FSL CATARACT SURGERY: CHANGES IN THE CLINIC AND ASC

April 26, 2014
ASOA: ASC, Boston, MA

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

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

Financial Disclosure

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- Member of the OptiMedica MSAB

Agenda:

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

While manual cataract surgery is highly successful procedure, it does have room for improvement….

…Especially when we factor in growing expectations of our patients
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 \(^2\)

Studies conducted using LenSx and Catalys platforms
1. Ecsedy et al, JRS August 2011. LenSx

Other clinical benefits of FS laser cataract

- Improved BCVA 7 days post-op \(^1\)
- Potential Reduced Effective Lens Position Variability \(^2\)

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)
- **LENSAR** Laser System™
- **VICTUS™** Femtosecond Laser System (B + L)

What does a procedure look like?
What does a procedure look like?

• Indications for Use
• Clinical Results
• Technical Features

How do the systems compare?

• Indications for Use
• Clinical Results
• Technical Features

Indications for Cataract Use

Catalys® Precision Laser System (OptiMedica/AMO)

LenSx® Laser (Alcon)

LENSAR Laser System™

VICTUS

Clinical Results - Laser Capsulotomy Precision

• The width of a human hair is 85-100 microns on average.

• Laser Capsulotomy precision is:

<table>
<thead>
<tr>
<th></th>
<th>Catalys</th>
<th>LenSx</th>
<th>LENSAR</th>
<th>VICTUS</th>
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</thead>
<tbody>
<tr>
<td>Width</td>
<td>&lt;30μm</td>
<td>&lt;250μm</td>
<td>160μm</td>
<td>350μm</td>
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Clinical Results – Lens Fragmentation

Ultrasound energy reduction:

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<tr>
<th></th>
<th>Catalys</th>
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<th>LENSAR</th>
<th>VICTUS</th>
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<tbody>
<tr>
<td>Reduction</td>
<td>&gt;99% ¹</td>
<td>51% ²</td>
<td>55%-79% ³</td>
<td>&lt;50% ⁴</td>
</tr>
</tbody>
</table>

2-Teichman et al / JCRS 2011; A-Friedberg, Improving Effective Lens Position: Comparison of Femtosecond Laser-assisted Capsulotomy and Manually Created CCC, ASCRS abstract 2013
4-Rigal-Sastourne, Improving Effective Lens Position: Comparison of Femtosecond Laser-assisted Capsulotomy and Manually Created CCC, ASCRS abstract 2013

4-Rigal-Sastourne, Improving Effective Lens Position: Comparison of Femtosecond Laser-assisted Capsulotomy and Manually Created CCC, ASCRS abstract 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

LenSx: Lower IOP rise of 16 mm Hg
Catalys: IOP rise ~10 mm Hg
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
[4] VICTUS: IOP rise 45 mmHg

IOP rise not published
**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.

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

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

Alignment of treatment patterns to OCT images

Descriptions taken from company websites.

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**Summary of system features**

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<tr>
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<th>Catalys</th>
<th>LenSx</th>
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<th>Vistus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interface</td>
<td>Liquid Optics</td>
<td>Curved Lens + SoftFit™ Insert</td>
<td>Fluid-filled interface</td>
<td>Curved lens with Intelligent Pressure Sensor</td>
</tr>
</tbody>
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**Workflow Integration Considerations**

- **Center’s choice for system location is dependent on 4 key drivers:**
  - If of ORs
  - If of surgeons simultaneously operating
  - Avg OR time per case + turnover time
  - If of ORs used by each surgeon

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

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**What does flow look like?**

- Laser
- Phaco/IOL (post Laser)
- Laser x 2-3
- Phaco/IOL x 2-3 (post Laser)
- Manual surgery
- Laser
- Manual surgery

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
- Some adjustments to phaco technique

Activity 3: Lens removal and IOL insertion

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?

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
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

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

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

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

Why should I care about laser cataract surgery?

- 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

Issues to resolve. . .
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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