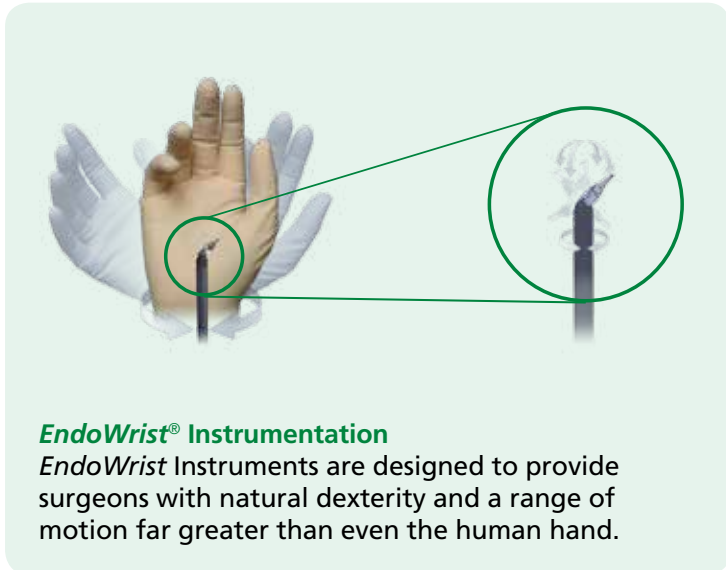


da Vinci
SACROCOLPOPEXY



Solutions for minimally invasive gynecologic surgery

The *da Vinci* Surgical System



EndoWrist® Instrumentation

EndoWrist Instruments are designed to provide surgeons with natural dexterity and a range of motion far greater than even the human hand.

Dual Console: Available exclusively on the *da Vinci* S[®]™

Dual console capability allows an additional surgeon to provide an assist or can facilitate teaching and proctoring by connecting a second surgeon console.

- High-definition 3D vision
- *EndoWrist*® instrumentation
- *Intuitive*® motion

Surgeon Benefits

Enables surgeons to offer an effective, reproducible, minimally invasive approach to pelvic organ prolapse repair for indicated patients.

The visualization, dexterity and control provided by the *da Vinci* System offer the potential for:

- ❖ Long-term symptomatic and anatomic pelvic support of Stage III and IV prolapse^{1,2}
- ❖ Lower blood loss and length of stay as compared to open surgery^{3,4}
- ❖ Ability to fully dissect the pubovaginal and rectovaginal spaces through minimally invasive incisions
- ❖ Surgeons to provide patients with a minimally invasive sacrocolpopexy at a lower overall cost than open surgery^{5,6}



Monopolar
Hot Shears™

Application Highlights

Four ways *da Vinci* technology facilitates a precise sacrocolpopexy:

Vaginal Apex Dissection



Improved visualization allows for optimal exposure of the vaginal apex for later mesh attachment. The surgical dexterity afforded by the Maryland Bipolar Forceps and *Hot Shears*™ (Monopolar Curved Scissors) enable precise, controlled dissections to fully and safely develop the anterior bladder flap and posterior rectovaginal septum.

Presacral Space Dissection & Exposure of Anterior Longitudinal Ligament



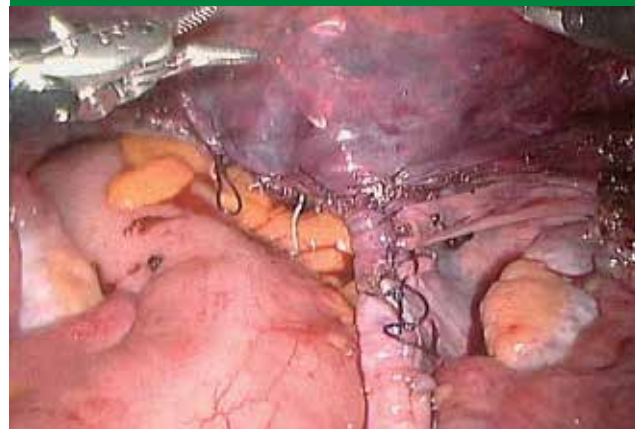
The sacral promontory, pelvic vasculature and ureters can be clearly seen using a 30° down scope and the 3rd instrument arm for sigmoid retraction. The Maryland Bipolar Forceps and *Hot Shears* (Monopolar Curved Scissors) are used to delicately incise the peritoneum towards the cul-de-sac and to expose the anterior longitudinal ligament while controlling hemostasis.

Vaginal Apex Mesh Attachment



Using a *SutureCut*™ Needle Driver, *Gore-Tex*® sutures easily attach the mesh to the vaginal wall, while penetration into the vaginal epithelium is avoided with the aid of 3D HD visualization. The *SutureCut* Needle Driver facilitates balanced suture placement and helping to distribute force evenly over the mesh. It also provides integrated cutting following knot tying for improved operative efficiency. The 3rd instrument arm can be used to hold the sacral end of the mesh for improved mesh placement and visualization.

