New Laparoscopic Tools for Gynecology

Jeannette Lager, MD
Assistant Professor
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco

Disclosures:
None

Introduction

• History
• FDA approval process
• Review devices
  • Monopolar loop
  • Uterine manipulators
• Revisit criticisms of FDA approval process
• Conclusion

History of laparoscopy

1901 - George Kelling

"I asked myself, how do organs react to the air introduction? To find this out, I devised a method to use an endoscope on an unopened abdominal cavity (Koelioskopie) in the following way."
Early progress

1911 - Bertram M. Bernheim, from Johns Hopkins Hospital introduced laparoscopic surgery to the United States.

1918 - O. Goetze developed an automatic pneumoperitoneum needle characterized for its safe introduction to the peritoneal cavity.

1938 - J Veress, of Hungary, developed the spring-loaded needle.

1939 - Richard W. Telinde, tried to perform an endoscopic procedure by a culdoscopic approach, which was abandoned because of the presence of small intestine.

Noteworthy events

In 1936, in Switzerland, Bosch performed the first laparoscopic tubal occlusion.

Establishment into the gynecological field

• 1944 - Raoul Palmer, of Paris performed gynecological examinations using laparoscopy and placing the patients in the Trendelenburg position
• 1960 - Kurst Semm, a German gynecologist, who invented the automatic insufflator.
• 1971 - Jordan M. Phillips, founded the American Association of Gynecological Laparoscopist
FDA Approval Process

1976: Congress passed the Medical Device Amendments to the FDCA
- To prevent the distribution of dangerous and ineffective devices
- Provide "reasonable assurance of ... safety and effectiveness

New Medical Device
- Premarket approval (PMA)
- Premarket notification (PMN)/510(k)
- Analogous to NDA-clinical trials
- "Substantially equivalent" to a predicate device

Criticisms

- Lower approval standard for devices
- Disparate technological characteristics
- Permissive interpretation of "same intended use"
- Failure to complete review of some devices
- Some devices have never been classified

Criticism


New technology

New Devices
**Electrosurgical loop**

- Supracervical hysterectomy
- Total laparoscopic hysterectomy
- Myomectomy

---

**Lina Loop clip**

---

**Lap Loop Procedure**

---

**Cost**

<table>
<thead>
<tr>
<th>Device</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lina Loop (6 per box)</td>
<td>$350</td>
</tr>
<tr>
<td>Laploop instrument</td>
<td>$850</td>
</tr>
<tr>
<td>Laploop electrodes (5 per box)</td>
<td>$40</td>
</tr>
<tr>
<td>Cable LSC bovie</td>
<td>$95</td>
</tr>
</tbody>
</table>
Comparison

<table>
<thead>
<tr>
<th></th>
<th>Mean cutting time (min)</th>
<th>Mean operative time (min)</th>
<th>Mean hospital stay (hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lap Loop</td>
<td>6.6 (actual 33.5 sec)</td>
<td>140.1</td>
<td>32</td>
</tr>
<tr>
<td>Traditional</td>
<td>14.4</td>
<td>131.5</td>
<td>29</td>
</tr>
</tbody>
</table>


Study Complications

1st Case Controlled study
- 3 complications—1 incisional hernia, 1 Veress needle puncture of the left lobe of the liver, 1 UTI


2nd Descriptive study
- 127 pts, no complications
- 5 required repeat cautery after loop applied


Study Complications

3rd prospective study:
- 3 complications requiring admission—1 vasovagal reaction after anesthesia, 1 admitted for post-op pain, 1 XL due to major intra-abdominal bleeding.
- 5 complications did not require admission—1 infected intra-abdominal hematoma, 1 urinary retention, 1 cystitis, 1 cystitis & wound infection, 1 pneumonia


Maude Database

<table>
<thead>
<tr>
<th>Date</th>
<th>Complication</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/1/09</td>
<td>Lina Loop broke when tested touching the fundus—no injury noted</td>
</tr>
<tr>
<td>1/1/09</td>
<td>Lina Loop broke when activated—no injury noted</td>
</tr>
<tr>
<td>12/22/09</td>
<td>Lina Loop broke at tip and loop retracted into protective sheath—no injury noted</td>
</tr>
<tr>
<td>1/26/10</td>
<td>Lina Loop engaged, thought to be uncomplicated w/ PODS dx of distal left ureter transaction noted</td>
</tr>
<tr>
<td>4/16/10</td>
<td>Lina Loop broke, no current passing through loop—it tore into tissue and caused bleeding</td>
</tr>
<tr>
<td>6/25/10</td>
<td>Lina Loop did not cut and cautery—plume seen w/o tissue interaction—no injury noted</td>
</tr>
<tr>
<td>9/1/10</td>
<td>Lina Loop wire loop broke, pt had postop peritonitis, XL repair of bladder perforation</td>
</tr>
</tbody>
</table>
Maude Database

