Endo-urology

Preclinical Evaluation of the Versius Surgical System, a New Robot-assisted Surgical Device for Use in Minimal Access Renal and Prostate Surgery

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\textbf{Abstract}

\textbf{Background:} Minimal access surgery (MAS) is well-established in urological surgery. However, MAS is technically demanding and associated with a prolonged learning curve. Robot-assisted laparoscopy has made progress in overcoming these challenges.

\textbf{Objective:} The aim of this study was to evaluate the feasibility of a new robot-assisted surgical system (the Versius Surgical System; CMR Surgical, Cambridge, UK) for renal and prostate procedures in a preclinical setting, at the IDEAL-D phase 0.

\textbf{Design, setting, and participants:} Cadaveric sessions were conducted to evaluate the ability of the system to complete all surgical steps required for a radical nephrectomy, prostatectomy, and pelvic lymph node dissection. A live animal (porcine) model was also used to assess the surgical device in performing radical nephrectomy safely and effectively. Procedures were performed by experienced renal and prostate surgeons, supported by a full operating room team.

\textbf{Outcome measurements and statistical analysis:} Surgical access and reach were evaluated by the lead surgeon using a visual analogue scale. The precise surgical steps conducted to make the assessment that the procedures could be completed fully were recorded, as well as instruments used (including manual laparoscopic instruments) and endoscope angle.

\textbf{Results and limitations:} In total, all 24 procedures were completed successfully in cadavers by eight different lead surgeons. Positioning of the ports and bedside units reflected the lead surgeon's preferred laparoscopic set-up and enabled good surgical access and reach, as quantified by a median visual analogue score of ≥6.5. Radical nephrectomies performed in pigs were all completed successfully, with no device- or non–device-related intraoperative complications recorded. Testing in human cadavers 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.

\textbf{Conclusions:} This is the first preclinical assessment of the Versius Surgical System for renal and prostate procedures. The safety and effectiveness of the system have been demonstrated and warrant progressive assessment in a clinical setting utilising the IDEAL-D framework.

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1. Introduction

Minimal access surgery (MAS) in renal and prostate procedures was first performed almost 30 years ago and is now well established in urological surgery [1,2]. MAS offers several advantages over open surgery, including reduced postoperative pain, less blood loss, and reduced hospital stay [1–4]. However, MAS is technically demanding and associated with a prolonged learning curve [1,5–8], especially when working within restricted anatomical spaces, such as the pelvis and retroperitoneum, or when dissecting complex vascular anatomy, as in nephrectomy [6,9,10]. These challenges are exacerbated by the drawbacks of conventional laparoscopy, such as restricted movement, difficulty of accurate complex suturing, uncomfortable positions for the surgeon and bedside assistant, and two-dimensional vision [7,9].

Robot-assisted laparoscopy has made progress in overcoming these challenges by providing an ergonomic operating position, a stable magnified three-dimensional view, tremor filtration, motion scaling, and articulated or wristed instruments with greater degrees of movement allowing for precise tissue dissection and suturing [1,5,11]. These advantages enable surgeons to perform more complex MAS procedures, and extend the feasibility and therefore benefits of MAS to more surgeons by shortening the learning curve [1,2,12,13]. Consequently, robotic surgery continues to be rapidly adopted in renal and prostate surgery worldwide. As of 2013, approximately 90% of radical prostatectomies were performed with robotic assistance in the USA [14]; similarly, 81% of all radical prostatectomies conducted in England in 2016 were robot-assisted [15].

The Versius Surgical System (CMR Surgical, Cambridge, UK) is a new tele-operated robotic surgical system designed to assist surgeons in performing MAS and overcome some of the challenges associated with available surgical robots [11,16]. The robot mimics the articulation of the human arm, and the wristed instrument tip provides seven degrees of freedom inside the patient, allowing greater surgical access than standard laparoscopic surgery. Each instrument and visualisation arm is attached to its own wheeled cart to form a compact and mobile bedside unit (BSU). The surgeon interacts with the system through the “game controller” handgrip and visual feedback on the surgeon console. The console’s head-up display relays the three-dimensional video from the endoscopic camera together with a display overlay. Its open design allows surgeons to sit or stand, and allows easier communication between the surgeon and the team, facilitating training and teaching [17]. The operating room (OR) team accesses controls and feedback on the visualisation BSU and up to three instrument BSUs, and views a two-dimensional version of the endoscope feed and display overlay on an auxiliary display (Supplementary Fig. S1) [17]. The system’s modular design increases its potential for flexible use, as the BSUs are small enough to be used in a standard OR and can easily be moved within a single OR or between ORs.

