Advancements in Gynecologic Surgery

Presenter’s Name
Agenda

- Advancements in GYN Surgery
- What Procedures Do I Offer?
- Potential Patient Benefits & Risks
- Clinical Evidence
- Working Together
My Credentials

- Board certified OB/GYN since ___
  - [current title, fellowship training, hospital]

- Practicing robotic-assisted surgery since ___

- Completed ___ cases:
  - *da Vinci® Single-Site®* Hysterectomy ___
  - *da Vinci* multi-port procedures ___

[Please edit with your information and add the *da Vinci* procedures that you perform the most here]
Our Collective Goal: Patients First

- Care for patients’ overall, long-term health
  - Fibroids: 1 in 4 women\(^1\)
  - Endometriosis: 5+ million\(^2\)
  - Pelvic prolapse: 1 in 3 women with 1+ children\(^3\)
  - GYN cancer: 80,000 new cases/year\(^4\)

- Ensure patients are aware of all options for their conditions
  - Lifestyle changes
  - Medications
  - Hormone Therapy
  - Surgical options (e.g. hysterectomy by age 60: 1 in 3 women\(^5\) - 90% benign\(^6\))

- Provide the surgical options most appropriate for each patient

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4. CDC. http://www.cdc.gov/cancer/gynecologic/basic_info/index.htm  
Advancement Towards Less Invasive Surgery

Robotic-Assisted Surgery: Multi-port

Robotic-Assisted Surgery: Single-Site®

Abdominal (Open) Surgery

Vaginal Surgery

Laparoscopy

Single-Site® Instruments for the da Vinci® Si™ System bear the CE mark. This device is cleared for commercial distribution in the U.S. for laparoscopic cholecystectomy and hysterectomy and salpingo-oophorectomy for benign conditions.
Incision Comparison

One Large Incision
Open Hysterectomy

Multiple Small Incisions
Traditional Laparoscopic Hysterectomy

One Small Incision in the Belly Button
\textit{da Vinci}® Single-Site® Hysterectomy
\textit{da Vinci}® Single-Site® Hysterectomy
or
Traditional Laparoscopic Single Incision Hysterectomy
Why Have I Adopted *da Vinci®* Surgery?

- Have been skilled in Vaginal and Lap surgery since ____

- **XX% of my cases were still done Abdominally**
  - [please edit reasons why you couldn’t perform more MIS previously]
  - [e.g. cases too complex for lap or vaginal surgery]
  - [e.g. hard to access or suture with straight lap instruments]
  - [e.g. “shaky” camera view during lap surgery]
  - [......]
Why Have I Adopted da Vinci® Surgery? (Con’t)

- I want to offer minimally invasive surgery to my patients

[please double click the graph below to edit with your own data]
Compared to U.S. Adoption of MIS - Malignant Hyst.

U.S. MALIGNANT HYSTERECTOMY MARKET BY MODALITY
Estimated Adoption of Minimally Invasive Surgery (MIS)

Percentage of all procedures

- **OPEN**
  - Rapid decline
  - 92% in 2000, 88% in 2005, 80% in 2013

- **LAPAROSCOPY**
  - Rapid increase
  - 0.1% in 2005, 76% in 2013

- **VAGINAL**
  - Stable at 20%

**FDA clearance of da Vinci® Surgery GYN, 2005**

**IMPACT OF ROBOTIC-ASSISTED SURGERY:**
Prior to the introduction of robotics, most hysterectomies were performed using a large incision (open surgery). The overall rate of minimally invasive surgery (vaginal and laparoscopy) remained relatively unchanged.

Following the introduction of robotics (da Vinci Surgery), the rate of open surgery began to rapidly decline, while the rate of minimally invasive surgery (vaginal, laparoscopy and da Vinci Surgery) began to rise.

Today, open surgery is used in only about 20% of hysterectomies.

Intuitive Surgical, Inc.
PN 873930 rev F 4/2014

1. Inpatient data: Nationwide Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality
2. Outpatient data: Solucient® Database - Truven Health Analytics (Formerly Thomson-Reuters)
3. da Vinci data: ISI Internal Estimates
Compared to U.S. Adoption of MIS - Benign Hyst.

