Integrating Femtosecond Laser Cataract Surgery into Your Practice...

...A Lesson on the Clinical Application, Technology, and Workflow Dynamics

ASOA program: Monday March, 28 2011

Agenda:

- Surgeon Perspective
  - Applications, Outcomes, Technology
- Staff Perspective
  - Practice integration considerations
- Q&A

Steps:

Incision
Capsulorhexis
Phacoemulsification
IOL Centration
Relaxing Incisions (Astigmatism)

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  - Consultant to OptiMedica
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  - Consultant to OptiMedica
- Carlos Bravo, Surgical Tech (Specialty Surgical Center, Beverly Hills CA)
  - Consultant to OptiMedica

Potential Problems in Contemporary Cataract Surgery:

Leaking wound and endophthalmitis
Potential Problems in Contemporary Cataract Surgery:

**Steps:**
- Incision
- **Capsulorhexis**
- Phacoemulsification
- IOL Centration
- Relaxing Incisions (Astigmatism)

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Corneal Phaco Burn

Decentered Multifocal IOL
Potential Problems in Contemporary Cataract Surgery:

Steps:
- Incision
- Capsulorhexis
- Phacoemulsification
- IOL Centration
- Relaxing Incisions (Astigmatism)

Pre-op LRIs

Post-op LRIs

Laser Cataract Surgery

- Replaces least predictable surgical steps and enhances safety profile of procedure
- Performs four primary incisions:
  1. Capsulotomy
  2. Lens Fragmentation
  3. Relaxing Incisions
  4. Cataract Incision

Clinical Results

2010 data from LenSx, LensAR and OptiMedica
Clinical Results
Recent data from LenSx, LensAR and OptiMedica

Key Finding:
For all systems, the deviation between intended and observed size was significantly reduced for laser capsulotomy relative to manual.

Supporting Results:

<table>
<thead>
<tr>
<th>Company</th>
<th>Manual (μ±SD)</th>
<th>Laser (μ±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OptiMedica¹</td>
<td>0.339 ± 0.25mm</td>
<td>0.027 ± 0.025mm (p &lt;0.001)</td>
</tr>
<tr>
<td>LensAR²</td>
<td>0.42 ± 0.54mm</td>
<td>0.16 ± 0.17mm (p=0.03)</td>
</tr>
<tr>
<td>LenSx³</td>
<td>10% &lt; 0.25mm</td>
<td>All &lt; 0.25mm</td>
</tr>
</tbody>
</table>

¹Lane, Stephen MD, "Accuracy and Predictability of the OptiMedica Femtosecond Laser Capsulotomy", AAO 2010
²Data courtesy of LensAR, Nov 2010
³Nagy, Z "Comparative analysis of femtolaser-assisted and manual capsulorhexis during phaco", ESCRS 2010

Capsulotomy shape
Key Finding:
For all systems, laser capsulotomy was closer to a perfect circle than manual capsulorhexis.
**Capsulotomy shape**

- **Key Finding:**
  - For all systems, laser capsulotomy was closer to a perfect circle than manual capsulorhexis.
- **Supporting Results:**

<table>
<thead>
<tr>
<th>Company</th>
<th>Measurement Technique</th>
<th>Manual (mean ±SD)</th>
<th>Laser (mean ±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OptiMedica¹</td>
<td>Circularity [C = 4A/(πd²)]</td>
<td>0.765 ± 0.148</td>
<td>0.942 ± 0.040 (p&lt;0.001)</td>
</tr>
<tr>
<td>LensAR²</td>
<td>Consistency of Shape [Squared Residuals]</td>
<td>0.02 ± 0.04</td>
<td>0.01 ± 0.03 (p=0.09)</td>
</tr>
<tr>
<td>LenSx³</td>
<td>Roundness</td>
<td>Significant Rounder (p=0.028)</td>
<td></td>
</tr>
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</table>

¹Lane, Stephen MD, “Accuracy and Predictability of the OptiMedica Femtosecond Laser Capsulotomy”, AAO 2010
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**Clinical results – phaco energy**

For cataracts of all grades, laser pre-treatment of lens resulted in reduced phaco energy.

- For soft lenses (grade 1,2) laser pre-treated lenses often required no phaco energy at all.

