



Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology: X

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

Robotic transvaginal natural orifice transluminal endoscopic surgery for bilateral salpingo oophorectomy

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ARTICLE INFO

Article history:

Received 26 March 2020

Received in revised form 19 June 2020

Accepted 22 June 2020

Available online 23 June 2020

Keywords:

Robotic transvaginal surgery
Robotic vaginal natural orifice transluminal endoscopic surgery (RvNOTES)

NOTES

Bilateral salpingo-oophorectomy (BSO)
Gynecology

ABSTRACT

Objectives: The vaginal surgical approach has not become the standard of care, despite its advantages. The Hominis™ Surgical System is a humanoid shaped robot-assisted system that was designed specifically for robotic vaginal natural orifice transluminal endoscopic surgery (RvNOTES). We aimed to present our experience with the first RvNOTES bilateral salpingo-oophorectomy (BSO) performed by the Hominis system.

Study design: A two-center prospective study of BSO by RvNOTES in women with nonmalignant indications conducted between August and December 2018. Women older than 18 years were offered to participate. Exclusion criteria included a history of abdominal malignancy, pelvic or abdominal irradiation, Crohn's disease, pelvic inflammatory disease, severe infections in the lower abdomen, active diverticulitis, deep infiltrating recto-vaginal endometriosis, and an active vaginal infection. The primary outcome of the study was the rate of conversion to open or laparoscopic approaches. Secondary outcomes included intra- and postoperative adverse events, operative time, estimated blood loss, length of hospital stay, and 6-week follow-up assessment.

Results: Eight women aged 50–70 years with BMI of 19–30 kg/m² were recruited. All the procedures were completed successfully without conversions to open surgery. No intraoperative complications were observed. Median blood loss was 10 mL (range: 10–50). The median duration of the procedure was 45 min (range: 38–91), and decreased over the study period. Surgeons' usability assessment was very favorable, with a median of 5 on a 1–5 scale. The median visual analog scale (VAS) score was 1 (range: 1–3).

Conclusions: This is the first documentation of a surgery performed via the vagina using robotic instrumentation developed for this purpose. The disruptive technology of RvNOTES, with its fast learning curve, will make gynecological surgeries accessible to more women.

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Introduction

Over the last two decades, greater sophistication of instrumentation has given rise to laparoscopic and robotically-assisted procedures for diverse surgeries [1]. In parallel, smaller and more natural surgical ports have been used, thus requiring less incisions. Together, these developments have yielded less

invasive surgeries, with safer and better patient outcomes, such as shortened hospitalization and postoperative recovery times, reduced postoperative pain and risk of infection, and better cosmetic results [2,3]. Nonetheless, the challenges of maintaining adequate vision and contact of target organs remain. Laparoscopic surgery poses such disadvantages for the surgeon as limited dexterity, loss of depth perception, camera instability, hand tremor, awkward movement of instruments and camera, poor ergonomics, and fatigue [4,5]. FDA approval in 2000 of the da Vinci Surgery System, the first robotic system for general laparoscopic surgery, has yielded improvements in these parameters [6]. However, studies conducted on robotic surgery in various procedures have not shown overwhelming advantages in patient outcomes [7,8]. The current evidence, together with the

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risks associated with port placement and the bulky apparatus suggest that the full potential of robotic surgery has yet to be realized.

Compared to conventional laparoscopy, vaginal natural orifice transluminal endoscopic surgery (vNOTES) has developed as a single-access approach, with the objective of obviating the trauma that arises from abdominal wall access. vNOTES has been found to be associated with reduced complications, postoperative pain, hospitalization stay and recovery time, while avoiding a scar [9,10]. In gynecological surgery, the vaginal approach is well established and often recommended. For example, vaginal access is considered the preferred option for benign hysterectomy, when feasible [11,12]. Vaginal access is considered feasible in more than 60 % of hysterectomies for benign indications [13], including women without previous vaginal delivery [14]. However, this approach is underutilized in gynecological surgery due to the restricted surgical space, the lack of exposure and the limited training [15]. Indeed, the proportion of vaginally-feasible hysterectomies performed by other approaches increased since laparoscopic and robot-assisted laparoscopic surgeries became popular [13,16]; the consequence is longer operative time and higher infection rates. This trend suggests that more appropriate instrumentation could increase utilization of the vaginal approach.

