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NEW TECHNOLOGY

First series of total robotic hysterectomy (TRH) using new integrated table motion for the da Vinci Xi: feasibility, safety and efficacy

Andrea Giannini[1] · Eleonora Russo[1] · Paolo Mannella[1] · Giulia Palla[1] · Silvia Pisaneschi[1] · Elena Cecchi[1] · Michele Maremmani[1] · Luca Morelli[2] · Alessandra Perutelli[1] · Vito Cela[1] · Franca Melfi[3] · Tommaso Simoncini[1]

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Abstract

Background To present the first case series of total robotic hysterectomy (TRH), using integrated table motion (ITM), which is a new feature comprising a unique operating table by Trumpf Medical that communicates wirelessly with the da Vinci Xi surgical system. ITM has been specifically developed to improve multiquadrant robotic surgery such as that conducted in colorectal surgery.

Methods Between May and October 2015, a prospective post-market study was conducted on ITM in the EU in 40 cases from different specialties. The gynecological study group comprised 12 patients. Primary endpoints were ITM feasibility, safety and efficacy.

Results Ten patients underwent TRH. Mean number of ITM moves was three during TRH; there were 31 instances of table moves in the ten procedures. Twenty-eight of 31 ITM moves were made to gain internal exposure. The endoscope remained inserted during 29 of the 31 table movements (94%), while the instruments remained inserted during 27 of the 31 moves (87%). No external instrument collisions or other problems related to the operating table were noted. There were no ITM safety-related observations and no adverse events.

Conclusions This preliminary study demonstrated the feasibility, safety and efficacy of ITM for the da Vinci Xi surgical system in TRH. ITM was safe, with no adverse events related to its use. Further studies will be useful to define the real role and potential benefit of ITM in gynecological surgery.

Keywords da Vinci Xi · Table motion · TRH · Gynecological surgery · Robotic-assisted surgery

The advent of robotics in clinical practice has taken gynecological surgery to a new level, and several advantages have been universally demonstrated. Most gynecological surgeons use the da Vinci surgical system in oncologic and benign surgery where narrow pelvis, obesity or shallow sacral angle may represent operative limits [1]. These factors restrict the maneuverable space during minimally invasive dissection using laparoscopy and make for unsatisfactory exposure, leading to a suboptimal surgical field [2]. The robotic platform provides a stable camera view to identify vessel, autonomic nerve and muscular–fascial structures and allows for powerful countertraction under the surgeons' control, which could compensate for the level of surgical difficulty; in addition, the internal Endo-Wrist enables fine and precise movements even in limited spaces such as the pelvis [3].

Integrated table motion (ITM) for the da Vinci Xi surgical system (Intuitive Surgical Inc., Sunnyvale, CA, USA) is a new feature comprising a unique operating table by Trumpf Medical Systems that communicates wirelessly with the da Vinci Xi. The ITM feature allows surgical staff to reposition the patient without undocking the robot and without removing instruments from inside the abdomen.

The da Vinci Xi surgical system and the TruSystem 7000dV operating table (TS7000dV, TRUMPF Medizin

✉ Tommaso Simoncini
tommaso.simoncini@med.unipi.it

1 Division of Obstetrics and Gynecology, Department of Clinical and Experimental Medicine, University of Pisa, Via Roma, 67, 56126 Pisa, Italy

2 General Surgery Unit, Department of Oncology, Transplantation and New Technologies, University of Pisa, Pisa, Italy

3 Multidisciplinary Center of Robotic Surgery, Azienda Ospedaliero Universitaria Pisana, Pisa, Italy

Systeme GmbH & Co. KG, Saalfeld, Germany) have been specifically developed to address some technical limitations of the da Vinci Si surgical system and to improve multiquadrant robotic surgery. An important drawback during robotic procedures with the previous da Vinci Si system is the inability to move the table position with the robotic arms docked. This problem may be particularly amplified in pelvic surgery, in which orientation in a narrow space, the identification and attribution of structures and the estimation of the instrument's position in relation to the position of risk and target structures are difficult [4].

Thought that robotic assistance for surgical gynecological procedures has grown on a worldwide scale, improving surgery particularly for use in more complex operations, such operations usually require meticulous handling of tissue, involve a narrow working space and limit the surgeon's sense of orientation in the human pelvis [5].

The new da Vinci Xi system can enable patient repositioning without undocking the robot and with instruments still inside the abdomen, thus overcoming problems related to timely access tasks, poor exposure or patient safety [6, 7].