<table>
<thead>
<tr>
<th>Laser vs. Control</th>
<th>OptiMedica¹</th>
<th>LensAR²</th>
<th>LenSx³</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Lens Densities</td>
<td>38% reduction in CDE (p=0.028)</td>
<td>&gt;35% reduction in CDE²</td>
<td>54% reduction in average phaco power</td>
</tr>
<tr>
<td>Grade 4 Lenses</td>
<td>40% reduction in CDE</td>
<td>41.6% reduction in CDE (p=0.052)³</td>
<td>No published data</td>
</tr>
</tbody>
</table>

¹Data courtesy of OptiMedica
²Fishkind, W MD “Alternative fragmentation patterns in femtosecond laser cataract surgery”, ESCRS 2010
³Data courtesy of LensAR Nov 2010

**Key Finding:** Laser cataract system gives surgeon the ability to target desired center and hit the mark with incredible accuracy and precision.

**Supporting Results:**

Capsulotomy center within 86 ± 51 μm of dilated pupil center¹

¹Lane, Stephen MD, “Accuracy and Predictability of the OptiMedica Femtosecond Laser Capsulotomy”, AAO 2010

**Cataract incision**

- **Key Finding:** Laser system can create multi-planar wounds with better sealability.
- **Supporting Results from LenSx⁴:** 0/4 pairs of eyes receiving 2 plane laser incision required stromal hydration to seal. 17/18 pairs of eyes receiving manual Langerman incision required stromal hydration to seal.

Surgeon can configure depth at time of procedure based on measured corneal thickness.

System creates consistent and precise arc length and curvature.

How is this technology different from femtosecond lasers used for refractive surgery?

Cataract patients are generally older than LASIK patients and may have ocular co-morbidities.

Important to minimize IOP rise.

Globe must be stabilized relative to optical system.

Need to minimize globe distortion to enable precise laser delivery.

Need to minimize IOP rise due to cataract patient ocular co-morbidities.
- Globe must be stabilized relative to optical system
- Need to minimize globe distortion to enable precise laser delivery
- Need to minimize IOP rise due to cataract patient ocular co-morbidities

**Patient Interface Configurations**

<table>
<thead>
<tr>
<th>Flat Plate Interface</th>
<th>Curved Lens Interface</th>
<th>Water Lens Interface</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ex) Intralase 78mmHg</td>
<td>Ex) VisuMax 65mmHg</td>
<td>Ex) OptiMedica Liquid Optics: 12mmHg</td>
</tr>
</tbody>
</table>


- Imaging is diagnostic, need signal processing to turn the diagnostic into a controlled guidance system
- Signal processing is critical to:
  - Remove mirror image
  - Identify ocular surfaces
  - Create and maintain safety zones
  - Help surgeon accurately adjust treatment patterns

Images courtesy of OptiMedica
**Surgical Systems**

Catalys™ Precision Laser System - OptiMedica

LenSx® Laser

**System Equipped with:**
- **Imaging:** Proprietary, integrated 3D Fourier Domain OCT
- **Signal Processing:** Integral Guidance™ algorithms that automatically detect and accurately map ocular surfaces, including the curvature of the posterior capsule
- **Docking:** Liquid Optics™ Interface provides a clear optical path for laser delivery and a gentle dock for the patient

**Clearances:**
- Anterior capsulotomy currently under FDA review
- Lens fragmentation currently under FDA review
- Plan for corneal incisions

**Subset of Clinical Results**

<table>
<thead>
<tr>
<th>Manual Results</th>
<th>Laser Results (Mean ±SD)</th>
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<tr>
<td>Capsulotomy size (Deviation from intended diameter)</td>
<td>339 μm ± 248 μm</td>
</tr>
<tr>
<td>Capsulotomy circularity (1=perfect circle)</td>
<td>0.765 ± 0.148</td>
</tr>
<tr>
<td>Capsulotomy centration (Dist. from intended center)</td>
<td>N/A</td>
</tr>
<tr>
<td>Avg. CDE during ultrasound phacoemulsification</td>
<td>18.54 ± 12.07</td>
</tr>
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</table>

Slide courtesy of OptiMedica

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**LenSx Femtosecond Laser System**

