Safety in the Operating Room

Steven Dewey, MD
Randall Olson, MD
Jeffrey Pettey, MD

DISCLAIMER: This course is not about how to fix the errant complications one may encounter.

Rather, this course is designed to reduce the rate at which you encounter complications that may threaten the patient's outcome.

It starts somewhere...

Residency, Partners, Colleagues

Habits:
- Good: Stand the test of time, frequently challenged
- Bad: "That's the way I've always done it."
Interrelated Changes

- Any new technique brought into the surgical armamentarium will have consequences for other techniques
  - Changing incisions
  - Changing viscoelastics
  - Changing phaco styles (chop, etc.)

Seemingly Unrelated Changes

- Safety is absolutely the same
- Most “complications” result in incidental consequences to the surgical outcome
  - Right?
- It’s the potential for the complication to alter the chance for a good outcome for our patients.

The Perilous Cascade

- Every surgical disaster is the result of not one event—it takes two or more
  - The first event may be absolutely innocuous, and by itself easily ignored
    - No effect on the surgical outcome
  - The second event itself may be just as innocuous by itself
  - Together, the coupled sequence finds synergy, and the outcome is affected

Where to Start?

- It boils down to unwanted, unintended contact
  - Incidental—brief, sudden, unexpected
    - Movement, IFIS
  - Prolonged—anticipated, but with unintended consequences
    - Thermal injury, endothelial damage
Formulate a Strategy

- Start at the end—the worst situations—and work backwards
  - How did I get here?
- Review videos
  - Did what I thought happened really happen?
- Take notes
  - The conditions/situation will fade

Topics Today

- Inherent safety in a highly polished needle
- Surgical efficiency through better vacuum
  - Yes, speed (expediency) does improve safety
- 10 steps (or so) to reduce complications
- Improving surgical access when necessary
- Reducing the risk of thermal injury
The Dewey Radius Tip: 10-years Experience

Steven Dewey, MD
Colorado Springs, CO

Royalties from MST
Consultant to AMO

DRT: 10-years Experience

- I receive royalties from MST
- I am a consultant for AMO

Dewey Radius Tip

- Simply a rounded, radiused, polished edge
  - Any phaco needle
  - Any phaco machine
  - Any surgical technique
- Manufacturer: MicroSurgical Technology (Redmond, WA)
- Patent US7588553

First Observation: Cheating

- It certainly seems safer
  - Clinical experience
  - Am I just getting away with this?
- It is a safer phaco needle compared to a sharp counterpart
  - Cadaver eye studies
  - Capsule model studies v. sharp needles
Misconceptions

- Doesn’t cut dense cataracts
- Doesn’t work with my phaco machine
  - You’re really still using a Legacy?
- More expensive to use
  - Don’t you need a needle anyway?
  - What is the real cost of a vitrectomy?

Second Observation: Confidence

- It will change your technique
  - Safety increases the utility of the needle
    - Work closer to the capsule
    - Work closer to the iris
  - Higher levels of vacuum
  - Safely fetch nuclear fragments

Third Observation: Indispensable

- It’s a versatile tool working for you
  - Cortical removal
  - Capsule polishing
- It’s a confidence builder
  - Improves the consistency of the surgical result
Can a Rounded Phaco Tip Protect the Capsule?

RANDALL J. OLSON, MD
PROFESSOR, CHAIR, & CEO
JOHN A MORAN EYE CENTER
UNIVERSITY OF UTAH
DEPARTMENT OF OPHTHALMOLOGY
AND VISUAL SCIENCES
I have no conflict of interest to report.

Can such a small difference really have any effect on capsular breakage?

Even if it does protect the capsule, is there a price to pay (we rarely get something for nothing!).

Is There any Validity to this Claim?
Can we craft a clinical Study?

- Capsular breakage uncommon and uncontrolled variables a nightmare!
- Can we use fresh human lenses?
- Can try touching the capsule and see if there is a difference!

A Capsular Breakage Study: Step 1

- Started with fresh human lenses.
- 550mmHg, 75mm Bottle height, 60ml/min fluid flow
- Tap the posterior capsule until it breaks and compare number of taps to breakage.

