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Robotic-assisted hysterectomy using DEXTER®: the first prospective multicentre study

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ABSTRACT

Background: Minimally invasive hysterectomy is increasingly performed robotically as new systems expand options and address limitations of traditional platforms, including financial, infrastructure, and workflow demands. The DEXTER® Robotic Surgery System was designed to address some of these challenges.

Objectives: To confirm perioperative and early postoperative safety, and evaluate the clinical performance of DEXTER in hysterectomy.

Methods: This prospective multicentre study included 34 patients who underwent robotic-assisted hysterectomy for benign or low-risk malignant diseases between November 2022 and November 2023. DEXTER was integrated into the surgical workflows of the four participating centres, which used their existing laparoscopic towers.

Main Outcome Measures: Primary outcomes were procedural conversions and Clavien-Dindo grade III-V events up to 30 days post-surgery.

Results: Median patient age was 45.5 years; median body mass index was 26.0 kg/m^2. There were no conversions to laparotomy, intraoperative complications or transfusions, with a median estimated blood loss of 100 mL. Median skin-to-skin operative time was 125.5 min, including a median docking time of 5 minutes. Median length of hospitalisation was 2 days. Two Clavien-Dindo grade IIIb adverse events were recorded, neither of which was device-related. In 3 cases, the surgeons decided to finish the procedure laparoscopically.

Conclusions: Hysterectomy assisted with DEXTER can be safely performed even in the early learning phase. DEXTER facilitated an adaptable OR workflow allowing greater flexibility in procedural approaches. Further investigation with a larger cohort and a longer follow-up is required to evaluate long-term outcomes.

What is New? First prospective multicentre study to confirm robotic-assisted hysterectomy using DEXTER is a feasible and safe approach for treating benign and low-risk malignant conditions.

Keywords: Hysterectomy, intraoperative complications, laparoscopic, prospective, robotic-assisted, robotic surgery

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Introduction

Hysterectomy is the most common gynaecological surgery, with variable incidence rates among countries.[1,2] Approximately 10% of hysterectomies are performed for malignant conditions, whereas the majority address benign indications such as myomas, abnormal uterine bleeding, prolapse, and endometriosis.[1]

Robotics is increasingly adopted in gynaecology surgery,[3,4] combining the established benefits of minimally invasive surgery, such as reduced blood loss, faster recovery, and shorter hospital stays,[5-7] with robot-specific advantages, including improved ergonomics, natural movements, and enhanced dexterity through articulated instruments and elimination of the "fulcrum effect".[8-10] Additionally, robotics may be gaining popularity simply because it is perceived by surgeons as easier and more comfortable to use.[11]

Robotic hysterectomy is considered non-inferior to conventional laparoscopic hysterectomy in terms of peri- and postoperative complication rates, though further studies are needed to determine clear advantages in clinical outcomes.[12,13] Most comparative studies to date have been retrospective, prone to underreporting of adverse events, or limited to the learning phase, which may not capture a comprehensive assessment of the robotic approach.[6,14]

Conventional robotic systems also introduce challenges, including increased costs compared to other surgical approaches,[15] limited availability when shared with other surgical departments, and operative room (OR) setups that physically separate surgeons from their teams. This separation can hinder situational awareness and decision-making,[16] disrupt communication through the closed console (noise, missing non-verbal cues), and increase reliance on surgical assistants during emergencies while the non-sterile console surgeons scrub in.[17] Furthermore, the large footprint of existing systems around the operating table often impedes patient access.[18]

The DEXTER® Robotic Surgery System (Distalmotion SA, Epalinges, Switzerland) is CE marked for use in gynaecology, urology, and general surgery, and has been routinely utilised in clinical practice since 2022.[19-23] It was designed with an open-architecture and small, mobile footprint, so it could integrate into diverse laparoscopic workflows without dedicated room or installation requirements, while offering the full articulation, precision, and ergonomic benefits of a robotic system.[24]

One of the design features of DEXTER is its compact, modular layout, which provides unobstructed access to the surgical table, allowing both the table assistant and the uterine manipulator assistant to work alongside the robotic arms without interference. DEXTER furthermore allows scrubbed surgeons to alternate easily between conventional laparoscopy and robotic surgery as desired within seconds.[25]

Evidence on the use of DEXTER in real-world gynaecology surgery remains limited.[19,26] This study analysed the safety and performance of hysterectomy with DEXTER in a prospective, multicentre setting during the initial learning phase of participating surgeons.

