Femtosecond Laser Cataract Surgery

Stephen D. McLeod, MD
Theresa M. and Wayne M. Caygill, MD Distinguished Chair
Professor and Chair, Department of Ophthalmology
Francis I. Proctor Foundation
University of California San Francisco
Femtosecond Lasers in Cataract Surgery

- High bar set by standard phacoemulsification
- Swedish National Cataract Register, 2002-2009
  - Capsule complications: of 602,553 procedures, 12,574; 2% overall
  - Rate as of 2006: 1.6%
- Royal College of Ophthalmologist’ National Ophthalmology Database Study 2006-2010
  - Capsule complications in 1.95 percent of cases
  - BSCVA of 20/20 in 50% of cases without co-morbidity
- European Registry of Quality Outcomes for Cataract and Refractive Surgery
  - 368,256 cataract extractions
  - BSCVA of 20/40 in 94% of cases, 20/20 in 60% of cases

Phaco vs Femto

- Phacoemulsification
  - Highly evolved technology
  - Relatively fast
  - Excellent outcomes
Femtocataract Applications

- Creation of corneal entry wounds
- Creation of arcuate incisions
- Creation of capsulorhexis
- Nuclear pre-phaco segmentation

Corneal Wounds

- Relationship between corneal wound incontinence and endophthalmitis risk
- Wound architecture considered important
- Can be standardized with femtosecond laser
Corneal Wounds

Any significance for induced astigmatism or vision?
• 600 eyes
  – 300 femto, 300 manual
• No significant difference
  – SIA
  – Flattening effect
  – Torque
• Slightly better wound dimension reproducibility by OCT

Corneal Wounds

Wound stability or integrity?
• Donnenfeld et al, JCRS March 2018
• 110 reverse cut vs 70 forward cut vs metal
• 15 eyes in each group
Corneal Wounds

- "Higher would leak pressure in reverse side cut"
- POD 1 Seidel test with pressure
  - None in 110 reverse
  - 53% in 70 forward
  - 87% in metal

Creation of Arcuate Incisions

- Corneal arcuate incisions can be readily performed with femtosecond laser
- With standard blade, frequently performed at limbus as well as cornea
- No evidence of greater effectiveness or predictability of femtosecond arcuates
Creation of Capsulorhexis

- Femtosecond can place perfectly sized and located capsulorhexis
- Can be important in lens optic centration and PCO rates

- Nagy et al, JRS 2009;25:1053-60
- Serrao et al, J Ophthalmol 2014;ID 520713

- Abell et al (Ophthalmology 2014;121:17-24)
  - 1626 patients undergoing FLACS or PCS
  - 3 femto platforms studied for incidence of anterior capsule tears
  - Tissue submitted for EM
  - 1.87% of AC tears in FLACS group, compared to 0.12% in PCS group
  - Edge irregularity in FLACS group not seen in PCS group
• Abell et al (JCRS 2015;41:47-52)
  – 1852 FLACS vs 2228 PCS
  – 1.84% of AC tears in FLACS group, 0.22% in PCS group
  – 8 PC rents in FLACS group, 4 PC rents in PCS group, NS

<table>
<thead>
<tr>
<th>Complication</th>
<th>Laser Assisted (n = 1852)</th>
<th>Phacoemulsification (n = 2228)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incomplete capsulotomy</td>
<td>21 (1.13)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Anterior capsulotomy tag</td>
<td>30 (1.62)</td>
<td>1 (0.004)</td>
<td>.0001</td>
</tr>
<tr>
<td>Anterior capsule tear</td>
<td>34 (1.84)</td>
<td>5 (0.22)</td>
<td>.0001</td>
</tr>
<tr>
<td>Posterior capsule tear</td>
<td>8 (0.43)</td>
<td>4 (0.18)</td>
<td>NS</td>
</tr>
<tr>
<td>Corneal haze</td>
<td>12 (0.65)</td>
<td>1 (0.04)</td>
<td>.009</td>
</tr>
<tr>
<td>Unstable pupil</td>
<td>30 (1.65)</td>
<td>14 (0.65)</td>
<td>.003</td>
</tr>
<tr>
<td>Iris hooks/Malaygum ring</td>
<td>5 (0.27)</td>
<td>1 (0.04)</td>
<td>NS</td>
</tr>
</tbody>
</table>

NA = not applicable; NS = not significant

Zepto
Zepto Capsulotomy

1. Paired comparisons
   - 8 femto vs. 8 zepto
   - 8 manual vs. 8 zepto
   - 8 femto vs. 8 manual

2. Zepto tear strength greater than both femto and manual
   - Zepto vs femto: x3
   - Zepto vs manual: x4
   - femto = manual

Zepto Clinical Data

Comparison of Manual vs. Femtosecond vs. “Precision Pulse Capsulotomy”

- Paired comparisons
  - 8 femto vs. 8 zepto
  - 8 manual vs. 8 zepto
  - 8 femto vs. 8 manual

- Zepto tear strength greater than both femto and manual
  - Zepto vs femto: x3
  - Zepto vs manual: x4
  - femto = manual

Ophthalmology 2016;123:265-74
Nuclear Fragmentation

- Studies have generally shown a decrease in phacoemulsification power and time using the femtosecond laser compared to standard phaco
- None have taken into account the cumulative energy delivered by femtosecond PLUS phaco
- Endothelial cell count or central corneal thickness significantly related to operating time and fluid flow

Intraoperative Complications

- Anterior capsule issues
  - Tags
  - Incomplete circle
  - Anterior capsule rent
  - Extension to posterior capsule, dropped lens
- Acute capsular block syndrome
  - Dropped lens
- Miosis
- Transient ocular hypertension
- Retained subincisional cortex
  - Can increase cornea edema due to prolonged I/A time
  - Addressed with bimanual approach
Visual Outcomes

• Most studies have failed to show a difference in visual outcome measures in comparing FLACS to PCS.

