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The *McCarus-Volker ForniSee®* System: A Novel Transilluminating Colpotomy Device and Uterine Manipulator for Use in Conventional and Robotic-Assisted Laparoscopic Hysterectomy

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Abstract

The purpose of this paper is to introduce a novel transilluminating colpotomy and uterine manipulator device, and demonstrate its safety and clinical efficacy in conventional and robotic-assisted laparoscopic hysterectomy, as well as illustrate its advantages when compared with predicate devices.

Preclinical cadaver trials were first conducted for performance and product testing, followed by clinical trials. The study was a prospective, non-randomized, non-blinded observational clinical study involving 50 female patients undergoing total laparoscopic hysterectomy (TLH) or supracervical hysterectomy (LSH) for benign indications. The surgeries were performed during March through May 2012 at two institutions, Florida Hospital and Las Vegas Minimally Invasive Surgery and Pelvic Health Center. The primary objectives were to demonstrate the safety and adequate clinical performance of the uterine manipulator device, as well as illustrate its potential widespread future use in minimally invasive gynecologic procedures.

Average patient age was 45.06 years. Of the 50 patients, 33 had undergone previous intra-abdominal surgery. 38 patients underwent TLH with only one conversion to total abdominal hysterectomy (TAH), due to a 1,695-gram uterus. 12 patients underwent successful LSH.

There were no reports of adverse events, difficulty with placement of the instrument, multiple attempts at placement or difficulty with uterine manipulation. There was one device-related uterine perforation. Pneumoperitoneum was maintained in all cases during colpotomy. Vaginal tissue left on specimens was less than 5 mm. There were no ureteral injuries. There were two reported incidental cystotomies. Average blood loss was 99.04 ml. Average uterine weight was 269.87 grams, with a range of 45 grams to 1,695 grams. The largest uterus successfully removed laparoscopically weighed 1,096 grams. Postoperative courses were normal for all patients with only two reported postoperative complications; possible vaginal cuff abscess, and a 2cm vaginal mucosal cuff separation.

A literature review was performed to compare the ForniSee uterine manipulator to predicate devices, and physician surveys were conducted to evaluate its design, functionality, innovation and value.

The McCarus-Volker ForniSee® is a novel transilluminating colpotomy device and uterine manipulator that is safe, efficient, functional, and easy to use. It displaces the cervix away from the ureters, displaces the bladder anteriorly, reduces blood loss, and defines the dissecting planes for colpotomy. It prevents trauma to the vagina, cervix or uterus, maintains vaginal length, and prevents loss of pneumoperitoneum during colpotomy incision. Transillumination delineates and enhances identification of critical anatomic planes, such as the vesicovaginal junction and cervicovaginal junction. It is easier assemble and install, more ergonomic, and offers enhanced uterine manipulation when compared to predicate manipulators. It is cost-effective with pricing comparable to other similar manipulation devices. Its functions can potentially improve patient outcomes and reduce procedure times.

Background

Hysterectomy is one of the most frequently performed surgical procedures in the United States. Hysterectomy surveillance in the United States from 1997 through 2005 showed that approximately 600,000 hysterectomies are performed each year. The prevalence of hysterectomy in women over the age of 45 reached forty-eight percent (1, 2). The most common reasons for hysterectomy include fibroids, abnormal uterine bleeding, endometriosis, and uterine prolapse. Since the introduction of laparoscopic hysterectomy, numerous studies have shown that when compared to abdominal hysterectomy, the laparoscopic approach is associated with less pain, shorter hospital stay, and less blood loss. Despite advancements in laparoscopic training and instrumentation, including the DaVinci Robot system, abdominal hysterectomy continues to be the most common approach to hysterectomy in the United States. A recent national study on hysterectomy rates found that 66% of hysterectomies were performed abdominally, whereas vaginal hysterectomy rates were 22%, and laparoscopic hysterectomy rates were only 12% (3). Several studies have addressed this discrepancy in route of hysterectomy. One study published in JMIG surveyed approximately 380 gynecologic surgeons regarding potential barriers to performing minimally invasive hysterectomy, and found that the top five barriers were training during residency, technical difficulty, operating time, personal surgical experience, and potential for complications (4). Another study published in JMIG surveyed physicians attending the AAGL conference in 2008 and looked at the main determinants in the decision of route of hysterectomy. This survey found that one of the main determinants was surgical skill, including training and comfort with the procedure. The main limitations in the performance of advanced laparoscopic cases were reported as anatomic dissection and suturing (5).

