Advancements in Gynecologic Surgery

Presenter's Name

1007142 Rev. C 09/16

Agenda

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

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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

1. U.S. Department of Health and Human Services, Office of Women's Health. The Healthy Woman: A Complete Guide for All Ages.
2. Office on Women's Health. http://www.womenshealth.gov/publications/our-publications/fact-sheet/endometriosis.pdf **3.** International Urogynecologic Association. Pelvic Organ Prolapse: A Guide for Women. 2011 **4.** CDC. http://www.cdc.gov/cancer/gynecologic/basic_info/index.htm
5. NIH. http://www.nlm.nih.gov/medlineplus/hysterectomy.html **6.** American College of Surgeons. About Hysterectomy: Surgical removal of the uterus, or womb.

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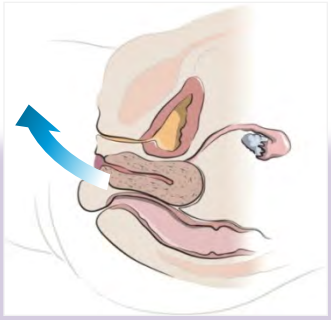
Advancement Towards Less Invasive Surgery

Abdominal (Open) Surgery



Vaginal Surgery

Laparoscopy

Robotic-Assisted Surgery: Multi-port

Robotic-Assisted Surgery: *Single-Site*®

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.

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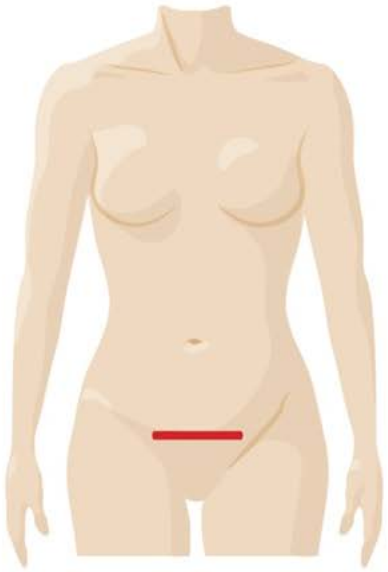
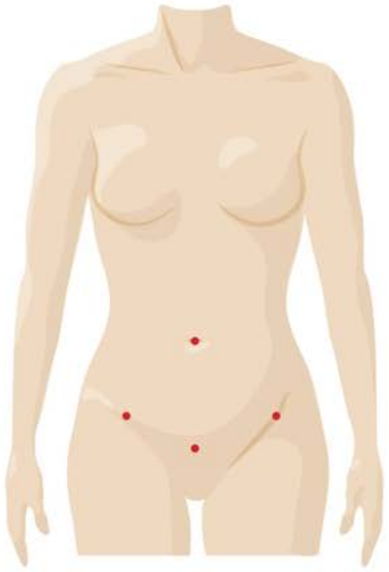
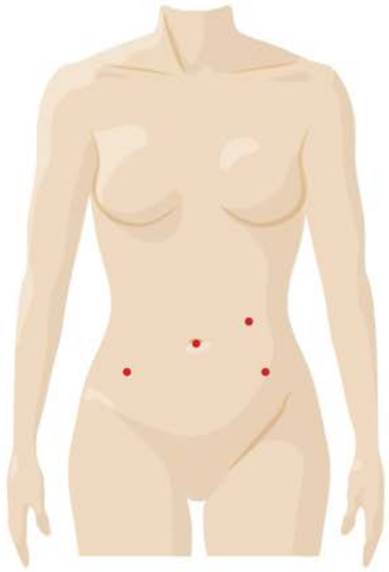
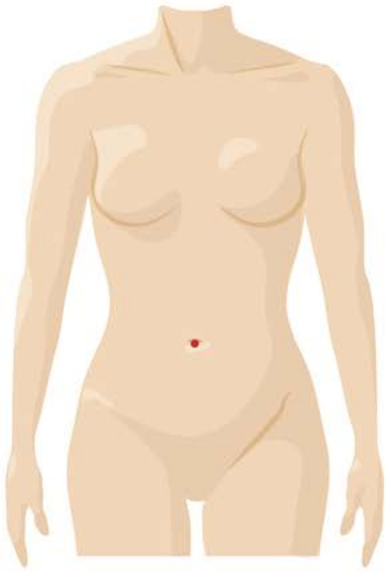
Incision Comparison









One Large Incision	Multiple Small Incisions		One Small Incision in the Belly Button
Open Hysterectomy	Traditional Laparoscopic Hysterectomy	*da Vinci*® Hysterectomy: Multi-port	*da Vinci*® *Single-Site*® Hysterectomy or Traditional Laparoscopic Single Incision Hysterectomy

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Why Have I Adopted *da Vinci*® Surgery?

