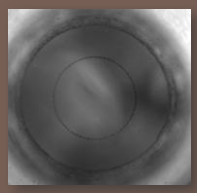
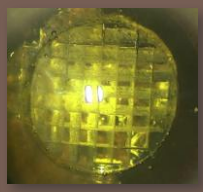
FSL CATARACT SURGERY: CHANGES IN THE CLINIC AND ASC





April 26, 2014
ASOA- ASC, Boston, MA

Financial Disclosure

- **Amy Jost**, BS, COT, CCRC (Cincinnati Eye Institute, Cincinnati, OH)
  - Member of the OptiMedica MSAB

Agenda:

- Surgical Perspective
  - Applications, Outcomes, Technology Comparison
- Staff Perspective
  - Workflow integration considerations
  - Clinic tech responsibilities
- Q & A

Cataract Surgery Today

Market Size and Financials:

- Over 3 Million procedures performed last year in the US
- Growing incidence of cataracts as population ages

Market Behavior:

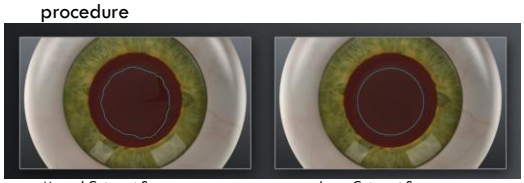
- Increasing desire for spectacle independence
- Increasing safety expectations
- More common for patients to "shop" around for surgeon and surgical center

Goal of Laser Cataract Surgery

- While manual cataract surgery is highly successful procedure, it does have room for improvement….
- …Especially when we factor in growing expectations of our patients

Goal of Laser Cataract Surgery

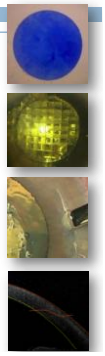
- Using femtosecond laser technology in cataract surgery to make cataract removal a more predictable, more gentle and potentially safer procedure



Manual Cataract Surgery | Laser Cataract Surgery

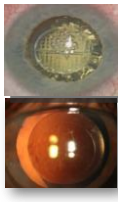
Laser Cataract Surgery – 4 Indications

1. **Capsulotomy –** up to 10x more precise
2. **Lens Fragmentation –** ability to soften lens, and nearly eliminate ultrasound energy
3. **Arcuate Incisions for astigmatism correction** – more precise control, option for intrastromal
4. **Cataract Incisions** – 3D architecture for better sealability



Other clinical benefits of FS laser cataract

- Postoperative cystoid macular edema risk may be reduced[1]
- Better for the cornea
  - 25% less corneal edema[2]
  - 47% less endothelial cell loss [2]
  - 19% less inflammation post-op[2]

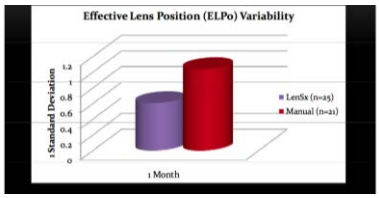


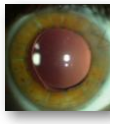
Images courtesy of OptiMedica

Studies conducted using LenSx and Catalys platforms
1 – Ecsedy et al, JRS August 2011. LenSx
2 – Vote B. Proceedings of AUSCRS 2012. Abell et al, Clin Exp Opthal 2012, in press.: Conrad Hengerer et al. JCRS Sept. 2013. Catalys.

Other clinical benefits of FS laser cataract

- Improved BCVA 7 days post-op [1]
- Potential Reduced Effective Lens Position Variability[2]





1. Conrad-Hengerer et al. Corneal endothelial cell loss and corneal thickness in conventional compared with fs laser-assisted cataract surgery: 3 month follow up" JCRS, Sept 2013.
2. Graph sourced from Kiawah Eye website; Procedures performed by Zoltan Nagy MD at Semmelweis University Budapest Hungary.

The future is femto. . .

- The field of ophthalmology has experienced…
  - Paradigm shift from extra cap to phaco
  - Paradigm shift from microkeratome to femto for LASIK
  - Paradigm shift from phaco to Laser Cataract Surgery (LCS) has begun
- If your practice is considering LCS technology, important to evaluate your options and start thinking about what norms need to be modified for smooth integration

The Options – FS Cataract Surgery Systems

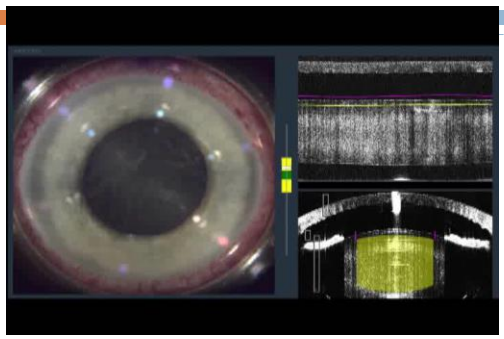
Catalys® Precision Laser System (AMO)

LenSx® Laser (Alcon)

LENSAR Laser System™

VICTUS™ Femtosecond Laser System (B + L)

What does a procedure look like?