Human Lens Results

<table>
<thead>
<tr>
<th></th>
<th>Signature (runs on 12mm off)</th>
<th>Ellips 100% power</th>
<th>ODZ 100% power</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 gauge sharp</td>
<td>Not tested</td>
<td>4+/2</td>
<td>Not tested</td>
</tr>
<tr>
<td>20 gauge dull</td>
<td>4+/2</td>
<td>4+/2</td>
<td>3+/1</td>
</tr>
</tbody>
</table>

P < 0.0001 for all 20 gauge dull vs. Ellips 20 gauge sharp.
P = 0.01 for ODZ 20 gauge dull vs the other two 20 gauge dull categories.

Is There Another Way?

- Can we find a capsule substitute?
- What about transversal vs Torsional?
- What about tip bore size?
- Does breakage require US and can just vacuum do it?
Saran Wrap to the Rescue!

<table>
<thead>
<tr>
<th>Tip Brand</th>
<th>100% Power</th>
<th>18% Power</th>
<th>0% Power</th>
<th>0% Power (w/o 100% Power)</th>
<th>P values for each row</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 Ga</td>
<td>18.5%</td>
<td>18.5%</td>
<td>18.5%</td>
<td>18.5%</td>
<td>No BREAKAGE WITHOUT US!</td>
</tr>
<tr>
<td>18 Ga</td>
<td>19.0%</td>
<td>19.0%</td>
<td>19.0%</td>
<td>19.0%</td>
<td>No BREAKAGE WITHOUT US!</td>
</tr>
<tr>
<td>20 Ga</td>
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<td>19.5%</td>
<td>19.5%</td>
<td>No BREAKAGE WITHOUT US!</td>
</tr>
</tbody>
</table>

Conclusions

- No BREAKAGE WITHOUT US!
- Very much power dependent.
- Radiused tip is VERY protective!!
- 19 Ga tip worse than 20 Ga worse except for Torsional.
- What's up with torsional?

The 20 vs 19 Gauge Conundrum!

- Breakage should be related to the exposed tip bore area and the active vacuum.
- But peristaltic systems have no vacuum until the tip is occluded.
- Or does it?

The 20 vs 18Ga Mystery Resolved!

<table>
<thead>
<tr>
<th></th>
<th>Signature 19Ga</th>
<th>Signature 18Ga</th>
<th>20Infini 19 gauge</th>
<th>20Infini 18 gauge</th>
<th>P values for each row</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unoccluded flow vacuum (mmHg)</td>
<td>77.3 ± 0.6</td>
<td>125.0 ± 1.5</td>
<td>164.4 ± 1.1</td>
<td>245.2 ± 0.7</td>
<td>P &lt; 0.0001 for all comparisions</td>
</tr>
<tr>
<td>Actual Flow (mL/min)</td>
<td>37.0 ± 0.9</td>
<td>54.7 ± 0.7</td>
<td>56.1 ± 1.1</td>
<td>50.3 ± 0.6</td>
<td>P &lt; 0.0001 for 20 gauge vs all others &amp; 19 vs 20 gauge</td>
</tr>
</tbody>
</table>
Clinical Importance of This Study

- Capsular contact with active ultrasound is risky business!
- A radiused tip is very protective!
- Latest peristaltic systems can have Venturi like active vacuum at the tip!
- As actually used, Torsional and Transversal may increase capsular breakage risk.

