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Senhance Robotic Platform System for Gynecological Surgery

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ABSTRACT

Background and Objectives: Laparoscopic hysterectomy provides patients and surgeons with benefits of less pain, quicker recovery, and better scar cosmesis. Previously, robotic surgical hysterectomy was reserved for patients with complicated disease issues. The objective of this case series was evaluating a new robotic surgical platform, Senhance Surgical System, as a surgical tool in common gynecological procedures.

Methods: The clinic routinely collects surgical and outcome data for all patients and procedures. Data on robotic surgery in hysterectomy, salpingectomy, endometriosis excision, and lysis of adhesions was evaluated.

Results: Fifteen consecutive patients that underwent gynecological surgery using the Senhance System were assessed. Average age was 47.27 years (31 – 63 years). Ten procedures were robotic total laparoscopic hysterectomy and 14 of 15 procedures had at least one salpingectomy. Average blood loss was 52.7 mL (10 – 100 mL). Pain scores at discharge averaged 1.42 and 2.73 at two weeks post-surgery. Minimal pain medication was used. Patient satisfaction with the surgery was 98% and satisfaction with scarring was 100%. Return to normal activities and to work averaged 7.93 and 11.1 days respectively. The haptic feedback and the platform visualization of the procedure was useful. The system provided more surgeon control over both camera and tools compared to previously used robotic systems and traditional laparoscopic surgery.

Conclusion: This initial experience with Senhance Surgical System provided a stable, precise surgical technique with enhanced visualization within the confined space of the abdomen during gynecological surgery. The initial results suggest high patient satisfaction with gynecological surgery and resulting scars. Further study is needed to validate the findings.

Key Words: Hysterectomy, Robotic surgery, Laparoscopy, Mini-laparoscopy, Gynecology.

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INTRODUCTION

Hysterectomy is one of, if not the most common surgical procedure in gynecological patients worldwide.[1,2] In the US, an estimated 33% of women over 60 have had a hysterectomy.[1] The procedure can be performed for either benign or malignant indications, but approximately 70% are for benign causes.[1,2]

Over the years, the hysterectomy surgical technique has evolved from laparotomy with a multiple day hospital stay to laparoscopic techniques with smaller incisions and shorter hospital stays.[2] There are now four approaches for the hysterectomy procedure: abdominal laparotomy (AH), vaginal (VH), total laparoscopic (TLH), and robotic (RTLH).[1–4] Prior to 1989, the approach was limited to either abdominal or vaginal. Once laparoscopic hysterectomies became more common, the benefits of less anesthesia, pain and blood loss, and faster recovery, more surgeons made the transition to offering this route as an alternative.[1–3] Similar to the rapid integration of TLH in the US, use of TLH in the Netherlands jumped from 3% in 2002 to 36% in 2012 while the abdominal approach fell 68% to 39% in the same years.[5] The same study found that in 2012, the TLH surpassed the use of VH (25%) in the same hospitals. As laparoscopic tools became smaller, the procedures became more minimally invasive. Patients have enjoyed quicker recovery times and the more cosmetically pleasing scars offered by the TLH approach. As hospitals and insurers became more cost conscious and the technique improved, hospital stays shortened or became outpatient procedures.[2]

Like other surgical procedures, robotic surgery has the advantage of minimally invasive laparoscopic techniques and the added advantage of delicate precision. Procedures that are complicated by the disease such as severe endometriosis, extensive LV adhesions, and patient comorbidities often appear to receive the greatest benefit of the robotic precision.[4,6,7] Introduction and acceptance of the robotic surgical technique was initially slow. The first robotic surgical platform, Robotic Assisted Laparoscopy (RAL) was developed in the 1970s as a project by the US military and NASA.[4] In 2000, the FDA approved robotic RAL-type systems for general surgery and in 2005, its use in gynecological surgery was approved. The first systems had a large cost and space requirement which limited the use to hospitals that could afford and house them.[4,7] The first robotic systems also had a steep learning curve because of reduced visual and haptic feedback and were better suited for experienced surgeons.[4] Like any surgical tool or technique, robotic surgery platforms and tools have continuously improved over the years. Newer robotic systems have more haptic feedback and even 3D viewing which lowers the learning curve.[4] The laparoscopic tools can be as small as 3 mm which not only enhances the precision, but also helps minimize tissue damage and scar formation. As robotic instrumentation develops, the cost and size of the equipment has also decreased over the years. As more facilities have access to robotic platforms, benign diseases can be surgically treated in addition to malignant diseases thereby increasing the number of patients treated by the same platform.