How do the systems compare?

- **Indications for Use**
- Clinical Results
- Technical Features

Indications for Cataract Use

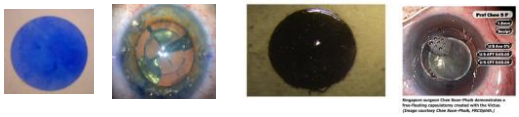
How do the systems compare?

- Indications for Use
- **Clinical Results**
- Technical Features

Clinical Results - Laser Capsulotomy Precision

- The width of a human hair is 85-100 microns on average.
- Laser Capsulotomy precision is:

Catalys	LenSx	LENSAR	Victus
< 30µm[1]	< 250 µm[2]	160µm[3]	350µm[4]

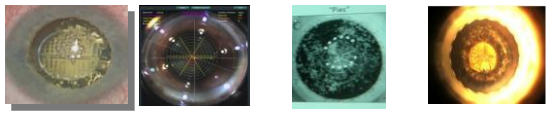


1-Friedman et al / JCRS 2011 ;2-Slade et al / AAO 2010; Nagy et al / JRS 2011; Kranitz et al / JRS 2011
3-Tackman et al / JCRS 2011; 4-Rigal-Sastourne, Improving Effective Lens Position: Comparison of Femtosecond Laser-assisted Capsulotomy and Manually Created CCC, ASCRS abstract 2013

Clinical Results – Lens Fragmentation

Ultrasound energy reduction:

Catalys	LenSx	LENSAR	Victus
>99%[1]	51%[2]	55%-79%[3]	< 50%[4]



1-Conrad-Hengerer et al. JRS 2012; 28(12): 879-83. , Conrad-Hengerer et al. J Cat Refract Surg. 2012; 2 - CRST Supplement June 2011; 3-Harvey Uy, CRST Europe, May 2012
4-Daya et al, Ultrasound Power, Translenticular Hydrodissection, and Lens Fragmentation in Femtosecond Laser Cataract Surgery, ASCRS 2013

How do the systems compare?

- Indications for Use
- Clinical Results
- **Technical Features**

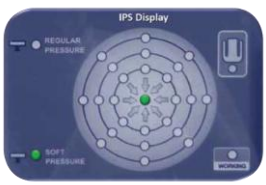
Patient Interfaces (applanating)

LenSx® SoftFit™ Patient Interface

- Silicone hydrogel lens insert

Patient Interfaces (applanating)

B+L VICTUS™: Curved Interface with Intelligent Pressure Sensor



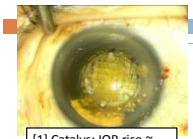
Interface modalities: non-applanating

Catalys®: Liquid Optics™ Interface

Interface modalities: non-applanating

LensAR Fluid-filled interface

IOP rise with different systems



[1] Catalys: IOP rise ~ 10mmHg

LenSx SoftFit: [2] Lower IOP rise of 16 mm Hg

[3] Victus: IOP rise 45 mmHg

LensAR: IOP rise not published

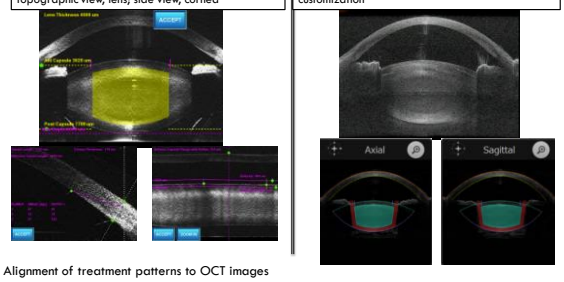
IOP-related Contraindications:
LenSx: No contraindication with SoftFit
LENSAR: Hypotony, uncontrolled glaucoma
VICTUS: No data reported
Catalys: NOT contraindicated for glaucoma

[1]: Kerr et al, JCRS ; Schultz et al JCRS
[2] 510K Statement, Alcon Marketing Deck – October 2012 and Alcon Live Surgery Event – AAO 2012
[3] ReLACS ed. Krueger; Reddy et al, pg 239

Image Guidance Modalities by System

LenSx: onboard, proprietary OCT. Can visualize multiple views including – side view, capsular bag; topographic view, lens; side view, cornea

Catalys: 3D Full Volume OCT, Automated and user-adjustable 3D surface identification and treatment customization