U.S. BENIGN HYSTERECTOMY MARKET BY MODALITY

Estimated Adoption of Minimally Invasive Surgery (MIS)

IMPACT OF ROBOTIC-ASSISTED SURGERY:
Prior to the introduction of robotics, most hysterectomies were performed using a large incision (open surgery). The overall rate of minimally invasive surgery (vaginal and laparoscopy) remained relatively unchanged.

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Today, open surgery is used in only about 20% of hysterectomies.

Intuitive Surgical, Inc.
PN 873931 rev F 4/2014

1. Inpatient data: Nationwide Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality
2. Outpatient data: Solucient® Database - Truven Health Analytics (Formerly Thomson-Reuters)
3. da Vinci data: ISI Internal Estimates
da Vinci® Surgery: How Does It Work?
*da Vinci®* Surgery: Over 3 Million Procedures Worldwide

**High Definition 3D Vision**
- Surgeon-controlled
- Stable and immersive view
- Up to 10x zoom

**Precision & Dexterity**
- Mimics surgeon’s hands
- Scales down movements
- With tremor filtration

**Intuitive® Motion**
- Advanced software enables intuitive control (instead of cross-handed)
**da Vinci® Single-Site® Surgery**

- Curved cannula & semi-rigid instruments
- Designed to limit cannula shift
- A single incision in the belly button

Access from many angles & instrument triangulation
Minimize potential port-site trauma & post-op pain\(^1\),\(^2\)
Virtually scarless\(^1\),\(^3\)

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Results, including cosmetic results, may vary.
*da Vinci®* Surgical Procedures That I Offer
I Offer These da Vinci® Surgical Procedures

Fibroids / Abnormal Uterine Bleeding
- Hysterectomy (Single-Site® or Multi-port)
- Myomectomy (uterine preservation)

Endometriosis
- Endometriosis Resection (with or without a Hysterectomy)

Pelvic Organ Prolapse
- Sacrocolpopexy (with or without a Hysterectomy)

GYN Cancer
- Hysterectomy with Lymphadenectomy (Multi-port only)

[Please edit to show the specific da Vinci procedure you offer]
Patient Selection for Referring GYN Patients to My Practice

Patient Selection:
Nearly every GYN patient in need of surgery, with the following conditions:

Conditions:
- Benign Pathology
  - Fibroids
  - Endometriosis
  - Pelvic Prolapse
  - Abnormal Uterine Bleeding
- Cancers
  - Cervical
  - Endometrial (Uterine)
  - Ovarian

Not Limited by:
- Incidence of prior surgeries
- Prior pelvic infection
- Large uteri
- Presence of single or multiple adnexal masses
# Patient Case: Hysterectomy [Template]

<table>
<thead>
<tr>
<th>Patient History</th>
<th>[Sex and Age]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[Diagnosis]</td>
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<tr>
<td></td>
<td>[Condition]</td>
</tr>
<tr>
<td></td>
<td>[Symptoms]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-Surgical options</th>
<th>[Has your patient tried non-surgical options]</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>[Has your patient taken OTC pain medication to relieve pain when needed]</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Concerns</th>
<th>[Concern 1]</th>
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<tbody>
<tr>
<td></td>
<td>[Concern 2]</td>
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<tr>
<td></td>
<td>[Concern 3]</td>
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<table>
<thead>
<tr>
<th>Post-op</th>
<th>Hospital LOS: _____ hours/days</th>
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<tr>
<td></td>
<td>Return to normal activities: in _____ days</td>
</tr>
<tr>
<td></td>
<td>Currently: _____ (e.g. disease and complication free)</td>
</tr>
</tbody>
</table>

*da Vinci® Hysterectomy*

[Please add/replace content in brackets with your own patient case data]
Potential Patient Benefits & Risks
Potential Patient Benefits & Risks
da Vinci® Hysterectomy (Benign)

