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# Preclinical evaluation of a new robot-assisted surgical system for use in gynecology minimal access surgery

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## Abstract

Robot-assisted laparoscopy has been developed to overcome some of the important limitations of conventional laparoscopy. In particular, the provision of stable magnified three-dimensional vision, tremor filtering, motion scaling, and articulated instruments with robot-assisted surgery has the potential to enable more surgeons to perform more complex surgery compared with conventional laparoscopy. The aim of this study was to evaluate the utility of a new robot-assisted surgical system (Versius, CMR Surgical, Cambridge, UK) for gynecologic procedures in a preclinical setting. Cadaveric sessions were conducted to evaluate the ability of the system to complete all surgical steps required for a robot-assisted total laparoscopy hysterectomy. A live animal (porcine) model was used to assess the system in performing oviduct removal as a surrogate for robot-assisted total laparoscopy hysterectomy. Procedures were performed by experienced gynecologic surgeons, supported by a surgical team. The precise surgical steps conducted to conclude that the procedures could be fully completed were systematically recorded, as well as instruments used and endoscope angle. In total, six gynecologic procedures were performed in cadavers by four surgeons; 16/17 procedures were completed successfully. Positioning of the ports and bedside units reflected the surgeons' preferred laparoscopic setup and enabled good surgical access and reach, as exemplified by the high procedure completion rate. Oviduct removal procedures performed in pigs were all completed successfully by a single surgeon. This preclinical study of a new robot-assisted surgical system for gynecologic procedures demonstrated the safety and effectiveness of the system in cadaver and porcine models. Further studies are required to assess its clinical utility.

**Keywords:** Minimally invasive surgical procedures, Robotic surgical procedures, Gynecologic Surgical procedures, Hysterectomy

## Introduction

Over the last 25 years, minimal access surgery (MAS) has become an essential component of modern gynecology surgery, with many laparoscopic techniques now considered routine [1]. Gynecologic MAS is associated with a number of advantages over open surgery, including reduced blood loss, fewer perioperative complications, reduced post-operative pain, earlier

recovery, shortened hospital stay, and improved cosmesis [1–3]. However, MAS for complex surgery is technically demanding and associated with a steep learning curve [1, 4–7]. This is due to certain limitations of conventional laparoscopy such as restricted movement, difficulty performing accurate suturing, uncomfortable positions for the surgeon and assistant, and two-dimensional vision [1–3, 8]. These limitations may contribute to the relatively low adoption of MAS for commonly performed gynecologic procedures, such as hysterectomy and sacrocolpopexy [4, 9–11].

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Robot-assisted laparoscopy has made progress in overcoming some of the important shortcomings of conventional laparoscopy by providing an ergonomic operating position, a stable magnified three-dimensional view, tremor filtering, motion scaling, and articulated or wristed instruments, allowing for precise tissue dissection and suturing [12, 13]. By shortening the learning curve, these advantages may enable more surgeons to perform complex MAS procedures, and could extend the feasibility of MAS to a greater body of surgeons [2]. In addition, robot-assisted MAS could be feasible in a wider range of patients, such as those with a higher body mass index (BMI) [14, 15].

The new robot-assisted surgical system (Versius, CMR Surgical, Cambridge, UK; Supplementary Figure 1) used in this study was developed to aid surgeons in performing MAS. The system has been designed to mimic the articulation of the human arm, and the wristed instrument tip provides seven degrees of freedom inside the patient, with the purpose of improving surgical access compared with standard laparoscopic surgery. The surgeon interacts with the system through hand controllers, with feedback provided on the system's open surgeon console, which allows the surgeon to sit or stand during surgery. The console's head-up display provides a three-dimensional video from the endoscopic camera together with a display overlay. The bedside team view a two-dimensional version of the endoscope feed and display overlay via an auxiliary display on the visualisation bedside unit (BSU), and are able to access controls and feedback on up to four instrument BSUs. The BSUs are small enough to be used in a standard operating room (OR) and moved easily within a single OR and between ORs [16].

The IDEAL-D (Idea, Development, Exploration, Assessment, Long-term study for medical devices) framework provides recommendations for improving the evidence base from research at each stage of surgical innovation [17]. The operational safety and ease of use of the system was validated previously in human cadaver studies [18]. Consistent with the IDEAL-D framework, the next step in evaluating the system's suitability for use in gynecology surgery is preclinical evaluation [17, 19]. The preclinical studies described here had two aims: (1) demonstrate the ability of the system to perform several gynecologic procedures using cadavers and (2) assess the system's ability to perform oviduct removal, as a surrogate for robot-assisted total laparoscopic hysterectomy (RALH) in a live animal (porcine) model.