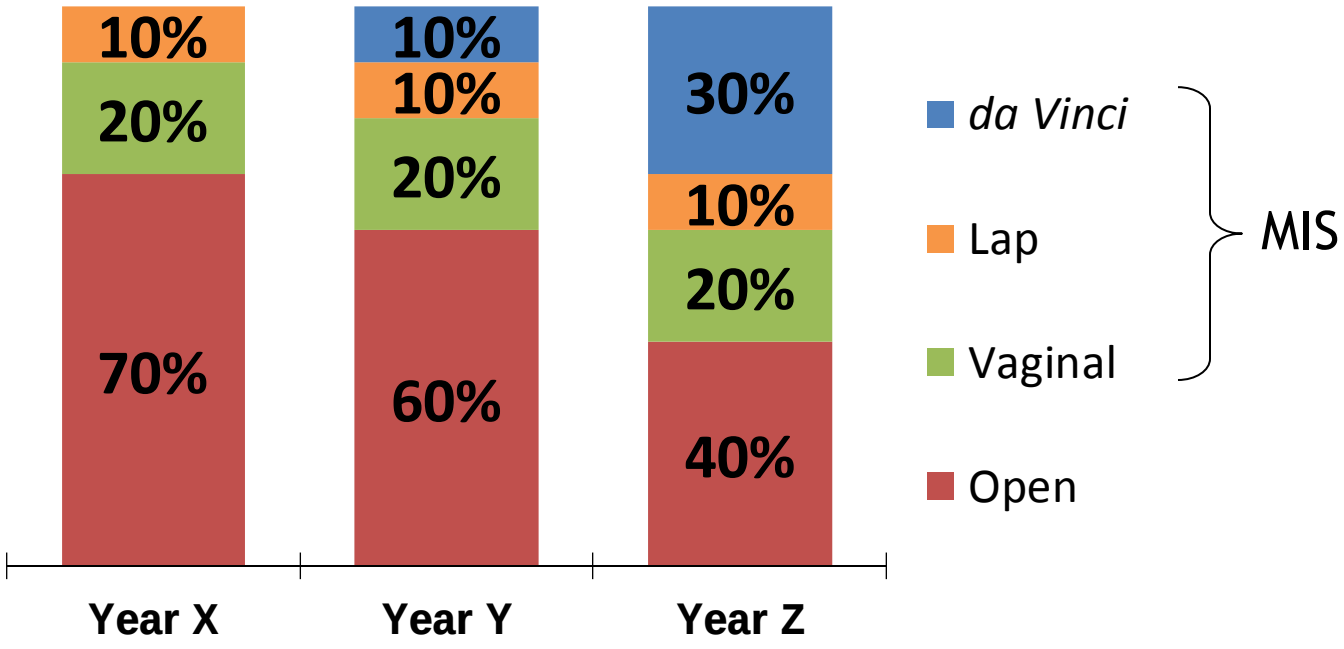
- Have been skilled in Vaginal and Lap surgery since _____

