Improving Safety in Cataract Surgery: What Matters and What Doesn’t

Steven Dewey, MD
Colorado Springs, CO
Consultant to AMO
Royalties from MST
Why Sharp Edges Just Don’t Make Sense

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Dewey Radius Tip

• Simply a change to the edge configuration of any standard phacoemulsification needle

• The internal and external edges of the distal lumen are rounded

• Requires virtually no changes on the part of the surgeon to use
Phaco Dogma, Circa 1969 - Present

- Sharp needles are required to cut nuclear material when using ultrasound
- Vacuum applied directly to the posterior capsule will damage the posterior capsule.
- Don’t even think about applying ultrasound to the posterior capsule . . .
  - That is a proven disaster, because, well, the vacuum has already broken it.
• So if you can’t touch the posterior capsule with the needle . . .
• Because vacuum will break it . . .
• If not, ultrasound will break it (if it wasn’t already broken by the vacuum)
• And, the needle has to be sharp for the ultrasound to work. . .
• We are exceptionally limited in our options to make phacoemulsification safer for our patients.
Cortical Removal

- Challenges: 1990s
  - Difficulty with cortical aspiration in subincisional space
  - Highest risk stage of cataract surgery for capsular rupture
  - “Vacuum” rupture by aspirating capsule into the lumen of the I & A tip
  - “Powerwash” the posterior capsule
  - Completely removes cortex in as little as 30 seconds
  - Clears subincisional cortex without direct visualization
  - A single capsule rupture during cortical removal in 3000 cases when using this technique (JCRS, 2002)
J-cannula Irrigation
Steerable I & A

- Charles Kelman envisioned a steerable I & A tip
  - Designed to bend and twist into subincisional space to remove cortex
  - Silicone sleeve enveloped the device to establish a fluid channel
Steerable I & A
Steerable I & A: Safety Miyake Style

Steerable I/A
(Miyake View)
Dr. David Apple published his report on posterior capsule opacification, citing thorough cortical clean-up as the primary means of PCO reduction for lenses available at that time for pathologic evaluation.

- The key surgical step of his six steps in reducing rates of PCO

April, 2001: Tested J-cannula irrigation at Dr. Apple’s Lab

- Found that J-cannula irrigation thoroughly and completely removes cortex from the capsule
  - Single layer of LECs remain
  - In some cases, LECs also stripped from capsule
J-cannula Irrigation: Safety Miyake Style
Early Phacoemulsification

• First Phacoemulsification Unit: The Cavitron
• Early systems required a technician to operate
• Titanium needles: $500
  • Returned for “inspection” and sharpening
• Fluidics
  • Plain lousy
Proposed Mechanisms

- Jackhammer: Sheer brute force
- Sonic: Acoustic dispersion
- Cavitation: Some unseen notion of ultrasound
- Fluidics: Weren’t any

Summary:
- The needle had to be sharp to emulsify nuclear tissue by physical contact
What effect takes place in front of the tip?
The Tooth Fairy?!?
Phacoemulsification:

Mark Shafer’s Perspective 2002

MECHANICAL ("jackhammer")

THERMAL

WOUND BURN

ACOUSTICAL 28-40kHz Sound

CAVITATION

STREAMING Turbulence “Repulsion” Bioeffects (?)

MATERIAL EROSION

HOW TO MAXIMIZE BENEFIT & MINIMIZE DAMAGE?
Acoustically: The Tip is a “Monopole Source”

- Low frequency Acoustic Energy produces no useful effect, in and of itself, but may cause unwanted side effects
- Energy measured using 8103-type hydrophone
- Ultrasonic “dose” of up to 0.35J, quantified in IEC 61847, correlates with clinical conditions
- Energy is concentrated and “focused” by cavitation action

www.kettering.edu/~drussell/Demos/rad2/mdq.html
Phaco cutting is caused by Acoustic Cavitation, of which there are two types:
- Transient Cavitation
  - Violent bubble collapse that disintegrates tissue

  - Gives way to Stable Cavitation
  - Stable Cavitation
    - Bubble vibration with fewer collapses
    - Releases less energy than Transient Cavitation
Cavitation: One Bubble At A Time
Cavitation: Miyoshi
Cavitation: Animation
Cavitation: Miyoshi Enhanced
Maybe Cavitation?
Does the needle have to be sharp?