The operational safety and ease of use of the system were validated previously in human cadaver studies [18]. The next step in assessing its suitability for use in renal and prostate surgery is preclinical evaluation, as per the IDEAL-D framework and recommendations for surgical innovation (IDEAL-D phase 0) [19,20]. The preclinical studies described herein had two aims: (1) to evaluate the ability of the system to complete all surgical steps required for a radical nephrectomy, prostatectomy, and pelvic lymph node dissection using cadavers, and (2) to assess its ability to perform radical nephrectomy safely and effectively in a live animal (porcine) model, evaluating the impact of live tissue manipulation in terms of intraoperative bleeding and tissue injury and recovery.

2. Materials and methods

2.1. Study design

All cadaver studies were conducted at The Evelyn Cambridge Surgical Training Centre, UK. All cadavers were donated with consent. The live animal porcine study was performed at Covance CRS Ltd (formerly Envigo Ltd; Huntingdon, UK) between 18 and 23 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 OR in order to mimic clinical practice.

2.2. Surgical team

Procedures were performed by a lead surgeon supported by an OR team. The lead surgeon performed the surgical steps for the procedure and evaluated the system in line with the objectives of the specific study. The bedside assistant worked the robotic arms and carried out any additional manual tasks as instructed by the lead surgeon. Additional personnel present recorded port and BSU floor placements in relation to the operating table and procedure-specific outcomes.

The eight lead surgeons who performed the procedures in cadavers were accredited, practising, high-volume renal or prostate consultant surgeons, as defined by >50 cases/annum for the procedures performed. The lead surgeon performing procedures in pigs was also a practising
consultant surgeon (A.P.) who was trained and certified by Good Laboratory Practice, possessed UK Home Office licences, and was supervised by a high-volume consultant urological surgeon. All users were trained to use the robot and had experience in performing procedures on the system in prior studies [18].

2.3. Cadaver studies

Radical nephrectomy, prostatectomy, and pelvic lymph node procedures were performed in cadavers or cadaver specimens (torso to mid femur).

The lead surgeon determined the port placement on the abdominal wall and BSU positions on the floor, according to their experience in performing the same procedure by conventional laparoscopic or current robot-assisted means. Instrument and accessory ports were inserted following insufflation either using a Veress needle or using the open Hasson technique. Port placement on the abdominal wall and BSU positions on the floor were recorded using a 20 cm grid (covering 320 cm × 320 cm) laid out on the OR floor (Supplementary Fig. S2). BSU positions in relation to anatomical landmarks on the cadaver were also recorded. Surgical access and reach were evaluated by the lead surgeon using a visual analogue scale (VAS). The precise surgical steps conducted to make the assessment that the procedures could be fully completed were recorded, as well as the instruments used (including manual laparoscopic instruments) and endoscope angle. Procedure success was judged by the lead surgeons, based on their satisfaction with the system’s ability to perform the steps necessary to complete the procedure.

2.4. Porcine study

Large White, hybrid domestic female pigs aged 18–20 wk and weighing 39.5–44.0 kg (median weight = 40.5 kg) underwent transperitoneal radical nephrectomy. Prior to the procedure, each pig was sedated before transfer to the OR, where the animal was placed under general anaesthesia and intubated. The pneumoperitoneum was established using the Veress needle technique, and ports (5 mm for instrument ports and 12 mm for accessory ports) were introduced into the abdominal cavity under directed vision.

During the procedure, intraoperative blood loss and adverse events were measured and recorded. Pigs were divided into two groups: non-recovery and recovery. Nonrecovery pigs were euthanised without recovery from anaesthesia with pentobarbitone upon procedure completion. Successful and safe procedure completion was confirmed in nonrecovery pigs before the procedure was attempted in recovery pigs. In recovery pigs, wounds were closed, general anaesthesia was discontinued, and animals were observed for signs of ill health or changes in behaviour and/or activity. Postoperative analgesia, antibiotic treatment, and other treatments as appropriate were administered as directed by a veterinary surgeon. Recovery pigs were euthanised after 22–29 d and subjected to a detailed necropsy, with specific reference to surgical sites.

2.5. Ethical approval

All cadaver studies were conducted at The Evelyn Cambridge Surgical Training Centre Hertfordshire, UK. The Evelyn Centre is certified as Health Tissue Authority HTA compliant under licence number 12603. The HTA designated individual responsible at the facility is Mr. Christopher Constant MA [Cantab] LLM MCh FRCS RMIMI. 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 UK Animals Scientific Procedures Act 1986, Amendment Regulations 2012, and in compliance with the requirements of current, internationally recognised 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/CHEM9817, and EC Commission Directive 2004/10/EC and was designed to align with the principles of the 3Rs.

