Flexible Laparoscopy: A Paradigm Shift in Minimally Invasive Surgery

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Disclosures

• Allergan, Inc.
  – Faculty Member
  – Educational Consultant

• TransEnterix, Inc.
  – Clinical Advisory Board Member
  – Educational & Development Consultant
Goals & Objectives

- Discuss the clinical & market factors leading to development of flexible laparoscopy platform
- Review the current state of clinical applications of flexible laparoscopy
- Discuss future development & application
- Identify opportunities for multi-disciplinary clinical expansion
Innovation

An important aspect of medicine, especially in an academic setting, is self reflection, professional reassessment, and improvement of our art through a combination of science and innovation.
Innovation

• First came into modern use in 1540
  – Derives from the Latin *innovatio*, the noun of action from *innovare* "to renew or change"
  – Generally refers to the creation of better or more effective products, technologies, or ideas
  – Distinguished from renovation in that innovation generally signifies a substantial change versus more incremental changes

Wikipedia
Identifying Need

• Central tenet of clinical innovation
• Balancing safety and momentum with economic and market forces…
• Can we improve our clinical methods, instrumentation, or techniques to better serve our patients, and return them to health without compromising safety or outcomes?
Single site / incision access
Potential Benefits Include

• Decreased pain?
• Faster recovery?
• Better cosmetic results?
• Fewer potential complications?
• Discretion & privacy in bariatric patients?
Emerging Clinical Data …

• Outcomes: Superiority vs. Non-inferiority
• Cost: Higher operative costs, but assessing broad economic factors accurately remains difficult
• Learning curve: Remains a sticking point for many potential surgeons, teams, and programs
Ergonomic? Visualization? Trainable at all levels?
Introduction of Flexible Laparoscopy in Central Texas

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A New Class of Surgery: Flexible Laparoscopy

Single Port Instrument Delivery
Extended Reach
MIS Revolution #1

Cardiac Surgery → Interventional Cardiology

1990
553,000 CABGs (18)
300,000 PTCAs (14)
16 days in hospital (4)
42 days return to normal activity (19)

2005
427,000 CABGs (12)
900,000 PTCAs (13)
4.5 days in hospital (6)
7 days return to normal activity (20)
MIS Revolution #2 Neurosurgery → Interventional Neuroradiology

1990
8,000 open aneurysm surgeries (22)
50 interventional aneurysm procedures (22)

2005
7,000 open aneurysm surgeries (22)
5,000 interventional aneurysm procedures (22)
**MIS Revolution #3**

**Open Surgery → Traditional Laparoscopy**

<table>
<thead>
<tr>
<th>Year</th>
<th>Open Cholecystectomies</th>
<th>Laparoscopic Cholecystectomies</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1990</strong></td>
<td>450,000</td>
<td>50,000</td>
</tr>
<tr>
<td><strong>2005</strong></td>
<td>140,000</td>
<td>560,000</td>
</tr>
</tbody>
</table>
Today there are over 1 million LapChole's each year, nearly twice the number of open choles in 1985. Why?
Surgical Evolution

Open Surgery

Rigid Laparoscopy

Flexible Laparoscopy
How is *Flexible Laparoscopy* different?

<table>
<thead>
<tr>
<th>Rigid Laparoscopy</th>
<th>Flexible Laparoscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triangulation via multiple ports</td>
<td>Triangulation via single incision</td>
</tr>
<tr>
<td>Multiple operators</td>
<td>Single operator</td>
</tr>
<tr>
<td>Rigid, non-articulating instruments</td>
<td>Flexible articulating instruments</td>
</tr>
<tr>
<td>Multiple entry sites across abdomen</td>
<td>Single entry site at umbilicus</td>
</tr>
<tr>
<td>Loss of control of operative field</td>
<td>Control of operative field</td>
</tr>
<tr>
<td>Fulcrum effect with long instruments</td>
<td>No fulcrum effect at incision site</td>
</tr>
</tbody>
</table>
Strategic Hospital Opportunity

– Focus on High Impact Areas (Bariatrics)

– Improve Inward Patient Migration

– Increase Admissions & Referrals

– Improve Patient Care and Satisfaction

– S&W’s drive to remain among leading Hospitals in the U.S for Innovation and MIS Leadership
Focusing on Surgeons’ Feedback

