Femtosecond Laser Technology in Modern Eye Care

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2 Hrs
31917-RS

Disclosures

- Bill Tullo, OD
  - TLCVision – employee

Femtosecond Technology

- Sub-micrometer surgery
- Minimally invasive
- Incremental Improvements
  - Shorter pulses
  - Lower energy
  - Lower cost
  - Less complex
  - More accessible

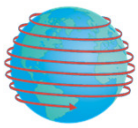
Femtosecond Photodisruptive Infrared Laser = 1053 nm

Definitions:

- Nanosecond = 10^{-9}
- Picosecond = 10^{-12}
- Femtosecond = 10^{-15}

Femtosecond Laser

- Femtosecond laser
  - (Nd:Glass) 1053 nm (near infrared)
- Each pulse of focused laser light lasts approximately 10^{-13} seconds (100 femtoseconds)



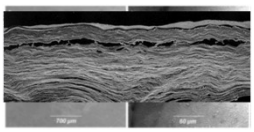
- In one second, light travels 7.5 times around the globe
- In 100 femtoseconds, light travels across a human hair
- Power = Energy/Time, extremely high power attained at relatively low energy

Femtosecond Laser

- Surgical effect is achieved through "Photodisruption" at a molecular level
  - No thermal or shock wave transmission to surrounding tissues
- Laser pulses focused to precise locations (± 5 microns)
- Computer controlled optical delivery system places thousands of pulses next to each other

Femtosecond Laser Applications

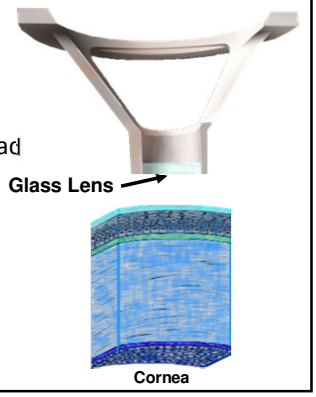
- Ophthalmic Surgery
  - Corneal
    - Incisions
    - LASIK Flaps – 1st Commercial Application
    - Keratoplasty
    - Refractive error and Presbyopia
  - Cataract
    - Capsulorhexis
    - Nuclear disection
  - Retinal
- Dental Surgery – painless and safer



Chung SH, Mazur E. Surgical Applications of Femtosecond Lasers. J of Biophoton 2009;2(10) 557-572.

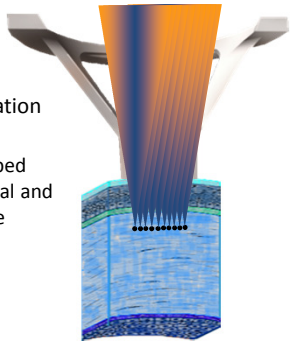
Optical Delivery System

- Glass lens applanates cornea to fixate eye & maintains precise distance from laser head to focal point

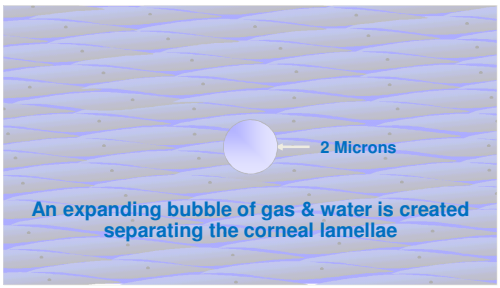


Optical Delivery System

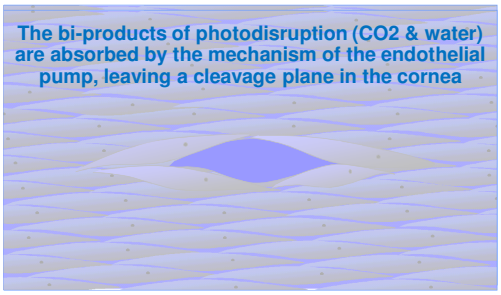
- Laser is set to desired depth
  - Defined distance from bottom of glass applanation lens (in microns)
- Pulses delivered in a prescribed pattern creating a horizontal and vertical cleavage plane in the cornea



Femtosecond Photodisruption

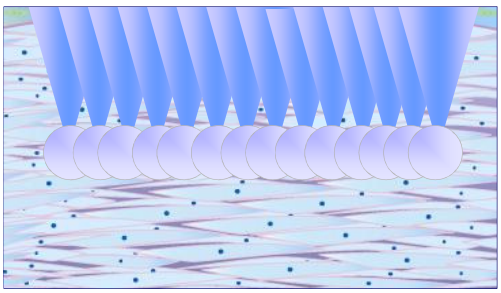


Femtosecond Photodisruption

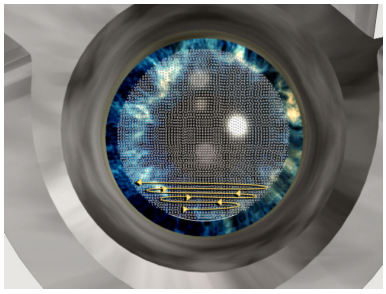


Advanced Performance

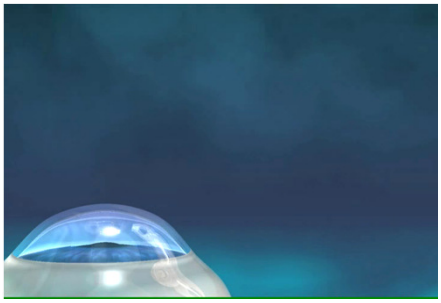
Tighter spot placement facilitates easier flap lifts