A critical area of dissection when performing a total laparoscopic hysterectomy (TLH) is at the cervicovaginal junction. It is near this junction that important structures must be avoided when making the colpotomy incision. Urinary tract injuries have been reported to be as high as 4% during laparoscopic hysterectomy. One of the most common sites for ureteral injury is at the level of the uterine arteries, where it is located less than 1.5 cm lateral to the cervix at the level of the internal cervical os (6). In cases

of distorted pelvic anatomy due to endometriosis, adhesive disease, fibroids, or adnexal masses, it can be difficult to identify the ureter, making dissection during hysterectomy challenging. Even in cases involving normal pelvic anatomy this dissection can be difficult for surgeons in training or new to minimally invasive surgery.

During total laparoscopic hysterectomy or laparoscopic supracervical hysterectomy (LSH), uterine manipulation plays a pivotal role. Small changes in the uterine position and delineation of the vaginal fornix, provided by an adequate manipulator, may optimize exposure to the vulnerable structures involved during the procedure and facilitate their dissection.

Where a sponge stick was once our only choice, today in our world of minimally invasive surgery, a variety of uterine manipulators have evolved with broader functionality. The currently marketed uterine manipulators enable the surgeon to create traction and rotate the uterus. Some models have added a cervical cup for delineation of the cervico-vaginal junction only via tactile recognition of the vaginal fornix. In more complicated cases involving scarring, endometriosis, or during robotic-assisted laparoscopic surgery, tactile delineation may not always be feasible. There have been very few studies comparing available uterine manipulators. One study compared 7 manipulators in regards to range of movement for anteversion and retroversion, elevation, and lateral movement; presentation of the vaginal fornices; ease of assembly and handling; and maintenance of pneumoperitoneum. This article concluded, “no single uterine manipulator seems to have all the attributes of an ideal manipulator” (7). As surgeons may be held back from performing minimally invasive hysterectomies due to this deficiency, there exists a need for a better uterine manipulator, one that could not only lead to more conventional and robotic-assisted laparoscopic hysterectomies, but also to better patient outcomes.

Seeking to address this need, The *McCarus-Volker* FORNISEE SYSTEM® is introduced for use as a uterine manipulator in conventional and robotic-assisted laparoscopic hysterectomy to identify the vaginal fornix via transillumination. More and better minimally invasive surgical procedures may be possible with the advanced technology offered in this device.

Design/Functionality

The McCarus-Volker ForniSee® (FS) is an illuminated uterine manipulator device for use in laparoscopic surgery, including conventional and robotic TLH, LSH, and other gynecologic procedures. The ForniSee Device® comprises a 5 mm reusable sound, available in a set of four different lengths: 6, 8, 10, and 12 cm. It has a rotational anchor at the end of the angled shaft that firmly affixes to the uterus for comfortable and reliable manipulation. Its pivoting head enables ante/retro flexion of the uterus and prevents rotation of the device within the uterus when torsion is applied that is off a direct plane. Not only does it provide a greater range of motion, it does not require an assistant to maintain uterine position, and allows manipulation without a cervical tenaculum. The anchor also allows simultaneous removal of the manipulator and uterine specimen after completion of the colpotomy.