**da Vinci Hysterectomy (Benign)**

**Potential Patient Benefits**

vs. Open Surgery
- Reduced complication rate\(^1, 2, 3, 9\)
- Reduced length of hospital stay\(^1, 2, 3, 4, 9\)
- Reduced blood loss and less likelihood for transfusion\(^1, 3, 4, 9\)
- Reduced readmission rate\(^4, 9\)

vs. Traditional Laparoscopic Surgery
- Reduced complication rate\(^1, 5, 9\)
- Reduced length of hospital stay\(^1, 2, 4, 5, 6, 7, 9\)
- Reduced blood loss\(^1, 2, 4, 7\)
- Reduced chance of procedure converting to an abdominal procedure\(^2, 5\)
- Less likelihood of blood transfusion\(^8, 9\)

vs. Vaginal Surgery
- Reduced length of hospital stay\(^2, 4, 9\)
- Reduced blood loss\(^2, 4\)

**Hysterectomy, incl. da Vinci Hyst.**

**Potential Patient Risks**

- Injury to the ureters (the ureters drain urine from the kidney into the bladder)
- Vaginal cuff problems (scar tissue in vaginal incision, infection, bacterial skin infection, pooling/clotting of blood, incision opens or separates)
- Injury to bladder (organ that holds urine), bowel injury, vaginal shortening, problems urinating (cannot empty bladder, urgent or frequent need to urinate, leaking urine, slow or weak stream)
- Abnormal hole from the vagina into the urinary tract or rectum, vaginal tear or deep cut.
- Uterine tissue may contain unsuspected cancer. The cutting or morcellation of uterine tissue during surgery may spread cancer, and decrease the long-term survival of patients.

See the last slide for references.
Potential Patient Benefits & Risks
da Vinci® Single-Site® Benign Hysterectomy

**da Vinci Single-Site Benign Hysterectomy**

Potential Patient Benefits

- Early clinical data suggests:
  - Low blood loss\(^{10,11,12,13}\)
  - Low complication rate\(^{10,11}\)
  - Low likelihood of blood transfusion\(^{11}\)
  - Low chance of procedure converting to an abdominal procedure\(^{11,12,13}\)
  - Short hospital stay\(^{11,12}\)
  - Low post-operative pain\(^{13}\)

Hysterectomy, incl. da Vinci Hyst.

Potential Patient Risks

- Injury to the ureters (the ureters drain urine from the kidney into the bladder)
- Vaginal cuff problem (replaces cervix): scar tissue in vaginal incision, infection, bacterial skin infection, pooling/clotting of blood, incision opens or separates
- Injury to bladder (organ that holds urine), bowel injury, vaginal shortening, problems urinating (cannot empty bladder, urgent or frequent need to urinate, leaking urine, slow or weak stream)
- Abnormal hole from the vagina into the urinary tract or rectum, vaginal tear or deep cut.
- Uterine tissue may contain unsuspected cancer. The cutting or morcellation of uterine tissue during surgery may spread cancer, and decrease the long-term survival of patients.

See the last slide for references.
**Potential Patient Benefits & Risks**

**da Vinci® Myomectomy**

### da Vinci Myomectomy Potential Patient Benefits

**vs. Open Surgery**
- Similar rate of complications\(^1\)
- Shorter hospital stay\(^1,14,15,16\)
- Lower rate of blood transfusions\(^1,14,16\)
- Less blood loss\(^1,14,15,16\)
- Less chance of post-operative fever \(^1\)

**vs. Traditional Laparoscopic Surgery**
- Similar rate of complications\(^1,14,16,17\)
- Similar hospital stay\(^1,14,16,17\)
- Similar conversion rate (switch to open surgery)\(^1,14,15,17\)
- Similar or less blood loss\(^1,14,15,17\)

### Myomectomy, incl. da Vinci Myomectomy Potential Patient Risks

- Tear or hole in uterus
- Split or bursting of the uterus
- Pre-term (early) birth
- Spontaneous abortion
- Uterine tissue may contain unsuspected cancer. The cutting or morcellation of uterine or fibroid tissue during surgery may spread cancer, and decrease the long-term survival of patients.