Hence, the field of gynecological surgery that often required conservative approaches has been identified as an important focus for studying the new ITM [8]. Herein we present the first study on human use of this device in gynecological surgery. The purpose of this study was to evaluate the efficacy, feasibility and safety of ITM for the da Vinci Xi system in performing TRH.

Materials and methods

Between May and October 2015, the first human use of ITM was carried out in a post-market study in the EU in which 40 cases from different specialties (general surgery, urology or gynecology) were prospectively enrolled. The ethics committee of our institution approved this study. Patients who planned to undergo minimally invasive surgery within the specialties of general surgery, urology or gynecology with the commercially available da Vinci Xi surgical system and who were eligible based on the inclusion and exclusion criteria of this study were offered enrollment. Study-specific informed consent was obtained in writing from each patient before any procedure specific to the clinical investigation was performed.

Inclusion criteria were: body mass index $\leq$45 kg/m^2; age 18 years or older; suitable for minimally invasive surgery; undergoing a surgical procedure in urology, gynecology or general surgery; ability to tolerate the Trendelenburg position; willingness to participate as demonstrated by giving written informed consent. Exclusion criteria were: American Society of Anesthesiologists (ASA) IV patients; pregnancy; lack of cooperation due to psychological or severe systemic illness; comorbid medical conditions contraindicating general anesthesia or standard surgical approaches; vulnerable population (such as prisoners, mentally disabled); anatomy unsuitable for endoscopic visualization or minimally invasive surgery; extensive previous abdominal surgery; patient not compatible with the Trumpf TS7000dV operating table due to weight >1000 lbs, allergy to table material, stature not fitting on table, inability to be positioned for surgery or inability to get low enough for robotic docking.

The gynecological study group comprised 11 patients. Ten of 11 patients were selected for TRH for different clinical indications. Preoperative imaging was achieved by ultrasound examination, with biopsies taken of endometrial or cervical lesions; patients also underwent computed tomography scanning, magnetic resonance imaging and other specific examinations when necessary. Variables examined included patient demographics and characteristics such as age, height, weight, sex, ASA score, comorbidities and previous abdominal surgery. We collected data regarding the patient position on the table, surgical approach, targeting, procedure operative times, distinguishing operating room enter/exit time, anesthesia start/stop time, operative start/stop time and robot dock/undock time.

Primary endpoints were ITM efficacy, safety and feasibility. We evaluated efficacy and feasibility by assessing the number of ITM moves made per case, duration of each table motion, table position attained, reasons for moving the table, and the state of the instruments and endoscope during table motion (inserted or removed). We evaluated the safety of ITM by analyzing patient vital data (pre- and postoperative mean blood pressure and heart rate), estimated blood loss, urine volume, total administered fluid, port-site condition, intra- and postoperative complications, adverse events related to the use of ITM (incidence of tissue/nerve/organ injuries) and discharge date (Table 1).

Device notes

The TruSystem 7000dV operating table can interact with the da Vinci Xi surgical system to support ITM, enabling table motion with the robotic side-cart while it is docked (attached) to cannulas inside the patient. The operating table is an optional third-party auxiliary product for use with the da Vinci Xi system; it is not required for normal use of the da Vinci Xi system. Two types of wireless interfaces (infrared and radiofrequency) enable communication between the table interface module (TIM) in the da Vinci Xi system and the operating table. A remote connected to the table via cable is used by surgical staff to command table motion (Figs. 1, 2). Da Vinci ITM allows

Table 1 Characteristics of patients, intra- and postoperative data of total robotic hysterectomy (TRH) using integrated table motion

Baseline characteristics	
Patients, number	10
Age, mean (range)	58.6 years (41–77)
Body mass index, mean (range)	25.3 kg/m^2 (18–37)
ASA physical status classification, number (%)	
II	9 (90%)
III	1 (10%)
Comorbidities, number (%)	7 (70%)
Previous abdominal surgery, number (%)	6 (60%)
Intra-operative and postoperative data	
Robotic operating time, minutes mean (range)	152 (120–240)
ITM moves, mean number (range)	3.3 (1–6)
Instance of ITM moves, total number	31
Internal exposure (%)	28 (90%)
Endoscopic observation (%)	2 (6%)
Improve external access (%)	1 (4%)
ITM duration, minutes mean (range)	32 (6–73)
Instruments left inside during ITM (%)	27/31 (87%)
Port-site condition with damage (%)	0 (0%)
In hospital morbidity (%)	0 (0%)
Type of surgical technique, number (%)	
Full robotic technique	10 (100%)
Hybrid technique	0 (0%)