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/18/10</td>
<td>Lina Loop slipped and transected bowel in 2 places. Also loss of transection in left anterior thigh (possible transection of left lateral cutaneous nerve)</td>
</tr>
<tr>
<td>10/19/10</td>
<td>Lina Loop wire loop broke w/ risk of live wire—no injury noted</td>
</tr>
<tr>
<td>11/30/10</td>
<td>Lina Loop handle pulled off, and wire pulled out 2 inches—no injury noted</td>
</tr>
<tr>
<td>12/13/10</td>
<td>Lina Loop tip dislodged—no injury noted</td>
</tr>
<tr>
<td>12/6/10</td>
<td>Lina Loop piece of insulation attached, deployed w/o incident—no injury noted</td>
</tr>
<tr>
<td>12/17/10</td>
<td>Lina Loop broke w/ colon injury noted and repaired</td>
</tr>
<tr>
<td>5/17/11</td>
<td>Lap Loop wire broke/disengaged from screw end. Small bowel abrasion noted.</td>
</tr>
</tbody>
</table>

Summary

Lina Loop
- 2 bowel injuries
- 1 bladder injury
- 1 delayed dx or ureteral injury
- 6 loops broke

Lap Loop
- 1 bowel abrasion

FDA Device recall Database

- On June 28, 2011, 3 announcements were made
  - Voluntary class 2 recall

Total
- 27 Batches
- 2720 pieces

Areas affected: GA, MN, PA, WA, TN, MA, IN, Ontario Canada

Criticism

- Lower approval standard for devices
- Disparate technological characteristics
- Permissive interpretation of “same intended use”
- Failure to complete review of some devices
- Some devices have never been classified

Test Data

- 510(K) application submitted Jan 2007
- Description: The Lina Loop is a 5mm monopolar electrosurgical device intended for cutting and removal of soft tissue in gynecologic procedures involving endoscopic hysterectomy.
- Electrical testing which deems the Lina Loop to be safe under those conditions
- No clinical tests have been performed
- 510(K) premarket notification approved Oct 2007

Criticism

- Lower approval standard for devices
- Disparate technological characteristics
- Permissive interpretation of “same intended use”
- Failure to complete review of some devices
- Some devices have never been classified

“Substantial Equivalence”

- Relates to technological characteristics of a new device and its predicate

“Substantial Equivalence”

- Relates to technological characteristics of a new device and its predicate


http://www.laparoscopy.com
“Substantial Equivalence”

- Relates to technological characteristics of a new device and its predicate

Uterine manipulators

- Purpose:
  - Elevate, antevert, retrovert, and lateralize the uterus
  - Define the cervicovaginal junction
  - Distend the uterine fornices
  - Elevate the uterus to visualize the uterine arteries
  - Create a distance between the ureter and uterine arteries
  - Non conductive

Humi

Advantages
- Easy to place
- Minimal dilation

Disadvantages
- Disposable
- Pneumoperitoneum is not maintained
- Does not provide presentation of fornices
- However…

Uterine manipulators

Humi Rumi V-Care

- Elevate, antevert, retrovert, and lateralize the uterus
- Define the cervicovaginal junction
- Distend the uterine fornices
- Elevate the uterus to visualize the uterine arteries
- Create a distance between the ureter and uterine arteries
- Non conductive

http://www.gastrointestinalatlas.com
**Humi**

**Advantages**
- Easy to place
- Minimal dilation

**Disadvantages**
- Disposable
- Pneumoperitoneum is not maintained
- Does not provide presentation of fornices

**V-care**

**Advantages**
- Easy to place
- Wide range of uterine movements
- Pneumoperitoneum is maintained
- Easy to manipulate

**Disadvantages**
- Disposable
- May be too light for large uteri

**Rumi with Koh**

**Advantages**
- Excellent mobility (90-130 degrees)
- Pneumoperitoneum maintained
- Delineates fornices well
- Can be used w/ energy sources

**Disadvantages**
- Difficult to place
- Complex to assemble

**Steps for assembly**

1. Select tip
2. Select Koh
3. Insert to handle
4. Select size
5. Select size
6. Select size
7. Attach to handle
Comparison