See the last slide for references.
**Potential Patient Benefits & Risks**

*da Vinci® Sacrocolpopexy*

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**da Vinci Sacrocolpopexy**

**Potential Patient Benefits**

- vs. Open Surgery
  - Lower rates of complications ¹⁸,¹⁹
  - Reduced estimated blood loss ¹⁸,¹⁹,²⁰
  - Comparable rates of blood transfusions ¹⁸
  - Shorter length of hospital stay ¹⁸

- vs. Traditional Laparoscopic Surgery
  - Comparable rates of complications ¹⁸,¹⁹,²¹,²²
  - Comparable rates of blood transfusions ¹⁸,²¹
  - Comparable or shorter length of hospital stay ¹⁸,¹⁹,²²,²³
  - Comparable conversion rate ¹⁸,¹⁹,²³
  - Comparable or reduced estimated blood loss ¹⁸,¹⁹,²¹

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**Sacrocolpopexy, incl. da Vinci Sacrocolpopexy**

**Potential Patient Risks**

- Mesh erosion/infection caused by mesh moving from vaginal wall into surrounding organs causing the need for another operation
- Injury to rectum/bowel, injury to bladder (organ that holds urine), injury to the ureters (the ureters drain urine from the kidney into the bladder)
- Front wall of the rectum pushes into the back wall of the vagina
- Prolapsed bladder (bladder budges into vagina when supportive tissue weakens)
- Vaginal incision opens or separates, loss of bladder control, pooling of blood between bladder and pubic bone, pooling of blood between the anus and vagina.

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See the last slide for references.
**Potential Patient Benefits & Risks**

**da Vinci® Endometriosis Resection**

**da Vinci Endometriosis Resection Potential Patient Benefits**

Early Clinical Data Suggest:

- Ability for surgeon to complete difficult dissections (separating of tissue)\(^{24,25,26}\)
- Low rate of complications\(^{24,26,27,28}\)
- Low blood loss\(^{26,28,30,31}\) and low chance for blood transfusion\(^{26,28}\)
- Low rate of switching to open surgery (through a large incision)\(^{24,26,29,30}\)

**Endometriosis Resection, incl. da Vinci Endo Resection Potential Patient Risks**

- Injury to the bowel, bladder (organ that holds urine) or ureters (the ureters drain urine from the kidney into the bladder)

See the last slide for references.
Potential Patient Benefits & Risks
da Vinci® Hysterectomy (Cancer)

*da Vinci* Hysterectomy (Simple Total) for Cancer

Potential Patient Benefits

vs. Open Surgery
- Fewer complications 32,33,34,35
- Fewer blood transfusions 32,33,34,35
- Shorter length of stay 32,33,34,35,36
- Reduced estimated blood loss 32,33,34,35,36

vs. Traditional Laparoscopic Surgery
- Comparable or fewer complications 32,33,34,35,36
- Comparable or fewer blood transfusions 32,33,34,35,36
- Comparable or shorter length of stay 32,33,34,35,36
- Comparable operative time 32,33,34,35,36
- Comparable or lower conversion rates 32,33,34,35,36
- Reduced estimated blood loss 32,33,34,35,36

Potential Patient Risks

- Injury to the ureters (the ureters drain urine from the kidney into the bladder)
- Vaginal cuff problem (replaces cervix): scar tissue in vaginal incision, infection, bacterial skin infection, pooling/clotting of blood, incision opens or separates
- Injury to bladder (organ that holds urine), bowel injury, vaginal shortening, problems urinating (cannot empty bladder, urgent or frequent need to urinate, leaking urine, slow or weak stream)
- Abnormal hole from the vagina into the urinary tract or rectum, vaginal tear or deep cut

See the last slide for references.
Clinical Evidence
Multicenter analysis comparing robotic, open, laparoscopic, and vaginal hysterectomies performed by high-volume surgeons for benign indications

Peter C. Lim, John T. Crane, Eric J. English, Richard W. Farnam, Devin M. Garza, Marc L. Winter, Jerry L. Rozeboom