Meyer J, Kuo A, Olson R: The Risk of Capsular Breakage from Phacoemulsification Needle Contact with the Lens Capsule. AJO 2010;149:882.
10 Steps to Increased Safety in the Operating Room

Steven Dewey, MD
Colorado Springs, CO
Consultant to AMO
Royalties from MST

The Dewey Radius Tip

- If unintended contact is inevitable
- And, the sharp edge isn’t necessary
- Lose the sharp edge

Everyone Has IFIS

- Intracameral Dilation
- Viscomydriasis
- All small pupils are IFIS pupils
  - No stretching or manipulation
  - Stable iris retraction only
- Improve chamber stability
  - Smaller gauge phaco needles
  - Non-traditional phaco with higher vacuum

Reduce Movement

- Tape the head
  - Blunts sudden movements
  - Reduces the slow drift
- Tessalon Perles (Sodium Benzonate)
  - Reduces coughing
- Effective anesthesia/sedation
Avoid Superior Approach

• Adds complexity to positioning
• Difficult access
  – Brow
  – Normal chin-down drift
• Respiration adds to challenge
  – Tidal breathing
  – Greater risk with coughing

Shield the Non-operative Eye

• Reassures the patient
• Avoids accidental incidental intervention
  – Dilation
  – Surgical Prep
• Avoids worse
• Protects the non-operative eye during surgery

Judicious Viscoelastics

• Secure the safety hubs
  – Not just decoration
• Viscomydriasis
• Avoid overfilling

Improved Chamber Stability 1

• Smaller Gauge Phaco Needles
  – Inherent flow restriction
  – Allows for higher vacuum levels
**Improved Chamber Stability 2**
- Careful incision sizing
  - Avoid oarlocking
  - Improves visualization
  - Reduces wound leakage

**Orient Irrigating Sleeve**
- Misdirected flow can pummel the endothelium
  - Shallow AC
  - Denser cataracts
  - Fuch's

**Subincisional Cortical Removal**
- Bimanual
- Silicone sleeve
- J-cannula irrigation
DOES VENTURI VACUUM INCREASE THE RISK OF CAPSULAR BREAKAGE?

Randall J Olson, MD
Professor, Chair and CEO
John Moran Eye Center
University Of Utah School of Medicine

I have no conflicts to report

VENTURI AND PHACO

- We recently showed that Venturi vacuum doubles the efficiency and decreases chatter during phaco (JCRS March 2015).
- Because there is no lag time for maximum vacuum and all vacuum is active at the tip, might this be a risk for capsular breakage in comparison to a peristaltic pump?
- Is there a way to safely study this?

STUDY DESIGN

- Based on our 2010 AJO paper where we used Saran wrap as a capsular substitute and correlated this with work with human cadaver capsules.

- Compared venturi to peristaltic vacuum with the same Signature machine and set-up.

- Tested 200 taps per modility for plenty of statistical power.

STUDY PARAMETERS

- 550mmHg for both.
- 50cm bottle height.
- 40ml/min flow for peristaltic (venturi at least twice this).
- 20G with 30 degree bevel (transversal also a Kelman bend).
- 50% power for both.
- Looked at tip contact and also tip occlusion.
RESULTS

<table>
<thead>
<tr>
<th></th>
<th>PERISTALTIC</th>
<th>VENTURI</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIP CONTACT</td>
<td>66.3%*</td>
<td>60.3%*</td>
</tr>
<tr>
<td>TIP OCCLUSION</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

* P = 0.013. FOR OCCLUSION P<0.0001

RESULTS

<table>
<thead>
<tr>
<th></th>
<th>PERISTALTIC</th>
<th>VENTURI</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRANSVERSAL</td>
<td>71% (2)</td>
<td>68.5% (3)</td>
</tr>
</tbody>
</table>

FOR 1, 2, & 3, P < 0.0001

CONCLUSIONS

- VENTURI VACUUM DOES NOT INCREASE THE RISK OF CAPSULAR BREAKAGE!!
- CAPSULAR BREAKAGE COMES FROM TIP CONTACT WITH ULTRASOUND AND NOT TIP OPENING OCCLUSION.
- TRANSVERSAL SIGNIFICANTLY INCREASED THE RISK OF CAPSULAR BREAKAGE WITH CONTACT ESPECIALLY WITH VENTURI VACUUM.
Wound Burn: Incidence, Etiology and Prevention

RANDALL J. OLSON, MD
PROFESSOR, CHAIR and JMEC CEO
U of U DEPARTMENT OF
OPHTHALMOLOGY AND VISUAL SCIENCES

I have no conflict of interest to report.