Recently, a new robotic surgical system received FDA clearance in 2017, the Senhance Surgical System (TransEnterix, Morrisville, NC) was introduced to the market. The ability to use existing equipment, such as existing third-party visualization systems and electrical surgical generators, in conjunction with the robotic platform, having a small footprint, and competitive pricing was attractive. **Figure 1** displays the platform surgical "cockpit" and three robotic arms. From a surgical perspective, the platform can use 5 mm instruments, 3 mm instruments for micro-laparoscopy, and fluorescence for enhanced visualization, all of which could be beneficial for gynecological procedures. Our hospital purchased a unit for all departments to use. This paper details our initial, early experience with the Senhance system for benign gynecological surgery, including TLH.

METHODOLOGY

This was a retrospective consecutive case series using the Senhance Surgical System. The clinic normally collects outcome data for all patients and procedures and follows the Declaration of Helsinki ethics and principles. Data was also collected from the surgical reports, notes, and medical records. All surgeries were performed by one surgeon (SDM) at Advent Health Winter Park (Winter Park, FL) using a Senhance Surgical System between January 2019 and February 2020. The surgeon has been performing advanced laparoscopic gynecological surgery since 1990. Only patients that expressed an interest in a cosmetically minimal scar using minimally invasive laparoscopic surgery and were appropriate for robotic surgery underwent procedures using the Senhance system. All patients had the procedures performed through three ports placed in the lower abdomen, usually 5 mm in size at the umbilicus, left lower quadrant, and right lower quadrant. Procedures requiring a hysterectomy had the uterus removed trans-vaginally. Other procedures could

Figure 1. Image of the senhance platform with a surgical "cockpit" and three robotic arms.

have a 5 mm port enlarged with a larger trocar for tissue or specimen removal.

The Anesthesia Department provided routine general anesthesia as well as enhanced recovery after surgery protocols specific to the gynecological patient. Postoperative pain management protocols were followed and routine intravenous and postoperative analgesics were provided for all patients on an as needed basis. This included the use of Acetaminophen-Codeine, Ketorolac, and Oxycodone-Acetaminophen.

The first postoperative visit occurred approximately 2 weeks following surgery. At this visit, information about any potential adverse events as well as pain and scar assessments were performed. The pain assessment at discharge and the follow up visit used a 10-point scale whereas the scar assessment used a 7-point scale with multiple questions about the scar cosmesis of appearance (color), size, thickness, flatness, and texture quality. Patient satisfaction with their scar and with the surgery were also assessed on a 7-point scale. Patients self-assessed their return to normal daily activities and when they returned to work based on their pre-operative activities and work. The physical assessment of the follow-up visit included examination of the port incisions, inspection of the abdominal wall, use of a bivalve speculum to inspect the vaginal cuff, and a bimanual examination.

RESULTS

Fifteen gynecological patients had Senhance robotic laparoscopic surgery and were part of the outpatient service (**Table 1**). Age ranged between 31 and 63 years of age, median was 46 and average was 47.27 years. The ethnicity of the 15 patients were 60% Caucasian, 20% Hispanic, and 20% African-American.

Ten of the 15 procedures were robotic TLH. Of 15 procedures, all but one patient had at least one salpingectomy performed. One patient with stage 2 endometriosis underwent lysis of the endometriosis and fluid aspiration. At the start of each procedure, patients had three 5 mm trocars inserted into the lower abdomen, except for one patient who had one 3 mm and two 5 mm trocars used. One patient received an additional fourth trocar during the procedure. Blood loss ranged between 10 and 100 mL with the median of 50 mL and averaged 52.7 mL. Pre-operative and postoperative hemoglobin levels were monitored for patients that underwent a hysterectomy and averaged 12.5 and 11.2 gm/dl respectively. Uterine weight for the hysterectomy procedures averaged 155g. See **Table 1** for specific surgical details.