## Materials and methods

### Study design

This was an observational study with cadaver and live animal surgery components. The main purpose of the

cadaver component was to assess the system's capabilities in a variety of gynecologic procedures. The main aims of the live animal component were to evaluate surgical complications and post-operative recovery. Cadaver studies were undertaken at the Evelyn Cambridge Surgical Training Centre, UK, between 26 July 2018 and 16 April 2019. All cadavers were donated with consent. The live animal porcine study was undertaken at Covance CRS Ltd (formerly Envigo Ltd), Huntingdon, UK between 12 and 24 October 2018. This study was designed to align with the principles of the 3Rs (replacement, reduction and refinement) and was conducted in accordance with current, internationally recognised Good Laboratory Practice Standards and the UK Animals (Scientific Procedures) Act 1986, Amendment Regulations 2012. All procedures were performed in a simulated operating room in order to mimic clinical practice.

### Surgical team

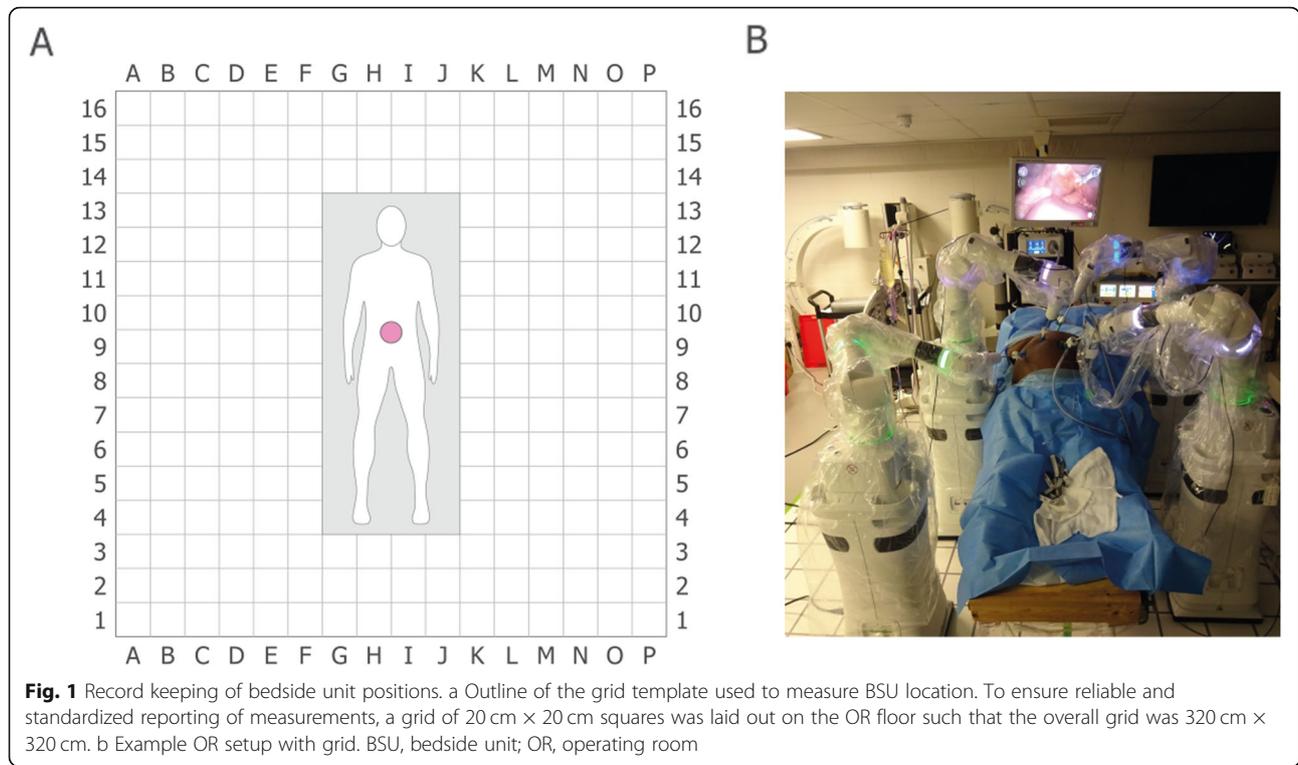
Procedures were performed by a surgeon supported by a surgical team. The surgeon performed the surgical steps for the procedure and evaluated the system. The assistant surgeons carried out any additional manual tasks as instructed by the surgeon. Trained observers recorded port and BSU placements, intra-operative events, and outcomes.