Methods

Study Design and Population

This was a prospective, single-arm study, approved by the Ethics Committees according to local and national regulations of the participating countries (Switzerland: protocol number: 2021-00079, date: 14.09.2022; Germany: protocol number D525/22, date: 23.08.2022; France: not required for observational studies). All patients provided informed consent. The study was conducted in line with the Declaration of Helsinki and ISO 14155:2020 standards and was registered in the ClinicalTrials.gov database (NCT05537727). The study was completed in the context of the post-market clinical follow-up evaluation, which included 3 surgical procedures: hysterectomy, partial nephrectomy, and right colectomy. This article reports the results from the hysterectomy cohort only.

All enrolled patients were adult women scheduled to undergo minimally invasive hysterectomy with DEXTER according to its intended use. The study methodology aimed to reflect a real-world surgical environment, capturing a range of typical indications encountered in every gynaecology practice, including myomas, abnormal uterine bleeding, endometriosis, as well as confined uterine malignancies with minimal risk of metastasis. Patients requiring additional procedures such as salpingo-oophorectomy, lymphadenectomy, or excision of endometriosis were also included if these interventions were part of the planned treatment. All patients were followed for 30 days postoperatively.

Exclusion criteria included morbid obesity [body mass index (BMI) ≥40], contraindications for endoscopic surgery, bleeding diathesis, presence of pacemakers or internal defibrillators, pregnancy, or concurrent participation in

another interventional clinical trial. Procedure-specific exclusion criteria included a history of major abdominal or pelvic surgery (defined as abdominal incisions >10 cm or extensive organ resections significantly altering anatomy), malignancies with intraabdominal spread, and uterine fibroids >8 cm.

The primary safety endpoint was the occurrence of Clavien-Dindo grade III-V adverse events during the perioperative period and up to 30 days postoperatively. The primary clinical performance endpoint was a successful completion of the procedure without conversion to open or fully laparoscopic surgery due to any robotic system deficiency. This endpoint reflects the intended application of DEXTER as an assistive robotic system, deployed at the surgeon's discretion for selected procedural steps. Secondary safety endpoints included perioperative and early postoperative outcomes such as intra- and postoperative complications, estimated blood loss, length of hospital stay, procedure-related rehospitalisation, and mortality. Secondary performance endpoints included docking time and total operative time. Total (skin-to-skin) operative time was measured from the first skin incision to the final suture, including any concomitant procedures. Docking time was measured from the moment the patient carts approached the operating table until the final docking step was completed, defined as either the removal of the last incision pointer or the secure placement of the endoscope in the docking arm, whichever occurred later.

Procedures were performed by six laparoscopic surgeons with a minimum of ten years of surgical experience, stratified by robotic surgery proficiency: two novice users (no prior robotic experience before training on DEXTER), two intermediate users (limited robotic experience either with DEXTER or another robotic platform, defined as <2 years of robotic practice), and two expert users (≥3-5 years of routine robotic use for both simple and complex procedures across one or more robotic platforms). All centres completed the mandatory manufacturer training prior to the first surgeries. The training curriculum included an online didactic course focusing on the DEXTER hardware, preparation and procedural steps, as well as multiple hands-on sessions in dry-lab and wet-lab environments, and optional simulator exercises. Additionally, all centres had treated three roll-in patients using DEXTER prior to enrolling in the study.

DEXTER® Robotic Surgery System

The DEXTER system consists of four modular components: two patient carts with robotic instrument arms, an endoscope cart with a robotic endoscope arm, and an open surgeon console with height-adjustable ergonomic armrests. The console includes two pedals for clutching and endoscope control.