**System Equipped with:**
- **Imaging:** Proprietary OCT
- **Signal Processing:** Image-guided, computer-controlled
- **Docking:** Curved lens

**Clearances:**
- Anterior Capsulotomy
- Phacofragmentation
- Single-plane and multi-plane arc cuts/incisions in the cornea

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<td>-0.02 ± 0.04</td>
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<tr>
<td>Phaco energy reduction (CDE)</td>
<td>100% in grade 1 lens; 63.6% in grade 2; 40.5% in grade 3; 41.6% in grade 4 (p&lt;0.05 for all but grade 4)</td>
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<tr>
<td>Presbyopia Treatment (photodisruption within lens)</td>
<td>Max. subjective accommodation: 1.25D; Max objective accommodation: 0.75D</td>
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Technical specs and clearances sourced from Lipner, M. Femto technology changing the cataract landscape, Eye World Dec 2010.

Clinical Results sourced from slide deck provided by LenSx.

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**Catalys™ Precision Laser System**

**System Equipped with:**
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<td>Capsulotomy size (Deviation from intended diameter)</td>
<td>10% within 250 microns</td>
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<tr>
<td>Capsulotomy roundness</td>
<td>Significantly rounder</td>
</tr>
<tr>
<td>Phaco</td>
<td>43% reduction in average phaco power; 53% reduction in effective phaco time</td>
</tr>
<tr>
<td>Effective lens position</td>
<td>Significantly less variability (p=0.05)</td>
</tr>
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Technical specs and clearances sourced from Lipner, M. Femto technology changing the cataract landscape, Eye World Dec 2010.

Clinical Results sourced from slide deck provided by LenSx.

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**LensAR Laser**

**System Equipped with:**
- **Imaging:** Proprietary OCT
- **Signaling:** Automatic biometry and measurement system to allow delivery of the laser beam precisely aligned with surgeon-selected algorithms
- **Docking:** RoboCone no contact corneal interface for enhanced patient comfort, accuracy and safety

**Clearances:**
- Anterior capsulotomy in May 2010
- Lens fragmentation up to grade 4 cataracts currently under FDA review

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Technical specs and clearances sourced from Lipner, M. Femto technology changing the cataract landscape, Eye World Dec 2010.

Clinical Results sourced from slide deck provided by Lenses.
Technolas Femtosecond Workstation: CUSTOMLENS module

System Equipped with:
- **Imaging/Signal Processing:** integrated OCT continuously measuring before and during procedure
- **Docking:** Curved patient interface with suction permanently computer controlled

Clearances:
- FDA: CUSTOMFLAP LASIK flaps
- CE- Mark ONLY: CUSTOMSHAPE therapeutic indications and INTRACOR presbyopia treatment
- Not yet submitted for approval: CUSTOMLENS procedure, SUPRACOR procedure

CUSTOMLENS Feasibility Study:
- **Methods:** Anterior capsulotomy and lens fragmentation performed on 25 eyes
- **Results:**
  - Capsulotomy performed with high degree of predictability and accuracy
  - Lens fragmentation was efficient and safe, reduced phaco energy required to take out the lens

Technical specs and clearances sourced from Lipner, M. Femto technology changing the cataract landscape, Eye World Dec 2010.
Clinical Results from G Auffarth, Preliminary investigation into a New Femtosecond Laser Cataract Surgery Procedure, ESCRS Winter Meeting 2011, Istanbul.

Potential benefits of Laser Cataract Surgery

- **Efficacy Gains:**
  - More predictable and accurate size, shape, placement of capsulotomy
  - Better refractive outcomes
  - More consistent construction of corneal incisions

- **Safety Gains:**
  - Decreased risk capsule tears/vitreous loss
  - Reduction in ultrasound phaco energy & fewer instrument manipulations
  - Decrease risk of cataract wound leakage

- **Marketing Gains:**
  - Now you can finally give patients the laser cataract surgery that they have been asking for

Why should I care about laser cataract surgery?

