal.



Experience the power and grace of the **WHITESTAR Signature** System.
www.WhitestarSignature.com

The WHITESTAR Signature System is a medical system for microsurgical work in the field free anterior segment ocular surgery. It does not comply and may include trademarks or patents, either in the U.S. or elsewhere. Please refer to the WHITESTAR Signature System Manual for more information on patents, U.S. and foreign trademarks.

AMOI is a registered trademark of Vision Medical, 2012 used under license from Vision Medical, WHITESTAR Signature, ELLIPS, and FUSION are trademarks owned by or licensed to Abbott Laboratories or subsidiaries or affiliates.

©2012 Abbott Medical Optics Inc. www.AbbotMedicalOptics.com
2012 01 04-014802

 **Abbott**
Medical Optics

For more information please contact : Tel. No. 0124-4618065, 080-49426666 / 49426608
E-mail: amoinfomarketing@abbott.com • Website: www.amo-inc.com



SOVEREIGN Compact System with Advanced ELLIPS FX Technology

DESIGNED FOR EASE OF USE, EFFICIENCY AND RELIABILITY.



ELLIPS FX technology is designed with over 100,000 laser pulses built into each pulse by simultaneously combining high speed and reversible motion.



- *Advanced fluidics for excellent control and chamber stability*
- *Affordable, full-featured phacoemulsification system in a space-saving package*
- *Enhanced user interface for ease of use*
- *Easy one-touch prime and tune*



ELLIPS FX6, ELLIPS FX6000, SOVEREIGN COMPACT SYSTEM AND ELLIPS FX6000 are trademarks of Abbott Medical Optics. © 2010 Abbott Medical Optics. All rights reserved. See www.amo.com for more information.

Abbott
Medical Optics

1000 Lakeside Drive
Lake Bluff, IL 60044-1099
Chicago, IL 60606-1099

For more information please contact : Tel. No. 0124-4618065, 080-49426666 / 49426608
E-mail: amoindefomarketing@abbott.com • Website: www.amo-inc.com

CHAPTER 4

Femtosecond Laser - Assisted Cataract Surgery

Dr Sri Ganesh

Modern cataract surgery is now a cataract refractive surgery with very little scope for refractive surprises. Both patients and surgeons alike are demanding more from a procedure which was initially designed to restore vision. The basic phacoemulsification procedure, on the other hand, has remained largely unchanged over the last two decades with developments in IOL technology being primarily responsible for the better outcomes.^{1,2,3}

With the introduction of femtosecond laser in 2001 there has been a revolution in the field of ophthalmology. The word femto is derived from the Danish word 'femten' which means fifteen. By generating microplasms inside corneal stroma with Femtosecond pulses, it is possible to achieve a cutting effect inside tissue while leaving the anterior layer intact. The Femtosecond Laser employs near infrared pulses to cut tissue with minimal collateral tissue damage.

The highly localized tissue effect of low energy Femtosecond Laser expand its capabilities that it may be used to create three dimensional intrastromal resection with micron precision.

Femtosecond laser technology is already being used as an alternative to manual and mechanical methods of creating a corneal incision for laser in situ keratomileusis (LASIK) procedures, the so called “Blade-less LASIK” or “All-laser-LASIK” and its advantages as we all know are real. The same laser is being used now to perform some of the steps of cataract surgery known as Femtosecond Laser Assisted

Cataract Surgery (FLACS) in the laser room like making clear corneal incisions, performing anterior capsulorhexis, lens fragmentation and if required, making corneal arcuate incisions for astigmatism correction.⁴ Rest of the surgical steps like removal of nuclear fragments, cortical aspiration and intraocular lens (IOL) implantation are carried out in the operating theatre.

Clear corneal incisions for the main or side-port(s) or incisions for astigmatic keratotomy performed with femtosecond laser are regular, smooth, reproducible and have consistent outcomes with minimum collateral damage.⁴ Single or three-plane incisions can be created, the latter being more stable. Some surgeons prefer to make trapezoidal incisions locating them peripherally enough to touch the limbal vessels as they seal and heal well. These self-sealing incisions allow considerable waiting time before commencing removal of nuclear fragments in the operation theatre. Arcuate incisions are possible in sub-Bowman corneal stroma, while leaving the corneal epithelium and Bowman layer intact.⁵ The length, depth and orientation are precise. Minimally invasive astigmatic incisions decrease the risk of epithelial ingrowth and infection. Manual incisions created with blade, on the other hand, are affected by certain variables like surgeon's technique, experience and instrumentation with the possible complication of an occasional corneal perforation.^{5,6,7}