The four surgeons who performed the procedures on cadavers were accredited, practicing high-volume gynecologic surgeons as defined by > 50 complex laparoscopic procedures/annum. The surgeon performing procedures in pigs was also a practicing surgeon, certified in good laboratory practice (GLP) and possessed UK Home Office licenses. All users were trained to use the robot-assisted surgical system, and three of the four surgeons had experience performing procedures using the system in prior studies [18]. During the procedures described here, a professional CMR Surgical education team also provided expert advice at the console.

### Cadaver studies

A variety of gynecologic procedures were performed on 11 female cadavers which had not undergone previous abdominal or pelvic surgery. Cadavers were selected to represent a spectrum of BMIs to reflect the wide range in size and shape of human anatomy.

Each surgeon determined the port and BSU positions, based on their established, standard technique of performing the same procedure by conventional laparoscopy. Instrument and accessory ports were inserted into the abdominal cavity after establishing pneumoperitoneum using a 14 gauge disposable Veress insufflation needle. Port and BSU positions were recorded using a 20-cm grid (covering 320 cm × 320 cm) laid out on the OR floor (Fig. 1); BSU positions in relation to anatomical



land marks on the cadaver were also recorded. Port and BSU positions were altered from one procedure to the next in response to difficulties in surgical access and reach such as inability to reach surgical site, instruments too close to surgical site, and arms clashing due to port positioning. Positions were deemed suitable if good access to the surgical site(s) was achieved without arm clashing and there was a minimal need to reposition BSUs. The precise surgical steps conducted to make the assessment that the procedures could be fully completed were recorded, as well as instruments used (including manual laparoscopic instruments) and endoscope angle.

**Porcine study**

Six large white hybrid domestic female pigs aged 18–20 weeks with a median weight of 42.0 kg (range 37.5–44.5 kg) underwent oviduct removal as a surrogate for RALH. Prior to the procedure and in accordance with GLP in animal studies, each pig was sedated before transfer to the OR, where the animal was placed under general anesthesia and intubated. Instrument and accessory ports were inserted into the abdominal cavity in insufflated bodies using a 14 Gauge disposable Veress insufflation needle. Local anesthesia was applied to the intended port positions; ports were placed by the surgeon according to a predetermined protocol.

