Introduction

Since commercial introduction in 2005 for use in gynecological procedures, the da Vinci Surgical System has rapidly displaced open surgery across a range of gynecological surgery procedures. Perhaps the broadest impact has been seen in benign hysterectomy. In fact, more da Vinci hysterectomies are performed than any other da Vinci procedure (Intuitive Surgical Investor Presentation, http://phx.corporate-ir.net/phoenix.zhtml?c=122359&p=irp-IRHome, Q4, 2013).

Drawn by the key differentiators of minimally invasive robotic surgery, including 3-dimensional visualization, tremor filtration, and fully wristed, articulated instrumentation, gynecologists used the da Vinci surgical system in 25% of all benign hysterectomies performed in the United States in 2011. (see Fig. 1)

While the overall rate of minimally invasive approaches within benign gynecological procedures continues to grow, the technical limitations of laparoscopic and vaginal surgery continue to present obstacles for many patients with complex pathology seeking minimally invasive options for hysterectomy.

To that end, continual technological development has led to the release of advanced robotic instrumentation, with the goal of allowing more surgeons to offer a minimally invasive solution to a broader spectrum of patients, and to do so in a way that is economically feasible for their institutions.
The EndoWrist® One™ Vessel Sealer

In February 2012, Intuitive Surgical released the EndoWrist One Vessel Sealer, exclusively for use on the da Vinci Si™ Surgical System. Boasting a fully wristed architecture with 50 degrees of articulation, the instrument is utilized for sealing and transecting vessels up to 7 mm in size. The ability to apply energy while maintaining a low outer jaw temperature (Figure 2) and at the same time create robust seals comparable to those made with laparoscopic advanced bipolar technology (Figure 3) is now possible on the da Vinci platform for the first time.

Recently, the Vessel Sealer received an expanded indication for grasping and blunt dissection of tissue, providing gynecologists with a multi-functional, 8 mm instrument which can be utilized for sealing and cutting, grasping, and blunt dissection all with a single instrument. In 2013, Intuitive Surgical also released the SmartPedal™ system upgrade for the da Vinci Si System. This upgrade has allowed additional flexibility with respect to the instrument configurations that are possible while performing surgery. Following the upgrade to SmartPedal™, using a monopolar instrument as a primary dissector and the EndoWrist One Vessel Sealer in the opposite hand for vessel sealing and tissue transection has rapidly become the instrument configuration of choice for many gynecologists performing benign hysterectomy.

This whitepaper highlights the initial experiences of three gynecologists that have fully adopted the EndoWrist One Vessel Sealer.

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

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Figure 1. U.S. benign hysterectomy market by modality

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1The EndoWrist One™ Vessel Sealer is a bipolar electrosurgical instrument cleared for commercial distribution in the U.S. for use with the da Vinci Si™ Surgical System and the ERBE VIO 300 D electrosurgical generator. It is intended for grasping and blunt dissection of tissue and for bipolar coagulation and mechanical transection of vessels up to 7 mm in diameter and tissue bundles that fit in the jaws of the instrument. The EndoWrist One Vessel Sealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures. Use of the Vessel Sealer with other generators could result in injury to the patient or surgical team, or cause damage to the instrument.
Dr. Tom Shultz began his journey as a *da Vinci* surgeon in 2008. A skilled laparoscopic surgeon, Dr. Shultz’s voyage has been marked by a continual refinement of his technique. His initial goal was to increase patient satisfaction by reducing the need for rescue opioids post-op, to potentially facilitate early discharge.²

More recently, he has focused on improving cosmetic outcomes by reducing the number of ports and lowering their placement.

Toward the end of 2009, Dr. Shultz began more aggressively introducing a multi-modal analgesic protocol, increasing his ability to discharge women only hours after completing a hysterectomy.² Never satisfied, however, Dr. Shultz continued to search for ways to improve his procedural efficiency by reduction of ports and the use of more advanced instrumentation. “Early in my learning curve, I was still performing a four or five port technique. After 30-40 cases, I began removing the assistant port. The driving force for this was that many patients were complaining of pain at this site. Unless it was a very large uterus or complex pathology, I realized I rarely needed help from my assistant.”