ASA American Society of Anesthesiologists, *TRH* total robotic hysterectomy, *ITM* integrated table motion

the surgical staff to reposition the patient by adjusting the table while still docked to the da Vinci Xi surgical system. When users turn on ITM, brakes release the joints of the da Vinci Xi system's patient cart, allowing the instrument arms to passively and safely move with the patient. If instruments remain on the arms during the motion, the surgeon must have them in view and under active control for the table motion to be allowed. When users turn off da Vinci ITM, these joint brakes reapply, and the arms return to typical surgical use. If the joints reach a range of motion limit during ITM, the boom compensates by moving in a direction that gives the arms additional range of motion.

Statistical analysis

Variables of interest were analyzed retrospectively after institutional review board approval. Sample characteristics were assessed using descriptive statistics. Continuous variables were expressed as the mean, median and range, whereas categorical variables were expressed as counts and percentages. Analyses were performed using the statistical package SPSS®, version 17 (SPSS Inc., Chicago, IL, USA).

Results

During the study period, ten patients underwent total robotic hysterectomy (TRH) with TME. In detail, six patients underwent TRH for benign uterine pathology and four patients for malignant indication. In consideration of menopausal pre-surgical condition, ten patients underwent concomitant bilateral salpingo-oophorectomy (BSO), while four patients with oncological indication underwent concomitant pelvic lymphadenectomy. Mean operating room enter/exit time was 152 min (median 125 min, range 120–240 min), and mean robotic time was 115 min (median 94 min, range 83–192 min). We obtained targeting success in all cases. The mean number of ITM moves was 3.3 (median 3, range 1–6), resulting in 31 instances of table moves in ten procedures. The mean duration of each table motion was 32 s (median 28 s, range 6–73 s). The desired table position was attained in all cases. The reason for moving the table was to gain internal exposure in 28 cases (90%), to perform endoscopic observation in two cases (6%) and to improve external access in one case (4%). The endoscope was left inserted during 29 of the 31 table movements (94%), as well as the instruments were left inserted during 27 of the 31 table movements (87%). The ITM duration was <1 min per move in 25 of 31 of moves (80%). Mean estimated blood loss was 52 ml (median 210 ml, range 0–400 ml), mean urine volume was 783 ml (median 640 ml, range 350–1800 ml), and mean total volume of administered fluid was 2550 ml (median 2500 ml, range 2000–4000 ml). The mean pre- and postoperative blood pressure was 132/75 mmHg (median 130 mmHg, range 105–155 mmHg) and 125/70 mmHg (median 130 mmHg, range 100–160 mmHg), respectively. The mean pre- and postoperative heart rate was 65.4 bpm (median 57.5 bpm, range 45–80 bpm) and 56.3 bpm (median 57.5 bpm, range 40–84 bpm), respectively. The mean hospital stay was 3.6 days (median 3 days, range 2–5 days). The port-site condition was undamaged in all cases. No external instrument collisions or other problems related to the operating table were noted. There were no ITM-related intra- and postoperative complications or need to convert to laparoscopy or laparotomy. There were no ITM safety-related observations and no adverse events (Table 1).

Discussion

The da Vinci Xi is the latest release product of Intuitive Surgical systems; this product represents an important change and innovation in form and functionality compared with the previous version. The new overhead architecture combines the functionality of a boom-mounted system with