<table>
<thead>
<tr>
<th>Device</th>
<th>Resusable</th>
<th>Anteversion/Retroversion</th>
<th>Lateral</th>
<th>Elevation</th>
<th>Vaginal fornices ID</th>
<th>Ease of use</th>
<th>Pneumoperitoneum Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rumi w/ Koh cup</td>
<td>++</td>
<td>++++</td>
<td>+++</td>
<td>++</td>
<td>++++</td>
<td>+</td>
<td>+++</td>
</tr>
<tr>
<td>Vcare</td>
<td>No</td>
<td>++</td>
<td>++</td>
<td>+++</td>
<td>++++</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>Humi</td>
<td>No</td>
<td>++</td>
<td>++</td>
<td>--</td>
<td>++</td>
<td>+</td>
<td>--</td>
</tr>
</tbody>
</table>

Cost

<table>
<thead>
<tr>
<th>Device</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humi</td>
<td>$30.75</td>
</tr>
<tr>
<td>Rumi</td>
<td>$43.87</td>
</tr>
<tr>
<td>Koh ring</td>
<td>$80.10</td>
</tr>
<tr>
<td>V care</td>
<td>$80.10</td>
</tr>
</tbody>
</table>

Alternatives

Maude Database

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>5/9/11</td>
<td>ConMed Vcare retained cup found at PO visit</td>
</tr>
<tr>
<td>5/16/11</td>
<td>ConMed Vcare handle broke</td>
</tr>
<tr>
<td>6/30/11</td>
<td>Spring loaded Rumi manipulator broke—spring lacerated patient</td>
</tr>
<tr>
<td>7/22/11</td>
<td>ConMed Vcare retained cup found on POD9</td>
</tr>
<tr>
<td>8/24/11</td>
<td>ConMed Vcare handle broke w/ maneuvers</td>
</tr>
</tbody>
</table>

Test Data

- 510(K) application submitted Nov 2009
- Description: The V-care Dx uterine manipulator is indicated for manipulation of the uterus and injection of fluids during laparoscopic gynecologic procedures...
- Performance testing, biocompatibility information, sterilization and labeling to address identified risks
- 510(K) premarket notification approved Feb 2010

“Substantial Equivalence”

- Relates to technological characteristics of a new device and its predicate

V-Care Uterine Dx Manipulator

“Substantial Equivalence”

- Relates to technological characteristics of a new device and its predicate

Rumi II
“Substantial Equivalence”

- Relates to technological characteristics of a new device and its predicate

Koh colpotomizer

Pneumo-occluder balloon

IOM

2009 FDA asked the Institute of Medicine to study the medical device approval pathways

1. Does the current 510k process protect patient optimally and promote innovation in support of public health?

2. If not, what legislative, regulatory or administrative changes are recommended to achieve the goals?

IOM Response

- “the current 510K process is flawed…
- rather than continuing to modify the 35 year-old 510k process…
- better invested in developing an integrated premarket and postmarket regulatory framework…
- that provides a reasonable assurance of safety and effectiveness”

Medical Devices and the Public’s Health: The FDA 510(k) Clearance Process at 35 Years
Released: July 29, 2011 Type: Consensus Report Topics: Public Health, Quality and Patient Safety
Activity: Public Health Effectiveness Board: Board on Population Health and Public Health Practice
In the news

CBC news:
Panel says medical device review system ‘flawed’
The Associated Press
Posted: Jul 29, 2011 12:01 PM ET

NY Times:
Study of Medical Device Rules Is Attacked, Unseen
By BARRY MEIER
Published: July 27, 2011

In Medicine, New Isn’t Always Improved
NY Times June 25, 2011

Conclusion

• Innovation
• Technological advances
• Tightened regulation
• Clinical trials

Ensured safety to support patient confidence
Re-evaluate the medical device process
Streamline the approach for low risk devices
Stricter standards in research

Our goal: To create safe and effective devices

• Clarify criteria for “same intended use” and “substantially equivalent”
• More involvement in post market surveillance
• Guidelines to enforce device recall
Sci-Fi Surgery: Medical Robots

Enter the world of medical robots where surgeons can operate without even touching their patients and visionary mini-robots will creep, crawl and swim around your body, diagnosing disease and performing vital surgery.

Sci-Fi Surgery: Medical Robots & Surgery Superhero
Manga Workshop
Sep. - Dec 09, London

http://robotcentral.com