Wound Burn: What do we know?

• Created by friction and mechanical stress in the phaco needle!
• Technically thermal collagen contracture.
• At 60 degrees C. takes a second to occur.
• Near misses common!

PHACO MACHINE RATIOS IN WATER (J CRS 2006;32:288)

Continuous: 2.31 (SOV/LEG) ; 0.84 (SOV/MILL) ; & 1.65 (SOV/INF)

So 20% of A has no relationship to B, etc

LEG @ 100% = SOV @ 43% = MILL @ 36% = INF @ 71%

INCISION FRICTION AND LOAD THE MAIN CULPRITS!
Wound Burn: Other factors

- Greatest risk is when phaco needle is occluded.
- The higher the energy the greater the risk.
- Does Energy modulation make a difference?
- So the longer the ultrasound run with occlusion, the bigger the risk.

What role does OVD Play?

- 2006 JCRS Study
- OVD variably exothermic with ultrasound
- Big outliers were Viscoat (7.1 x) and Healon 5 (5.2X water)

### Block Temperature Rise in OVD as a Ratio over Water @ 40% Power
Valentine & Floyd et al JCRS 2006;32:1222

Stat. Sig.: Viscoat > all others; Healon 5 > all but Viscoat; Healon GV < all others

Also showed incision friction equivalent to hanging a 280 gram weight from the sleeve! (recently confirmed in a new study!!)

<table>
<thead>
<tr>
<th>OVD</th>
<th>VISCOAT</th>
<th>HEALON 5</th>
<th>PROVISC</th>
<th>ITRAX</th>
<th>HEALON</th>
<th>AMVISC PLUS</th>
<th>HEALON GV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ratio</td>
<td>7.14</td>
<td>5.20</td>
<td>3.87</td>
<td>3.72</td>
<td>3.56</td>
<td>2.77</td>
<td>2.38</td>
</tr>
</tbody>
</table>
Study Results

- 910 surgeons reported on surgical experience.
- 419 wound burns were reported that could be correlated with practice patterns.
- Represents 963,543 Surgeries.

Multivariate analysis

- Greatest Correlate was with Surgical Volume (Inverse; P < 0.0001).
- Second Correlate was with Surgical Approach (P = 0.0001).
- Third Correlate was with the OVD used (P = 0.0025).
- No other group correlated statistically significantly with wound burn.

Individual variations most important!

### Surgical approach burn rate (adjusted for all significant factors)

<table>
<thead>
<tr>
<th>Surgical Approach</th>
<th>Burn/1000</th>
<th>Lower CL</th>
<th>Upper CL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Divide &amp; Conquer</td>
<td>0.36</td>
<td>0.20</td>
<td>0.54</td>
</tr>
<tr>
<td>Carousel</td>
<td>0.32</td>
<td>0.11</td>
<td>0.92</td>
</tr>
<tr>
<td>Stop &amp; Chop</td>
<td>0.22</td>
<td>0.12</td>
<td>0.39</td>
</tr>
<tr>
<td>Vertical Chop</td>
<td>0.10</td>
<td>0.05</td>
<td>0.21</td>
</tr>
<tr>
<td>Phaco Flip</td>
<td>0.08</td>
<td>0.02</td>
<td>0.19</td>
</tr>
<tr>
<td>Horizontal Chop</td>
<td>0.07</td>
<td>0.02</td>
<td>0.19</td>
</tr>
<tr>
<td>Prechop</td>
<td>0.06</td>
<td>0.01</td>
<td>0.52</td>
</tr>
</tbody>
</table>