“Initially, I would use four instruments for every case: *PK*, *MCS*, *Cobra*, *Needle Driver*. I was still very efficient, even with these four instruments. But prior to robotics, I had been doing LAVH and TLH with *LigaSure™* and *EnSeal®*. I adopted robotics despite the lack of advanced energy because of the technological advantages of 3D visualization, and articulating instruments.”

In late 2012, Dr. Shultz was introduced to the *EndoWrist One* Vessel Sealer. Finally, he had access to a technology to address his desire for a fully articulating, robotically controlled, advanced vessel sealing instrument. For Dr. Shultz, the change in his surgical choreography created by the advanced sealing technology was obvious.

“The first thing I noticed with the Vessel Sealer was that I didn’t have to go back and look at pedicles anymore. For my first 5-10 cases, I would band my vascular pedicles. As I gained confidence in the new technology, I realized that banding was no longer necessary.”

Even with these advantages, however, Dr. Shultz was not fully sold until *SmartPedal™* Technology introduced the ability to utilize the Vessel Sealer opposite monopolar energy. “I loved the sealing capability, but I did not like the logistics of always having to use the Vessel Sealer in the right hand. It slowed me down. It created more instrument swaps, which was just more procedural time. Now with *SmartPedal*, my surgical assistant makes one swap at the end of the case to put in a needle driver. To me, *SmartPedal* Technology brought back my efficiency of not having to make instrument exchanges. And the degree of articulation in the wrist of the Vessel Sealer has allowed me to approach the uterine vessels of even a moderately sized uterus without swapping my Vessel Sealer into the right hand.”

Dr. Shultz initially felt constrained by the geometry of the Vessel Sealer’s grasping tooth, which limited energy delivery at the tip of the instrument. However, this perceived shortcoming quickly evolved into an efficient new approach with unexpected economic benefits. “Because the energy doesn’t go to the tip, I developed a technique where I use the monopolar hook to skeletonize and release vessels, and to help feed them into the Vessel Sealer. This is something I wouldn’t be able to do with the Monopolar Curved Scissors (MCS). I was pleasantly surprised by the ability to manipulate and advance tissue with an articulated hook. I added it to the instrument mix for its cost savings and now I rarely use the MCS.”

But while Dr. Shultz had come to fully appreciate the technical advantages the Vessel Sealer afforded him, he also had to deal with the realities of operating in an economically sensitive climate. Fortunately, for Dr. Shultz, the benefits of the Vessel Sealer were more than adequate to address these concerns.

“I had to justify the Vessel Sealer to my institution. I was able to reduce the cost of I&A to them on every case by replacing the MCS with the Monopolar Hook, and using the Vessel Sealer as a grasper, eliminating the need for the Cobra Grasper. Once I realized that I could dissect and grasp with it, it was a no-brainer to do the whole case with only three instruments.”

In addition to reducing his utilization of instrumentation, the Vessel Sealer has allowed Dr. Shultz to reduce his overall procedure time as well.

“What is it that makes me inefficient in the O.R. and extends my console time? Every instrument exchange that I ask for will take time. Having to wait for steam or smoke to clear from bipolar instruments causes further delay. Going back and chasing vessels that are bleeding again…that’s another few minutes. All of these things start adding up. Am I going to close five incisions or three? Most of the time, with the Vessel Sealer, my colpotomy is done by 14 or 15 minutes of console time. If you aren’t at 30-45 minutes of total console time, you need to reassess how you can improve your technique. With the Vessel Sealer, I’ve probably shaved off 10-12 minutes as compared to my previous approach and up to 20 minutes for more complex pathology.”

For Dr. Shultz, 2013 has largely been focused on improving the cosmetic outcomes for his patients through full integration of the Vessel Sealer with SmartPedal.

“I began focusing on more cosmetic port placement; focusing on eliminating the assistant port, on utilizing an 8.5 mm endoscope, and on bringing my instrument arm ports below the iliac crest. I had to examine how this would impact my technique and avoid the iliac vessels. With very low ports, working on the contralateral side can be challenging. But the articulation of the Vessel Sealer still allows me to reach the uterine vessels easily.”

Most importantly for Dr. Shultz, da Vinci Surgery with the EndoWrist One Vessel Sealer has fundamentally changed his approach to MIS surgery for many patients.