- 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

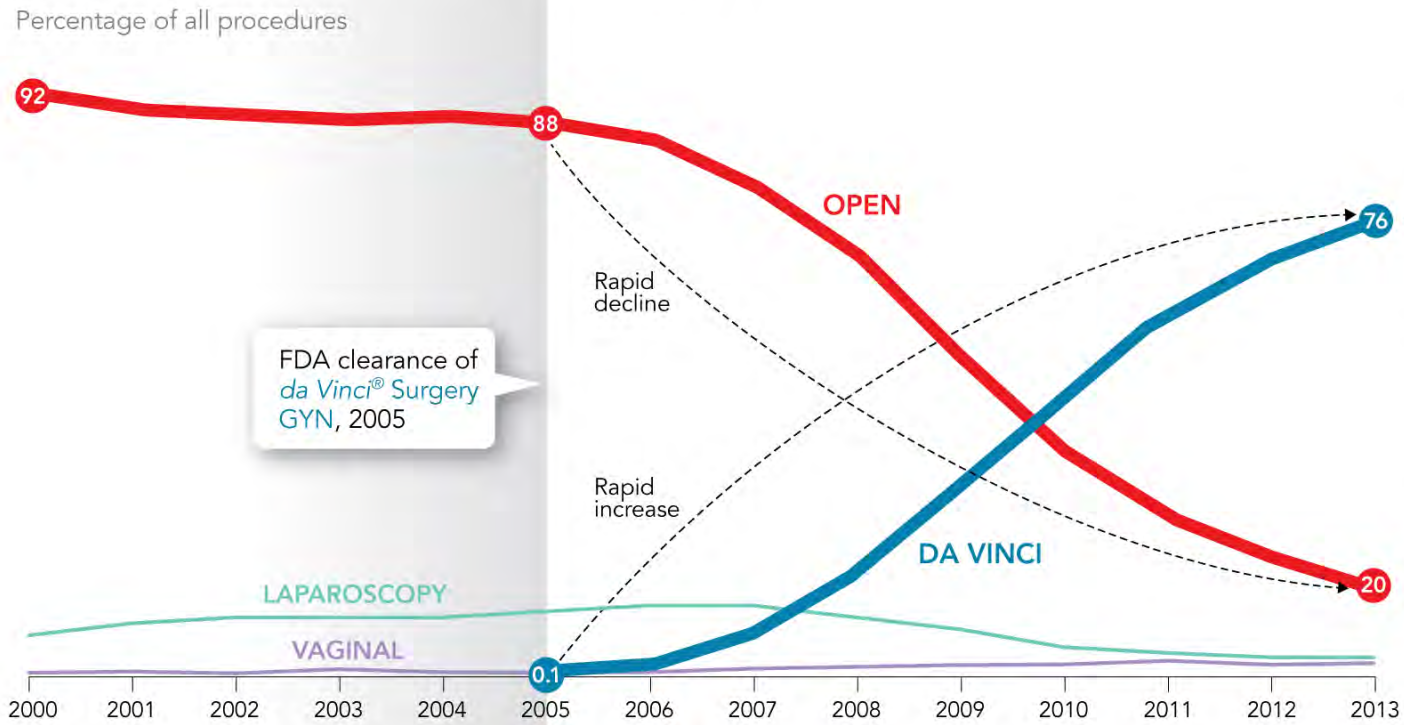
[please double click the graph below to edit with your own data]



Compared to
U.S. Adoption of MIS – Malignant Hyst.

U.S. MALIGNANT HYSTERECTOMY MARKET BY MODALITY

Estimated Adoption of Minimally Invasive Surgery (MIS)