Once the FS sound is in place, the device is easily advanced over it. The FS device is disposable and is constructed with a cervical cup available in 30mm, 35mm, and 40mm, to accommodate different cervical diameters. The cervical diameter should be measured prior to inserting the manipulator. The cervical cup serves to displace the cervix away from the ureters and help define and create the bladder flap. The cervical cup includes an incision ridge and a transparent seal through which the light source trans-illuminates tissue planes and important anatomic structures, making identification of the colpotomy plane very simple. Once the device is fitted over the cervix, a vaginal occluder is advanced into the vaginal vault. This occluder maintains pneumoperitoneum after the colpotomy is made. The light cord is then inserted into a slot at the distal end of the device, and connected to a standard illumination optical fiber bundle. (See Figures 1-4, reprinted with permission from LSI Solutions)

Innovation

The ForniSee System® is the first uterine manipulator that has been developed and trialed, which employs both a cervical cup as well as a light source for both tactile and visual identification of the vaginal fornix. This is especially useful in robotic surgery, and deep pelvic disease, where tactile feedback is absent, thus addressing many of the key issues lacking in other manipulator devices.

Value

The ForniSee System® is priced at \$180 per disposable device, which is purchased by the box, and includes a package of six devices (two of each size). There is an additional one-time cost of \$600 per reusable sound, available in a set of three or four, containing the various sizes 6 to 12 cm. There is also a one-time purchase of \$250 for the light guide. This pricing is comparable to the RUMI® manipulator.

Physician Survey

A physician survey was conducted at Las Vegas Institute of Minimally Invasive Surgery. There were a total of eight gynecologic surgeons included who had experience using the ForniSee® manipulator during laparoscopic hysterectomy. The survey was written in the same format as that used by an author who has reviewed several uterine manipulators (8, 9). The survey addressed four categories; design/functionality, innovation, value, and overall score. Surgeons were asked to rate each category on a scale of 1-5. Design/functionality was rated as 1= poor design, many deficits; 2= solid design, many deficits; 3= good design, few flaws; 4= excellent design, few flaws; 5= excellent design, flaws not apparent. Innovation was scored as 1= nothing new, 2= small twist on standard technology, 3= major twist on standard technology, 4= significant new technology, 5= game changer. The value scale was graded as 1= added cost with limited benefit, 2= added cost with some benefit, 3= added cost but significant benefit, 4= marginal added cost but significant benefit, 5= significant cost savings. Overall score was rated as 1= don't bother, 2= niche product, 3= worth a try, 4= must try, 5= must have. Score averages are shown below:

Design/Functionality Score: 5 Innovation Score: 4.5 Value Score: 3.625 Overall Score: 4.406

Preclinical Trials

The ForniSee System® was designed and manufactured by LSI Solutions®, under the direction of Dr. Jude Sauer, general surgeon and CEO of LSI Solutions®. Performance and product testing were carried out with thorough bench top and cadaver research. It was initially tested using ex vivo porcine vaginal and uterine tissues, followed by testing on the human cadaver model. The cadaver was obtained through University of Rochester Medical Center Anatomical Gift Program and testing was performed in the laboratory at Strong Memorial Hospital. The primary objectives of cadaver testing were to test ergonomics and evaluate light output and temperature changes. Bench top and cadaver study outcomes proved the device to be safe and feasible and a clinical performance IRB study was proposed and classified as a “Nonsignificant Risk” device study.

Clinical Trials

The study was a prospective, non-randomized, non-blinded observational clinical study with the primary objective of demonstrating safe and adequate clinical performance of the ForniSee®, as well as illustrating its potential widespread future use in minimally invasive gynecologic procedures. The secondary objective was to establish an understanding of the lighting parameters employed for transillumination during actual surgery.

The Principal Investigators for the clinical trials are two advanced pelvic surgeons; both internationally recognized experts in minimally invasive techniques and technologies, Dr. Steven McCarus and Dr. K. Warren Volker.

The ForniSee® was tested on a total of 50 patients who underwent total laparoscopic hysterectomy or supracervical hysterectomy using the ForniSee® uterine manipulator during the period March 2012 through May 2012. The procedures were performed at two institutions, Las Vegas Institute of

Minimally Invasive Surgery and Pelvic Health Center and Florida Hospital. Inclusion criteria are listed below. All patients who did not meet the below criteria were excluded from the study.