**Table 1** Summary of procedures performed and successful completion in cadavers

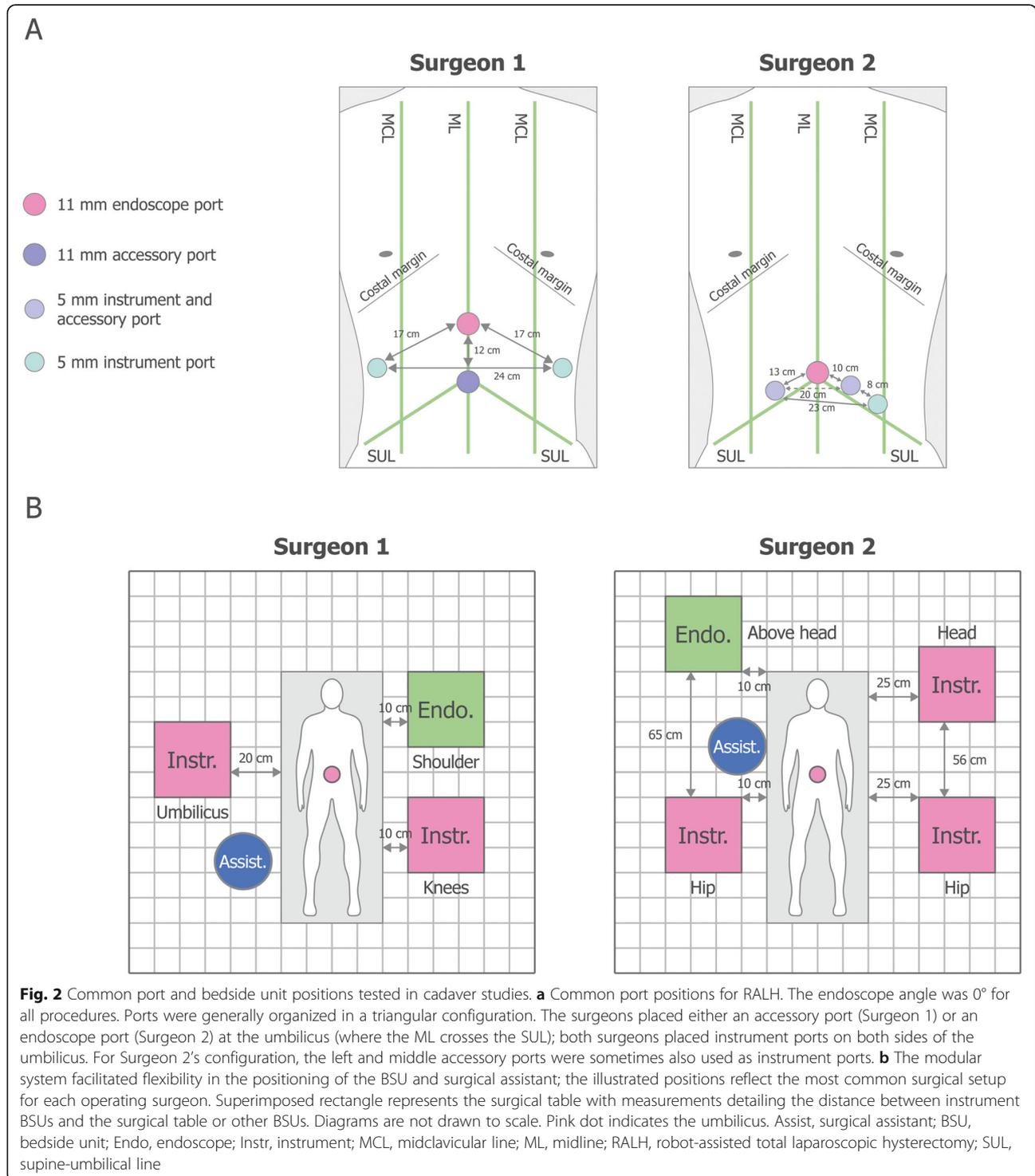
Procedure	Number performed	Number successfully completed	Number of surgeons*	Number of unique port configurations
Burch colposuspension	3	3	2	3
Para-vaginal wall repair	1	1	1	1
Sacrocolpopexy	1	1	1	1
Sacrohysteropexy	3	3	1	2
Sub-total laparoscopic hysterectomy with sacrocervicopexy	3	3	3	3
Robot-assisted total laparoscopic hysterectomy (RALH) <sup>a</sup>	6	5	2	4
Total	17	16 (94.1%)	–	14

<sup>a</sup>One procedure could not be completed due to the physical condition of the cadaver

\*Total number of surgeons who completed a given procedure; individual cases were completed with one surgeon

During the procedure, intra-operative blood loss was measured, and intra-operative adverse events were recorded. Pigs were divided into two groups: non-recovery and recovery. Non-recovery pigs were euthanized without recovery from anesthesia with pentobarbitone. Successful and safe procedure completion was confirmed in

non-recovery pigs before the procedure was attempted in recovery pigs. In recovery pigs, wounds were closed, anesthesia was discontinued, and animals were observed for signs of ill health or changes in behavior and/or activity. Post-operative analgesia, antibiotic treatment, and other treatments as appropriate were administered by a



veterinary surgeon. Pigs were euthanized after 22–29 days and subject to a detailed necropsy, with specific reference to surgical sites and assessment of successful organ removal.

## Results

### Procedure completion in cadavers

The cadavers represented a wide range of BMIs; median BMI was 22.31 kg/m<sup>2</sup> (range 14.5–33.0 kg/m<sup>2</sup>). In total, six types of gynecologic procedures were performed. The main gynecologic procedure evaluated was RALH (six procedures performed by two surgeons). Burch colposuspension, paravaginal wall repair, sacrocolpopexy, sacrohysteropexy, and sub-total laparoscopic hysterectomy with sacrocervicopexy were also performed to demonstrate the ability of the system to complete complex gynecologic procedures particularly where suturing is involved. A total of 17 procedures were performed, of which 16 (94.1%) were successfully completed. One RALH could not be completed due to the poor physical condition of the cadaver (Table 1).

### Common port and BSU positions for RALH in cadavers

RALH was selected to be the main procedure for evaluation because hysterectomy is one of the most common gynecology surgeries performed and exemplifies the difficulties of achieving good access and challenging suturing of the vaginal cuff. Robotic assistance has been considered helpful in overcoming these issues [1, 4, 9, 10].