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

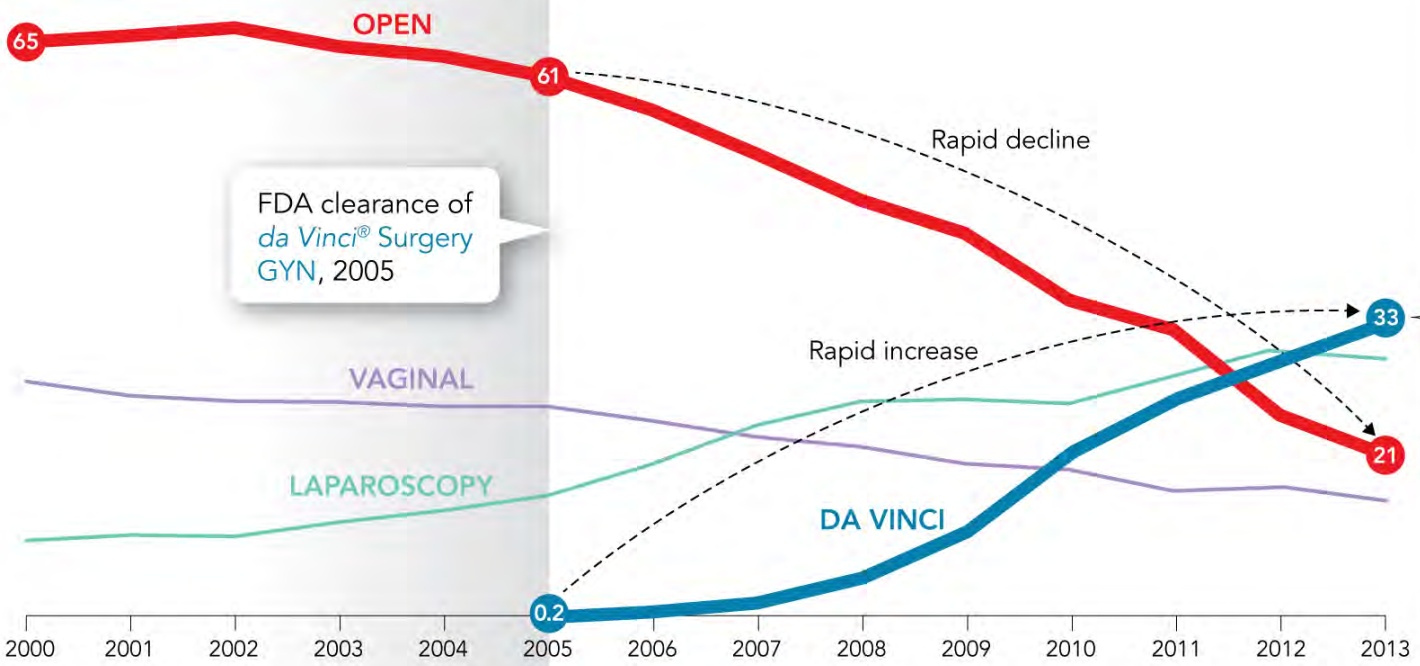
1. Inpatient data: Nationwide Inpatient Sample (NIS), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality
2. Outpatient data: Solucient® Database - Truven Health Analytics (Formerly Thomson-Reuters) 3. *da Vinci* data: ISI Internal Estimates

Compared to
U.S. Adoption of MIS – Benign Hyst.

U.S. BENIGN HYSTERECTOMY MARKET BY MODALITY

Estimated Adoption of Minimally Invasive Surgery (MIS)

Percentage of all procedures



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

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

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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?

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da Vinci® Surgery: Over 3 Million Procedures Worldwide

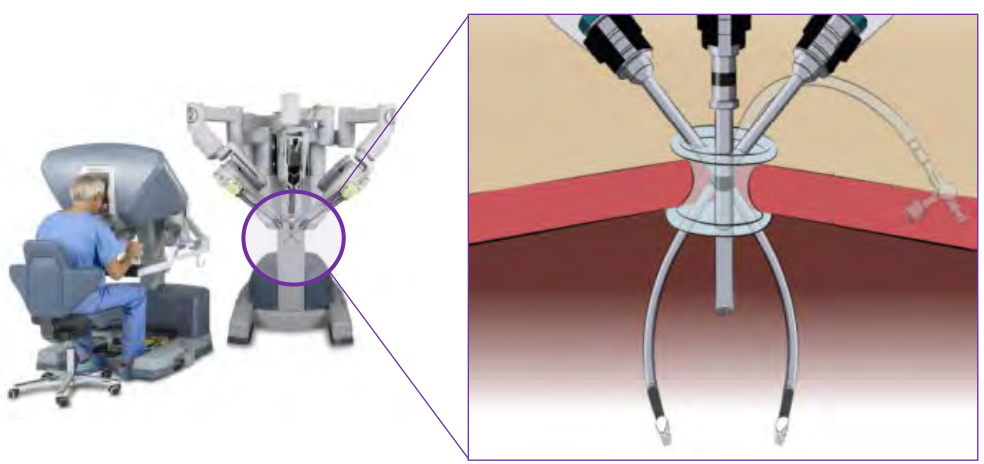
High Definition 3D Vision
- Surgeon-controlled
- Stable and immersive view
- Up to 10x zoom

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 → Access from many angles & instrument triangulation
- Designed to limit cannula shift → Minimize potential port-site trauma & post-op pain[1,2]
- A single incision in the belly button → Virtually scarless[1,3]



Results, including cosmetic results, may vary.