Robotic-assisted transvaginal NOTES (RvNOTES) is a disruptive technology that provides the technical capabilities that will encourage surgeons to prefer procedures through natural orifices, thus bridging the gaps of both robotic-assisted surgery and conventional vNOTES. RvNOTES realizes the full potential of robotic surgery and facilitates performing procedures via natural orifices, with all the associated advantages to patients. RvNOTES overcomes challenges of vagina access, such as distance from the target site and technical difficulties related to the single-port. Robotic systems were demonstrated in vNOTES in animal models [17,18]. The first human cases of transvaginal robotic surgery were presented by Dr. J. Baekelandt at the 7th Annual SERGS meeting on Robotic Gynaecological Surgery in Istanbul in June 2015.

In an attempt to overcome the shortcomings of the vaginal approach, Memic Innovative Surgery Ltd developed a robotic-assisted surgical system that combines the advantages of laparoscopic surgery, robot-assisted surgery, and the vaginal approach. The Hominis™ Surgical System is a humanoid shaped robot-assisted system that was designed specifically to facilitate vNOTES procedures and to make the performance of robotic surgery as natural as possible. Accordingly, the highly articulated humanoid shaped Hominis Arms™ mimic the surgeon's entire upper extremity (shoulder, elbow, and wrist joints). The surgeon

controls the arms with two joysticks that are very similar in their structure to the mechanical arms and end-effectors. Here we demonstrate the technology of RvNOTES, using the Hominis™ Surgical System (Memic Innovative Surgery Ltd., Or Yehuda, Israel), on vaginal bilateral salpingo-oophorectomy (BSO) indicated for nonmalignant etiology.

Methods

Study design and patients

This is a report of eight women who underwent BSO by robotic vNOTES at two sites: Rambam Health Care Campus, Haifa, Israel (N = 7) and Imelda Hospital, Bonheiden, Belgium (N = 1), during August – December 2018. The study was approved by the local ethics committees of both institutions (RMB 18-0421) (Imelda: 180519).

Study inclusion criteria were: age 18–75 years, BMI ≤ 40 kg/m², an indication for BSO, and willingness and suitability to undergo RvNOTES under general anesthesia. Women were considered not suitable to undergo the procedure if they had a history of abdominal malignancy or disease, pelvic or abdominal irradiation, chronic abdominal pain, Crohn's disease, pelvic inflammatory disease, severe infections in the lower abdomen, diverticulitis, frozen pelvis or deep infiltrating recto-vaginal endometriosis, previous vaginal surgery, no previous sexual intercourse, reduced access to the vagina, or an active vaginal infection. Suitability for undergoing the procedure was ultimately determined by a diagnostic laparoscopy, through a 5 mm entry at the umbilical site. Accordingly, the surgeon inserted the laparoscopic camera through the umbilicus to inspect the anatomy and suitability for vaginal access.

All the women who underwent procedures that used the Hominis™ Surgical System were invited for a follow up visit at six weeks postoperative. This visit included a physical exam and the recording of adverse events since the procedure, and symptoms of rectal or bladder injury.

The Hominis™ Surgical System

The Hominis™ Surgical System is an endoscopic instrument control system that is intended for single site, transvaginal surgical procedures. The System consists of sterile (disposable and reusable) components such as the Hominis Arms™ and the GYN Trocar Kit, and non-sterile capital equipment such as the Control Console and the Motor Units (Fig. 1). The Arms are inserted



Fig. 1. Hominis™ Surgical system components: Hominis Arms™ and Control Console.