Peritoneal Closure



The mesh can be easily retroperitonealized using the *EndoWrist* instrumentation. The *SutureCut* and Large Needle Drivers facilitate a continuous locking suture to close the previously incised peritoneum, while the 3rd instrument arm retracts the bowel.

For technology videos visit
www.daVinciSurgeryCommunity.com

Clinical Data

Short-Term Outcomes of Robotic Sacrocolpopexy Compared With Abdominal Sacrocolpopexy

E.J. Geller et al. Short-Term Outcomes of Robotic Sacrocolpopexy Compared With Abdominal Sacrocolpopexy. *Obstetrics & Gynecology*. 2008;112:1201-6

The analysis included 178 patients (73 robotic and 105 abdominal sacrocolpopexy). There were no differences in age, race, or body mass index. Robotic sacrocolpopexy showed slight improvement on POP-Q "C" point (-9 compared with -8, $P = .008$) when compared with abdominal sacrocolpopexy and was associated with less blood loss (103 ± 96 mL compared with 255 ± 155 mL, $P < .001$), longer total operative time (328 ± 55 minutes compared with 225 ± 61 minutes, $P < .001$), shorter length of stay (1.3 ± 0.8 days compared with 2.7 ± 1.4 days, $P < .001$), and a higher incidence of postoperative fever (4.1% compared with 0.0%, $P = .04$). There were no differences in other secondary outcomes. Operative time remained significantly greater in the robotic group ($P < .001$), and estimated blood loss remained lower ($P < .001$) when controlling for possible confounders. Robotic sacrocolpopexy demonstrated similar short-term vaginal vault support compared with abdominal sacrocolpopexy, with longer operative time, less blood loss, and shorter length of stay.

Limitations of this study include its retrospective design and the potential for misclassification bias (but this is expected to be non-differential between the robotic and abdominal groups). Other limiting factors are that the study was not adequately powered to assess secondary outcomes, the control group was not derived from the same time period as the study group, and the majority of robotic hysterectomies performed were supracervical, whereas the majority of abdominal hysterectomies were total.

	Robotic N=73	Abdominal N=105	p Value
Pre-op POP-Q: C point	+3	+1	0.002
Post-op POP-Q: C point	-9	-8	0.008
EBL (ml)	103	255	<0.001
Length of Stay (days)	1.3	2.7	<0.001

Robotic vs Abdominal Sacrocolpopexy: 44-Month Pelvic Floor Outcomes

E.J. Geller et al. Robotic vs Abdominal Sacrocolpopexy: 44-Month Pelvic Floor Outcomes, *Urology*. 2012 Mar;79(3):532-6

The analysis included 51 subjects: 23 robotic and 28 abdominal. Mean time since surgery was 44.2 ± 6.4 months. Postoperative POP-Q improved similarly from baseline in both the robotic and abdominal groups: C (-8 vs -7), Aa (-2.5 vs -2.25), Ap (-2 vs -2) (all $P > .05$ based on route of surgery). Pelvic floor function also improved similarly in both groups: PFDI-20 (61.0 vs 54.7), PFIQ-7 (19.1 vs 15.7), with high sexual function PISQ-12 (35.1 vs 33.1) (all $P > .05$ based on route of surgery). Two mesh exposures occurred in each group for a rate of 8% and 7%, respectively. Robotic sacrocolpopexy demonstrates similar long-term outcomes compared with abdominal sacrocolpopexy. The robotic approach offers an effective treatment alternative to abdominal sacrocolpopexy for the lasting treatment of advanced POP.

Limitations of this study include its retrospective design, external validity of the findings (because the procedures were performed at a single site and that the POP-Q examinations were performed by the study investigators themselves) and the low follow-up rate which is appropriate considering the time delay since surgery.

	Robotic N=23	Abdominal N=28	p Value
Pre-op POP-Q: C point	+2 (-1 to +5)	-1.5 (-3 to +5)	0.08
Post-op POP-Q: C point	-8 (-7 to -9)	-7 (-7 to -8)	0.22
Estimated Blood Loss (mL)	151 ± 111	219 ± 157	0.09
Cure Rates	100%	100%	-



For additional data pertaining to these studies visit
www.daVinciSurgeryCommunity.com

Potential Patient Benefits & Risks

POSSIBLE BENEFITS COMPARED TO OPEN SURGERY:

- ❖ Less blood loss^{1,2}
- ❖ Shorter hospital stay^{1,2}
- ❖ Small incisions for minimal scarring

POSSIBLE BENEFITS COMPARED TO TRADITIONAL LAPAROSCOPY:

- ❖ Shorter operation⁶
- ❖ Less blood loss⁶
- ❖ Shorter duration with catheter⁶

Additional potential benefits of *da Vinci* Sacrocolpopexy include:









- ❖ Low rate of complications^{7,8}
- ❖ High sexual function⁷
- ❖ Improved urinary, bowel, and pelvic symptoms⁷

POSSIBLE RISKS INCLUDE:

- ❖ Separation of the vaginal incision
- ❖ Blocked lung artery
- ❖ Urinary tract injury⁶