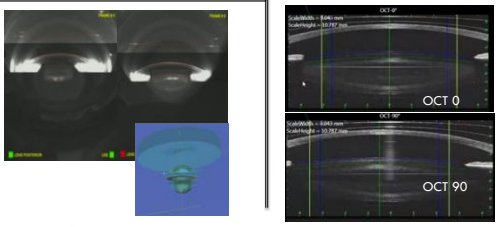


Alignment of treatment patterns to OCT images

Image Guidance Modalities by System

LENSAR: proprietary Augmented Reality System – collects biometric data, then uses optical ray tracing to generate accurate 3D model of eye

VICTUS: Real-time, high contrast OCT facilitates planning and control. Designed to facilitate simple centering and incision adjustment



Descriptions taken from company websites.

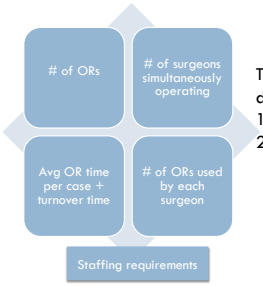
Summary of system features

	Catalys	LenSx	LENSAR	Victus
Interface	Liquid Optics	Curved Lens + SoftFit™ insert	Fluid-filled interface	Curved lens with Intelligent Pressure Sensor

1-www.lensxlasers.com, 2/28/2013; 2-www.lensar.com, 2/28/2013; 3- www.esoirs.com/files/ESOIRS2012-Presentations/024001.pdf; 4-LenSx operator manual; 5-LensAR pre-market notification K112098; 6-victus tech specs document

Workflow Integration Considerations

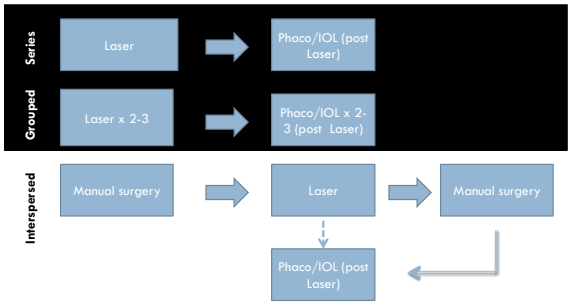
Center's choice for system location is dependent on 4 key drivers:



These are some of the main factors for determining whether system is placed:
1) inside an operating room or
2) in a room outside of the operating room

You also need to consider – how decision influences:
1) Installation and Clinical Training
2) Daily Use

What does flow look like?



Laser Cataract Surgery Workflow

Activity 1: Pre-procedure
- Dilate patient (45-60 min before laser)
- Dilation determines MAX size for capsulotomy

Activity 2: Laser procedure
- Dock patient
- Confirm customized plan
- Perform treatment

Activity 3: Lens removal and IOL insertion
- Some adjustments to phaco technique

Options for cataract surgery workflow

One Option…

The Situation:
- 2 Operating Rooms
- 1-2 Surgeons Operating Simultaneously
- 3000 Cataracts per Year

Key Questions: -
- Where is the laser?
- What does flow look like?
- Who is in the laser room?
- What's different about cataract removal?
- How long is certification?

Where is the laser?

In the Operating Room

Advantages of this location:
- Different schedule modules
- Quicker delivery/construction
- More than 50% can be done

Disadvantages
- Lose OR for training
- Lose OR for laser procedure
- Fewer # surgeries/slower schedule

Another Option…

The Situation:
- 6 Operating Rooms
- 4-6 Surgeons Operating Simultaneously
- 8,000 Cataracts per Year
- 1 Laser, outside the OR
- Staffing Requirements for Laser Procedure:
  - Anesthesia, Nurse Circulator, Surgeon, Laser Operator

Where is the laser?

Outside the Operating Room

Advantages of this location:
- Different schedule modules
- Shared laser for multiple surgeon use
- Allows for greater # of surgeries/more opportunities

Disadvantages
- Construction caused temporary delay in shipping/set-up
- Lose two post-op bays

FSL Laser in action at our facility

Tasks for laser operator and who fulfills them?

Staff tasks for laser procedure

Per treatment:

- Input treatment plan
- Prepare patient interface
- Monitor docking process
- Monitor and/or assist in making adjustments to treatment plan once patient is under dock
- Monitor progress of treatment as laser is applied

Periodic:

- System calibration/alignment tests
- Order patient interfaces

Who is in laser room? 3 Options

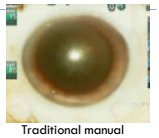
- **Refractive laser technician:**
  - Certified to operate lasers
  - May be familiar with femtosecond lasers already: treatment plan entry, patient interface prep, treatment monitoring, etc.
- **Scrub technician:**
  - Familiar with the anatomy being treated
  - More likely that this person is already employed by group that purchases the laser system
  - Same individual could support surgeon during laser treatment and lens removal/IOL insertion?