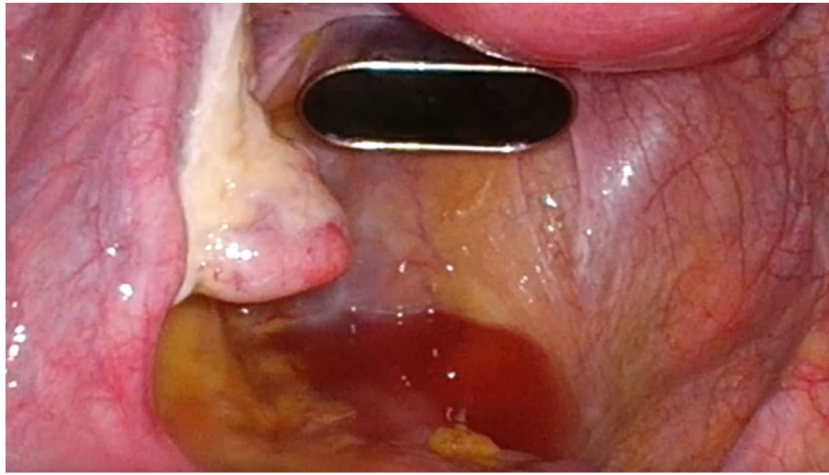


Fig. 2. The GYN Trocar Kit is inserted transvaginally through the posterior fornix to the pelvic cavity.

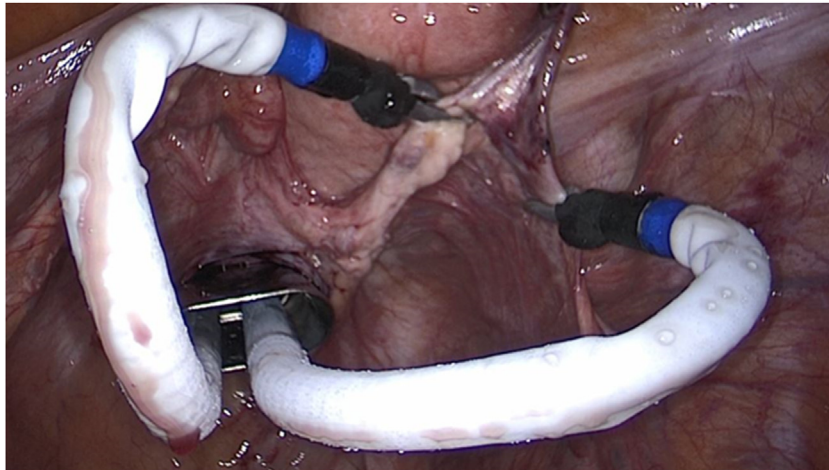


Fig. 3. The Hominis Arms™ are retroflexed towards the point of entry, thereby enabling performing the procedure with a laparoscopic point of view and reaching various structures in the pelvic cavity.

transvaginally through the posterior fornix to the pelvic cavity (Fig. 2), retroflexed towards the point of entry (Fig. 3). This enables performing the procedure with a laparoscopic point of view and reaching various structures in the pelvic cavity, in a manner not possible with traditional manual vaginal tools. For accuracy and user-friendly capacity, each Arm corresponds to the respective

hand of the surgeon as controlled by the right and left Joysticks. The Arms include a rigid section (shaft) and a flexible section; the latter is composed of three joints, according to the design of the human arm: Shoulder, Elbow, and Wrist. Both Shoulder and Elbow joints can rotate and flex (Fig. 4). The Wrist joint can rotate about its axis. Each Joystick has three corresponding joints: Shoulder, Elbow, and Wrist, such that each Hominis Arm™ moves according to the Joystick's movement. Effectors at the distal ends of the Arms enable grasping, blunt dissection, approximation, and electro-surgery.