For RALH, the cadaver was placed in lithotomy to allow abdominal and vaginal access. Steep Trendelenburg position was used for all procedures. Two surgeons performed three procedures each. Figure 2a illustrates the two different port placement configurations used by each of the two surgeons. Two different BSU configurations were used, indicative of the different port placements used by each surgeon (Fig. 2b): (1) the visualisation BSU was located around the left shoulder, and two instrument BSUs were positioned on both sides of the operating table (Fig. 3); (2) the visualisation BSU was located above the head on the right side, and three instrument BSUs were used, one by each knee and a third by the head on the left side.

The port and BSU configurations used were all found to be suitable for successful procedure completion, which encompassed mobilization of the uterus, dissection of the parametria, extraction of the uterus, and closure of the vaginal vault (Table 2). Tissue manipulation, dissection, and suturing for the key surgical steps were achieved using the system's monopolar hook, bipolar Maryland grasper, curved scissors, fenestrated grasper, and needle holder. Manual graspers and manual laparoscopic scissors were also used.



**Fig. 3** Physical arrangement of the new robot-assisted surgical system. Image of the physical arrangement of the new robot-assisted MAS system setup during RALH, corresponding to the left panel shown in Fig. 2b. Visualisation BSU in white and instrument BSUs in orange and green. BSU, bedside unit; MAS, minimal access surgery; RALH, robot-assisted total laparoscopic hysterectomy

### Safety in live animals

Six oviduct removals (non-recovery  $n = 2$ , recovery  $n = 4$ ) were performed in pigs as a surrogate for RALH. All procedures were successfully completed. There was one device-related intra-operative complication in one non-recovery pig: evidence of thermal injury to the bowel from the monopolar instrument shaft. Only two non-device-related intra-operative complications were recorded (one related to port insertion and one related to replacement of a port that was removed too early). Intra-operative blood loss was recorded as  $\sim 10$  mL ( $n = 1$ ) or none ( $n = 5$ ). Clinical observations of the recovery pigs post-operatively revealed no signs of ill health or distress, and all recovery pigs gained weight post-surgery. Overall, recovery pigs remained in good health.

**Table 2** Surgical steps in robot-assisted total laparoscopic hysterectomy

Surgical steps
• Lift bowel out of pelvis
• Grasp right round ligament and pull uterus to the left
• Divide the right round ligament
• Divide the right infundibular ligament
• Open anterior leaf of broad ligament
• Open posterior leaf of broad ligament
• Skeletonize the uterine artery
• Grasp the left round ligament
• Pull the uterus to the right
• Divide the left round ligament
• Divide the left infundibular ligament
• Skeletonize the left broad ligament
• Incise and dissect the parametria on both sides
• Open the posterior vaginal cuff
• Open the anterior vaginal cuff
• Complete colpotomy and remove uterus
• Close vault with interrupted sutures

throughout the post-operative recovery period. At macroscopic post-mortem examination, assessments revealed minor signs of inflammation around one port site, and cysts presented on top of the vaginal cuff in two of four pigs. In one pig, when the cyst was removed, the vaginal cuff was noticed to be open (Fig. 4). In all pigs, surrounding organs appeared healthy with no signs of injury or inflammation.

## Discussion

The cadaver studies demonstrated that the new robot-assisted MAS system can be used for robotic surgery in a variety of gynecologic procedures. The system's flexibility enabled adequate surgical access and reach in the pelvis, even in specimens with a high BMI. The instrument articulation, ergonomic handgrip, and console allowed surgeons to successfully complete these procedures within the confines of the pelvis. The procedures described were performed in a manner reflecting how they would be performed in the clinical setting, from surgical setup to the surgical steps performed. Moreover, the ability to perform oviduct removal safely and effectively has been demonstrated in a live animal model, providing a good simulation of system performance expected in live humans.

The port placement for RALH with current robotic systems usually requires two or three instrument ports, one endoscope port, and one accessory port [20]. Therefore, an operating surgeon is often limited to a narrow range of port configurations. Findings from this study demonstrate that a variety of port placements provide adequate surgical access and reach; this flexibility enabled surgeons to effectively transfer their preferred laparoscopic port placements for use with the robotic system.