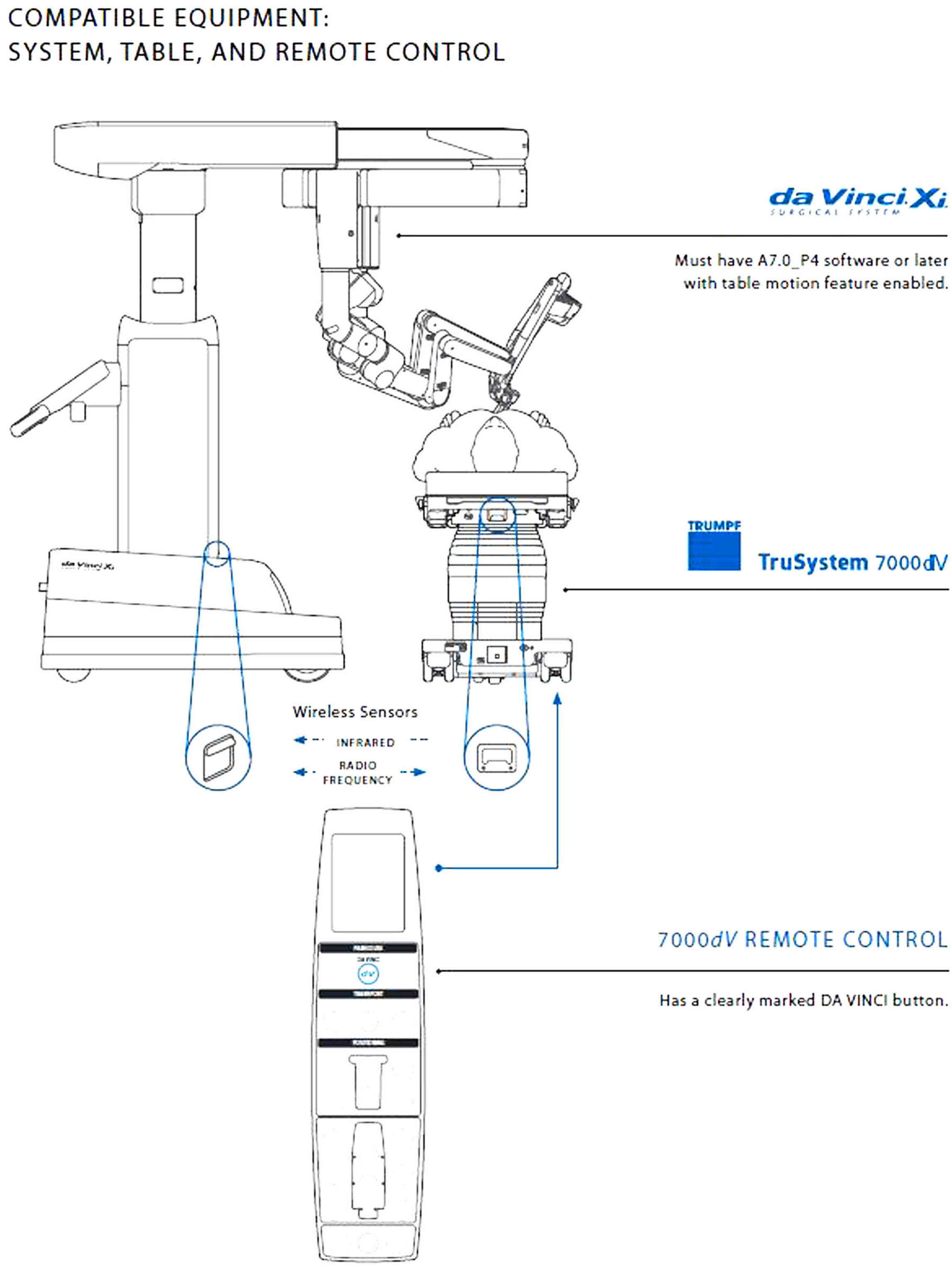

Fig. 1 Illustration of integrated table motion (ITM) for the da Vinci Xi surgical system (Intuitive Surgical Inc., Sunnyvale, CA, USA). ITM is a new feature comprising a unique operating table by Trumpf Medical Systems that communicates wirelessly with the da Vinci Xi. The da Vinci Xi surgical system and the TruSystem 7000dV operating table (TS7000dV, TRUMPF Medizin Systeme GmbH & Co. KG, Saalfeld, Germany) have been specifically developed to address some technical limitations of the da Vinci Si surgical system and to improve robotic surgery