• If vacuum won’t break the posterior capsule most of the time
  • Provided the instrument surface is smooth . . .
  • And the capsule isn’t pathologic
• And, if cavitation is removing the cataract . . .
  • Exploding bubbles certainly don’t need a sharp edge

• Why not make a phaco needle with rounded edges?

• Because . . .
  • You can’t machine titanium to that precision
  • Even if you could, ultrasound will still break the posterior capsule on contact
Perseverance

- Two years later, convinced Doug Mastel to make prototypes.
  - Standard AMO 19- and 20-gauge needles
  - Rounded in Rapid City, South Dakota
Visible Difference in Edge Configuration
First Accidental Capsule Grab

• “Ummmmm, I forgot to start the video”
  - Cindy, OR Circulating Nurse
  Penrose Hospital, July, 2004

• Fortunately, the patient and capsule survived the event uneventfully
First Day’s Experience

- No clinical difference in needle performance
- Same-day follow-up visit acuities, pressures, etc., well within the norm for sharp-edged surgical cases.
- Emboldened to determine if there is a difference in function or effect between a sharp and an rounded phaco needle.
Advancing Phaco Technology

• First testing was with 21st century micropulse phaco
• Advantages over “traditional longitudinal phaco”:
  • Highly refined fluidics (CASE)
  • Enhanced cavitation through micropulse energy delivery
Ultrasound Cavitation Bursts

- More cavitation (cutting) energy delivered with hyperpulses than continuous mode at same stroke.
- WhiteStar™ mode reduces total ultrasound delivered for same or better cutting effectiveness.
- Hyperpulse bursts can be “tuned” for further improved efficiency.
Mean EPT: Sharp v. Rounded

Non-stop chop and AMO Sovereign with WhiteStar™
Mean EPT: Sharp v. Round

Non-stop chop and Variable WhiteStar™ (6.0)

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Prototype Survival: Poor

- 30 to 40 uses
- 90+ uses
No significant difference in behavior

- Simple horizontal chop surgery showed no differences
  - EPT
  - Footpedal time
  - “Tip” time
  - Total case time
- So, then, what does matter?
- Around this time, I switched prototype vendors to MST (Redmond, WA)
  - “Steve, could you give this one a try?”
# Video Recording Log for Dr. Dewey's Cases

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Mean EPT: Comparing Techniques

Using Dewey Radius™ Tip and Variable WhiteStar™

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### Mean EPT: Comparing Instruments

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- **20 ga bent**
- **19 ga bent**
Configuration Changes Technique

Straight 20 ga Bevel Down
EPT = 3.42s

Bent 19 ga Bevel Forward
EPT = 2.62s
• Bent needles provide a sloped inner surface: internal cavitation decreases occlusive events
• No Bevel (Zero degree): Dullest sharp needles available
• Greater bevel provides a “wedge” effect to dissect the lamellar orientation of the nucleus (Steeper bevel = Sharper wedge)
• Greater bevel alters the configuration of the emulsified fragment, further diminishing the chance of occlusion
• Larger gauges apply force over a longer chord length of nuclear fragment—less force required to disrupt fragment

19 ga straight and bent
Zero and 45-degree angles
Larger gauge needles pose greater risk to chamber stability
Smaller gauge needles provide a flow restriction which modifies the effect of vacuum
Current surgical technology allows for efficient use of smaller gauge needles due to advances in ultrasound modulation
Smaller needles can take advantage of newer technologies to use higher vacuum levels safely
Throw away your 19-gauge needles