Docking is facilitated by so-called "incision pointers", which help align the instrument arms' remote centre of motion with the trocars (Figure 1a). The system is fully draped, allowing the surgeon to remain sterile when working at the console and immediately access the patient when necessary. The robotic instrument arms can be retracted into laparoscopic mode within seconds, allowing ample space and trocar access to perform certain steps laparoscopically (Figure 1c), even with two assistants and a scrub nurse present. This enables seamless transitions between robotics and conventional laparoscopy.

Dexter integrates with existing OR infrastructure, including electrosurgical and endoscopic equipment. The surgeon continues using the existing electrosurgery pedals from the laparoscopic tower. At the console, DEXTER integrates with the full visualisation system, including two-dimensional and three-dimensional (3D) imaging as well as indocyanine green (ICG) fluorescence. The system supports five single-use, fully articulated 8-mm robotic instruments: a monopolar hook, monopolar scissors, a bipolar Maryland dissector, a bipolar Johann grasper, and a needle driver. Each instrument offers seven degrees of freedom and a micro-clutching function on wrist rotation for precise, natural control, even at extreme angles.

Surgical Technique

Patients were placed in the supine position with a 15-20° Trendelenburg tilt. A uterine manipulator was used to facilitate adequate exposure of the uterus, optimise visualisation of anatomical planes and enable colpotomy. Three translucent laparoscopic 10-12 mm trocars were used: one for the 3D endoscope (positioned medially, at the umbilical level) and two for the robotic instruments (placed 8-9 cm lateral to the linea alba on both sides and at least 5 cm below the umbilical level) (Figure 2). An additional 5- or 10-mm trocar was typically placed for the assistant, either in a suprapubic position or in the right hypochondrium, more than 10 cm superior to the anterior superior iliac spine. The trocar placement closely followed the usual laparoscopic setup.

After abdominal inspection, in the presence of endometriosis or adhesions, the surgeon decided whether to perform endometriosis resection or adhesiolysis laparoscopically or robotically, depending on the diagnosis and personal preference. For docking, the two patient carts were positioned on either side of the operating table, with the endoscope arm placed at the cephalic level (Figure 1b). The endoscope arm was docked to the optical trocar, and the robotic instruments were inserted under direct visualisation.

The hysterectomy began with the division of the round ligaments and the mobilisation of the uterus. Salpingectomy or salpingo-oophorectomy was performed as indicated. Colpotomy and coagulation of the uterine artery followed, after which the uterus was retrieved either transvaginally or via morcellation within an endobag, according to the site's routine practice. The vaginal closure was subsequently performed using a 3-0 barbed suture. Additional procedures, such as endometriosis resection or sentinel lymph node dissection, were carried out before or after the hysterectomy as planned. The procedure concluded with haemostasis, inspection, trocar removal, and wound closure.

Data Acquisition and Analysis

Based on a comprehensive literature review on other robotic platforms, the expected rate of Clavien-Dindo grade III-V complications ranged from 2.7% (weighted mean) to a non-inferiority threshold of <9.8%, reflecting