1 Month follow-up after Surgery

Manual Surgery  Laser Surgery

Images courtesy of OptiMedica
Preparing for Practice Integration

Center's choice for system location is dependent on:

- Other facility considerations:
  - Room requirements for laser system
  - Facility layout
  - Procedural workflow
  - Potential Volume/Frequency of procedures
  - Storage of disposable patient interface

LenSx: Room Requirements Document

Document includes:
- Space Requirements
- Climate Control
- Input Voltage & Max Current
- Patient Bed Travel Requirements
- System Dimensions

Downloadable document from LenSx website.
### Temperature Requirements

<table>
<thead>
<tr>
<th>Femtosecond Laser Cataract System</th>
<th>Temperature Range</th>
<th>Humidity Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catalys Precision Laser System (OptiMedica)</td>
<td>15 - 32 degree C</td>
<td>0-90% range, at 32 degree C, non-condensing</td>
</tr>
<tr>
<td>LenSx Femtosecond Laser (Alcon)</td>
<td>18 – 22 degree C</td>
<td>30-40% Range</td>
</tr>
<tr>
<td>LensAR Laser System</td>
<td>18 – 30 degree C</td>
<td>35-70% Range</td>
</tr>
<tr>
<td>TECHNOLAS Femtosecond Workstation</td>
<td>19 – 23 degree C</td>
<td>30-60% Range, non-condensing</td>
</tr>
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Data sourced from Lipner, M. Femto technology changing the cataract landscape, Eye World Dec 2010.

### Center’s choice for system location is dependent on:

- Other facility considerations:
  - Room requirements for laser system
  - Facility layout
  - Procedural workflow
  - Potential volume/frequency of procedures
  - Storage of disposable patient interface

### Timing: Procedural Workflow

1. System Install
2. Patient Exam
3. Treatment Plan Entry
4. System Prep
5. Patient Check In
6. Patient Prep
7. Patient Transfer (In)
8. Procedural Timeout
9. Dock patient
10. Treatment Confirmation
11. Conduct Treatment
12. Patient Transfer (Out)
13. Lens Out/IOL In
14. Reporting
15. System Clean Up
16. Follow-Up
17. System Service

New steps with laser procedure

### Things to consider

- **Space**
- **Time**
- **Access**
- **Money & Marketing**
- **People**

S.T.A.M.P
Timing: Procedural Workflow

Main Steps: Incision Preparation, Incision Creation, Lens Removal, IOL Implantation, Wound Inspection

S.T.A.M.P

Timing Considerations: Comparison to existing practices

Procedure:
- Laser
- Cataract Removal/ IOL Implant

Main Steps: Incision Preparation, Incision Creation, Lens Removal, IOL Implantation, Wound Inspection

Outcome: Laser adds new procedure, may reduce OR time
Implication: Adding laser cataract surgery to your facility will require scheduling modifications
**Things to consider**

- Space
- Time
- Access
- Money & Marketing
- People

**Access: scheduling considerations**

- **Dependent on surgeon preference**
  - Schedule laser and immediate subsequent cataract removal / IOL implantation
  - Schedule block of several lasers then block of several subsequent cataract surgeries
- **Dependent on number of surgeons operating simultaneously**
  - Block laser time per surgeon
  - Schedule laser time chronologically with multiple surgeons
- **Other consideration**
  - OR time likely shorter in laser cataract cases

**Things to consider**

- Space
- Time
- Access
- Money & Marketing
- People

**Market: Cataract Surgery Today**

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

**Market Behavior:**
- Increasing desire for emmetropia and/or spectacle independence
- Increasing safety expectations
- More common for patients to “shop” around for surgeon and surgical center

More cataracts → More discriminating patients
**Laser cataract: potential revenue and cost considerations**

<table>
<thead>
<tr>
<th>Cost Increases</th>
<th>Cost Decreases</th>
<th>Revenue Increases</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Laser system cost</td>
<td>• Laser disposables</td>
<td>• More patients</td>
</tr>
<tr>
<td>• Laser system disposables</td>
<td>• Complications &amp; OR disposables</td>
<td>• More refractive cataract procedures</td>
</tr>
<tr>
<td>• Laser system service</td>
<td></td>
<td>• More premium IOL cases</td>
</tr>
<tr>
<td>• Laser system staffing</td>
<td></td>
<td>• Laser revenue</td>
</tr>
</tbody>
</table>

**Premium IOL surgery: Unmet Needs**

LenSx survey: What characteristic of current premium cataract surgery does NOT deliver on your expectations?