Inclusion criteria:

1. Female
2. Age 20-80 years
3. Patient and surgeon both agree that hysterectomy is her best current option
4. Ability to tolerate surgery without history of bleeding disorder, anesthesia problems, etc.
5. Absence of known dense pelvic or intra-abdominal adhesions or such dense adhesions found upon initiation of surgery that would preclude safe completion of the procedure through a laparoscopic approach
6. Non-pregnant patient proven by hospital standard testing; absence of desire for future pregnancy
7. Gynecologic anatomy including the presence of a uterus and patent cervix
8. No pre-existing known ureteral disease or abnormalities
9. Patient eligible and interested in study participation
10. Subject capable of giving informed consent

Patient information was gathered and acute surgical outcomes were recorded on a standardized intraoperative data form. Specific outcomes included successful laparoscopic completion, instances of uterine perforation, ureteral or bladder injury, bleeding complications, adequacy of vaginal occluder, light source and settings, duration of use of illumination, adverse events, and surgeon comments and opinions.

Data analysis showed the average patient age was 45.06 years. Of the fifty patients, 33 had undergone some form of previous intra-abdominal surgery. A total of 38 patients underwent TLH with only one conversion to total abdominal hysterectomy (TAH), due to a very large, 1,695-gram uterus. Twelve patients underwent successful LSH.

There were no reports of adverse events, difficulty with placement of the instrument, multiple attempts at placement or difficulty with uterine manipulation. There was one device-related uterine

perforation. Pneumoperitoneum was maintained in all cases during colpotomy, with only two reported incidents of "slight loss of pneumoperitoneum", not affecting the conduct of the procedure. Vaginal tissue left on specimens was less than 5 mm on all reported measurements. There were no ureteral injuries. There were two reported incidental cystotomies, one in a patient with stage IV Endometriosis involving the bladder, and the other was a 1,096 gram uterus with multiple large fibroids and significant bladder scarring from prior cesarean section. Average blood loss was 99.04cc. Average uterine weight was 269.87 grams, with a range of 45 grams to 1,695 grams. The largest uterus successfully removed laparoscopically weighed 1,096 grams.

Immediate postoperative comments by the physician noted the ForniSee® device to be very helpful in all cases but two, one was a case converted to laparotomy and the other patient failed screening due to severe adhesive disease.

Postoperative courses were normal for all patients with only two reported postoperative complications. One patient developed a fever and abdominal pain 6 days postoperative, due to a possible vaginal cuff abscess, and was treated with IV antibiotics. The second patient had a vaginal mucosal cuff separation of 2cm. Two other patients reported some vaginal spotting. Vaginal cuff healing was normal in all other patients. One patient was treated for a UTI.

In the majority of cases the 8cm sound was utilized, and the 30mm diameter cup was used in 27 out of 50 patients. Average light power setting varied per case, with a majority (20) on high power. Duration of illumination also varied per case, the average duration was 26.83 minutes. In the majority of cases the light source did not have to be paused or turned off.

Comparison to Predicate Devices

During product development of the ForniSee System®, numerous visits were made to gynecologic operating rooms across the country to observe and evaluate competitive technology and potential design improvements.

Predicate uterine manipulator devices exist with design features similar to the LSI® ForniSee System®. Product development of the ForniSee System® was performed after first researching the functionality of these predicate devices, in an effort to create an improved manipulator. Similar uterine manipulators include the RUMI System® and Koh™ Colpotomizer System by Cooper Surgical and VCare® by ConMed Corporation.

The RUMI System® is comprised of a reusable metal shaft with a grip handle that has a locking trigger, which is pressed forward to unlock so that the handle can be moved left and right for anteflexion and retroflexion of the uterus, respectively. A disposable balloon tip available in various lengths is inserted on the distal shaft. The tip is connected to a catheter through which the balloon is inflated. This catheter must be inserted into grooves along the length of the shaft.

The Koh™ Colpotomizer System is used in conjunction with the RUMI System®. It consists of the Koh Cup™ Vaginal Fornices Delineator and a Colpo-Pneumo Occluder. The Koh Cup™ is a plastic cup, available in three sizes, that fits over the distal end of the RUMI® balloon tip. The pneumo-occluder is an inflatable silicone sleeve, which is attached to the proximal shaft of the RUMI®.