Femtosecond Laser Raster Pattern



> 80% of all LASIK flaps are now created using femtosecond technology



Femtosecond Lasers - LASIK

- AMO Intralase
  - iFS
- Ziemer
  - LDV
- Femtec
  - 2010 Perfect Vision
- Zeiss
  - VisuMax
- Alcon
  - Wavelight FS200
- Technolas PV
  - Victus

Advantages of Femtosecond Flap

- Independent specific diameter
- Independent specific thickness
- Precise flap centration
- Variable hinge size/location
- Customized edge side cut
- Smooth evenly hydrated stromal bed
- Conserve tissue
- Planar shape

Why Femtosecond Technology?

- Femtosecond Technology is ***SAFER*** than any mechanical metal blade microkeratome.
- Femtosecond Technology is ***MORE EFFICACIOUS*** providing better visual outcomes and quality of vision than any mechanical metal blade microkeratome.

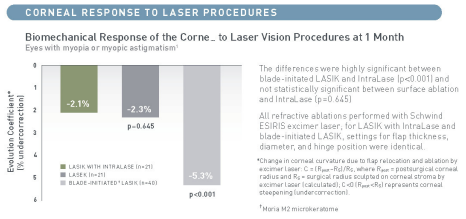
Safer

- There are fewer flap-related complications
- Eliminated common sight threatening complications
- Less loss of BCVA and more gain in BCVA
- Biomechanically stronger and more stable reducing the risk of post-LASIK ectasia

Significant Vision Threatening Events - Mechanical Microkeratome

- Globe Perforation
- Button-hole flap
- Thick Flap
- Thin Flap
- Free Cap
- Non-planar flap
- Epithelial slough
- Variable uncontrolled flap diameter
- Suction obtaining/maintaining
- Flap folds/striae
- Epithelial Ingrowth
- Neurotrophic Dry Eye
- Biomechanical destabilization
- Human error
  - Microkeratome Assembly
  - Microkeratome Sterilization
  - Metal Blade quality/inspection

Comparison of Biomechanical Response *Femtosecond vs. LASEK vs. Blade*



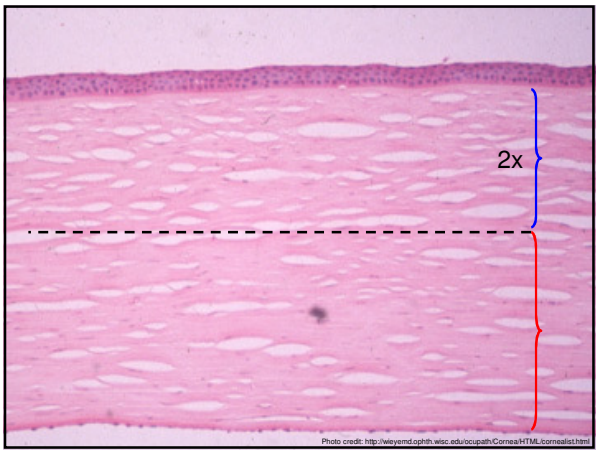
" The biomechanical effect of LASIK with IntraLase is equivalent to that of surface ablation."

Jorge L. Alió, MD, PhD
ESCRS, Sep 2005

Femtosecond LASIK
Why Stay Near the Surface?

- Anterior 40% of Cornea has strongest cohesive tensile strength
- Posterior 60% of Cornea is 50% weaker than the anterior 40%
- Increasing age is associated increased corneal cohesive tensile strength

– *Randleman, J. et al, Journal of Refractive Surgery, January, 2008*

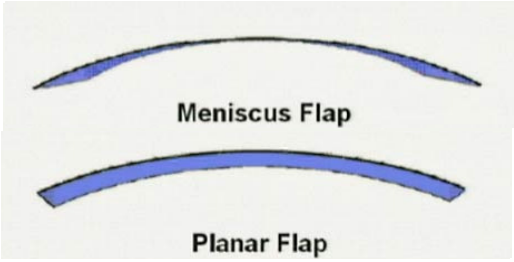


Why are Femtosecond flaps more *EFFICACIOUS* than mechanical microkeratome flaps?

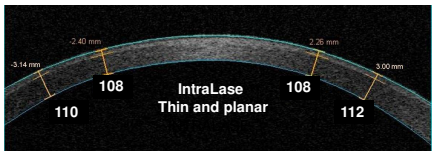
Better flaps = Better Vision!