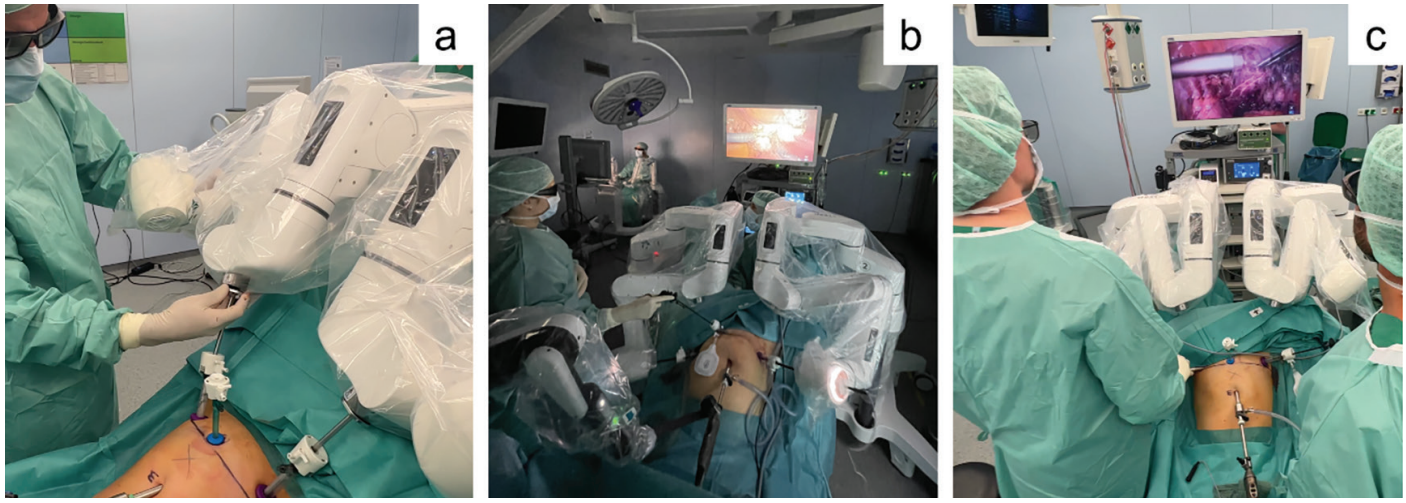

Figure 1. Docking DEXTER using incision pointers to align the remote centre of motion of the instrument arms with the trocars **(a)**, OR hysterectomy setup **(b)**, DEXTER instrument arms folded in laparoscopic mode **(c)**.

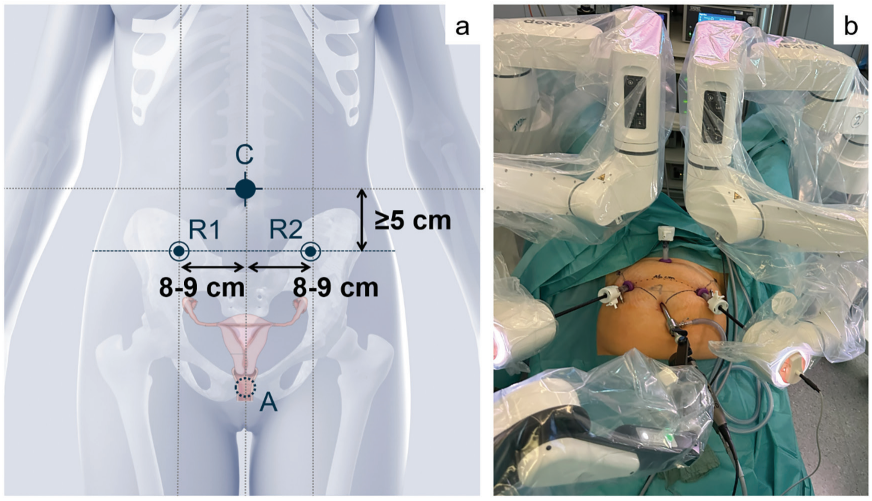

Figure 2. Port placement for hysterectomy as outlined in the procedure guide **(a)** and in actual surgery **(b)**. The setup includes one port C for the endoscope camera (medially, at the umbilical level), 2 ports, R1 and R2, for robotic instruments (8-9 cm lateral to the linea alba on both sides, at least 5 cm below the umbilical level), and 1 assistant laparoscopic port A (suprapubic).

the variability in published data.[12,27] A sample size of 30 patients in the hysterectomy group was chosen, as it allows the calculation of a one-sided 95% confidence interval for observed complication rates, with upper bounds of 14.9% for a 3.3% rate (one event) and 23.9% for a 10% rate (three events), ensuring an acceptable level of precision.

Adverse events were reviewed and adjudicated by an independent Clinical Event Committee. Descriptive statistics were used in this study; median values with interquartile range (IQR) were used to present the data. Data were analysed using StataCorp (2023. Stata Statistical Software: Release 18. College Station, TX: StataCorp LLC).

Results

Between November 2022 and November 2023, 34 patients were enrolled, with a median age of 45.5 years (IQR: 42.0-52.0) and a median BMI of 26.0 kg/m^2 (IQR: 22.8-28.2). Each participating centre enrolled at least five patients. Detailed patient characteristics and indications for surgery are presented in Table 1.