- Bent 900 and 700 micron
- 30 degree bevels
Internal Cavitation: Bevels Only

Ellips™ with Bent Radius Tip (in Water)
Rounded-Edged Cutting: 3+ NS
Rounded-Edged Cutting: 3+ NS
Rounded-Edged Cutting: 4+ NS
Sharp-Edged Cutting: Technique

- Penetrates intact layers
  - Trenching for Divide & Conquer
  - Impaling for horizontal or vertical chop
- Less respect for “grain”
- Edge can catch to create chatter
Rounded-Edged Cutting: Technique

- Will penetrate intact layers
  - No difference for softer cataracts
  - Needs more power for denser nuclei
- Respects “grain”
  - Delaminates nuclei
  - Finds a plane of dissection
- No edge to catch means less chatter
Clinical Differences Emerge
Clinical Differences Emerge
Studying Floppy Iris Syndrome
Time to Prove the Concept

- No clinical difference in the performance of the needle
  - No changes in technique for chopping surgery
  - Mild changes for divide & conquer (trenching dense cataracts)
  - Any needle configuration, any current phaco unit
    - Non-longitudinal phaco, advanced fluidics
- Far less concern about contacting the capsule
- Far safer for the iris
- BUT: Incidental anecdotal evidence of safety not enough
- Back to the David J Apple lab, this time in Salt Lake City
Ultrasound and the Posterior Capsule
Ultrasound and the Posterior Capsule
Ultrasound and the Posterior Capsule
Ultrasound and the Posterior Capsule
Results of the Cadaver Eye Study

• We successfully broke every capsule we tried to break

• Undamaged needles did not break the capsule with vacuum alone
  • Surprisingly resilient to the larger bore phaco needle

• All capsules survived direct application of ultrasound
  • Absolutely surprised that they didn’t pop like a child’s balloon against the ceiling light fixture

• Big Failure:
  • Did not have a sharp-edged needle control
Ultrasonic Capsule Polishing
19-Gauge/Venturi: Not A Sharp Move
Continuously Evolving Technology

- Torsional Phaco
  - First developed by Kuwabara in Japan, 1970s
    - Commercial failure due to poor fluidics
  - Ozil blends rotational with longitudinal movements
  - Sheers material with rotation
  - Clears it with longitudinal
  - Still involves cavitation
Torsional Phaco Imaged: Sharp Tip
Torsional Phaco: Radius Tip
Vacuum: Peristaltic Magnitude

B&L Stellaris

400 mmHG  500 mmHG
WhiteStar™ ICE

Dr. Dewey Case #15
August 9, 2006
EPT time 0.16 to 0.34

Aspiration (00-50)
FP Zone (00-03, 04 Reflux On, 05 Reflux Off)
Occ Mode (00 Unocc, 01, Occ, 02 CASE)
Vacuum (000-500)

Power (000-100)
Vacuum: Venturi v. Peristaltic
## Vacuum: Venturi v. Peristaltic

<table>
<thead>
<tr>
<th>Reconstructed</th>
<th>Ellips Phaco Time</th>
<th>Tip Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peristaltic</td>
<td>6.18</td>
<td>58.3 seconds</td>
</tr>
<tr>
<td>Venturi</td>
<td>5.17</td>
<td>51.19 seconds</td>
</tr>
<tr>
<td>“Winner”</td>
<td>Venturi 20% less</td>
<td>Venturi 14% less</td>
</tr>
</tbody>
</table>
Transversal Phaco: Radius Tip

Ellips™ with Straight Radius Tip (in Air)
700m Tip Venturi Vacuum
Mechanisms of Phacoemulsification

- What matters is relative to the density of the nucleus
  - Softer cataracts
    - Use more vacuum
  - Denser cataracts
    - Use more power
Mechanisms of Phacoemulsification

- Edge configuration: Sharp or Rounded
  - Doesn’t make a significant difference compared to:
    - Technique
    - Bend
    - Bevel
    - Gauge
    - Vacuum
      - Magnitude
      - Type
“Never play with sharp objects. You might poke an eye out!”

-- Every Mom Everywhere
Or, maybe just break a capsule.

Thank You.