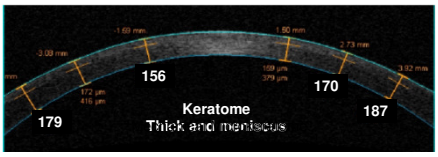
Better Efficacy

- Flaps are planar not meniscus shape
- Stromal bed is smoother
- Less high order aberrations
- Stromal beds are evenly hydrated
- Faster visual recovery



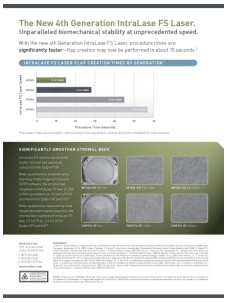
Uniform Flap Thickness

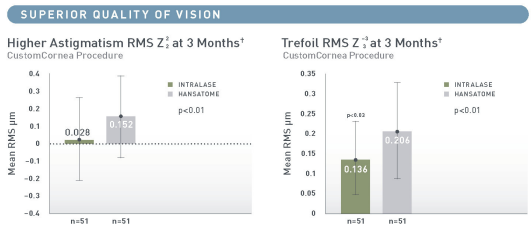




Zeiss Visante images, courtesy of Jon Dishler MD

Smooth Stromal Beds





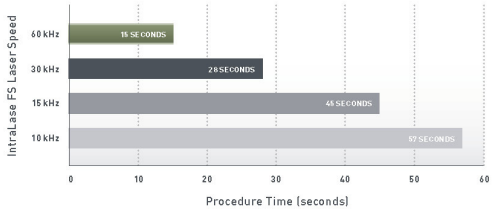
†Preoperatively, there were no significant differences between the IntraLase group and the Hansatome group in any aberration.

Durrie DS, Kezirian GM. Femtosecond laser versus mechanical keratome flaps in wavefront-guided laser in situ keratomileusis. J Cataract Refract Surg. 2005;31(1):120-126.

Better Efficacy

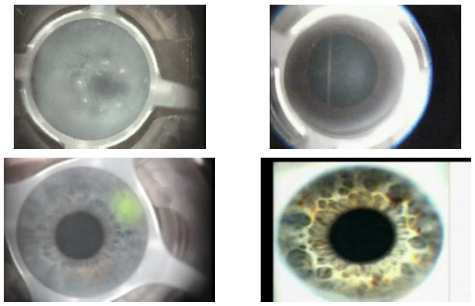
- Better quality of vision (Night Vision) as seen in *Contrast Sensitivity* studies
- Less quality of visual disturbances (haze, glare and light sensitivity)
- Less post-operative dry eye symptoms
- Technology continues to improve over time

IntraLase FS Laser Flap Creation *Times By Generation*



*Equivalent flap size and depth, optimized spot line separation, and pocket option disabled for each sample

Generation 2-5



Real-Time

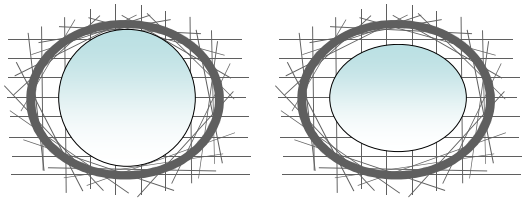
Inverted Bevel-In Side Cut Angle

- Provides better wound healing for enhanced biomechanical stability of the post LASIK cornea[1,2]
- Significantly stronger flap adhesion post-operatively for improved wound healing
  - 3x more force required for iFS™ laser (150° side cut) vs. microkeratome during flap lift[2]
- Virtually effortless flap lift, replacement, and positioning for maximum flap stability[3,4]
- Significantly reduced flap gutter[3]

1. Prof J Marshall, PhD. Data on file, AMO Development, LLC.
2. Prof M Knorz, MD. Presented ASCRS 2008.
3. P Binder, MD, A Chayet, MD. Presented ASCRS 2008.
4. A. Chayet, MD. Data on file, AMO Development, LLC.

Elliptical Flaps

- Preserves peripheral vital lamellar fibers



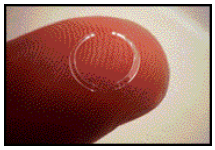
Femtosecond Science – LASIK Flaps

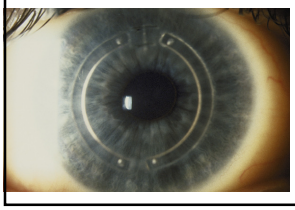
- Less intraoperative complications > x10
- Eliminates most devastating flap complications
- Reduce risk of ectasia – increased flap accuracy
- Less post-op complications
  - Dry eye
  - Flap Striae
  - Epithelial Ingrowth
- Faster visual recovery
- Better Night Vision
  - Improved low contrast VA
  - Reduced HOA
- Reduced enhancement rates

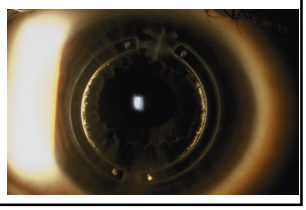
Femtosecond Laser Keratomes

- What I tell patients
  - Less flap-making risk
    - Less long-term consequences if problems
  - Thinner flaps
    - More tissue left
    - Less dryness
  - More 20/20's-better visual outcom predictability
  - Better low contrast [night] vision