No device-related adverse events or intraoperative complications were reported. Median blood loss was 100 mL (IQR: 50-200), and no blood transfusions were required (Table 2). There were no conversions to open surgery. In three cases, however, one surgeon converted to laparoscopy towards the end of the procedure due to multiple instrument arm collisions caused by suboptimal trocar placement and docking. In one of these cases, the surgeon did not keep both robotic instruments visible on the screen, which contributed to the collision. None of these incidents was associated with adverse events.

Transvaginal specimen extraction was reported in 17 (50%) patients, while the abdominal specimen extraction route was reported in 8 (23.5%) patients. In the remaining 9 (26.5%) cases, the specimen extraction route was not documented in the operative report.

Median operative time was 125.5 minutes (IQR: 107.0-159.0). Concomitant procedures such as lymph node dissection and endometriosis resection were performed either laparoscopically or robotically, depending on the surgeon's clinical judgement, robotic experience and the specific demands of each case. For instance, lymph node dissection was performed robotically with ICG-3D near-infrared visualisation (Figure 3). In another case, a patient with stage IV deep infiltrating endometriosis required a concomitant rectosigmoid resection, which was performed laparoscopically by an assisting colorectal surgeon. For this step, the robot was switched to its laparoscopic mode, as the colorectal surgeon was not trained on DEXTER.

Median length of hospitalisation was 2.0 days (IQR: 1.0-3.0). During the 30-day follow-up period, Clavien-Dindo grade III-V adverse events occurred in two patients (5.9%), both

Table 1. Patient characteristics.

Parameter (n=34)	Value
Age (years), median (IQR)	45.5 (42.0-52.0)
BMI (kg/m^2), median (IQR)	26.0 (22.8-28.2)
ASA score, n (%)	
I	7 (20.6)
II	26 (76.5)
III	1 (2.9)
Indications for surgery, n(%)	
Uterine fibroids	13 (38.2)
Heavy uterine bleeding	8 (23.5)
Endometriosis	5 (14.7)
Low-risk endometrial cancer	3 (8.8)
Symptomatic adenomyosis	2 (5.8)
Endometrial intraepithelial neoplasia	1 (2.9)
Borderline tumour of the ovary	1 (2.9)
Endometrial hyperplasia	1 (2.9)

IQR: Interquartile range; BMI: Body mass index; ASA: American Society of Anaesthesiologists.

Table 2. Perioperative results.

Parameter (n=34)	Value
Conversion to open, n	0
Conversion to laparoscopy, n	3
Operative time (skin-to-skin) (min), median (IQR)	125.5 (107.0-159.0)
Docking time (min), median (IQR)	5.0 (5.0-7.0)
Estimated blood loss (mL), median (IQR)	100 (50-200)
Blood transfusions, n	0
Length of hospital stay (days), median (IQR)	2.0 (1.0-3.0)
Concomitant procedures, n (%)	
Salpingectomy	26 (76.5)
Salpingo-oophorectomy	5 (14.7)
Adhesiolysis	8 (23.5)
Endometriosis	7 (20.6)
Lymphadenectomy	3 (8.8)

IQR: Interquartile range.

classified as grade IIIb. One patient, who had five previous pregnancies, was readmitted six days after the hysterectomy with radical lymphadenectomy and reoperated for an umbilical trocar-site hernia at the 12-mm endoscope port. The hernia occurred despite fascial closure with Endo Close™ (Medtronic, Macquarie Park, NSW, Australia) and resolved without further sequelae. Another patient was readmitted on postoperative day six with suspected anastomotic leakage following the rectosigmoid resection. The leak was not confirmed intraoperatively, and the patient did not require a stoma. Both patients who had Clavien-Dindo III events were released with antibiotics without further complications. The remaining adverse events, as detailed in Table 3, were classified as Clavien-Dindo grade I (6 patients) and grade II (5 patients). These included two further readmissions for wound infection and faecaloma with abdominal pain. All grade I-II adverse events were managed conservatively, with patients recovering fully and without long-term sequelae.