### OVD Related Burn Rate (adjusted for all significant factors)

<table>
<thead>
<tr>
<th>OVD</th>
<th>Burns/1000</th>
<th>Lower CL</th>
<th>Upper CL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healon 5</td>
<td>1.35</td>
<td>0.34</td>
<td>5.38</td>
</tr>
<tr>
<td>Ocucoat</td>
<td>0.28</td>
<td>0.07</td>
<td>1.12</td>
</tr>
<tr>
<td>Duovisc/Viscoat</td>
<td>0.20</td>
<td>0.11</td>
<td>0.35</td>
</tr>
<tr>
<td>Provisc</td>
<td>0.17</td>
<td>0.08</td>
<td>0.39</td>
</tr>
<tr>
<td>DisCoVisc</td>
<td>0.11</td>
<td>0.05</td>
<td>0.29</td>
</tr>
<tr>
<td>Amvisc Plus</td>
<td>0.10</td>
<td>0.04</td>
<td>0.26</td>
</tr>
<tr>
<td>Amvisc</td>
<td>0.05</td>
<td>0.01</td>
<td>0.26</td>
</tr>
<tr>
<td>Healon GV</td>
<td>0.05</td>
<td>0.01</td>
<td>0.24</td>
</tr>
<tr>
<td>Healon</td>
<td>0.04</td>
<td>0.01</td>
<td>0.17</td>
</tr>
</tbody>
</table>
OVD Burn 100% Preventable!

- Never start the case with ultrasound energy!
- I-A for the first 10-15 seconds to clear an area of OVD above the lens.
- Ultrasound is then safe from an OVD interference.
- Now do you understand the burn case?

Machine Burn Rates (adjusted for surgical volume)

<table>
<thead>
<tr>
<th>Machine</th>
<th>Burn/1000</th>
<th>Lower CL</th>
<th>Upper CL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legacy</td>
<td>0.54</td>
<td>0.40</td>
<td>0.73</td>
</tr>
<tr>
<td>Sovereign</td>
<td>0.32</td>
<td>0.21</td>
<td>0.50</td>
</tr>
<tr>
<td>Infiniti</td>
<td>0.31</td>
<td>0.25</td>
<td>0.38</td>
</tr>
<tr>
<td>Millennium</td>
<td>0.31</td>
<td>0.18</td>
<td>0.52</td>
</tr>
<tr>
<td>Signature</td>
<td>0.24</td>
<td>0.09</td>
<td>0.65</td>
</tr>
<tr>
<td>Stellaris</td>
<td>0.15</td>
<td>0.04</td>
<td>0.59</td>
</tr>
</tbody>
</table>

Power Burn rates (adjusted for surgical volume)

<table>
<thead>
<tr>
<th>Power Setting</th>
<th>Burn/1000</th>
<th>Lower CL</th>
<th>Upper CL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous</td>
<td>0.64</td>
<td>0.45</td>
<td>0.92</td>
</tr>
<tr>
<td>OZIl + Long.</td>
<td>0.39</td>
<td>0.30</td>
<td>0.52</td>
</tr>
<tr>
<td>Hyperpulse</td>
<td>0.31</td>
<td>0.20</td>
<td>0.46</td>
</tr>
<tr>
<td>OZIl</td>
<td>0.26</td>
<td>0.19</td>
<td>0.37</td>
</tr>
<tr>
<td>Burst</td>
<td>0.26</td>
<td>0.14</td>
<td>0.49</td>
</tr>
<tr>
<td>Pulse</td>
<td>0.25</td>
<td>0.15</td>
<td>0.41</td>
</tr>
<tr>
<td>Ellips</td>
<td>0.0</td>
<td>?</td>
<td>?</td>
</tr>
</tbody>
</table>

New Study (JCRS Submitted)

- Transversal FX 2.5 times Hotter than Torsional IP!
- Incisional temperature for Torsional IP 4.0 times hotter than In Vitro!
- Actual clinical difference, if any, is not known.
Conclusions

- Wound Burn incidence today is about 1 per 2000 surgeries.
- Strongest independent correlate is inversely to ones surgical volume.
- Surgical approach and OVD used are in order the next two independent correlates.
- Transverse ultrasound is not protective of wound burn as it is clinically used.

Wound Burn Prevention Recommendations

- Be parsimonious of ultrasound use no matter what the machine or power modality.
- Consider a more mechanical approach in your nucleus disassembly technique.
- Aspirate all OVD over the lens surface for at least 10 seconds prior to the use of any ultrasound!