Intacs for Keratoconus







History of Intacs

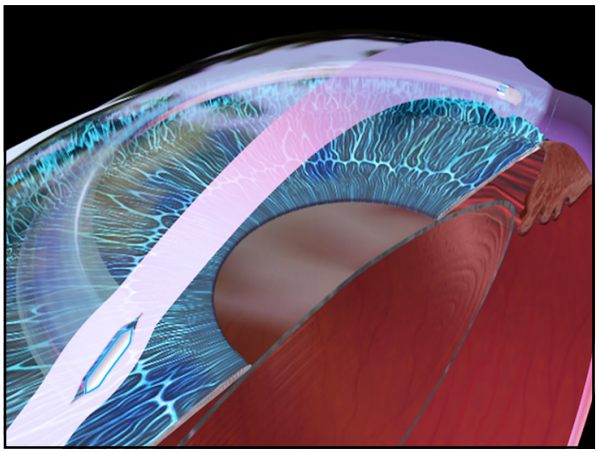
- Originally FDA-approved in 1999 for mild myopia (-1.0 to -3.0 D
- Intacs are two tiny, clear crescent-shaped pieces of a plastic polymer that are inserted into the cornea.
- FDA, July 2004 -allow corrections of keratoconus using intacs largely because of Intacs' safety record and because only a few treatment options, such as corneal transplants, are available for keratoconus.

Femto-Intacs Patient Selection

- Keratometry less than 58D
- No central scarring
- 500 microns thick at area of tunnel
- REALISTIC EXPECTATIONS!

Femto-Intacs Goals

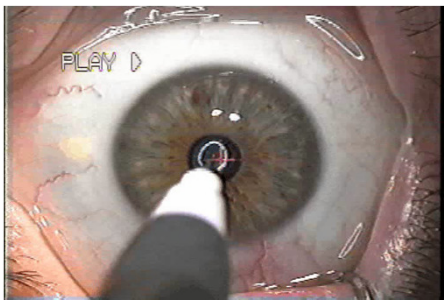
- Delay need for corneal transplant
- Increase BCVA
- Improve ability to fit/wear CL's
- Increase UCVA



Intacs Complications

- Infection
- Difficulty with night vision
- Glare, halos, blurry and fluctuating vision.
- Neovascularization
- Blepharitis
- Intacs may produce no corrective effect in fewer than 5 percent of individuals with keratoconus.

Intacs for Keratoconus



Femto-Intacs Advantages

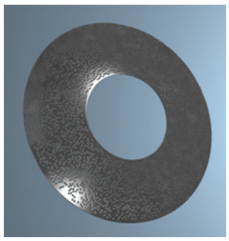
- Less surgeon dependent
- Reduced risk anterior/posterior perforation[1]
- Increased reduction in HOA (increased BCVA)[2]
- More precise placement[3]
- More effect[3]
- Easier to center on pupil
- Faster vision recovery
- Less pain
- Greater patient satisfaction!

1. Piñero DP, Alio JL. Intracorneal ring segments in ectatic corneal disease - a review Clin Experiment Ophthalmol. 2010 Mar;38(2):154-67
2. Piñero DP, Alio JL, El Kady B, Coskunseven E, Morbelli H, Uceda-Montanes A, Maldonado MJ, Cuevas D, Pascual I. Refractive and aberrometric outcomes of intracorneal ring segments for keratoconus: mechanical versus femtosecond-assisted procedures. Ophthalmology. 2009 Sep;116(9):1675-87. Epub 2009 Jul 29.
3. Rabinowitz YS Intacs for keratoconus Curr Opin Ophthalmol. 2007 Jul;18(4):279-83.

Corneal Inlay Pocket

Example: Acufocus

Overall diameter: 3.8 mm

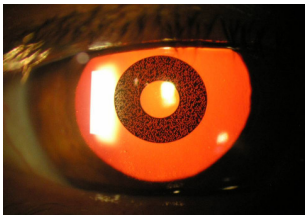


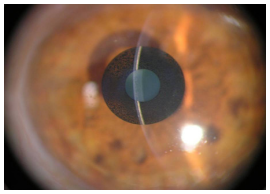
Central aperture:1.6 mm

- Designed to improve near vision in patients with Presbyopia
  - Easily implanted
  - Minimal impact on distance vision
  - Removable

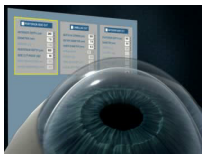
Corneal Inlay Pocket

- Example Acufocus



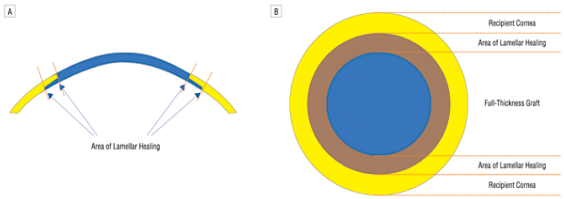


IntraLase Enabled Keratoplasty

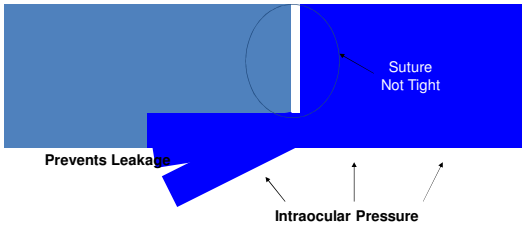


History: Advanced Shaped PK

- Massimo Busin (2003)
  - Similar technique to the posterior two-level graft
  - Adapted from modern day penetrating keratoplasty using modern instruments