Machines

Currently, 4 femtosecond laser technology platforms are commercially available for cataract surgery: Catalys (Optimedica), Lensx (Alcon Laboratories, Inc.), Lensar (Lensar, Inc.), Victus (Technolas).⁸



| Femtolaser | Catalys | Lensx | Lensar | Victus |
|-------------------------------|--|---|--|--|
| Pulse | 120 | 50 | 80 | Upto 160 |
| FDA Approvals | Corneal + arcuate incisions,ant capsulotomy,lens fragmentation | Corneal + arcuate incisions,ant capsulotomy,lens fragmentation,corneal flap | Corneal + arcuate incisions,ant capsulotomy,lens fragmentation | Corneal + arcuate incisions,ant capsulotomy |
| Patient interface design | Liquid optics, non applanating,liquid interface,2 piece vacuum docking | Soft fit curved lens, applanating, 1 piece , vacuum docking | Robocone, non applanating , fluid interface , 2 piece vacuum docking | “Dual modality” curved lens applanating 2-piece spherical , solid + liquid |
| Docking | Ocular surface bathed in saline solution, no corneal applanation,no | Curved applanation , no glaucoma contraindication | No corneal applanation | Soft docking for capsulotomy and lens fragmentation, regular docking |
| Patients interface dimensions | Inner diameter , 13.5mm, inner suction skirt, 14.1mm, outer suction skirt, | Inner diameter, 12.5mm, outer diameter, 19.8mm | Inner diameter > 12.7mm, outer diameter , 24mm | Curved PI >12mm, inner diameter suction clip, 15.5 mm, outer diameter |
| Iop rise | 10.3mm Hg | 16.4 mm Hg | Under evaluation | Under |
| Ocular surface | Automatic + user adjustable | Manual | Automatic | Manual |
| Imaging type | 3D spectral domain OCT, video microscope and FS Laser to enable image | 3D spectral domain OCT, video microscope and FS Laser to enable image guided cataract | 3D ray tracing CSI(confocal structural illumination) | 3D spectral domain OCT, video microscope and FS Laser to |
| Integrated | Yes | No | No | Yes |
| Laser | 0.68 x 0.87 μ | 1.524 x 1.828μ | 1.65 x 1.97 μ | 2.075 x 0.825 μ |

CATALYS Precision Laser System

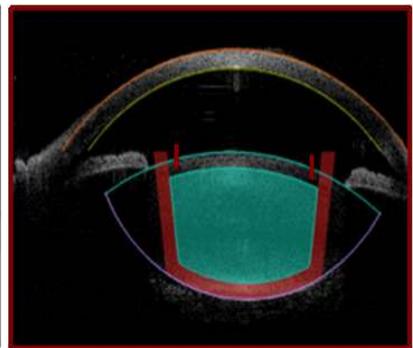
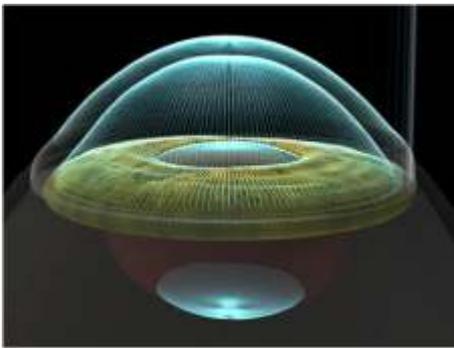
Surgical steps involved in the Catalys Precision Laser System (OptiMedica Corp., Santa Clara, California) combines an ultra-rapid femtosecond laser, integrated optical coherence tomography (OCT) imaging, and OptiMedica's pattern scanning technology



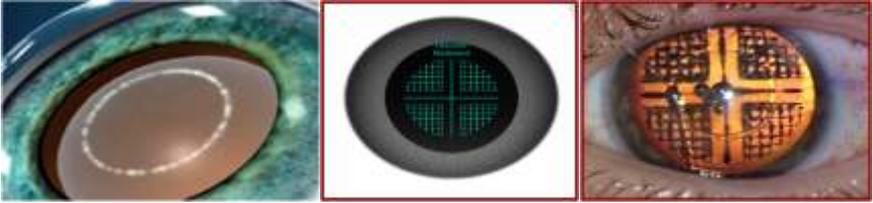
- Step 1- Entering the data for planning surgical incisions etc.
- Step 2- Docking. - LIQUID OPTICS Interface, gentle docking with minimal intraocular pressure rise and clear optics for excellent imaging and laser delivery