Who is in laser room? 3 Options

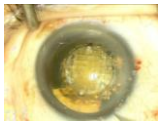
- **Surgical Nurse:**
  - Familiar with the anatomy being treated
  - More likely that this person is already employed by group that purchases the laser system
  - Same individual could support surgeon during laser treatment and lens removal/IOL insertion?
  - Be able to fulfill 2 roles at once – i.e. laser operator and monitoring patient

What's different about cataract removal?

- Post laser procedure, prior to cataract removal:
  - Incisions already created
  - Lens pre-softened
- Potential Implications
  - Different instruments – tray and disposables
  - New phaco machine parameters



Traditional manual



Laser cataract

How long is certification?

- System operators certified after 10 cases

Helpful tips:

- Develop **and train a team** that is comfortable with the laser and knowledgeable about what each step means
- Ensure 1 lead user for system operator
- Recognize and accept new situations will arise
- Debrief every time you encounter new situations

TIPS: Steps to do in advance of laser arrival

- 1- decide where to put laser / HVAC requirements
- 2- train your staff, pick the right person to assist the surgeon at the laser
- 3- plan for training, more surgeons will want to get trained than you anticipate
- 4- consider and optimize workflow
- 5-anticipate changes in operating room

Clinic technician involvement in laser cataract surgery

Clinical tech role – patient exam

- Clinical technician has significant interaction with patient leading up to scheduling for cataract surgery
- Impact of laser cataract surgery for clinical tech
  - Same diagnostics used
  - Various new things to consider

Clinical tech role – patient exam

- **New things to consider:**
  - Dilated pupil size
  - IFIS (intra-operative floppy iris syndrome)
  - Ability to fixate with operative eye
  - Lid/orbit anatomy
  - Ability to lay flat/still
  - Astigmatism
  - Opportunity to educate patients on laser cataract surgery (procedure, potential benefits, etc)

Patient Education tips for clinic techs

- The laser does NOT ensure…
  - Better outcomes
  - Faster surgery time
  - Faster healing time
- The laser does NOT disintegrate the cataract itself
- The laser does NOT guarantee good vision
- The laser may NOT provide plano refraction &/or spectacle independence after surgery
- The laser may NOT be right for every patient

Patient Education tips for clinic techs

- The laser…
  - Helps the surgeon perform cataract surgeries which are customized for the unique needs of each patient
  - Performs critical steps mentioned above with precision
  - Makes cataract surgery bladeless
  - Reduces astigmatism
  - Is right for some patients. Ask if it is a good option for you.

Clinic Tech - Laser Cataract Surgery Nomograms

- Work still needs to be done to see how laser arcuate incisions compare to manual LRIs
- Clinic tech may be involved in helping surgeon determine arcuate incision plan for patients
- Starting points:
  - Donnenfeld Nomogram (with/without subtracting 30%)
  - www.lricalculator.com (with/without subtracting 30%)
  - Nichamin Nomogram (with/without subtracting 30%)

Clinic tech – opportunities for career growth through FS Laser Cataract

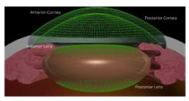
- Work with surgeons on:
  - Arcuate incision nomograms
  - Customization of IOL calculations
- FS cataract opens new clinical research opportunities
  - ELP, Visual acuity, Comfort studies
  - Nomogram accuracy studies
- Recommendations to get ahead
  - Be knowledgeable about the technology options
  - Observe live FS cataract surgery
  - Show an interest and support

Why should I care about laser cataract surgery?

The future is femto….

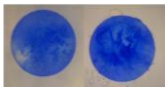
….and the future is here

- Over 600 FS cataract systems placed worldwide
- Over 300k procedures performed to date
- Offering patients:



Customization with 3D imaging

High tech, premium experience



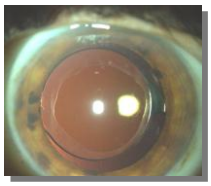
Laser precision

Issues to resolve. . .

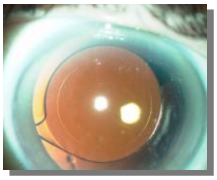
- Can we afford the extra:
  - Time
  - Cost
  - Personnel
- How will we provide widely in this regulatory environment?
  - AAO and ASCRS Guidelines in Jan 2012
  - CMS Guidance Fall 2012

On the other hand. . .

- We want the best technology for our patients
- Won't we want to provide it?



Manual Surgery: 1 month post op



Laser Surgery: 1 month post op

Images courtesy of OptiMedica

Questions?

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