The Hominis™ Control Console is the main Human Machine Interface for the Hominis™ Surgical System. The surgeon is seated and controls the Hominis Arms™ through two Hominis Motor Units. The Motor Units contain motors, sensors, drivers, and the electronic board required to drive the Hominis Arms™. Each Motor Unit drives one Arm and connects the Arms to an electro-surgical generator through two connectors, one for monopolar energy and another for bipolar energy. The Motor Units house a motorized prismatic joint that enables controlled linear motion to insert or extract the Arms from the pelvic cavity. The movement is operated via the Joysticks. The Motor Units are attached to the surgical table using a Surgical Fixation Arm and covered with a sterile cover; and are thus not in contact with the patient. Alternatively, the Motor Units can be attached to a cart as a floor mounted system.



Fig. 4. Hominis Joysticks™ components: rigid section (shaft) and a flexible section; the latter is composed of three joints, according to the design of the human arm: Shoulder, Elbow, and Wrist.

Table 1
Sociodemographic data and medical history.

Age (years), median and range	64 (50–70)
Parity, median and range	3 (0–5)
Gravida, median and range	3 (0–5)
BMI (kg/m ²), median and range	24 (19–30)
Smoking, number (%)	Current 2 (25 %) Previous 1 (12.5 %)
Hypertension, number (%)	1 (12.5 %)
Hyperlipidemia, number (%)	2 (25 %)
Cardiac disease, number (%)	1 (12.5 %)
Diabetes, number (%)	1 (12.5 %)

BMI-Body Mass Index.

The surgical procedure

All the surgeries were performed by two primary surgeons: L.L (Israel) and J.B (Belgium), who were assisted by 2 residents each. The surgical procedure using The Hominis™ Surgical System was performed similarly to standard transvaginal surgery. The surgical area and transvaginal access were prepared by the site staff according to standard of care. Following insertion of the two robotic Hominis Arms™ through the posterior fornix, BSO proceeded as per standard of care, with dissection of the suspensory ligament and ovarian ligament using bipolar electrocautery for hemostasis and nonpolar electrocautery for cutting (**Video**). Target organs were removed through the posterior fornix. For vaginal closure we used Vicryl (Ethicon Inc.) continuous suture. Surgical data were collected during the procedures. Postoperative care was in accordance with the local protocols.

Endpoints and outcome measures

The primary endpoint of the study was the occurrence of peri-procedural (i.e., from procedure onset until hospital discharge) major complications related to the Hominis™ system. These include major hemorrhage (requiring transfusion), hematoma (requiring transfusion or surgical drainage), bowel injury, ureteric or bladder injury, bladder injury, pulmonary embolus, major anesthesia problems, wound dehiscence, and conversion to laparotomy.

Secondary endpoints were: 1) device success, defined as the ability to perform required tasks with the Hominis™ Surgical System; 2) procedure success, defined as device success with no peri-procedural major complication; 3) usability assessment by the physician and operating room staff on a scale from 1 (poor) to 5 (good). Other observational measures included procedure duration (docking time, robotic time, total operation time, skin to skin),

Table 2
Intraoperative and postoperative data.

BSO time, minutes, median (range)	45 (38–91)
Docking time, minutes, median (range)	5 (1–28)
Blood loss, ml, median (range)	10 (10–50)
Pain assessment (VAS: 0–10), median (range)	1 (1–3)
Demand for analgesics:	
P.O Paracetamol, number (%)	8 (100 %)*
P.O NSAIDS, number (%)	2 (25 %)
Opioids, number (%)	0
I.V Analgesics, number (%)	0
Length of hospital stay, median (range) (days)	1 (1–2)

VAS – visual analog scale; NSAIDS - nonsteroidal anti-inflammatory drugs P.O-per os; I.V-intravenous.

* Routinely administered.

duration of postoperative hospital stay, intraoperative and postoperative complications and adverse events, blood loss, and pharmacological treatment. Every 8 h during the first 24 h following the procedure, patients were asked to rate their pain on a visual analog scale, from 0 (no pain) to 10 (maximum pain).