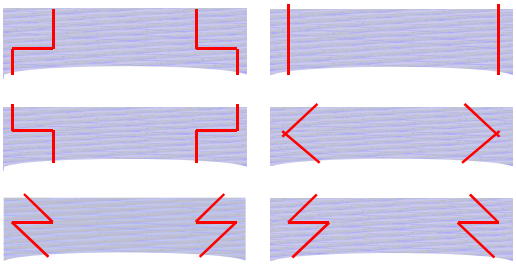


Valve-Sealing Edge Design

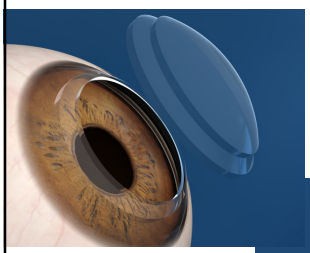


IntraLase Enabled Keratoplasty

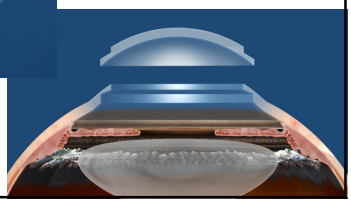
Example Pattern Combinations



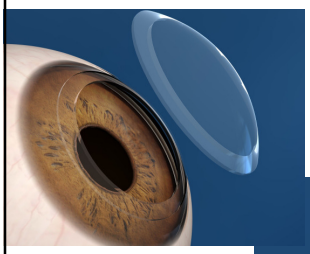
TopHat Shape



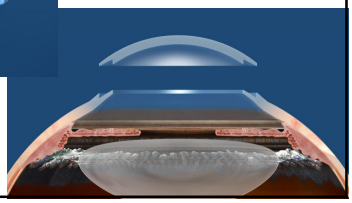
- Provides large endothelial surface transplantation



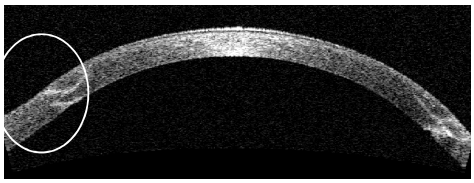
Mushroom Shape



- Preserves more host endothelium



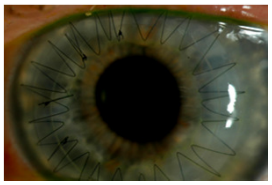
IntraLase Advanced Keratoplasty



The Zig-Zag shaped incision has shown a smooth corneal contour immediately after surgery with less distortion of the corneal optics and less astigmatism.

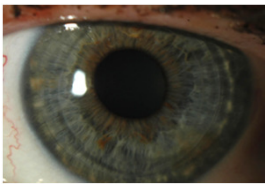
*Personal communication, Roger Steinert, M.D.

Slitlamp



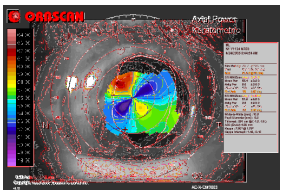
1 week

3 months

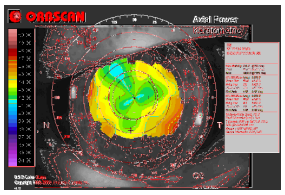


6 months

Astigmatism

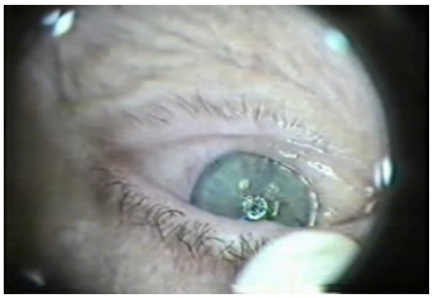


Typical 1 yr post-op result with standard trephine cut PKP = **8 diopters of astigmatism**



IntraLase Advanced Keratoplasty at 3 months post-op = **½ diopter of astigmatism**

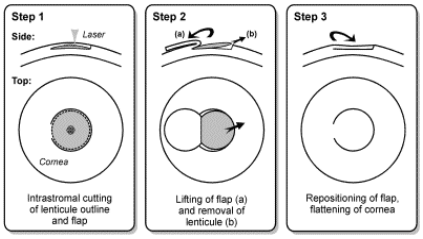
IEK Surgical Video



Femtosecond Lenticular Extraction – Off label in US

- **SMILE**
  - Small Incision Lenticular Extraction
- **FLEx**
  - Femtosecond Lenticular Extraction
- ***Re-LEx***
  - Carl Zeiss Meditec's brand of FLEx with SMILE