<table>
<thead>
<tr>
<th></th>
<th>Robotic-Assisted (n = 2300)</th>
<th>Abdominal (n = 9745)</th>
<th>Vaginal (n = 8121)</th>
<th>Laparoscopic (n = 11952)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>49.3 ± 11.5</td>
<td>46.7 ± 10.7*</td>
<td>48.7 ± 13.3*</td>
<td>43.9 ± 9.4*</td>
</tr>
<tr>
<td>Large uterus (&gt;250g)</td>
<td>366 (15.9%)</td>
<td>368 (3.8%)*</td>
<td>589 (7.3%)*</td>
<td>1,671 (14%)*</td>
</tr>
<tr>
<td>Intraoperative complications</td>
<td>17 (0.7%)</td>
<td>174 (1.8%)*</td>
<td>142 (1.8%)*</td>
<td>142 (1.2%)</td>
</tr>
<tr>
<td>Postoperative complications</td>
<td>131 (6.3%)</td>
<td>2,047 (21%)*</td>
<td>1,314 (16.2%)*</td>
<td>1,953 (16.3%)*</td>
</tr>
<tr>
<td>Conversion to open surgery</td>
<td>2 (0.1%)</td>
<td>NA</td>
<td>1 (0.0%)</td>
<td>11 (0.1%)</td>
</tr>
<tr>
<td>Inpatient length of stay (days)</td>
<td>1.37 ± 1.1</td>
<td>3.0 ± 1.6*</td>
<td>1.9 ± 1.0*</td>
<td>1.7 ± 1.2*</td>
</tr>
<tr>
<td>Hospital readmission (related to index surgery)</td>
<td>28 (1.3%)</td>
<td>340 (3.5%)*</td>
<td>130 (1.6%)</td>
<td>186 (1.6%)</td>
</tr>
<tr>
<td>Reoperation rate</td>
<td>17 (0.8%)</td>
<td>187 (1.9%)*</td>
<td>84 (1.0%)</td>
<td>118 (1.0%)</td>
</tr>
</tbody>
</table>

Robotic patients had:
- Larger uteri
- Fewer complications
- Shorter hospital stay
- Similar conversions, readmissions & reoperation rate as other MIS approaches

In this study, two sided p < 0.05 was considered significant. * Indicates statistically significant difference (p<0.05) versus robotic-assisted hysterectomy.

Study limitations: Retrospective data review—missing data is a common, inherent limitation of retrospective data collection; The Premier database relies on ICD-9-CM diagnostic and procedure codes; there is a potential for miscoding.; If patients were readmitted to non-Premier hospitals, patient readmission data could have been lost, which raises the potential for under-reporting. The length of stay for outpatients was not available in the Premier database.

Financial disclosure: This study was funded by Intuitive Surgical for independent research and editorial support Dr. Lim, Dr. Crane, Dr. English, Dr. Farnam, Dr. Garza, Dr. Winter, and Dr. Rozeboom have received compensation from Intuitive Surgical for consulting and/or educational services.

Lim PC, et al, Multicenter analysis comparing robotic, open, laparoscopic, and vaginal hysterectomies performed by high-volume surgeons for benign indications, Int J Gynecol Obstet (2016), http://dx.doi.org/10.1016/j.ijgo.2015.11.010
A Comparison of Quality Outcome Measures in Patients Having a Hysterectomy for Benign Disease: Robotic vs. Non-robotic Approaches


Study limitations: Retrospective data review, single institution experience, inability to account for patients who were readmitted to outside hospitals (though the authors state that this finding was expected to be similar for all 4 cohorts)

Financial disclosure: “Dr. Martino has received travel reimbursement from Intuitive Surgical for educational research.”

