Femtosecond Laser Technology in Modern Eye Care

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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 = $10^{-15}$

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**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

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


Optical Delivery System

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

- 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
An expanding bubble of gas & water is created separating the corneal lamellae.

Femtosecond Photodisruption

The bi-products of photodisruption (CO2 & water) are absorbed by the mechanism of the endothelial pump, leaving a cleavage plane in the cornea.

Advanced Performance

Tighter spot placement facilitates easier flap lifts.
9/15/2013

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

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

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

Planar Flap

Meniscus Flap

Smooth Stromal Beds
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
Generation 2-5

Inverted Bevel-In Side Cut Angle

- Provides better wound healing for enhanced biomechanical stability of the post LASIK cornea.
- 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.
- Virtually effortless flap lift, replacement, and positioning for maximum flap stability.
- Significantly reduced flap gutter.

1. Prof. J. Marshall, PhD. 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 outcome 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
- Increased reduction in HOA (increased BCVA)
- More precise placement
- More effect
- Easier to center on pupil
- Faster vision recovery
- Less pain
- Greater patient satisfaction!


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
  - Similar technique to the posterior two-level graft
  - Adapted from modern day penetrating keratoplasty using modern instruments

Valve-Sealing Edge Design
- Prevents Leakage
- Intraocular Pressure
- Suture Not Tight
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

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
FEMTO-AK
ALTERNATIVE TO THE BLADE

INTRALASE ENABLED ASTIGMATIC KERATOTOMY - IEAK

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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

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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. \(^3\)


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)

Intracor Procedure
Intrastromal Femtosecond Ablation for Presbyopia

Femtosecond Lasers
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

- Cavitation gas in ring cuts
- Gas escaped from cornea

4 days preop 1 hour postop 1 day postop

4 days preop 1 hour postop 1 week postop

Intracor Video
**Intracor**

- High potential for correction of presbyopia¹
- Non invasive → very low risk for infections²
- Stable refractive outcome during follow up period³
- Significant gain in uncorrected near visual acuity¹
- Slight central steepening and negative q-value
- No weakening of cornea


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**Manual Cataract Surgery Today**

- Ophthalmic surgeon uses hand-held instruments to create an 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.

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**Surgical Systems**

- Catalyze Precision Laser System OptiMedica
- LensX Laser
- TECHNOLAS Femtosecond Workstation
FEMTO CATARACT SURGERY

- The Players
  - LenSx –
    - Aug 2009 – Anterior Capsulotomy
    - Sept 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
Image-Guided Treatment

OCT Image-Guided Surgery

Manual vs. Catalys Cataract Surgery
1 month postop
Catalys Clinical Results:
Capsulotomy Shape

More predictable and precise cuts
More predictable outcomes
Better outcomes

Images courtesy of OptiMedica Corp.

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Laser Capsulotomy Results

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

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Clinical Trial Results: Precise Capsulotomy & Effective Fragmentation

-96% reduction in effective phaco time

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**

<table>
<thead>
<tr>
<th>LOCS II</th>
<th>LOCS III</th>
<th>LOCS IV / IV+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard</td>
<td>Catalys</td>
<td>Standard</td>
</tr>
<tr>
<td>Effective Phaco Time (s)</td>
<td>4.07 ± 3.14</td>
<td>1.6 ± 0.21</td>
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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.
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

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

FEMTO – Cataract Conclusions

• Femtosecond laser applications in liquefaction was safe, effective and efficient

• Capsulotomy size, shape and reproducibility is statistically improved over manual techniques

• Corneal incisions are reproducible and have precise dimensions and geometry

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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