EndoWrist® Instruments Optimized for *da Vinci*® Sacrocolpopexy

STANDARD/S, Si PNs	FEATURES	STANDARD/S, Si PNs	FEATURES
 <p>Hot Shears™ (Monopolar Curved Scissors) 400179/420179 Requires Tip Cover: 400180</p>	<ul style="list-style-type: none"> ❖ Combined scissors and monopolar cautery ❖ Tapered tip profile 	 <p>Fenestrated Bipolar Forceps 400205/420205</p>	<ul style="list-style-type: none"> ❖ Grasping, dissecting and coagulating ❖ Retracting sigmoid colon
 <p>Maryland Bipolar Forceps 400172/420172</p>	<ul style="list-style-type: none"> ❖ Fenestration at the base of the jaw ❖ Curved, tapered jaw design ❖ Bipolar energy device 	 <p>Graptor™ (Grasping Retractor) 400278/420278</p>	<ul style="list-style-type: none"> ❖ Atraumatic grasping and dissecting ❖ Retracting sigmoid colon
 <p>Double Fenestrated Grasper 400189/420189</p>	<ul style="list-style-type: none"> ❖ Fenestrated smooth outer jaw profile 	 <p>Cadiere Forceps 400049/420049</p>	<ul style="list-style-type: none"> ❖ Grasping and resecting ❖ Provides atraumatic retraction
 <p>Large SutureCut Needle Driver 00296/420296 Mega SutureCut Needle Driver 400309/420309</p>	<ul style="list-style-type: none"> ❖ Strong grasping force ❖ Scissor blades at the base ❖ Tapered, smooth outer jaw 	 <p>PK™ Dissecting Forceps 400214/420214 (PK, SP Generators) 400227/420227 (G400 Generator)</p>	<ul style="list-style-type: none"> ❖ Grasping, dissecting and coagulating ❖ Delineating apex of pubocervical fascia and rectovaginal space ❖ Dissecting presacral space ❖ Maintaining hemostasis during dissection



INTUITIVE SURGICAL®

Taking Surgery Beyond the Limits of the Human Hand.™

While clinical studies support the use of the *da Vinci*® Surgical System as an effective tool for minimally invasive surgery for specific indications, individual results may vary. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all *da Vinci* instruments, including *Single-Site*® Instrumentation. General contraindications for endoscopic surgery include bleeding diathesis, morbid obesity and pregnancy. Be sure to read and understand all information in the applicable user manuals, including full cautions and warnings, before using *da Vinci* products. Failure to properly follow all instructions may lead to injury and result in improper functioning of the device. Unless otherwise noted, products featured are cleared for commercial distribution in the U.S. and bear the CE mark. For availability and clearances outside the U.S., please check with your local representative or distributor. We encourage patients and physicians to review all available information. Clinical studies are available through the National Library of Medicine at www.ncbi.nlm.nih.gov/pubmed.

All materials will eventually become obsolete. When referencing printed or digitally replicated materials, please note the revision date located near the part number (PN), located on the material. Consult your *da Vinci* representative or visit the *da Vinci* Online Community for the latest revision.

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¹ Geller EJ, Siddiqui NY, Wu JM, Visco AG. Short-term outcomes of robotic sacrocolpopexy compared with abdominal sacrocolpopexy. *Obstetrics & Gynecology*. 2008;112:1201-6. ² Siddiqui NY, Geller EJ, Visco AG. Symptomatic and anatomic 1-year outcomes after robotic and abdominal sacrocolpopexy. *Am J Obstet Gynecol*. 2012 May;206(5):435.e1-5. Epub 2012 Feb 1. ³ Geller EJ, Parnell BA, Dunivan GC. Robotic vs abdominal sacrocolpopexy: 44-month pelvic floor outcomes. *Urology*. 2012 Mar;79(3):532-6. ⁴ Hoyte L, Rabbinafard R, Mezzich J, Bassaly R, Downes K. Cost Analysis of Open Versus Robotic-Assisted Sacrocolpopexy. *Female Pelvic Med Reconstr Surg* 2012;18: 335-339. ⁵ Elliott CS, Hsieh MH, Sokol ER, Comiter CV, Payne CK, Chen B. Robot-Assisted Versus Open Sacrocolpopexy: A Cost-Minimization Analysis. *J of Urology*. 2012: 187. 638-643. ⁶ Seror J, Yates DR, Seringe E, Vaessen C, Bitker MO, Chartier-Kastler E, Rouprêt M. Prospective comparison of short-term functional outcomes obtained after pure laparoscopic and robot-assisted laparoscopic sacrocolpopexy. *World J Urol*. 2012 Jun;30(3):393-8. Epub 2011 Aug 20. ⁷ Geller EJ, Parnell BA, Dunivan GC. Pelvic floor function before and after robotic sacrocolpopexy: one-year outcomes. *J Minim Invasive Gynecol*. 2011 May-Jun;18(3):322-7. Epub 2011 Apr 1. ⁸ Elliott DS, Krambeck AE, Chow GK. Long-term results of robotic assisted laparoscopic sacrocolpopexy for the treatment of high grade vaginal vault prolapse. *J Urol*. 2006 Aug;176(2):655-9.

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