Femtosecond Lenticular Extraction – Off Label



FEMTO-AK ALTERNATIVE TO THE BLADE

INTRALASE ENABLED ASTIGMATIC KERATOTOMY - IEAK

BENEFITS OF FEMTO-AK/LRI

- Incomparable safety
- Decisive control of all surgical parameters
- Fully computerized control
- Maximal patient comfort
- Minimal learning curve
- Precision & predictability in the creation of AK resections ± *10 Microns*

FEMTO-AK/LRI PROCEDURE

Femto-AK/LRI Conclusions

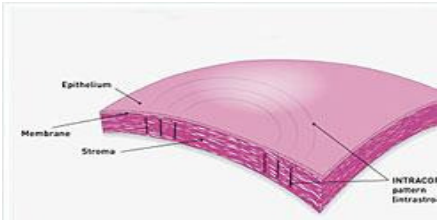
- The correction of astigmatism with the femtosecond laser is safe and effective [1,2]
- Femtosecond assisted astigmatic keratotomy is more predictable and can correct more astigmatism than mechanized astigmatic keratotomy[3].

1. Kook D, Bühren J, Klaproth OK, Bauch AS, Derhartunian V, Kohnen T. Astigmatic keratotomy with the femtosecond laser : Correction of high astigmatisms after keratoplasty Ophthalmologe. 2010 Oct 6.
2. Kumar NL, Kaiserman I, Shehadeh-Mashor R, Sansanayudh W, Ritenour R, Rootman DS IntraLase-enabled astigmatic keratotomy for post-keratoplasty astigmatism: on-axis vector analysis. Ophthalmology. 2010 Jun;117(6):1228-1235.e1. Epub 2010 Feb 16.
3. Hoffart L, Proust H, Matonti F, Conrath J, Ridings B. Correction of postkeratoplasty astigmatism by femtosecond laser compared with mechanized astigmatic keratotomy Am J Ophthalmol. 2009 May;147(5):779-87, 787.e1. Epub 2009 Feb 20

- **Investigational Surgical Applications**
  - **Presbyopia Correction (off label)**
    - Photo-disruption within the lens to restore flexibility and the ability to accommodate
      - Peripheral lens incisions (enhanced lens elasticity)

Femtosecond Lasers

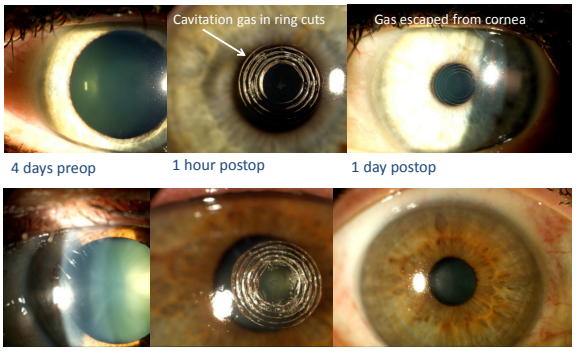
Intracor Procedure
Intrastromal Femtosecond Ablation for Presbyopia



Intracor

- Circular intrastromal rings
- Central steepening of ant/post cornea to a multifocal hyperprolate shape
- Number, spacing, size of intrastromal cylindrical rings varied
- Variable power enhances depth of focus for better near vision

INTRACOR Presbyopia



Mike P. Holzer, MD

Intracor Video

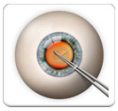
Intracor

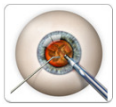
- High potential for correction of presbyopia[1]
- Non invasive → very low risk for infections[2]
- Stable refractive outcome during follow up period[1]
- Significant gain in uncorrected near visual acuity[1]
- Slight central steepening and negative q-value
- No weakening of cornea

1. Holzer MP, Mansfeld A, Ehmer A, Auffarth GU. Early outcomes of INTRACOR femtosecond laser treatment for presbyopia. J Refract Surg. 2009 Oct;25(10):855
2. Ruiz LA, Cepeda LM, Fuentes VC. Intrastromal correction of presbyopia using a femtosecond laser system. J Refract Surg. 2009 Oct;25(10):847

Manual Cataract Surgery Today

- Ophthalmic surgeon uses hand-held instruments to create a opening in the lens capsule (capsulorhexis) that is as circular as possible
- The surgeon then breaks up the clouded lens with surgical instruments and ultrasound energy
- An artificial intraocular lens (IOL) is then placed in the eye.