Fig. 2 Details of different elements of ITM in the operating room

the flexibility of a mobile platform. Although the maneuverability of this new generation of the da Vinci system seems superior to its precursor, the fixed patient position still limits the working space in some border areas such as the pelvis. Undocking, instrument extraction and cart repositioning could remain necessary for better exposure or patient safety, similarly to the previous da Vinci Si; this may impede the flow of the operation [6, 7]. ITM makes it possible to move the operating table without removing the instruments from inside the abdomen, which simplifies the work flow without struggle or taking time to undock/redock the platform. ITM allows surgeons to maximize all the advantages of the robotic technique while reducing its specific drawbacks, enabling access to different parts of the anatomy in a faster manner during procedures that involve difficult target anatomy. In these situations, similarly to laparoscopy, the da Vinci Xi plus the new operating table give the potential to optimize gravity exposure and provide the quick access to narrow spaces that is important in gynecological surgery. These can be accomplished robotically by regulating the Trendelenburg and lateral tilt of the ITM without undocking the robotic platform. In the present study, most ITM movements during TRH took <1 min, permitting a fine regulation during all surgical phases that is not possible without its use. With increasing familiarity with this new device and having established its safety, we have tried to follow a standardized approach regarding table movements and reasons for ITM usage for both TRH procedures. During TRH, the patient was generally arranged in a shifting 21°–30° Trendelenburg position in relation to different surgical steps or patient-specific anatomical setting and needs. During lymphadenectomy, patients were tilted to the right or left for iliac vessels exposure. In two cases, maximum Trendelenburg position was required in order to obtain a good exposure of the recto-vaginal and vesical–vaginal spaces during deep dissection of these anatomical sites. ITM provided stable patient repositions and powerful gravity traction under the surgeons' control, providing ideal surgical exposure in all phases of the intervention. Another important consideration is that the TruSystem 7000dV could increase patient safety in extreme Trendelenburg positions. In our preliminary experience, some anesthesiologic parameters were considered as indirect signs of ITM safety. There were no important hemodynamic changes during the entire course of surgery, and pre- and postoperative blood pressure and heart rate were similar. ITM may contribute to patient relief during Trendelenburg surgery (not only from an hemodynamic point of view but also by preventing increased intraocular pressure, neurologic or soft tissue injuries), minimizing use of extreme positions by starting with a less extreme patient position and changing to more extreme positions only when necessary. Moreover, it gives anesthesiologists the ability to precisely control patient positioning and display the table position to the entire surgical team (the degree of Trendelenburg and tilt are displayed on the remote, Vision System Cart monitor and Surgeon Side Console monitor). Limitations of the present pilot study are related to the small sample size, the heterogeneity of surgical procedures (both benign and malignant indications) and differences in the learning curve period of surgeon groups that preclude definitive conclusions about ITM clinical advantages in reduction in overall operative time. Moreover, the debate about real indications for robotic surgery in gynecology is still open and unclear. Despite a lack of evidence showing improved clinical outcomes with robotic-assisted hysterectomy over other minimally invasive routes for benign indications, this route has increased in popularity over the last decade. Robotic-assisted laparoscopy does not decrease major morbidity following hysterectomy for benign indications when compared to other minimally invasive routes. While superficial surgical site infection and blood transfusion rates were statistically lower in the robotic-assisted approach, in the absence of substantial reductions in clinically and financially burdensome complications, it will be challenging to find a scenario in which robotic-assisted hysterectomy is clinically superior and cost-effective [8].

Nevertheless, further studies may demonstrate whether ITM could enable procedures (or part of procedures) to be done robotically that would otherwise be difficult and whether ITM could improve operative efficiency by reducing surgical operative time. In fact, it has been recently demonstrated a direct, independent association between operative time and 30-day complications after laparoscopic and robotic hysterectomy. In this view, future research should aim to further delineate risk factors for prolonged operative time and morbidity in laparoscopic hysterectomy to allow surgeons to maximize preoperative planning and optimize patient selection for minimally invasive hysterectomy [9].

Cost analysis is also important in evaluation of ITM devices. In conclusion, TRH procedures may require deep operative field in the pelvis and anatomical targets that often are localized in narrow spaces. The advent of the da Vinci Xi and the new operating table that communicates wirelessly with the robotic platform can overcome the intrinsic limits of robotic surgery, while maintaining its specific advantages. Even if acquired data derived from a small subgroup of patients detracting somewhat from its scientific value, this preliminary study demonstrated the feasibility of ITM in performing da Vinci Xi TRH, which enabled patient repositioning without disrupting surgical workflow by allowing the surgeon to leave instruments in place and the endoscope docked to the patient. This is particularly important in the uterine surgery (both benign and malignant) to accomplish all surgical steps with optimal exposure due to robotic dexterity. ITM was safe, and no adverse events related to its use were reported. Moreover, patient safety is increased as it is possible to modify extreme positions to reach a good compromise between optimal visceral exposure and anesthesiologic risks. Further studies with a greater number of patients are mandatory for the assessment of real ITM surgical advantages and values.

Compliance with ethical standards

Disclosures Dr. Andrea Giannini, Dr. Eleonora Russo, Dr. Paolo Mannella, Dr. Giulia Palla, Dr. Silvia Pisaneschi, Dr. Elena Cecchi, Dr. Michele Maremmani, Dr. Luca Morelli, Dr. Alessandra Perutelli, Dr. Vito Cela, Dr. Franca Melfi and Prof. Tommaso Simoncini have no conflicts of interest or financial ties to disclose.

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