Compared to non-robotic approaches:
- Less blood loss
- Shorter hospital stay
- Lower rate of <30-day readmission
- Significant readmission related cost savings

<table>
<thead>
<tr>
<th></th>
<th>Robotic-assisted (N=601)</th>
<th>Laparoscopic (N=427)</th>
<th>Abdominal (Open) (N=1,194)</th>
<th>Vaginal (N=332)</th>
<th>p-Value (non-robotic vs. robotic-assisted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Estimated Blood Loss (mL)</td>
<td>108.2</td>
<td>315.08</td>
<td>318.8</td>
<td>340.8</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Mean Length of Stay (minutes)</td>
<td>1570.3</td>
<td>3038.5</td>
<td>3440.5</td>
<td>3789.2</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Total Readmissions &lt;30 days (Total No.)</td>
<td>1.00% (6)</td>
<td>2.58% (11)</td>
<td>3.52% (42)</td>
<td>2.41% (8)</td>
<td>≤0.03</td>
</tr>
<tr>
<td>Total Readmission Cost (adjusted for inflation to 2012 $)</td>
<td>$32,946</td>
<td>$50,290</td>
<td>$328,230</td>
<td>$51,264</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>
The MISC group had shorter hospitalization, less blood loss, but longer operative times compared with ASC group.

LSC was associated with more complications compared with RSC. Patients who underwent LSC were more likely to have their procedure converted to open.

Study limitations: Retrospective study; study investigators used a composite complication score which may not account for all adverse events; definition of failure did not include subjective data which were inconsistently available.

Financial disclosure: None

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<table>
<thead>
<tr>
<th>Intraoperative &amp; Postoperative Complications</th>
<th>ASC (n=589)</th>
<th>MISC (n=535)</th>
<th>P-Value</th>
<th>LSC (n=273)</th>
<th>RSC (n=262)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Complications</td>
<td>20%</td>
<td>12.7%</td>
<td>&lt;0.01</td>
<td>18%</td>
<td>7%</td>
<td>&lt;0.01</td>
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<tr>
<td>Cystotomy</td>
<td>4%</td>
<td>2%</td>
<td>&lt;0.01</td>
<td>2.5%</td>
<td>1.5%</td>
<td>0.7</td>
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<tr>
<td>DVT/PE</td>
<td>1.5%</td>
<td>1%</td>
<td>0.3</td>
<td>3%</td>
<td>0.0%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Ileus/SBO</td>
<td>5%</td>
<td>2%</td>
<td>&lt;0.01</td>
<td>1.8%</td>
<td>1.5%</td>
<td>1</td>
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<tr>
<td>Conversion to Open</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>4%</td>
<td>0.4%</td>
<td>&lt;0.01</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Anatomical Failure</th>
<th>ASC</th>
<th>MISC</th>
<th>P-Value</th>
<th>LSC</th>
<th>RSC</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At or beyond hymen</td>
<td>15.1%</td>
<td>7.4%</td>
<td>&lt;0.001</td>
<td>6.5%</td>
<td>8.4%</td>
<td>0.49</td>
</tr>
<tr>
<td>Stage 2 or higher</td>
<td>25.3%</td>
<td>14.2%</td>
<td>&lt;0.001</td>
<td>11.3%</td>
<td>17.2%</td>
<td>0.069</td>
</tr>
</tbody>
</table>

ASC=abdominal sacrocolpopexy, MISC=minimally invasive sacrocolpopexy, LSC=laparoscopic sacrocolpopexy, RSC=robotic sacrocolpopexy
## Robotic-Assisted, Laparoscopic, and Abdominal Myomectomy: A Comparison of Surgical Outcomes

Ehab E. Barakat, MD, Mohamed A. Bedaiwy, MD, Stephen Zimberg, MD, Benjamin Nutter, Mohsen Nosseir, MD, and Tommaso Falcone, MD

<table>
<thead>
<tr>
<th></th>
<th>Abdominal (N=393)</th>
<th>Lap (N=93)</th>
<th>Robotic (N=89)</th>
<th>P-Value</th>
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</thead>
<tbody>
<tr>
<td>Surgical Time (min)</td>
<td>126</td>
<td>155</td>
<td>181</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Open vs. Robotic=.003</td>
<td>Lap vs. Robotic=.083</td>
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<tr>
<td>Myoma Weight (g)</td>
<td>263.00</td>
<td>96.65</td>
<td>223.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Open vs. Robotic=.36</td>
<td>Lap vs. Robotic=.021</td>
<td></td>
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<tr>
<td>Estimated Blood Loss (mL)</td>
<td>200</td>
<td>150</td>
<td>100</td>
<td></td>
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<tr>
<td></td>
<td>Open vs. Robotic&lt;.001</td>
<td>Lap vs. Robotic=.818</td>
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<tr>
<td>Hemoglobin Drop (g/dL)</td>
<td>2.00</td>
<td>1.55</td>
<td>1.30</td>
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<tr>
<td></td>
<td>Open vs. Robotic&lt;.001</td>
<td>Lap vs. Robotic=.431</td>
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<tr>
<td>Length of Hospital Stay (days)</td>
<td>3</td>
<td>1</td>
<td>1</td>
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<tr>
<td></td>
<td>Open vs. Robotic&lt;.001</td>
<td>Lap vs. Robotic=.506</td>
<td></td>
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</tr>
</tbody>
</table>