Results

The median age was 64 years (range: 50–70) and the median BMI was 24 kg/m² (range: 19–30 kg/m²). Three (37.5 %) women had co-morbidities (**Table 1**). The median duration of the procedure was 45 min (range: 38–91). Evaluation of the learning curve of the procedures that were done in Rambam (7/8) demonstrated a decrease in procedure time when comparing between the first two cases (91 and 60 min) and the following five cases (40,38,40,51 and 51 min) (**Fig. 5**). The median docking time was 5 min (range: 1–28) (**Table 2**). Estimated blood loss was minimal in all the procedures, with a median of 10 mL (range: 10–50).

The median hospital stay was one day (range: 1–2). The median postoperative pain score according to the visual analog scale (VAS) was 1 (range: 1–3). Two women requested analgesia beyond the routinely administered postoperative paracetamol; both were treated with oral ibuprofen. None of the women needed oral opioids or intravenous analgesics (**Table 2**).

There were no conversions to open surgery and no intra-operative complications. Both device and procedure success were demonstrated; as all the required surgical tasks were performed as intended. Qualitative assessment of ergonomics and comfort showed that operating via the Hominis platform was feasible and easily mastered, without a requirement of extra technical skills (**Table 3**).

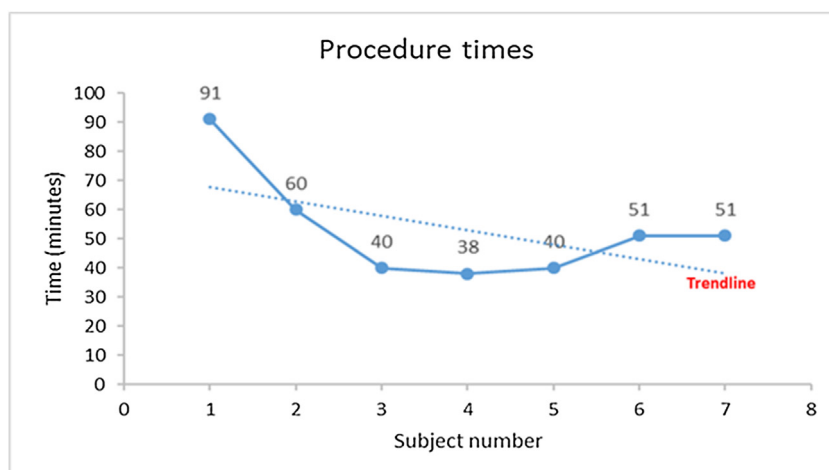


Fig. 5. The duration of seven consecutive procedures performed at one institution.

Table 3
Surgeon usability assessments.

Usability assessment	Median (Range)
Accuracy and precision of the device	5 (3–5)
Device responsiveness	4 (4–5)
Device articulation and accessibility	5 (3–5)
Device robustness	5 (4–5)
Integration in the operating room	5 (4–5)
General impression of the system	5 (4–5)

There were no postoperative adverse events. At the 6-week follow-up visit, the vaginal tissue was fully recovered in all the participants.

Discussion

Previous IDEAL stage 1 reports on transvaginal robotic surgery used a robotic system that was not developed for transvaginal use [19,20]. Those studies concluded that transvaginal robotic surgery is feasible but that further developments in robotic technology are necessary to overcome practical problems such as arm collision, and to improve time efficiency.

This is the first documentation of a surgery performed via the vagina using robotic-assisted instrumentation developed for this purpose. All the operations were completed as intended, with no conversions to laparoscopic or open surgeries. No device-related perioperative or postoperative adverse events were observed; and blood loss was minimal. The operation time (median 45 min, range: 38–91) was considerably shorter than the mean time (182 min) reported for 18 transvaginal BSO that were not robotic-assisted [21]; and similar to that reported for 15 robot-assisted laparoscopic BSO procedures (mean 47 min, range: 15–120) [22]. In the current series of RvNOTES, the decreasing operation time with subsequent surgeries indicates a rapid learning curve.