• Triangulation
• Retraction
• Low Profile Port – Minimum 4 Working Channels
• Common Tools: Grasp, Clip, Cut, Dissect, Cautery, Suction / Irrigation
• Procedure Time – Comparable to Current Surgery
• No crossing of instruments
• Single Operator
SPIDER Overview

- True Left and Right Flex Ports
- North and South Channels
- Instrument Clamp
- Docking Ball
- Triangulation Ratchet
- 3 Pnuemo/Vac Ports
Flexible Instrumentation
Introduction to Flexible Laparoscopy
SPIDER Surgical Platform at Scott & White Memorial

- October 2009
  - Initial contact with TransEnterix at ACS in Chicago
- January 2010
  - On-site interview at Scott & White with our regional account representative Jeff Mountain
- February – April 2010
  - Application process for introducing SPIDER at S&W
  - VATS then New Technology committees
  - Internal financial impact projection lead to “trial period”
16 Facilities in the US at March 2010 launch
Two Texas Hospitals launched in 2010
SPIDER Surgical Platform at Scott & White Memorial

• May 5, 2010
  – First SPIDER procedure in TX and Southwestern USA
    • Young active woman
    • Excellent clinical and cosmetic result
    • Back to long distance running within 2 weeks
SPIDER Surgical Platform at Scott & White Memorial
Ongoing Platform Improvement

• Setup & docking
• Tear-away insertion sheath
• Extraction sheaths & specimen Bag
• Specific instrumentation improvements
  – Ratcheting handles
  – IDT responsiveness & strength
  – Effector strength, precision, & versatility
SPIDER Gen 2.0
Cholecystectomy
• Opportunities to expand limited incision laparoscopic surgery beyond the current demographic bounds
  – Higher BMI patients
  – Bariatric procedures
  – Multi-quadrant / multi-organ procedures
  – Potential for ease of training and application leading to increased adoption / utilization / access to care
SPIDER Surgical Platform at Scott & White Memorial

• June 6, 2010
  – First SPIDER Lap Band
    • Woman whose family had standard Lap Band
    • Very pleased with EWL, pain, and cosmesis
Laparoscopic Adjustable Gastric Banding

- A silicone band is placed around the upper part of the stomach
  - A small pouch is created
  - Stomach holds less food
  - Induces feeling of satiety
- Operating time = 1 hour
- Usually same day procedure
- Return to work in 1-2 weeks
Clinical Course by June 2012

- **Baseline:**
  - Preop weight was 216 pounds with a calculated BMI > 40
- **To achieve a BMI < 25**
  - Ideal weight is 134 pounds or 82 pound weight loss
- **One year postop:**
  - Weight was 160 #’s with a BMI of 29.9
  - 68.3% excess weight loss
- **Two years postop:**
  - Weight is 144 #’s with a BMI of 26.7
  - 87.8% excess weight loss
SPIDER Surgical Platform at Scott & White Memorial

- Clinical series to date
  - Careful selection given financial scrutiny
  - Diagnostic laparoscopy prior to deployment
  - 55 SPIDER Cholecystectomies
    - 1 conversion to multiport for choledocholithiasis
    - 1 conversion to open for biliary cancer
  - 4 SPIDER Lap Bands
    - 1 conversion to standard placement due to first generation left IDT joint failure
SPIDER Surgical Platform at Scott & White Memorial

- Ongoing Innovation
  - Colorectal applications
  - Gynecologic applications
  - Expanded bariatric applications
  - Multi-quadrant / multi-organ procedures
  - Cadaveric and invitro training development
First concurrent SPIDER ileoproctostomy & cholecystectomy
SPIDER Sleeve Gastrectomy
TransEnterix / SPIDER
Gyn/Colorectal Concept Lab

March 13, 2012
Temple College Simulation Lab
Temple, Texas
SPIDER Surgical Platform at Scott & White Memorial

• Challenges
  – Ongoing cost/impact analysis

• Hopes and plans for the future
  – Continue to broaden application beyond general and bariatric surgery in our system
  – Develop a regional multi-specialty training center for “flexible laparoscopy” and innovation
Questions?
Thank You

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Your choice. The trusted choice.