- **Refractive accuracy (55% respondents)**
- Management of astigmatism (45%)
- Need for accommodating IOL (45%)
- Managing expectations vs. price (35%)
- High grade near vision (25%)
- Others, including: enhancements required, leak free wounds, complications (10%)

Study conducted by LenSx. Data sourced from Donnenfeld, E. Femtosecond Limbal Relaxing Incisions, AAO 2010.

**Cataract Surgery Today: Refractive Outcomes**

- **Refractive goals**
  - Monofocal IOL: ± 1.0 D, functional vision
  - Premium IOL: ± 0.5 D, spectacle independence
  - Emmetropia
- **Refractive outcomes¹**
  - 28% of time we are not delivering refraction within ± 1.0 D
  - 55% of time we are not delivering refraction within ± 0.5 D

Study conducted by LenSx. Data sourced from Donnenfeld, E. Femtosecond Limbal Relaxing Incisions, AAO 2010.

**Marketing Laser Cataract Surgery**

- **To patients:**
  - Some already assume that laser cataract surgery is the norm
  - Desire for refractive outcomes beyond what we may be able to deliver with manual technique
  - Centers need to demonstrate: safety, cost-benefit of procedure to patients
- **To surgeons (2 types):**
  - In your center, but not yet using the system
  - Outside of your center, that you would like to attract to your facility
- **To consulting physicians:**
  - Opportunity to boost volume of referrals if affiliated optometrists talk to patients about laser cataract surgery

Things to consider

- Space
- Time
- Access
- Money & Marketing
- People

S.T.A.M.P

Surgeon: Procedural Workflow

5. Patient Check In → 6. Patient Prep → 7. Patient Transfer (In)
12. Patient Transfer (Out) → 13. Phaco/IOL Implant
17. System Service

Steps with Potential Surgeon Involvement

Nurse: Procedural Workflow

5. Patient Check In → 6. Patient Prep → 7. Patient Transfer (In)
12. Patient Transfer (Out) → 13. Phaco/IOL Implant
17. System Service

Steps with Potential Nurse Involvement

Tech: Procedural Workflow

5. Patient Check In → 6. Patient Prep → 7. Patient Transfer (In)
12. Patient Transfer (Out) → 13. Phaco/IOL Implant
17. System Service

Steps with Potential Tech Involvement
People: Procedural Workflow

1. System Install
2. Patient Exam
3. Treatment Plan Entry
4. System Prep
5. Patient Check In
6. Patient Prep
7. Patient Transfer (In)
8. Procedural Timeout
9. Dock patient
10. Treatment Confirmation
11. Conduct Treatment
12. Patient Transfer (Out)
13. Phaco/IOL Implant
14. Reporting
15. System Clean Up
16. Follow-Up
17. System Service

**S.T.A.M.P**

• Steps require different skills, may require a team of nurse, surgeon, and technician depending on ease of use of system and facility regulations
• Important to consider workflow when making staffing decisions

People: Staffing the Laser

- **Laser technician:**
  - Certified to operate lasers
  - 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?

People: OR activities

- **Same:** Patient preparation for surgery
- **Different:** State of eye at beginning of surgery

OR activities

- Post laser procedure, state of eye:
  - Incisions already created
  - Lens pre-softened
- Potential Implications?
  - Fewer instruments in kit
  - New phaco machine parameters
  - Reduced OR time, quicker room turnover

Eye at start of surgery in conventional cataract surgery
Eye at start of surgery after laser procedure
Exciting new technology, potential game changer that:
- Offers significant improvements in accuracy and precision of incisions
- Offers improvements in safety of procedure by reducing reliance on phaco energy and creating truly self-sealing corneal incisions

When considering purchase and maximizing utility of technology, need to consider:
- **Space**: 4 driving factors, facility layout, room requirements
- **Time**: Procedural workflow, laser time vs. OR time
- **Access**: Scheduling considerations, system availability for multiple surgeons
- **Money & Marketing**: Consider all cost and revenue streams, educate staff so they can educate patients
- **People**: Procedural steps require different skills, staffing considerations important in context of workflow

Questions?