## Further development of the system

The system tested in these studies was not the final design. Incremental changes to instruments, hardware, and software were made throughout these studies to improve

the design of the system and the surgical setup for each type of procedure tested (e.g., repositioning BSUs after an arm clash to mitigate the risk of a reoccurrence). Further studies will be performed to more quantitatively assess instrument functionality, particularly that of the electro-surgical instruments, to improve their safety and mitigate the risk of tissue burning. Procedures that have been performed a limited number of times in cadavers will be repeated to further optimize the use of the new robot-assisted MAS system for these surgeries. The aim is to ensure the robot and its use are perfected ahead of clinical studies in gynecology surgery.

## Limitations

Cadaver and porcine models are frequently used in surgical training, and each model has advantages and disadvantages in terms of its ability to test robotic surgical ability in live humans. Porcine models bear greater similarity to live tissue handling, dissection, surgical plane identification, and control of bleeding in live human surgery. However, cadavers provide much greater anatomical relevance and realism to live humans than pigs [21]. Testing the new system in both cadaver and pig models balances the bias introduced by each model; however, it is impossible to completely replicate the experience and performance of the robot for surgery in live humans. Although only oviduct removal was performed in pigs, this procedure was selected to provide a good simulation of system performance for gynecologic procedures in live humans. The number of procedures performed was deemed suitable to generate sufficient evidence for the safety of the new robot-assisted MAS system whilst aligning with the 3Rs.

## Conclusion

The studies presented here cover the preclinical assessment of Versius for gynecologic procedures in cadaveric and porcine models. Several types of gynecology surgeries were tested in cadavers, with the surgeons evaluating



**Fig. 4** Necropsy findings from recovery pigs. Necropsy of oviduct removal from a recovery pig showing good healing of the vaginal cuff (left panel). Necropsy of oviduct removal from a recovery pig showing the presence of a cyst on the vaginal cuff (right panel)

a range of port and BSU positions; all but one procedure was successful. Oviduct removal was also performed safely and effectively in a live animal model. These results support the progression to assessment of the new robot-assisted MAS system in clinical studies of gynecology surgery as per the IDEAL-D framework [17].

## Supplementary information

**Supplementary information** accompanies this paper at <https://doi.org/10.1186/s10397-020-01069-0>.

**Additional file 1: Figure S1.** Schematic overview of the Versius system

## Abbreviations

3Rs: Replacement, reduction, and refinement; BMI: Body mass index; BSU: Bedside unit; GLP: Good laboratory practice; IDEAL-D: Idea, Development, Exploration, Assessment, Long-term study for medical devices; MAS: Minimal access surgery; OR: Operating room; RALH: Robot-assisted total laparoscopic hysterectomy

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## Authors' contributions

Substantial contributions to study conception and design: AB, MC, IP, AP, and MS; substantial contributions to analysis and interpretation of the data: AB, MC, IP, AP, and MS; drafting the article or revising it critically for important intellectual content: AB, MC, IP, AP, and MS; final approval of the version of the article to be published: AB, MC, IP, AP, and MS.

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## Availability of data and materials

All data generated or analyzed during this study are included in this published article [and its supplementary information files].

## Ethics approval and consent to participate

All cadaver studies were conducted at The Evelyn Cambridge Surgical Training Centre, Back Lane, Melbourn, Hertfordshire, SG8 6DP, UK. The Evelyn Centre is certified as Health Tissue Authority (HTA) compliant under license number 12603. The HTA designated individual responsible at the facility is Mr Christopher Constant MA (Cantab) LLM MCh FRCS RMIM. All studies conducted by CMR Surgical at The Evelyn Centre met the required HTA, health and safety, and ethical considerations relating to the use of donated cadaveric tissue in dissection, teaching, research, and development. Porcine work was conducted in accordance with the applicable sections of the United Kingdom Animals (Scientific Procedures) Act 1986, Amendment Regulations 2012 (the Act) and in compliance with the requirements of current, internationally recognized Good Laboratory Practice Standards (UK Good Laboratory Practice Regulations; Statutory Instrument 199 No. 3106, as amended by Statutory Instrument 2004 No. 994, OECD Principles of Good Laboratory Practice ENV/MC/CHEM(98)17, and EC Commission Directive 2004/10/EC) and was designed to align with the principles of the 3Rs (replacement, reduction, and refinement).

## Consent for publication

Not applicable.

## Competing interests

AB and AP are on the medical advisory board and are shareholders of CMR surgical. IP has received consultancy fees from CMR surgical. MC has no financial interest in CMR. However, CMR Surgical covered the cost of travel and accommodation to and from Melbourne, Australia, to allow MC to undertake the cadaver surgery. He received no honorarium. MS is the Chief Medical Officer and co-founder of CMR Surgical.

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