**Compared to Lap:**
- Bigger myomas can be removed

**Compared to open surgery:**
- Less blood loss
- Less hemoglobin drop
- Shorter hospital stay

**Study limitations:** Retrospective, Lack of long-term outcomes

**Financial disclosure:** None.

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Histological confirmation of endometriosis was significantly higher for the robotic cohort, suggesting robot-assisted techniques may provide more accurate visualization and, thus, excision of existing endometriosis.

**Study limitations:** Retrospective, single surgeon experience, lack of validated and longer-term outcome measures

**Financial disclosure:** Dr. Dulemba has received compensation from Intuitive Surgical for consulting and/or educational services.

A comparative study of 3 surgical methods for hysterectomy with staging for endometrial cancer: robotic assistance, laparoscopy, laparotomy

John F. Boggess, MD; Paola A. Gehrig, MD; Leigh Cantrell, MD; Aaron Shafer, MD; Mildred Ridgway, MD; Elizabeth N. Skinner, MD; Wesley C. Fowler, MD

OCTOBER 2008

<table>
<thead>
<tr>
<th>Open (n=138)</th>
<th>Lap (n=81)</th>
<th>Robotic (n=103)</th>
<th>p-Value</th>
</tr>
</thead>
</table>
| Mean age (years) | 64.0 | 62.0 | 61.9 | Open vs. dV=.06  
Lap vs. dV=.95 |
| Mean BMI (kg/m²) | 34.7 | 29.0 | 32.9 | Open vs. dV=.17  
Lap vs. dV=.0008 |
| Mean EBL (ml) | 266.0 | 145.8 | 74.5 | Open vs. dV<.0001  
Lap vs. dV<.0001 |
| Mean operative time (skin-to-skin) (min) | 146.5 | 213.4 | 191.2 | Open vs. dV<.0001  
Lap vs. dV<.0001 |
| Mean total lymph nodes (n) | 14.9 | 23.1 | 32.9 | Open vs. dV<.0001  
Lap vs. dV<.0001 |
| Mean hospital stay (days) | 4.4 | 1.2 | 1.0 | Open vs. dV<.0001  
Lap vs. dV=.001 |
| Complications | 29.7% | 13.6% | 5.8% | Open vs. dV<.0001  
Lap vs. dV<.0001 |
| Conversions to Open | --- | 4.9% | 2.9% | Lap vs. dV=.7 |

Compared to open surgery:
- Fewer complications

Compared to open and lap surgery:
- Less blood loss
- Higher lymph node yield
- Shorter hospital stay

Study limitations discussed by the authors: “it was not randomized; because of our relatively recent incorporation of robotic technology, we could not examine long-term oncologic results.”

Financial disclosure: None were included in the publication.

What Can We Do Together?

- Identify patients at risk
- Discuss all non-surgical & surgical options with patients
- Refer to specialists, as needed
- Introduce MIS as a surgical option, as appropriate
- Pre- & post-op consultation
- Improve Patient Satisfaction
- Return patients to you for long-term care
My Contact Information:

[Surgeon’s Name]
[Address]
[Phone]
[Email]

[Contact Name for managing referrals]
[Website]
Important Safety Information

Serious complications may occur in any surgery, including da Vinci® Surgery, up to and including death. Examples of serious and life-threatening complications, which may require prolonged and/or unexpected hospitalization and/or reoperation, include, but are not limited to, one or more of the following:

• Injury to tissues and/or organs
• Bleeding
• Infection
• Internal scarring that can cause long-lasting dysfunction or pain

Patients should consider that risks of any surgery also include, but are not limited to, the following:

• Potential for human error
• Potential for equipment failure
• Potential for anesthesia complications

Individual surgical results may vary.