Surgical instrument set up, docking, and undocking were quickly performed by a surgical assistant. The docking and undocking took place on a robotic arm using a clamp and lock system that does not require attachment of the robotic arm directly to an instrument. For the 15 procedures, docking time averaged 9.2 minutes, cockpit surgical time averaged 43.1 minutes, and undocking took an average of 2.3 minutes. For procedures that included a hysterectomy, the average time was 9.1 minutes docking, 48.9 minutes cockpit time, and 2.2 minutes undocking. The total procedure average was 54.6 minutes and the procedures with hysterectomy averaged 60.2 minutes. **Figure 2** shows an example of typical port site wounds following robotic TLH using the Senhance robotic platform.

There were three mild adverse events noted at time of discharge; "postoperative vaginal bleeding", "gas pain", and "gas pain with constipation". One patient did not require pain medication at the time of discharge, 12 patients received Acetaminophen-Codeine, one was given Ketorolac, and one was given Oxycodone-Acetaminophen. Pain scores at the time of discharge ranged from 0 to 6 with a median of 1 and average of 1.42 out of a 10-point scale. At the first follow-up visit two weeks post-surgery, the pain scores ranged from 0 to 10 with a median of 2 and an average of 2.73. At the first follow up visit post-surgery, one patient had a mild adverse event noted of "umbilical incision pain". See **Table 2** for specific details.

Patient satisfaction with the surgery ranged from 5 to 7 on a 7-point scale with a median score of 7 and an average score of 6.87 (98% satisfaction rating). Scar satisfaction scores were a unanimous 7 (100% satisfaction rating). This includes scar cosmesis of appearance (color), size, thickness, flatness, and texture. Fourteen patients had three incisions each and one patient had four incisions. Most scar incision sites were less than 5 mm (n = 41), one was 3 mm, and four incision sites were enlarged to 10 mm to accommodate tissue extraction. Days needed to return to normal activities ranged from 1 to 14 with a median of 7 and an average of 7.93 days. Days needed to return to work ranged from 3 to 21 with a median of 14 and an average of 110.1 days. See **Table 2** for more specific details.

DISCUSSION

The American College of Obstetricians and Gynecologists recommends that minimally invasive surgical techniques such as VH or LH be utilized for benign disease because

Table 1.
Patient Surgical Data*

Age	Diagnosis	Procedure	Trocars Used (mm)	Dock Time (Min)	Cockpit Time (Min)	Un-Dock Time (Min)	Total Time (Min)	Blood Loss (mL)	Pre Op Hb (gm/dl)	Post Op Hb (gm/dl)	Uterine Weight (g)	Medicine at Discharge	Adverse Events at Time of Discharge
53	Pelvic Pain, Adhesions	RL BSO LOA Cystoscopy	5, 5, 11	8	11	3	22	20				Acetaminophen-Codeine	
45	AUB, Dysmenorrhea Dysparunia	RTLH BS, Cystoscopy	5, 5, 5	25	109	2	136	50	12.8	11	151	Acetaminophen-Codeine	
43	Dysparunia, Menorrhagia, Pelvic Pain, IUD perforation	RTLH BS, IUD removal, Cystoscopy	5,5,10	8	37	2	47	50	12.3	12	177	Acetaminophen-Codeine	
46	Myoma Pain	RTLH, BS, Cystoscopy	5, 5, 5	7	48	2	57	75	13.9	12.8	170	Acetaminophen-Codeine	PO Gas pain treated with Simethicone
41	Myoma Pain, Menorrhagia, Anemia, AUB, Adhesions, Cuff prolapse, Abdominal wall trigger point	RTLH BS LOA, Colpopexy, Cystoscopy, Injection at trigger point	5, 5, 5	7	23	2	32	75	8.6	8.9	134	Acetaminophen-Codeine	PO vagina bleeding; no cuff complication
48	AUB, Dyspareunia, Pelvic pain	RTLH BS, IUD removal, Cystoscopy	5, 5, 5	11	22	2	35	100	13.8	12.5	133	Acetaminophen-Codeine	
44	Stage 4 Endometriosis, Pelvic pain, Ovarian cyst, Urinary frequency, Obliterated cul de sac	RTLH LSO RS LOA and cul de sac, Cystoscopy	5, 5, 5	5	51	2	58	100	13.9	12.9	95	Acetaminophen-Codeine	
46	Adhesions Ovarian Mass, AUB, Retro-peritoneal endometriosis	RL LSO, Hysteroscopy, D&C, Ureterolysis, Enterolysis, Cystoscopy	3, 5,5	10	27	2	39	50				Acetaminophen-Codeine	
63	Familial cancer history	RTLH BSO, Cystoscopy	5, 5, 5	9	83	2	94	25	13.4	11.3	199	Acetaminophen-Codeine	
57	B. Hydrosalpinx, Pelvic pain, Uterine fibroid	RL BS, D&C Hysteroscopy, Cystoscopy	5, 5, 11	5	12	2	19	10				Ketorolac	
52	Breast cancer, Pelvic pain, Uterine fibroids	RL BSO	5, 5, 5	15	25	2	42	25				None	