1. Kroh M, *et al*. First human surgery with a novel single-port robotic system: cholecystectomy using the *da Vinci Single-Site* Platform. Surg Endosc. 2011 Nov;25(11):3566-73. Epub 2011 Jun 3rd. 2. Wren SM, Curet MJ. Single-port robotic cholecystectomy results from a first human use clinical study of the new *da Vinci Single-Site* surgical platform. Arch Surg, Jun 2011; doi: 10.1001/archsurg.2011.143 3. Cela V, Freschi L, Simi G, Ruggiero M, Tana R, Pluchino N. Robotic single-site hysterectomy: feasibility, learning curve and surgical outcome. Surg Endosc. 2013 Jul;27(7):2638-43. doi: 10.1007/s00464-012-2780-8.

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da Vinci® Surgical Procedures That I Offer

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I Offer These *da Vinci*® Surgical Procedures

[please edit to show the specific *da Vinci* procedure you offer]

Fibroids / Abnormal Uterine Bleeding	Endometriosis	Pelvic Organ Prolapse	GYN Cancer
Hysterectomy (*Single-Site*® or Multi-port) Myomectomy (uterine preservation)	Endometriosis Resection (with or without a Hysterectomy)	Sacrocolpopexy (with or without a Hysterectomy)	Hysterectomy with Lymphadenectomy (Multi-port only)
✓	✓	✓	✓

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]

Patient History	❍ [Sex and Age] ❍ [Diagnosis] ❍ [Condition] ❍ [Symptoms]
Non-Surgical options	❍ [Has your patient tried non-surgical options] ❍ [Has your patient taken OTC pain medication to relieve pain when needed]
Patient Concerns	❍ [Concern 1] ❍ [Concern 2] ❍ [Concern 3]
Post-op	❍ Hospital LOS: _____ hours/days ❍ Return to normal activities: in _____ days ❍ Currently: _____ (e.g. disease and complication free)

[Please add/replace content in brackets with your own patient case data]

***da Vinci*®**

Hysterectomy

Potential Patient Benefits & Risks

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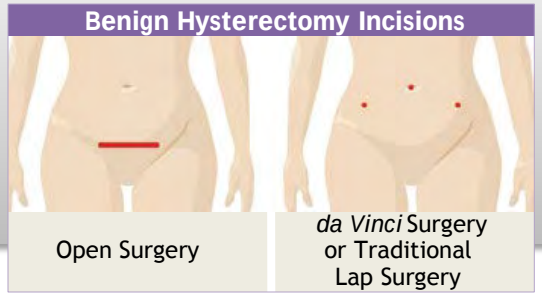
Potential Patient Benefits & Risks
da Vinci® Hysterectomy (Benign)



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.
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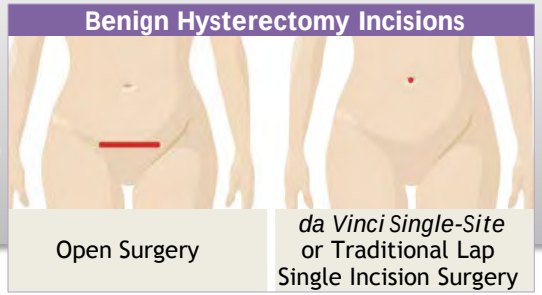
Potential Patient Benefits & Risks
da Vinci® Single-Site® Benign Hysterectomy



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.
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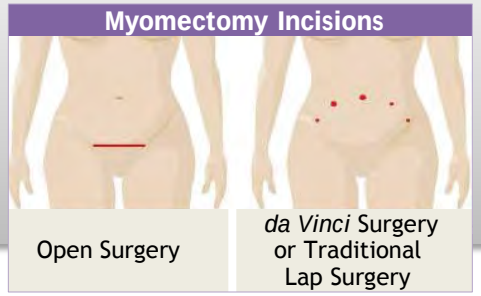
Potential Patient Benefits & Risks
da Vinci® Myomectomy