“The biggest change with the Vessel Sealer and SmartPedal is that it has allowed me to change the level of benign pathology that I can attack. As an advanced da Vinci surgeon with a Vessel Sealer that articulates, I can approach complex pathology, large 500 g -750 g uteri and stage 3-4 endometriosis, and still utilize my refined technique.”

“It has thrown larger benign pathology into a low, reduced port technique. When pathology dictates, I can always go back to a four or five port approach. Conversions are rare and the need for laparotomy for complex benign disease is almost absent from my practice. What continues to amaze me is the level of complex pathology that can be successfully managed without laparotomy.”

“The term ‘complex pathology’ doesn’t mean anything anymore, because it isn’t going to change my technique. Five years ago I would never have envisioned this; the impact on patient outcomes for large complex pathology is amazing. The real winners in this innovative technology are my patients.”
For Dr. Marc Winter, the motivation to pursue advanced technology with da Vinci Surgery has always been clear. “I’m always open to something that can potentially make me more efficient.”

A high-volume da Vinci surgeon since 2010, Dr. Winter has always been interested in evaluating various options for coagulation and vessel sealing.

“Before robotics, I used the harmonic scalpel and had begun using EnSeal as well to gain efficiency.” As Dr. Winter made his transition to robotic surgery in 2010, he used the technologies that were available with the da Vinci System at the time. “I used the PK and scissors, and then switched to a ProGrasp and a Mega™ SutureCut™ Needle Driver.” But even with these technologies, in combination with the enhanced visualization and precision of da Vinci Surgery, Dr. Winter felt that he could gain more efficiency.

Following the introduction in 2013 of the EndoWrist One Vessel Sealer and SmartPedal Technology, Dr. Winter had found his next leap forward.

“When SmartPedal came into play, that’s when it really changed everything. It changed the whole choreography of what we do. At that point, I was able to pare down from four instruments to three for most hysterectomies: monopolar on the right, Vessel Sealer on the left and a Mega SutureCut Needle Driver for the cuff closure.”

Very quickly, Dr. Winter began to realize advantages. “As I got used to the Vessel Sealer, it was just as easy to use on larger uteri or more complex cases. I like that it produces little smoke. It has some real advantages over standard bipolar or PK; less smoke, better sealing. And for 90% of hysterectomies, the grasping of the Vessel Sealer is perfect. I can use my Vessel Sealer at the end of a case for cuff grasping, so I have the advantage of fewer instruments and I’m efficient, which can translate into overall savings from a cost point of view.”

“Without even thinking about it, I noticed that my console times went down several minutes per case in the beginning, even on non-complex cases. The savings is all about the choreography and the efficiency, and now I can consistently complete procedures quickly with Vessel Sealer and SmartPedal.”

With his adoption of the Vessel Sealer, Dr. Winter has also been able to create a “win-win” for his institution and his patients; he has been able to reduce the number of da Vinci instruments he uses, while at the same time utilizing a technology that allows him to continue to pursue reduced port surgery with the da Vinci System in a more reproducible fashion.
“It has made certain technical aspects easier; I will remove the tubes but leave the ovaries in. To march across the mesosalpinx, it’s perfect. I prefer using the Vessel Sealer to techniques where I had to use two instruments. Taking the utero-ovarian arteries is extremely efficient. It allows us to be efficient even in a reduced port case, where an assistant port is not present. My analysis in my institutions shows that I have been able to make a significant reduction in direct costs by incorporating the Vessel Sealer.”

As a teacher and mentor of emerging da Vinci surgeons, Dr. Winter has been quick to share the potential benefits of the Vessel Sealer with others.

“I prefer technology with less thermal spread as an additional measure of safety. The sealing works well, even for larger vessels. In my observation, there is less back-bleeding to manage.”

But for Dr. Winter, the best part is that with the addition of the EndoWrist One Vessel Sealer, he also continues to refine his own technique.

“Every time something new is introduced that I feel provides improved efficiency, it’s hard to go back. After 400 cases, I’m still learning things. With da Vinci technology, we are just able to do a lot more with the tools that we have, and that makes all the difference.”