Table 1. Continued

Age	Diagnosis	Procedure	Trocars Used (mm)	Dock Time (Min)	Cockpit Time (Min)	Un-Dock Time (Min)	Total Time (Min)	Blood Loss (mL)	Pre Op Hb (gm/dl)	Post Op Hb (gm/dl)	Uterine Weight (g)	Medicine at Discharge	Adverse Events at Time of Discharge
31	Stage 2 Endometriosis, Dysmenorrhea Pelvic pain	RL Excision of Endo, Cul de sac fluid aspiration	5, 5, 5	9	83	3	95	10				Acetaminophen-Codeine	
57	Pelvic pain,Adhesions, Fibroids, PMB	RTLH BSO, Cystoscopy, Ureterolysis, Enterolysis	5, 5, 5	8	22	3	33	50	11.1	7.2	105	Acetaminophen-Codeine	
44	Myoma pain, Dyspareunia pain, Ovarian cyst	RTLH BS RO, Cystoscopy	5, 5, 5	6	69	2	77	50	12.3	10.8	179	Oxycodone-Acetaminophen	
39	Dyspareunia, Menorrhagia, Dysmenorrhea Pelvic pain, BRCA2 positive	RTLH BSO, Cystoscopy	10, 5,5,5	5	25	3	33	100	13	13	179	Acetaminophen-Codeine	Gas pain and constipation

AUB, abnormal uterine bleeding; B. Hydrosalpinx, blocked hydrosalpinx; PMB, post-menopausal bleeding; LOA, lysis of adhesions; OP, outpatient; PO, postoperative. Procedure codes: first R, Robot; T, Total; L, Laparoscopic; H, Hysterectomy; second R, Right; second L, Left; B, Bilateral; S, Salpingectomy; O, Oophorectomy; D & C, Dilation & Curettage.

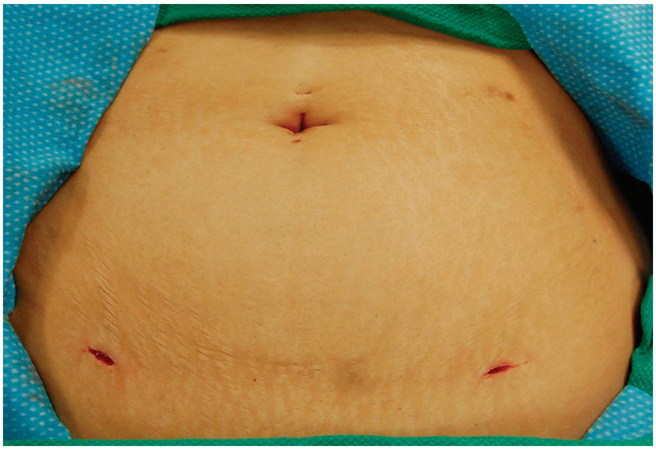

Figure 2. Typical Senhance Robotic total Laparoscopic Hysterectomy 3 millimeter ports prior to suturing and bandaging at time of outpatient discharge on Day 0 in September 2020.

of "well-documented advantages over abdominal hysterectomy".[8] Robotic surgical platforms have been used successfully for years for complicated procedures, many in complex oncological situations, which can benefit from minimally invasive surgery advantages.[9] Gynecological patients with benign (i.e., fibroids) or malignant disease or comorbidities (i.e., obesity) no longer have to be subjected to open laparotomy, but instead benefit from both surgical and post-surgical advantages offered by robotic minimally invasive surgery.[6,7,10]