da Vinci Myomectomy
Potential Patient Benefits

vs. Open Surgery

- Similar rate of complications[14]
- Shorter hospital stay[14,15,16]
- Lower rate of blood transfusions[14,16]
- Less blood loss[14,15,16]
- Less chance of post-operative fever [14]

vs. Traditional Laparoscopic Surgery

- Similar rate of complications[14,16,17]
- Similar hospital stay[14,16,17]
- Similar conversion rate (switch to open surgery)[14,15,17]
- Similar or less blood loss[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.
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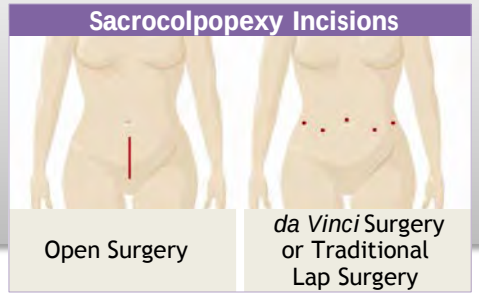
Potential Patient Benefits & Risks
da Vinci® Sacrocolpopexy



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]

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.

See the last slide for references.
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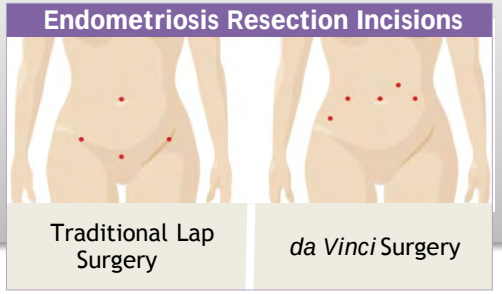
Potential Patient Benefits & Risks
da Vinci® Endometriosis Resection



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.
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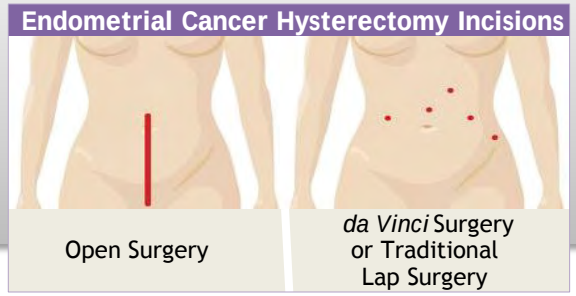
Potential Patient Benefits & Risks
da Vinci® Hysterectomy (Cancer)



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]

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
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Clinical Evidence

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Contents lists available at ScienceDirect

International Journal of Gynecology and Obstetrics

journal homepage: www.elsevier.com/locate/ijgo

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

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

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

Original Article

A Comparison of Quality Outcome Measures in Patients Having a Hysterectomy for Benign Disease: Robotic vs. Non-robotic Approaches

Martin A. Martino, MD*, Elizabeth A. Berger, DO, Jeffrey T. McFetridge, MS, Jocelyn Shubella, BS, Gabrielle Gosciniak, BA, Taylor Wejkszner, BA, Gregory F. Kainz, DO, Jeremy Patriarco, BS, M. Bijoy Thomas, MD, and Richard Boulay, MD

ARTICLE IN PRESS First published online 28 October 2013

	Robotic-assisted (N=601)	Laparoscopic (N=427)	Abdominal (Open) (N=1,194)	Vaginal (N=332)	*p-Value* (non-robotic vs. robotic-assisted)
Mean Estimated Blood Loss (mL)	108.2	315.08	318.8	340.8	<0.05
Mean Length of Stay (minutes)	1570.3	3038.5	3440.5	3789.2	<0.05
Total Readmissions <30 days (Total No.)	1.00% (6)	2.58% (11)	3.52% (42)	2.41% (8)	≤0.03
Total Readmission Cost (adjusted for inflation to 2012 $)	$32,946	$50,290	$328,230	$51,264	<0.05

Compared to non-robotic approaches:

- **Less blood loss**
- **Shorter hospital stay**
- **Lower rate of <30-day readmission**
- **Significant readmission related cost savings**

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."