- Step3. Imaging- INTEGRAL GUIDANCE System - proprietary 3D Full Volume Optical Coherence Tomography (OCT) and automated surface mapping algorithms that guide laser delivery



- Step 4. FemtoLaser application- Precise capsulorhexis within 30µm are performed first followed by lens fragmentation last corneal incisions



Complete segmentation and softening of the cataract with adjustable grid sizing

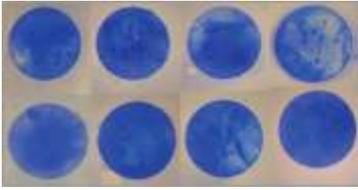
Multiple corneal incision options that are based on anatomical landmarks



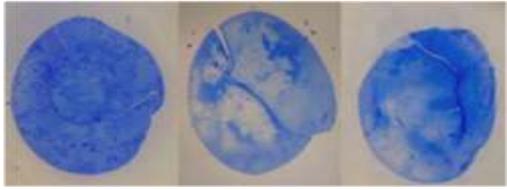
- Step 5. The patient is then removed from the laser interface and step of routine phacoemulsification are performed in the operation theatre

Advantages

- Perfect central circular capsulorhexis which are reproducible

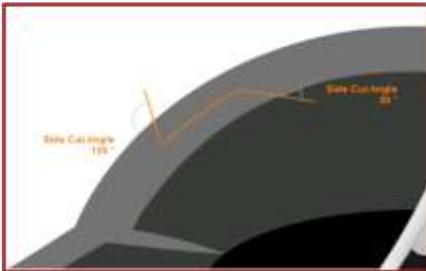


Made by femtosecond laser

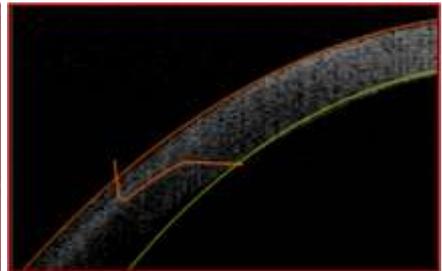


Manual capsulorhexis

- Less Phaco energy required for emulsification as lens is pre-fragmented
- Corneal incisions- precise with good architecture and hence more stable



Planning view



OCT view

Disadvantages and contraindications

- Cost- The biggest disadvantage of the use of femtosecond laser is the incremental cost that is passed on to the patient, which does make the procedure out of reach for most of the patient population of developing countries like India.
- Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy, as also an inadequate chamber depth resulting in inadequate clearance between the

intended capsulotomy depth and the endothelium are contraindications for capsulotomy using the femtosecond laser

- Suction loss
- Incomplete capsulotomies
- Computer related issues and software problems
- Staffing and logistics – dedicated trained staff required for operating the machine and as patient has to be shifted during the surgical procedure
- Relative contraindications - Corneal diseases that precludes applanation of the cornea or transmission of laser light at 1030 nm wavelength, descemetocoele with impending corneal rupture, hypotony and glaucoma.
- Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape are contraindication for the use of the procedure, as is residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease)
- Not intended for use in pediatric surgery.
- Problems while operating patients under general anaesthesia.

Conclusion

With the dawn of the femtosecond laser in ophthalmology the foundations have been laid for more precise and predictable surgical outcomes. The ability to offer customized treatment in improving patient's satisfaction in terms of exact iol centration, effective lens position, correction of residual astigmatism which is important in premium iols cannot be overemphasized. Situations like subluxated or intumescent cataracts where making a capsulorhexis is a nightmare can be easily tackled with femtosecond laser as it is less individual and surgical skill dependent. Once the procedure picks up in numbers the main disadvantage which is the cost is sure to get

addressed, which is the scenario in any new technology. One thing is sure that femtosecond laser assisted cataract surgery is here to stay, though still in its budding stage only time will tell whether it becomes the norm for cataract surgery as a preferred surgical practice.