For Dr. Paul Whitham, introduction of the EndoWrist One Vessel Sealer has been the latest technical evolution in his approach to expanding the benefits and applicability of minimally invasive surgery to his patients. Like many of his peers, Dr. Whitham’s drive to push the boundaries of MIS technology predates his initial exposure to da Vinci Surgery.

“We had been pushing more and more towards minimally invasive surgery – fewer scars, faster recovery, less blood loss, better patient satisfaction.”

Having been interested in laparoscopic approaches for many years, Dr. Whitham was also early to adopt advanced vessel sealing technology. The multifunction aspects of laparoscopic advanced energy technology, which combine the ability to seal and cut vessels and bluntly dissect tissue while maintaining minimal thermal spread, helped to augment the efficiency of his technique.

Feeling satisfied with the progress he was making laparoscopically, Dr. Whitham did not initially feel the motivation to consider adopting da Vinci Surgery. But by early 2012, as his interest in robotics began to grow, he decided to attend a case observation with Dr. Jerry Rozeboom in Cedar Rapids, Iowa. “I was blown away by the visualization provided by the 3D vision, the precise manipulation, and the finesse basically of the da Vinci technology. I realized that this was where the future was going – I jumped on board and never looked back.”

By June of 2012, Dr. Whitham had completed training and begun his initial series of da Vinci procedures. His first few cases left him looking for even more ways to optimize the use of the technology.

“For my initial cases, we used the Fenestrated Bipolar Forceps. At times it was frustrating because there was
difficulty managing small bleeders by the cardinal and utero-sacral ligaments. We switched over to the Maryland Bipolar and I was more comfortable with this instrument.”

After roughly 50 cases, Dr. Whitham was introduced to the EndoWrist One Vessel Sealer. For the second time, he found a technology that immediately became a mainstay in his MIS arsenal. The multifunctional design of the Vessel Sealer, complete with its grasping tooth at the tip of the instrument, provided him with a multi-use instrument that was also simple to use from the outset.

“The learning curve went quickly – it felt like it was a natural fit. From the first few times I sat down, I realized that this is what I’d been looking for; this is what I had been visualizing. This was what I had wished I could do with straight sticks but couldn’t. It just blew me away.”

“The Vessel Sealer has great tissue grasping capabilities, and I like the fact that it doesn’t cut all the way to the end. I am comfortable with the design of the tip. I can cut close to the bladder and I know that I’m getting a good seal and a good cut.”

Dr. Whitham added, “At the same time, my thermal spread is contained within 2 millimeters, and I have confidence that I won’t be damaging surrounding tissues. I find the instrument to be efficient. It doesn’t seem like the instrument generates much smoke. I now perform one seal and one burn, instead of two or three.”

Most importantly, the technology has helped Dr. Whitham provide a less invasive option to more of his patients than ever before.

“We have moved to either a 5 mm assistant port, or a 3 port technique for appropriate anatomy. We are always looking to decrease invasiveness and reduce cost. The Vessel Sealer is one of those things, because of the thermal spread, because of the better sealing, we are more comfortable working with a larger uterus.”

“Nowadays, 100% of my cases are robotic. When was the last time that I performed an open procedure? Oh, it’s been 2 or 3 years.”

Figure 3. Mean burst pressures, splenic, mesenteric & renal arteries
Source: Bench study conducted by Intuitive Surgical in a porcine model. Data on file.
Surgeons featured in this white paper have received compensation from Intuitive Surgical for providing educational services to other surgeons and/or patients, own stock in the company, and/or were paid stipend for their time working with the company to have their stories featured.

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 US, 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.

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The PK® Dissecting Forceps and PK instrument cords are intended to be used with the da Vinci and da Vinci S/Si Surgical System for endoscopic manipulation of tissue including: grasping, dissecting, approximation, coagulation, retraction and ligation. The PK Dissecting Forceps may only be used on soft tissue. Do not use it on cartilage, bone or hard objects. Doing so may damage the instrument or make it impossible to remove from the cannula. The PK Dissecting Forceps is not intended for contraceptive coagulation of the fallopian tube, but may be used to achieve hemostasis following transection of the fallopian tube. The PK Dissecting Forceps is classified as a BF applied part. This instrument is hence not suitable for direct cardiac applications.

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