Risks specific to minimally invasive surgery, including da Vinci Surgery, include, but are not
Important Safety Information

limited to, the following:
• Temporary pain and/or nerve injury associated with positioning;
• Temporary pain and/or discomfort from the use of air or gas in the procedure;
• A longer operative time and time under anesthesia;
• The need to convert the procedure to an open surgery;
• Converting the procedure could result in a longer operative time, a longer time under anesthesia, and/or the need for additional or larger incisions and/or increased complications.

Medical Advice & Surgeon Training
Patients should talk to their doctor to decide if da Vinci Surgery is right for them. Other options may be available and appropriate. Only a doctor can determine whether da Vinci Surgery is appropriate for a patient’s situation. Patients and doctors should review all available information on both non-surgical and surgical options in order to make an informed decision.

Only surgeons who have received specific training in the use of the da Vinci Surgical System should use the system. Training provided by Intuitive Surgical is limited to the use of its products and does not replace the necessary medical training and experience required to
Important Safety Information

perform surgery.

da Vinci System Description
There are several models of the da Vinci Surgical System. The da Vinci Surgical Systems are designed to help doctors perform minimally invasive surgery. The da Vinci Surgical System is not programmed to perform surgery on its own. Instead, the surgery is performed entirely by a doctor, who controls the system. da Vinci Systems offer doctors high-definition 3D vision, a magnified view, and robotic and computer assistance. They use specialized instrumentation, including a miniaturized surgical camera and wristed instruments (i.e., scissors, scalpels and forceps) – that are designed to help with precise dissection and reconstruction deep inside the body.

When is the da Vinci System Used?
One or more of the da Vinci Surgical System models are commercially available for use in the following specialty areas.

• Urologic surgery
• General laparoscopic surgery
• Gynecologic surgery
• Transoral robotic surgery restricted to benign (non-cancer) and malignant tumors (cancer) classified as T1 and T2 (early stage cancer) and for benign base of tongue
Important Safety Information

- resection procedures. * The safety and effectiveness of this device for use in the options of obstructive sleep apnea have not been established.
- Thoracic surgery
- Heart surgery

*Not cleared for use with the da Vinci Xi Surgical System.

When the *da Vinci* System Is Not Used?
Patients who are not candidates for non-robotic minimally invasive surgery are also not candidates for *da Vinci* Surgery.

More information about the *da Vinci* System and Locating a Doctor
If you have questions about the *da Vinci* System or *da Vinci* procedures, consult with a qualified surgeon. Surgeons experienced with the *da Vinci* System can be found using the Surgeon Locator at www.davincisurgery.com. Intuitive Surgical provides surgeons training on the use of the *da Vinci* System but does not certify, credential or qualify the surgeons listed in the Surgeon Locator.

When is *Single-Site* Used and What are the Risks?
*da Vinci* Surgery with *Single-Site*® Instruments is cleared for use in gallbladder removal, and for
Important Safety Information

Hysterectomy and ovary removal for benign conditions. Patients who are not candidates for non-robotic minimally invasive surgery are also not candidates for da Vinci Surgery, including da Vinci Surgery with Single-Site® Instruments. There may be an increased risk of incision-site hernia with single-incision surgery, including Single-Site surgery with da Vinci.

Precaution
The demonstration of safety and effectiveness for the specific procedure(s) discussed in this material was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence) or treatment of the patient’s underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.

Spontaneous opinions expressed during live presentations by individual doctors or patients belong to those individuals. These opinions are not necessarily shared by Intuitive Surgical, Inc.

Intraoperative video, including video labeled as showing full-length procedures, may have been edited for content, for length or to meet file-size limitations.
Thank You!

[name]
[practice name]
[phone]
[email]
[website]
References:


References, cont.

References:
My Results: [Procedure]

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