References:

1. Ophthalmology. 2011 ;118:1699-700. Improving cataract surgery refractive outcomes. Ladas JG, Stark WJ.
2. J Cataract Refract Surg. 2011 ;37:1069-75.Characterizing the learning curve in phacoemulsification.Taravella MJ, Davidson R, Erlanger M, Guiton G, Gregory D.
3. Rev Med Suisse. 2011 19;7:128-32. Ophthalmology. New trends in cataract surgery. Abouzeid
4. Mamalis N. Femtosecond laser: The future of cataract surgery(Guest editorial). J Cataract Refract Surg. 2011; 37: 1177-1178
5. Awdeh RM, Hanafee H, Canto AP. Using a laser for arcuate incisions. Cataract and Refractive Surgery Today. Sept 2011: 74-78
6. Masket S. Is there a relationship between clear corneal cataract incisions and endophthalmitis[Guest editorial]. J Cataract Refract Surg. 2005;31:643–645
7. Masket S. Sarayba M, Ignacio T, Fram N. Femtosecond laser-assisted cataract incisions: Architectural stability and reproducibility. J Cataract Refract Surg 2010; 36:1048-1049
8. Kendall E. Donaldson et al.femtosecond laser assisted cataract surgery :J Cataract Refract Surg 2013; 39:1753–1763 Q 2013 ASCRS and ESCRS

CHAPTER 5

Laser Cataract Surgery

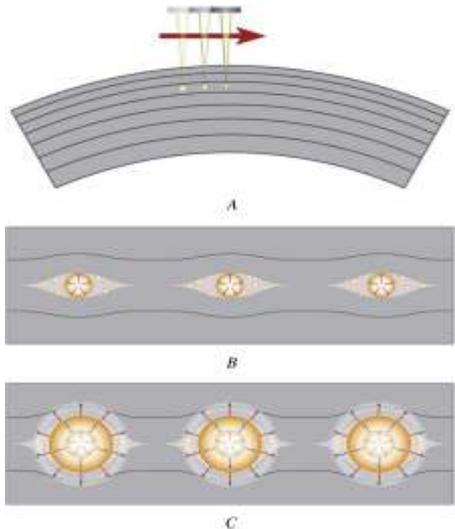
Abbott write up

Introduction

The use of the femtosecond laser in cataract surgery may prove to be one of the biggest innovation in the fields of cataract and refractive surgery in the last several decades. Commonly referred to as FLACS, Femto laser-assisted cataract surgery provides superior outcomes with very high precision, reproducibility and higher safety profiles and will allow for many future applications in the field

How The Femtosecond Laser Works?

The laser cuts its target through photodisruption, a process in which light is absorbed by a nonopaque structure through which infrared light can penetrate, allowing for the generation of a plasma of free electrons and ionized molecules that rapidly



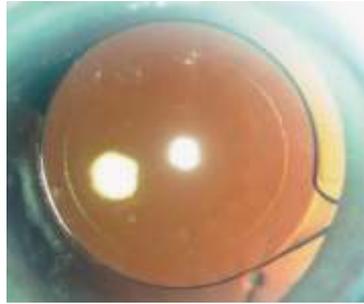
expand, collapse, and create microcavitation bubbles. An acoustic shock wave is produced which separates and incises the target tissue. In contrast with historical Nd:YAG laser technology using longer pulse durations, the microcavitation bubbles produced with FSL are much smaller, allowing for reduced collateral damage.

Benefits of Laser Cataract Surgery

The main benefits of the FSL are precise well centred capsulotomy, cataract incisions, LRI construction and lens softening & fragmentation.

Capsulotomy:

It gives precisely cut and well centered capsulotomies. The Capsulotomies are almost always free floating. These can be centered as per pupil, limbus or scanned capsule. Scanned capsule may give the best possible centration in majority of the cases as the iol centres according to the capsular bag and having



centration of capsulotomy as per bag would give uniform overlap of the capsulotomy margin on the anterior side of the iol. See below, this uniform overlap ensures good centration and predictable ELP's.

Lens Fragmentation:

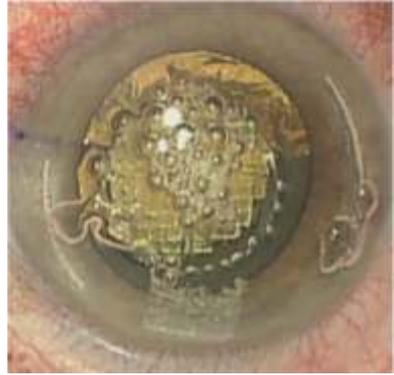
The other important role of the FSL is lens fragmentation and softening of the lens. Fragmentation is performed by dividing the lens into quadrants, sextants or octants, followed by softening the lens into cubes with preprogrammed grid patterns. These grid patterns may be customized, depending on the density of the



cataract. Lens pretreatment with Laser offers significant advantage compared with manual surgery, as pretreatment may allow for reduced instrumentation and Phaco energy(EPT) used during cataract removal, resulting in increased safety. Lower EPT's also often mean that less fluid and intraocular manipulation are needed during surgery, leading to improved clinical outcomes secondary to lower risk of injury to the capsule, iris, and corneal endothelium, reduced endothelial cell loss, postoperative inflammation and corneal edema.