Discussion

Main Findings

This study represents the first prospective multicentre investigation of robotic-assisted hysterectomy using DEXTER, providing early clinical experience with this system, and reflecting real-world utilisation across four different hospitals in three European countries. Importantly, despite the early experience with DEXTER and varying levels of robotic experience of the participating surgeons, all procedures were performed without conversion to open surgery or intraoperative complications. This finding is significant, as conversions to open surgery is a recognised risk early in the learning curve.[28]

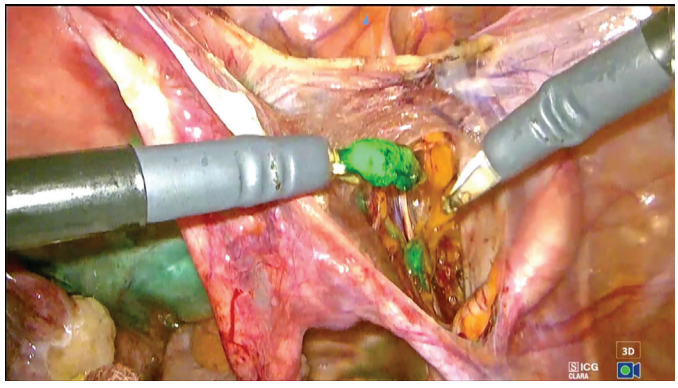

Figure 3. ICG fluorescence was used with DEXTER for sentinel lymph node removal performed concomitantly with hysterectomy.

There were no device-related complications. Most postoperative adverse events were minor and consistent with those commonly observed in hysterectomy patients regardless of the surgical technique, such as urinary incontinence and pelvic pain in endometriosis patients.[29,30] The patient who developed an umbilical trocar-site hernia had five previous pregnancies, which may have contributed to the abdominal wall weakness despite appropriate fascial closure. The second Clavien-Dindo grade III event involved a suspected anastomotic leak following a concomitant laparoscopic rectosigmoid resection for deep infiltrating endometriosis, which is a known concern after intestinal resection in such cases,[31] and must be ruled out by laparoscopy.[32]

The three procedures which could not be completed robotically were performed by a surgeon with previous robotic experience on another robotic platform**,** but during their initial learning phase with DEXTER. The main reasons for conversion were suboptimal patient positioning and suboptimal trocar placement, which limited access within the surgical workspace. These early learning cases were subsequently reviewed and analysed with the surgical team to highlight the importance of careful planning during initial implementation of the robotic system. We believe that with increased experience using DEXTER, such conversions can be avoided. During a conversion to laparoscopy with DEXTER, the operating sterile surgeon has direct and immediate access to the patient, enabling a rapid transition without the need for additional trocar placement. This flexibility may be of use to be able to perform different steps of the procedure

Table 3. Postoperative results.

Parameter (n=34)	**Value**
Patients with Clavien-Dindo events, n	
I	6
Minor bleeding, abdominal/pelvic pain, urinary incontinence, tachycardia, delayed wound healing, scar dehiscence in the flank	
II	5
Herpes genitalis, minor wound infection, low haemoglobin level, urinary tract infection, faecaloma	
III	2
Trocar-site hernia, suspected anastomotic leak	
IV-V	0
Rehospitalisation, n	4
Reoperation, n	2
Mortality, n	0

at the surgeon's preferred method, which is a unique feature of DEXTER.

Comparison with Other Studies

The rate of Clavien-Dindo III-V events in our study aligns with those previously reported in other studies for robotic-assisted hysterectomy.[12,27] Similarly, our observed conversion rate to laparoscopy is consistent with findings on other modular platforms, with a reported conversion rate of 4.2-6.25%.[28,33]

Literature on hysterectomy performed with robotic assistance reports mean operative times ranging from 70 to 298 minutes,[12,34] suggesting that integration of DEXTER into clinical workflows does not compromise efficiency, even during early experience with the system. Moreover, additional procedures like excision of endometriosis, lysis of adhesions, and lymph node dissection contributed to our total operative time. For reference, median operative times reported for other modular platforms were in the range of 127-158 minutes,[35,36] which is comparable to our findings. Estimated blood loss in our cohort was also comparable to, and in some cases lower than, that reported for other systems.[35,37-39] Similarly, the length of hospital stay was equal to or shorter than observed with other platforms.[35,38]

Strengths and Limitations

The study has several notable strengths. It provides real-world data collected during the implementation of the DEXTER system, offering valuable insights into outcomes that can be expected with broader adoption. The feasibility of various types of gynaecologic surgeries using DEXTER is described in detail. Its prospective, multicentre design ensured systematic and thorough documentation of adverse events, supported by independent adjudication through a Clinical Events Committee, delivering a level of rigour superior to many retrospective studies.