Martino MA, et al. A Comparison of Quality Outcome Measures in Patients Having a Hysterectomy for Benign Disease: Robotic vs. Non-robotic Approaches. Journal of Minimally Invasive Gynecology. E-Publication: http://dx.doi.org/10.1016/j.jmig.2013.10.008

Outcomes of Abdominal and Minimally Invasive Sacrocolpopexy: A Retrospective Cohort Study

Patrick A. Nosti, MD, Uduak Umoh Andy, MD,† Sarah Kane, MD,‡ Dena E. White, MD,§ Heidi S. Harvie, MD, MBA, MSCE,† Lior Lowenstein, MD, MS,// and Robert E. Gutman, MD**

ASC=abdominal sacrocolpopexy, MISC=minimally invasive sacrocolpopexy, LSC=laparoscopic sacrocolpopexy, RSC= robotic sacrocolpopexy

Intraoperative & Postoperative Complications	ASC (n=589)	MISC (n=535)	P-Value	LSC (n=273)	RSC (n=262)	P-Value
All Complications	20%	12.7%	<0.01	18%	7%	<0.01
Cystotomy	4%	2%	<0.01	2.5%	1.5%	0.7
DVT/PE	1.5%	1%	0.3	3%	0.0%	<0.01
Ileus/SBO	5%	2%	<0.01	1.8%	1.5%	1
Conversion to Open	-	-	-	4%	0.4%	<0.01
Anatomical Failure	**ASC**	**MISC**	**P-Value**	**LSC**	**RSC**	**P-Value**
At or beyond hymen	15.1%	7.4%	<0.001	6.5%	8.4%	0.49
Stage 2 or higher	25.3%	14.2%	<0.001	11.3%	17.2%	0.069

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

Patrick A. Nosti, Uduak Umoh Andy, Sarah Kane, Dena E. White, Heidi S. Harvie, Lior Lowenstein, Robert E. Gutman. Outcomes of abdominal and minimally invasive sacrocolpopexy: a retrospective cohort study. Female Pelvic Med Reconstr Surg. 2014 Jan-Feb; 20(1): 33-37. doi: 10.1097/SPV.0000000000000036

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

FEBRUARY 2011

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

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.

Ehab E. Barakat, Mohamed A. Bedaiwy, Stephen Zimberg, Benjamin Nutter, Mohsen Nosseir, Tommaso Falcone. Robotic-assisted, laparoscopic, and abdominal myomectomy: a comparison of surgical outcomes. Obstet Gynecol. 2011 February; 117(2 Pt 1): 256–265. doi: 10.1097/AOG.0b013e318207854f

Retrospective analysis of robot-assisted versus standard laparoscopy in the treatment of pelvic pain indicative of endometriosis

John F. Dulemba · Cyndi Pelzel · Helen B. Hubert

J Robotic Surg (2013) 7:163–169
DOI 10.1007/s11701-012-0361-4

	Robot-assisted	Laparoscopy	p Value
Operative time (minutes)	77.4	72.3	0.23
Patients w/ confirmed endometriosis	80.0%	56.8%	<0.001
Appendectomy	23.3%	30.0%	0.32
Appendix positive for endometriosis	28.6%	3.3%	0.02

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.

Dulemba, John F., Cyndi Pelzel, and Helen B. Hubert. "Retrospective Analysis of Robot-assisted versus Standard Laparoscopy in the Treatment of Pelvic Pain Indicative of Endometriosis." Journal of Robotic Surgery 7.2 (2013): 163-69. Print.

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

	Open (n=138)	Lap (n=81)	Robotic (n=103)	*p*-Value
Mean age (years)	64.0	62.0	61.9	Open vs. dV=.06 Lap vs. dV=.95
Mean BMI (kg/m^2)	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:

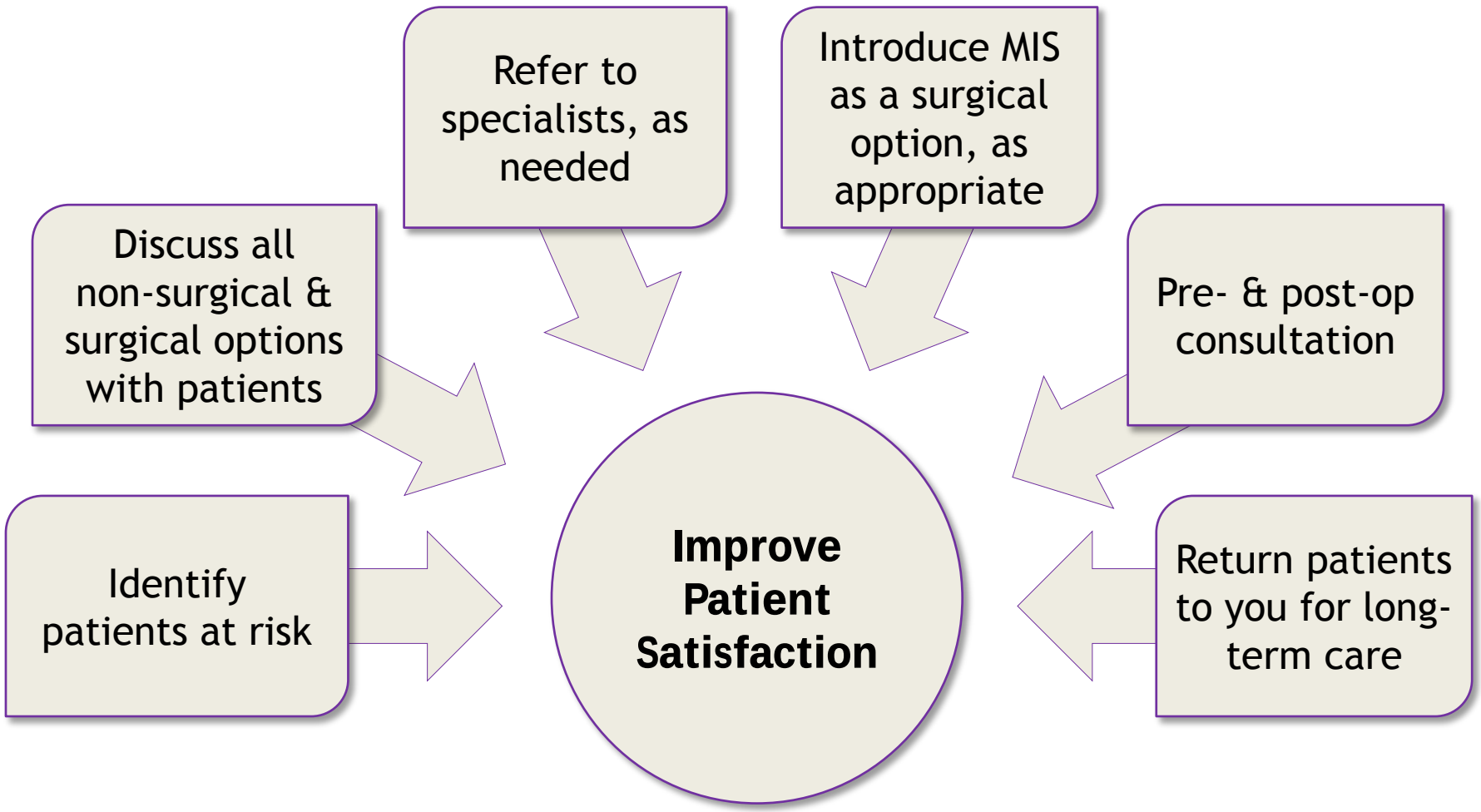
- **Less blood loss**
- **Higher lymph node yield**
- **Shorter hospital stay**

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.

31 Boggess, J, *et al*. The American Journal of Obstetrics & Gynecology. October 2008; 360.e1-360e9.

What Can We Do Together?



My Contact Information:

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

[Contact Name for managing referrals]
[Website]

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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

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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

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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 *s*ystem. *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

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- 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

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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.

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Thank You!

[name]
[practice name]
[phone]
[email]
[website]

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My Results: [Procedure]

(optional slide)

Mean	Open Surgery	Traditional Laparoscopy	*da Vinci*® Surgery	*p*-Value
N	xx	yy	zz	p
BMI	xx	yy	zz	p
EBL or Transfusion (mL)	xx	yy	zz	p
Complications (%)	xx	yy	zz	p
Conversion Rate	xx	yy	zz	p
Length of Hospital Stay (days)	xx	yy	zz	p
Other 1	xx	yy	zz	p
Other 2	xx	yy	zz	p

[Please share your own data]