Corneal Incisions

Anterior penetrating and intrastromal arcuate corneal incisions (Corneal relaxing incisions), and multiplanar clear corneal incisions (CCIs) used to access the anterior chamber can be done with the Laser with very high precision. Some studies have found that CCIs created with FSLs are square and significantly more resistant to deformation and leakage with increased stability compared



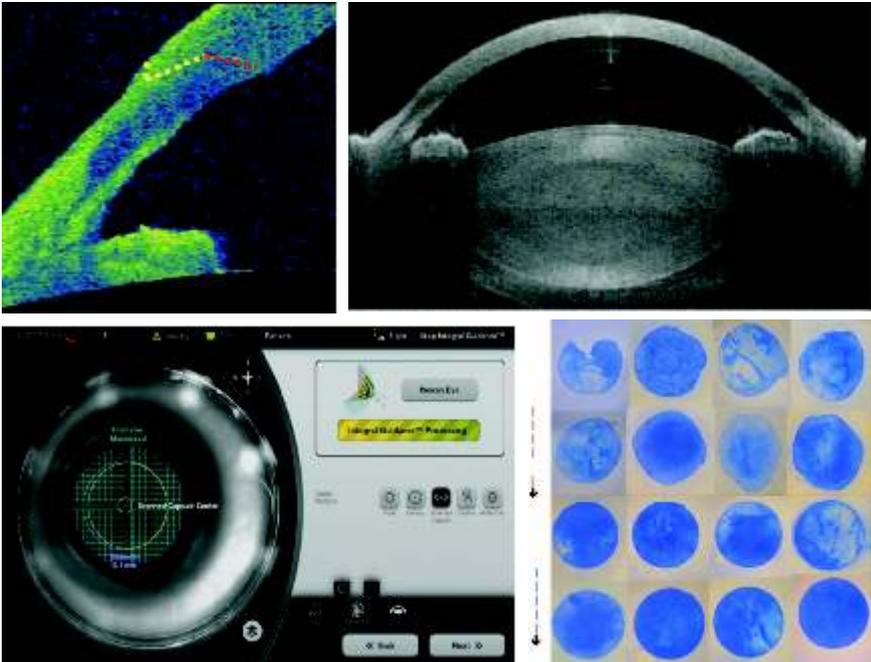
with manually created incisions. Consequently, FSL CCIs have lower risk of hypotony, iris prolapse, and endophthalmitis, and may also reduce the risk of wound slippage and induced astigmatism. Manual incisions may also offer more risk for descemet's tears and gaping of internal aspects of the wound at the point of anterior chamber entry. With image-guided FSL, the surgeon is able to specify the angles of incision into the cornea as well as its precise location in degrees. Being able to indicate precise location of the incision may be of benefit when treating astigmatism either in conjunction with CRIs or when used in isolation. CRI placement can be programmed reliably and precisely, and can be performed with either anterior penetrating or intrastromal incisions, based on the surgeon's preference.

With a FSL, the angular orientation, arc length, and a uniform incision depth (as % of total corneal thickness-not possible with a blade) can be executed more reproducibly and with less dependence on the surgeon's skill. Given the potential that even small amounts of astigmatism could be treated reliably and predictably with the FSL, the FSL could become the standard of care for the treatment of low astigmatism, rendering manual LRIs obsolete. For higher degrees of astigmatism, toric IOLs will likely continue to be used.

Conclusion

The use of FSL may revolutionize the treatment of cataracts and will likely have future applications. The advantages over conventional surgery, including capsulotomy formation, incision creations and lens fragmentation are very promising.

Image bank





www.aios.org

ALL INDIA OPHTHALMOLOGICAL SOCIETY

AIOS Secretariat : P.D. Hinduja National Hospital & MRC, Veer Savarkar Marg, Mahim, Mumbai - 400 016
Tel.: 022-24447165 • Email: aiosoffice@yahoo.com, secretary@aios.org • Website: www.aios.org

AIOS Headquarters : AIOS, 8A, Karkardooma Institutional Area, Karkardooma, Delhi - 110092 (India)
Tel.: 011-22373701-05 • Email: aiosoffice@yahoo.com, secretary@aios.org • Website: www.aios.org