Surgical Systems

FEMTO CATARACT SURGERY

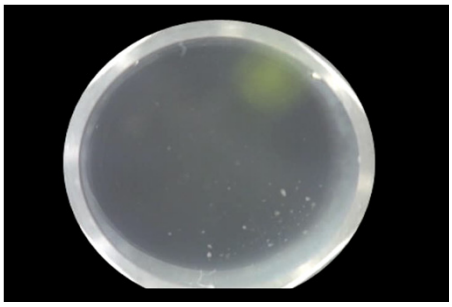
- The Players
  - LenSx –
    - Aug 2009 – Anterior Capsulotomy
    - Dec 2009 – Corneal Incisions
    - April 2010 – Lens Fragmentation
  - LensAR –
    - 3/21/11 Anterior Capsulotomy and Lens Fragmentation
    - Presbyopia licensing
  - OptiMedica –
    - Dec 22, 2011 FDA Approval
    - Proprietary OCT with Catalys
  - Technolas PV Victus
    - Both Refractive and Cataract
    - August 2012 – Anterior Capsulotomy and Corneal Incisions

Femtosecond Laser for Cataract Surgery

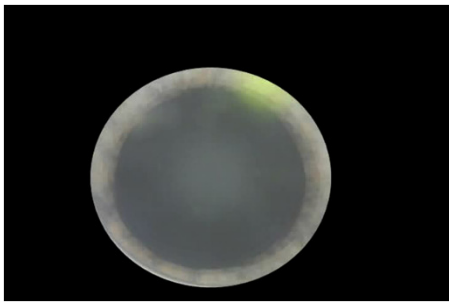
LenSx, LensAR, OptiMedica, Technolas

- Lens Fragmentation - Liquefy, soften or "chop" the lens
- Refractive Capsulotomy - Create a perfectly centered and sized
- Corneal Incisions - Create all required with perfect dimension & architecture
- LRI Corneal Incisions - Provide a refractive solution to pre-existing astigmatism

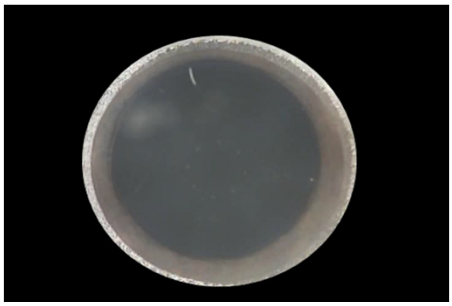
Clear Corneal Incisions



Laser Capsulotomy



Laser Lens Liquification



LenSx

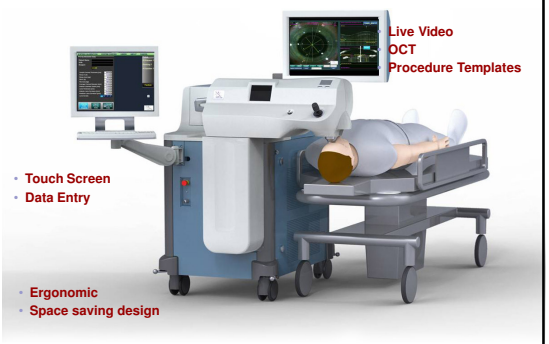
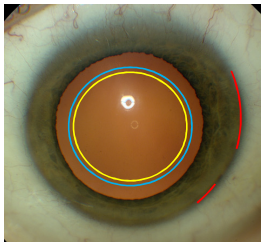
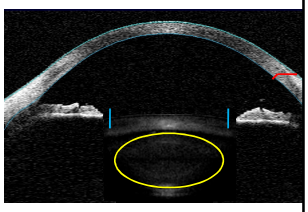
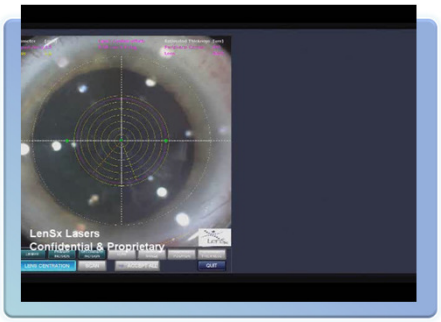


Image- Guided Treatment





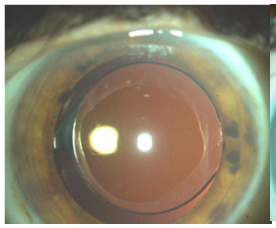
OCT Image-Guided Surgery



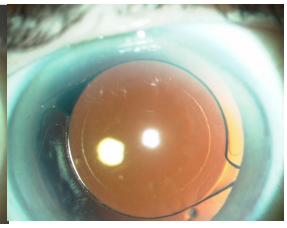
Procedure Precision & Integration

Manual vs. Catalys Cataract Surgery

1 month postop



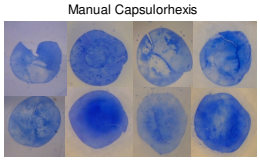
Manual Surgery



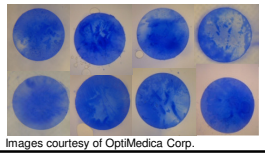
Catalys Surgery

Catalys Clinical Results: Capsulotomy Shape

Manual Capsulorhexis



Catalys Capsulotomy



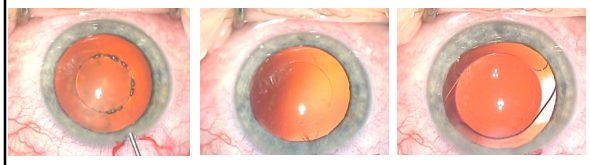
Images courtesy of OptiMedica Corp.