• Conrad-Hengerer et al randomized 200 eyes to FLACS vs PCS.
  – Unmasked post-operative evaluations?
  – Metal keratomes used for all corneal incisions
  – 92% of eyes in FLACS group were within 0.5D of target at 6 months compared to 71% in conventional group
  – Not considered “clinically significant” by authors
  – Lower laser flare AC cell in FLAC group until day 3

![Graph showing visual outcomes comparison between laser and conventional groups]
Meta-analysis of FLACS vs SUPS

Cochrane Review, Day et al

• 16 RCTs from Germany, Hungary, Italy, India, China, Brazil
• 1638 eyes of 1245 adults
• Primary outcome:
  – Intraoperative complications, primarily anterior and posterior capsule tears
• Secondary outcomes:
  – UCVA and BSCVA
  – Refractive outcomes
  – Quality of vision
  – Postop complications
  – Cost effectiveness

“overall, studies were at an unclear or high risk of bias”

In both groups (10 studies, 1075 eyes), the number of anterior and posterior capsule tears was low:
  – femto: 2 anterior tears
  – phaco: 2 anterior, 1 posterior tear

“inconclusive” difference in CME and elevated IOP rates

Small FLACS advantage for 6 month BSCVA (1.5 letters), not considered clinically significant

No quality of life data

Inadequate data from these studies to assess cost
Meta-analysis of FLACS vs SUPS

Cochrane Review, Day et al

• “the evidence from the 16 randomized controlled trials (RCTs) included in this review could not determine the equivalence or superiority of laser-assisted cataract surgery compared to standard manual phacoemulsification for our chosen outcomes due to the low to very low certainty of the evidence available from these studies”

Meta-analysis of FLACS vs SUPS

• Similar meta-analysis
  – 15 RCTs
  – 22 Observational cohorts
  – 14,567 eyes
• No difference for refractive and visual outcomes
• FLACS favored for:
  – Phaco time
  – Post-op pachymetry
  – Preservation of endothelial cell count
Retrospective FLACS vs SUPS

- Retrospective analysis of 1838 eyes
  - 883 manual
  - 955 FLACS
- Absolute error in refractive target
- Proportions 20/20 or better and 20/25 or better

No difference in refractive or visual outcomes

Table 4. Complications and Additional Postoperative Refractive Procedures

<table>
<thead>
<tr>
<th></th>
<th>MCS (N = 883)</th>
<th>FLACS (N = 955)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraoperative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterior capsule tear</td>
<td>4 (0.45)</td>
<td>9 (0.94)</td>
</tr>
<tr>
<td>Anterior capsule tear</td>
<td>0 (0)</td>
<td>4 (0.42)</td>
</tr>
<tr>
<td>Intraoperative decision to change IOLs or leave eye aphakic</td>
<td>2 (0.23)</td>
<td>5 (0.52)</td>
</tr>
<tr>
<td>Primary corneal incision requiring suture</td>
<td>0 (0)</td>
<td>15 (1.57)</td>
</tr>
<tr>
<td>Day 1 postoperative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild corneal edema (1−2+)</td>
<td>555 (62.9)</td>
<td>580 (60.7)</td>
</tr>
<tr>
<td>Marked corneal edema (3−4+)</td>
<td>37 (4.2)</td>
<td>56 (5.86)</td>
</tr>
<tr>
<td>Cystoid macular edema</td>
<td>2 (0.23)</td>
<td>2 (0.21)</td>
</tr>
<tr>
<td>Week 3 postoperative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild corneal edema (1−2+)</td>
<td>5 (0.57)</td>
<td>8 (0.84)</td>
</tr>
<tr>
<td>Marked corneal edema (3−4+)</td>
<td>0 (0)</td>
<td>2 (0.21)</td>
</tr>
<tr>
<td>Cystoid macular edema</td>
<td>2 (0.23)</td>
<td>2 (0.21)</td>
</tr>
<tr>
<td>Additional postoperative refractive procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterior capsule opacification requiring laser treatment</td>
<td>7 (0.79)</td>
<td>12 (1.26)</td>
</tr>
<tr>
<td>LASIK or PRK</td>
<td>2 (0.23)</td>
<td>5 (0.52)</td>
</tr>
<tr>
<td>Limbal relaxing incisions</td>
<td>8 (0.91)</td>
<td>17 (1.78)</td>
</tr>
</tbody>
</table>

FLACS = femtosecond laser–assisted cataract surgery; IOL = intraocular lens; MCS = manual cataract surgery; PRK = photorefractive keratectomy. Data are no. (%) of eyes.
Special Circumstances

Fuchs Endothelial Dystrophy

- Bascom Palmer 2018, Zhu et al
  - Retrospective review of 207 eyes (64 femto, 143 conventional)
  - 3 months minimum follow up, mean 30
  - No difference in corneal decompensation rates

Special Circumstances

Dense Nuclei

- LOCS III or greater
- Reduced phaco energy with FLACS pre-chop
Case selection: Limitations

- Small pupil
- Corneal opacity
- Orbital anatomy
- Patient cooperation
- Intumescent white cataract

Cost and Cost Effectiveness

- Requires
  - Additional instrumentation
  - Additional disposable supplies
  - Additional time

- Cost effective benefit
  - Increased safety?
  - Increased visual performance?
  - QUALY methodology attempts to fix dollar value to safety and vision

Abell and Vote, Ophthalmology 2014:

- Simulate complication rate and improved visual outcome of “5%”
- *Current models do not support cost effectiveness*