Once laparoscopic assisted hysterectomy techniques began being used, patient recovery and satisfaction were remarkably improved compared to prior patients receiving either the AH or VH procedures. Not long afterwards, most of our clinic hysterectomy patients received the 2006 McCarus Technique of TLH which required both 5 mm and 10 mm trocars and the use of an ultrasonic energy device.[11] A revision on this technique, the McCarus Cosmetic Hysterectomy, used a mini-laparoscopic approach with 3 mm and 5 mm trocars and an energy device resulting in smaller scars with less trauma, less pain, and faster recovery.[12] The physical and emotional impact of a surgical procedure and surgical scars on the patient's wellbeing should not be overlooked. A survey of 200 of our clinic patients demonstrated the importance of leaving the patient with an aesthetically acceptable scar following hysterectomy.[13]

The observations of less postoperative pain and smaller scar with TLH is not unique to our clinic or specialty. Use of smaller trocars ($\leq$ 5 mm) is associated with less postoperative pain, reduced postoperative pain medication, less risk of vascular injury, less risk of trocar site herniation, and smaller scars.[14–16] The improved scar cosmesis from use of 3 mm or 5 mm trocars in a mini-laparoscopic hysterectomy is barely noticeable and drives patient satisfaction. Use of the robotic system has an advantage over the traditional TLH because of its precise movements, small ports, and excellent visualization of the tissues. Patient satisfaction with robotic TLH surgery and scar is rated highly because of the small incisions and small scars.

There have been barriers to robotic surgical platforms in the past; namely the expense of the platform for hospitals and patient billing, training of users, and justification of use via clinical evidence of benefit.[4,7,9] The robotic systems have been in larger institutions for 20 years and in gynecological use for 15.[4] Short and long term clinical benefit data for surgeons and patients have been established.[9] Although robotic peri-operative costs are perceived to be higher than standard, a study of robotic oncological procedures demonstrated patient out-of-pocket cost and the payer's total payments were lower compared to other approaches.[9] As more hospitals incorporate the robotic systems, more surgeons are trained and can use the systems, which increases the number of users able to use the system as well as helps lower the overall system expense for the institution. Not only can the cost efficiency increase as the surgical volume increases, robotic hysterectomy can be feasible in benign disease or may be more cost effective with reductions in operating room time and direct costs in patients with comorbidities or abnormally large uteri.[6,10]

The expense of previous existing robotic systems have minimally declined over the years as improvements were made, more units were sold, and competitors emerged. Our hospital specifically selected the Senhance Surgical System for several reasons. The overall system cost was lower compared to other systems because it utilized existing in-house equipment and featured fully reusable instruments. The space requirements for the Senhance system were small and did not require any remodeling or use of our larger operating rooms, which was a benefit. The versatility of the system and the ability to use both reusable and standard laparoscopic instruments allow all surgical specialties to use the system thereby increasing its cost-effectiveness for the hospital. Ultimately, the ability to mimic the experience of laparoscopic surgery with digital assistance and lower cost with smaller incisions were deemed a compelling investment.

From an initial surgical perspective, the visual feedback and surgeon control of the Senhance system camera were

Table 2.
Patient Satisfaction Scar Data*

Age	Diagnosis	Procedure	Adverse Events Since Discharge	Pain Day 0	Pain Week 2	Surgery Score 1 – 7	Scar Score 1 –7	Return to Normal Activities (days)	Return to Work (days)
53	Pelvic Pain, Adhesions	RL BSO LOA Cystoscopy		0	10	7	7	14	3
45	AUB, Dysmenorrhea, Dysparunia	RTLH BS, Cystoscopy		3	3	7	7	2	2
43	Dysparunia, Menorrhagia, Pelvic Pain, IUD perforation	RTLH BS, IUD removal, Cystoscopy			2	7	7	3	3
46	Myoma Pain	RTLH, BS, Cystoscopy		0	2	7	7	5	14
41	Myoma Pain, Menorrhagia, Anemia, AUB, Adhesions, Cuff prolapse, Abdominal wall trigger point	RTLH BS LOA, Colpopexy, Cystoscopy, Injection at trigger point		0	2	7	7	5	14
48	AUB, Dyspareunia, Pelvic pain	RTLH BS, IUD removal, Cystoscopy		2	2	7	7	7	14
44	Stage 4 Endometriosis, Pelvic pain, Ovarian cyst, Urinary frequency, Obliterated cul de sac	RTLH LSO RS LOA, Lysis of cul de sac, Cystoscopy		0	2	7	7	7	14
46	Adhesions Ovarian Mass, AUB, Retroperitoneal endometriosis	RL LSO, Hysteroscopy, D&C, Ureterolysis, Enterolysis, Cystoscopy		0	0	7	7	7	Yes
63	Familial cancer history	RTLH BSO, Cystoscopy		0	0	7	7	7	
57	B. Hydrosalpinx, Pelvic pain, Uterine fibroid	RL BS, D&C Hysteroscopy, Cystoscopy		2	2	7	7	9	14
52	Breast cancer, Pelvic pain, Uterine fibroids	RL BSO		2	2	7	7	10	7
31	Stage 2 Endometriosis, Dysmenorrhea, Pelvic pain	RL Excision of Endo, Cul de sac fluid aspiration		0	4	7	7	14	7
57	Pelvic pain,Adhesions, Fibroids, PMB	RTLH BSO, Cystoscopy, Ureterolysis, Enterolysis		2	1	7	7	14	21
44	Myoma pain, Dyspareunia pain, Ovarian cyst	RTLH BS RO, Cystoscopy	Umbilical incision pain	3	4	5	7	14	N/A
39	Dyspareunia, Menorrhagia, Dysmenorrhea, Pelvic pain, BRCA2 positive	RTLH BSO, Cystoscopy		6	5	7	7	14	N/A