Once the system is set up and positioned properly inside the patient, the balloon tip is inflated to stabilize the manipulator within the uterine cavity. The cup is positioned to fit around the cervix in the vaginal fornices. The occluder is attached to a catheter through which 100cc of saline can be infused at time of colpotomy (10, 11).

The VCare® device is comprised of a curved shaft with a balloon tip on the distal end and a proximal handle through which air can be injected to inflate the balloon tip. A double cup system slides over the shaft. The forward cup fits over the cervix and delineates the vaginal fornix and has holes in it, which can be used to suture the cup in place. The back cup is placed vaginally to maintain pneumoperitoneum, and a locking screw secures the cup in place.

The RUMI®/Koh™ system and VCare® device are safe and practical manipulators, however there are aspects of each device that could be improved (12, 13). The RUMI®/Koh™ system can be tedious to set up, the silicone occluder can potentially fail to maintain pneumoperitoneum if it is not filled with enough saline, or if it ruptures from too much saline, or if it is defective with small tears or holes.

Additionally, lateral manipulation of the uterus can be difficult in cases where there is limited space between the patient's legs because lateral movement of the handle is often obstructed by the inner thighs or Allen-type stirrups.

The VCare® device is easier to setup, however it can be difficult to keep it locked in position. The fixed angle of the shaft and lack of an intrauterine anchor leads to rotation of the device relative to the plane of the uterus with bigger specimens, thus it does not always allow for appropriate anteflexion/retroflexion of the uterus. Suturing the cup to the cervix resolves this issue, but this can be cumbersome. Additionally, the back cup does not always provide maintenance of pneumoperitoneum due to its small, fixed size.

The ForniSee Device® was developed to address the above noted quandaries with predicate manipulators. It comprises some features similar to the manipulators described above including a colpotomy cup and a pneumo-occluder, however it is a novel and improved device in comparison. Device setup and placement is simplified with just four easy steps:

1. The metal sound is inserted into the uterine cavity and the distal anchor is secured.
2. The main device comes conveniently ready-made as one unit with the colpotomy cup and pneumo-occluder, and is fitted over the sound.
3. The occluder is then advanced into the vagina.
4. And lastly, the light cord is attached.

The FS device has a distal anchor on the shaft, rather than a balloon tip, which better stabilizes the manipulator within the uterine cavity. It also allows the uterine specimen to be retrieved vaginally at the same time as removal of the manipulator, after circumferential colpotomy is completed. The anchored shaft and ergonomic shape of the handle also allows 360-degree rotation of the device without loss of position and excellent anteflexion, retroflexion, and lateral uterine manipulation.

The most notable improvement is the ability to illuminate the cup. There is no other uterine manipulator available which allows transillumination of the cervico-vaginal junction for identification of colpotomy incision site. Other physicians have transilluminated the fornix by using a clear plastic vaginal

rod such as the Lucite Rod, but this has no light attachment and so requires the assisting surgeon to manually hold the light against the rod during the case and does not allow anteflexion or retroflexion of the uterus. Transillumination aids the surgeon in many things, namely identification of the cervicovaginal junction. This is especially helpful in cases where there is significant adhesive or deep pelvic disease, distorted anatomy, multiple prior surgeries, or enlarged fibroid uteri.

Summary

The McCarus-Volker ForniSee® is a novel transilluminating colpotomy device and uterine manipulator that is safe, efficient, functional, and easy to use. It displaces the cervix away from the ureters, displaces the bladder anteriorly, reduces blood loss, and defines the dissecting planes for colpotomy. It prevents trauma to the vagina, cervix or uterus, maintains vaginal length, and prevents loss of pneumoperitoneum during colpotomy incision. Transillumination delineates and enhances identification of critical anatomic planes, such as the vesicovaginal junction and cervicovaginal junction. It is easier to assemble and install, more ergonomic, and offers enhanced uterine manipulation when compared to predicate manipulators. It is cost-effective with pricing comparable to other similar manipulation devices. Its functions can potentially improve patient outcomes and reduce procedure times. Thus, for advanced minimally invasive surgeons, or for surgeons new to minimally invasive surgery, this device is an excellent first choice.

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