The feasibility and user-friendliness of RvNOTES demonstrated in this small study has substantial clinical implications. First, we expect that vNOTES, as a natural incision-less procedure, will grow in attractiveness to surgeons, due to its overcoming of technical challenges that have been barriers to greater utilization of such procedures. Second, we expect that the benefits of robotic-assistance will be particularly profound in the context of the natural single-access of vNOTES. Notably, while robotic-assistance has generally demonstrated similar patient outcomes as conventional laparoscopic surgery in gynecological procedures [23], a number of studies have reported better outcomes, including less estimated blood loss [24,25], fewer intraoperative complications [26], less conversion to open surgery [27], and shorter hospital stay [25,28]. In the setting of vNOTES, these advantages of robot-assisted surgery may increase. Perhaps the greatest advantage of RvNOTES will be the easy implementation of vNOTES procedures; the fast learning curve will enable performance by less experienced surgeons despite the relatively high level of expertise required. Other outstanding features of the novel vNOTES robotic apparatus include its portability and easy handling due to its light weight (less than 10 pounds), scarless surgery, and access to any part of the abdomen by articulation of the flexible robotic arms. No special maintenance is required. The approach combines the benefits of vaginal procedures and laparoscopic techniques and maintains safety in regard to proximity to pelvic organs. The era of robotic surgery is expected to evolve rapidly, and the potential of the described device may generally enhance the precision of surgery. The advent of computer and software technology that interfaces between the surgeon and the patient may promote a particularly functional robotic surgery system. This may ultimately facilitate minimally invasive surgery, improve surgeons' abilities to perform gynecological procedures and reduce complications.

This case series demonstrated the feasibility of using RvNOTES for BSO for benign gynecologic indications. A study on hysterectomies using RvNOTES is being finalized. Though the evidence is sparse, hysterectomy by vNOTES without robotic assistance, compared to laparoscopy, demonstrated less bleeding [29], shorter operative time and length of stay [30], less complications, lower pain scores, and less use of analgesics [31]. The technical advantage of robotic-assistance is expected to contribute substantially to the already positive patient outcomes achieved in hysterectomy by vNOTES.

The disruptive technology of vNOTES has the potential to dramatically increase the types and volume of gynecological surgeries performed vaginally [32–35], and to make this non-incision surgical option accessible to more women. In addition, robotic-assisted vNOTES will facilitate vaginal access for diverse non-gynecological surgeries including those of the upper-abdomen. Notably, vaginal access was demonstrated as safe and feasible also in older women and women with obesity [36]. Moreover, following transvaginal cholecystectomy, sexual function was not impaired and quality of life was reportedly unchanged or improved [37].

Though more than a decade and a half have passed since the first cholecystectomy by NOTES, the concept of natural orifice procedures has not become standard of care. During this period, accumulating evidence has demonstrated the safety and feasibility of natural orifice specimen extraction surgery (NOSES) [38,39], as well as of NOTES (40). Accordingly, a recent consensus statement was published regarding the use of NOSES to avoid abdominal incision in laparoscopic surgery [41]. In an online survey among surgeons in Brazil, 56 % of the respondents stated they would choose a transvaginal approach for extracting a kidney, for themselves or a close relative [42]. Among patients hospitalized in China, 45 % stated they would choose NOTES; the latter comprised predominantly females, and the younger and more educated patients [43]. Clearly, NOTES in general, and RvNOTES in particular, represents a new paradigm for both surgeons and patients. Nonetheless, the underutilization of NOTES even among gynecologists [13,16] highlights the urgent need for appropriate and designated instrumentation, in addition to the assimilation of a new paradigm. This is precisely the gap to be filled by robotic-assisted technology designed specifically for NOTES. Further studies are needed to evaluate the long-term outcomes and determine the ultimate utility of this modality.

Consent

Written informed consent was obtained from the patient for publication of these images.

Financial disclosure

This study was supported by MEMIC Medical Ltd.

Declaration of Competing Interest

L.L, E.M, Z.W report no conflict of interest, J.B discloses consultancy for Applied Medical.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.eurox.2020.100113>.

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