*Diagnosis-AUB = Abnormal Uterine Bleeding, B. Hydrosalpinx = blocked hydrosalpinx, PMB = Postmenopausal Bleeding. Procedure codes- first R = Robot, T = Total, L = Laparoscopic, H = Hysterectomy, second R= Right, second L = Left, B = Bilateral, S = Salpingectomy, O = Oophorectomy, D&C = Dilation & Curettage. Length of Stay- OP = Outpatient. Adverse Events- PO = Postoperative.
Pain Scores are 0 – 10 scale with 0 is no pain and 10 is worst pain. Surgery and Scar scales are 1 – 7 scale with 1 being worst and 7 being the best possible. Return to Normal Activities and Work are measured in days.

unique. Unlike traditional laparoscopy, the Senhance system has an eye tracking feature which allows the surgeon to control the camera pan and zoom features. When the 5 mm camera is under the surgeon's eye control, the visualization of the surgical area is efficiently managed by the surgeon, and the camera moves smoothly, avoiding the need for camera repositioning by a surgical assistant. The ability to utilize 3D and with high definition cameras and system monitor provided a clear visualization of the spatial relationships within the tissues. As seen with 3D viewing, the Senhance control with the robotic arm provided stability which was deemed useful, especially when working near vital organs. The indocyanine green fluorescence was useful to better differentiate the different tissues and organs during the procedure. The force sensors of this platform acts as a safeguard and provided immediate feedback. This haptic feedback of pressure and tension to the hand controls allowed the hands to feel the differences in tissue resistance and thus appropriate force to be applied via the instruments. Being able to adjust the force required and change as needed gave me (the surgeon) the ability to manage control of the instruments with robotic assistance without losing key haptic cues as experienced in the traditional laparoscopic procedures. The combination of the haptic feedback controls and the surgeon controlled 3D visualization of the surgical area was much improved compared to my experience in traditional laparoscopy and other robotic systems.

For a robotic TLH, our streamlined procedure uses the Senhance robotic platform, an anesthesiologist, a surgical gynecology assistant trained in robotic use, and the gynecological surgeon making the procedure cost efficient and surgically efficient. With a traditional TLH, I would need at least two surgical assistants in order to complete the procedure. This is primarily due to the limitation of not being able to stabilize and control a camera while simultaneously using two instruments in traditional laparoscopy. I frequently change out instruments like ultrasonic energy during a procedure depending on what the case dictates. Instrumentation like this are compatible with the system and the surgical assistant can readily change them using the clamping system, there is little delay during the procedure. In our clinic, the cost between robotic TLH and TLH are comparable, yet the robotic TLH provides precision and visibility control deemed beneficial to the surgeon experience. The high patient satisfaction with their surgery and subsequent scars provides additional support for utilizing the robotic platform to best meet their physical and financial needs in our clinic.

CONCLUSION

Our initial experiences with the Senhance Surgical System suggests the system is safe and feasible in gynecologic surgery. Early results suggest high patient satisfaction. Further study is needed to confirm these initial observations.

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