Despite these strengths, the study had limitations. The sample size was modest, limiting definitive conclusions on safety. Furthermore, while the patient population was heterogeneous, reflecting real-world case mix and clinical practice, this diversity simultaneously limited direct comparability with the available literature on other modular platforms. All surgeons were still in their learning curve with Dexter (having performed fewer than 40 hysterectomies each), with prior experience on the system varying from 3 to 20 cases before study recruitment. Three surgeons had prior experience with other robotic systems. The BMI distribution in this study reflects European demographics and may not extrapolate to higher BMI populations. The exclusion of patients with morbid obesity (BMI≥40) reflected a precaution in the system's instructions for use during its early clinical implementation, rather than suggesting that higher BMI is inoperable with DEXTER because of any technical limitations. The absence of a control group limited direct comparisons, requiring outcomes to be interpreted in the context of existing literature. Additionally, because the study focused on short-term safety and performance in routine use, it did not include uterine weight or oncologic outcomes for low-risk malignancies treated in this cohort. Potential selection bias and the relatively short follow-up period must also be acknowledged.

Clinical Implications

The DEXTER robotic arms setup preserves standard laparoscopic trocar placement, and the 'LAP' function allows the robotic instrument arms to be retracted within seconds. In addition, the draped surgeon console enables the sterile surgeon to rapidly access the patient when necessary, and to switch between robotics and laparoscopy without placing new trocars. This was particularly useful in more complex cases (e.g., adhesions outside the pelvis, deep endometriosis excision or dense adhesiolysis),[25] in combined procedures with other specialities (such as rectosigmoid resection performed by a colorectal surgeon), or when assistants were less experienced. It also facilitated the learning phase, as laparoscopically experienced surgeons could perform certain steps laparoscopically if preferred, while developing their robotic skills. This adaptability should not be seen as a system limitation, but as an intended design feature that allows intraoperative flexibility and adjustment of the surgical approach to case-specific requirements. However, this adaptability makes direct comparisons with other systems challenging. DEXTER is an open system**,** allowing surgeons to work with standard laparoscopic visualisation systems, including ICG 3D near-infrared imaging, which was successfully used for robotic-assisted lymphadenectomy in the study. This compatibility allows the surgeon to maintain familiar imaging protocols, improving safety for tasks such as vascular control or ureter identification, and has the potential to enhance surgical precision while facilitating integration into existing workflows.

Unanswered Questions and Future Research

Unanswered questions and long-term outcomes remain to be evaluated in future prospective studies. The dataset was not powered to enable robust learning curve analyses, but this should be an important focus for future research. Future studies with larger cohorts and more surgeries per surgeon would be beneficial to confirm these initial findings and further explore the long-term functional and oncological outcomes.

Conclusion

This multicentre prospective study is the first to describe robotic-assisted hysterectomy using the DEXTER system, demonstrating its feasibility and safety. Its open-architecture design enables surgeons to adapt the surgical approach in real time, making it well-suited to the diverse demands of gynaecological procedures in real-world clinical practice. Moreover, its compatibility with existing laparoscopic infrastructure supports its accessibility. Further studies with larger cohorts and extended follow-up are warranted to confirm these findings.

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Competing interests: MLB and DE are consultants of Distalmotion. All other authors declare that there are no conflicts of interest.

Ethical approval: Clinical Trial Registration: NCT05537727 (ClinicalTrials.gov). This study was approved by the Ethics Committee according to local and national regulations of the participating countries: Switzerland (reference 2021-00079), Germany (reference D 525/22). In France, observational studies that do not require any additional procedures over and above standard-of-care patient management are not subject to approval. The data protection requirements (GDPR) were followed for all patient data collection.

Data sharing: The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Transparency: The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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