More predictable and precise cuts

More predictable outcomes

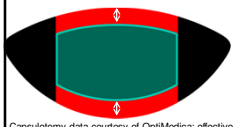
Better outcomes

Laser Capsulotomy Results

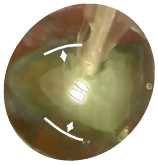


- Perfect centration
- Precision diameter: < 0.25 mm
- No radial tears
- Easy and complete removal of capsule
- No adverse events

Clinical Trial Results: Precise Capsulotomy & Effective Fragmentation



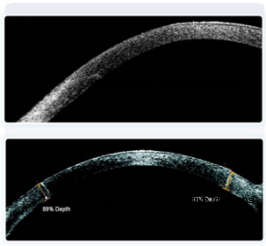
- 96% reduction in effective phaco time

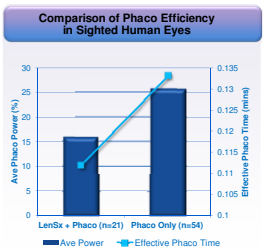


Capsulotomy data courtesy of OptiMedica; effective phaco time data courtesy of Prof. Burkhard Dick, MD, PhD. Ruhr University Eye Hospital. Bochum, Germany, Member of OptiMedica Medical Advisory Board

Images courtesy of OptiMedica

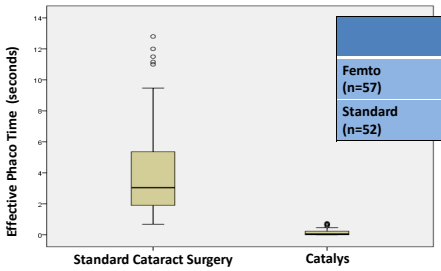
Corneal Incision and Lens Removal





- Automated reproducibility allows every surgeon to address astigmatism
- Reduces or eliminates ultrasound and related complications

Catalys Clinical Results: Impact on Effective Phaco Time

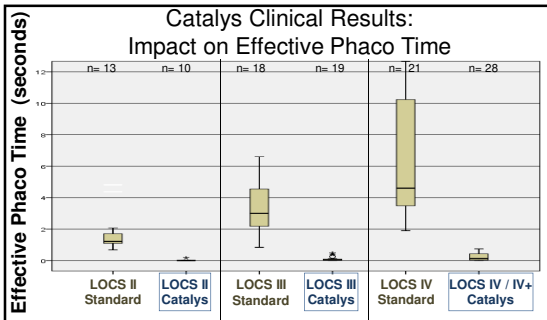


	Effective Phaco Time (s)
Femto (n=57)	0.16 ± 0.21
Standard (n=52)	4.07 ± 3.14

96% reduction in effective phaco time compared to standard

Data courtesy of Prof. Burkhard Dick, MD, PhD. Ruhr University Eye Hospital. Bochum, Germany, Member of OptiMedica Medical Advisory Board.

Catalys Clinical Results: Impact on Effective Phaco Time



LOCS	II: Standard	II: Femto	III: Standard	III: Femto	IV: Standard	IV/IV+: Femto
EPZ (s)	1.96 ± 1.29	0.02 ± 0.05	3.32 ± 1.83	0.10 ± 0.16	6.21 ± 3.68	0.24 ± 0.25

Data courtesy of Prof. Burkhard Dick, MD, PhD. Ruhr University Eye Hospital. Bochum, Germany, Member of OptiMedica Medical Advisory Board.

MK-00251 Rev A

Patient Experience

- *During procedure*
  - Docking: Slight pressure from vacuum pressure of interface (no pain or loss of vision)
  - During laser: A kaleidoscope of lights as the procedure occurs
- *Immediate to One-Day Post-op*
  - Same regimen as existing practices
  - Visual recovery may be faster because of reduced ultrasound energy
  - Patient may notice slight hemorrhaging on the conjunctiva

MK-00251 Rev A

Patient Experience

- Clinical Workup
  - *No major changes to standard procedure*
  - *Things to note:*
    - How well patient dilates
    - Is patient able to keep still during procedure
- Post-Surgery Follow-up
  - *Same regimen as existing practices*
  - *Things to note:*
    - Visual recovery may be faster because of reduced ultrasound energy
    - Patient may notice slight hemorrhaging on the conjunctiva

MK-00251 Rev A

FEMTO – Cataract Conclusions

- Femtosecond laser applications in liquefaction was safe, effective and efficient
- Capsulotomy size, shape and reproducibility is statistically improved over manual techniques[1]
- Corneal incisions are reproducible and have precise dimensions and geometry

1. Nagy Z, Takacs A, Filkorn T, Sarayba M. Initial clinical evaluation of an intraocular femtosecond laser in cataract surgery. J Refract Surg. 2009 Dec;25(12):1053

Future Femtosecond Developments

- Higher Power Oscillators
- Laser fiber technology
- Solid State Lasers
- Combined with advanced imaging techniques
  - Sub-diffraction imaging
  - Quantum dots
- Cellular surgery and manipulation
- Deep tissue applications

QUESTIONS?

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