3. Results

3.1. Procedure completion, and surgical access and reach in cadavers

The cadavers in which procedures were performed represented a wide range of body mass indices (BMIs), ranging from 14.5 to 42.0 kg/m² (median BMI = 21.1 kg/m²; Fig. 1). The predominant renal procedure evaluated was transperitoneal radical nephrectomy (right or left kidney) and was

![Fig. 1 – Plots of the range of cadaver body mass indices (BMIs) used for the surgical procedures.](image-url)
completed by three different surgeons; they performed nine, three, and three procedures each. The retroperitoneal approach was also tested in one procedure to demonstrate the versatility of the system to complete renal procedures. For prostatectomy, one surgeon completed two procedures, while the other two performed a single procedure each. Finally, two surgeons completed two pelvic lymph node dissections each. All 24 procedures performed were completed successfully (Table 1).

Tissue manipulation, dissection, and suturing for the key surgical steps in each procedure (Supplementary Table S1) were achieved using the Versius monopolar hook, bipolar Maryland grasper, curved scissors, fenestrated grasper, and needle holder. Manual grasping forceps used by the bedside assistant were also used in pelvic lymph node dissection. Manual grasping forceps, clip applicators, scissors, and suction were used by the bedside assistant during radical nephrectomy and prostatectomy. The supplementary video shows the feed from the endoscopic camera during surgery.

3.2. Port and BSU positions, and surgical access and reach in cadavers

The port and BSU positions reflected the lead surgeons’ standard technique of performing the same procedure by conventional laparoscopic means. This enabled good surgical access and reach, as quantified by a median VAS score of ≥6.5 (Fig. 2). In addition, there was no linear relationship between BMI and VAS score ($R^2 = 0.09$). The port and BSU positions are described below.

Cadavers were placed in left or right lateral position for right and left radical nephrectomy, respectively. The most common port positions tested for transperitoneal radical nephrectomy (three of five procedures removing the right kidney and reflecting one lead surgeon’s preference; four of 10 procedures removing the left kidney and reflecting two lead surgeons’ preferences) are illustrated in Figure 3A. The BSU configuration for transperitoneal radical nephrectomy involved one visualisation BSU positioned in the region of the umbilicus, and two instrument BSUs near the head/shoulder and knees/feet, all localised on the same side of the surgical table (15/15 transperitoneal radical nephrectomies; Fig. 4A).

For all prostatectomy and pelvic lymph node dissection procedures, the cadaver was placed in the Trendelenburg position. Eight different port configurations were used for the pelvic procedures performed in this study (Table 1; examples presented in Fig. 3B). The operational set-up is shown in Figure 3C. Additional port positions used for all procedures and port positions for retroperitoneal radical nephrectomy are detailed in Supplementary Figure S3.

The most common BSU configurations for prostatectomy and pelvic lymph node dissection procedures involved one visualisation BSU positioned above the head and two

Table 1 – Summary of procedures performed and successful completion in cadavers.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number performed</th>
<th>Number completed successfully</th>
<th>Number of lead surgeons</th>
<th>Number of unique port configurations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radical nephrectomy (transperitoneal)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right kidney</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Left kidney</td>
<td>10</td>
<td>10</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Radical nephrectomy (retroperitoneal)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right kidney</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Prostatectomy (transperitoneal)</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Retzius-sparing prostatectomy</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Pelvic lymph node dissection</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>24</td>
<td>–</td>
<td>18</td>
</tr>
</tbody>
</table>

Fig. 2 – Median surgical access and reach VAS scores for procedures performed in cadavers. Error bars indicate range. VAS scale ranged from 1 (clinically unachievable) to 10 (perfect access). One VAS score (3) for transperitoneal radical nephrectomy was an outlier. The surgeon qualitatively described reach as being adequate, and no further details were provided as to why a VAS score of 3 was given. VAS = visual analogue scale.
instrument BSUs near the head/shoulder, on opposite sides of the surgical table (four of eight procedures, reflecting three lead surgeons’ preferences), or an additional instrument BSU by the umbilicus, at the right side (two of eight procedures, reflecting two lead surgeons’ preferences; Fig. 4B). Additional BSU positions used for all procedures are detailed in Supplementary Figure S4.

### 3.3. Recovery pigs

Six radical nephrectomies (nonrecovery $n = 2$, recovery $n = 4$) were performed in pigs. All procedures were completed successfully, and there were no device- or non–device-related intraoperative complications in any procedure. Intraoperative blood loss during the procedure was
recorded as approximately 300 ml ($n = 2$) or none ($n = 3$). For one procedure, blood loss was not measured. Postoperatively, all pigs recovered well with no observations indicating ill health or distress, and all recovery pigs were gaining weight as an indication of good recovery after surgery. There was one instance of mild swelling around the surgical site 9 d after the operation, attributed to the healing process associated with an inflammatory reaction to the suture. At necropsy, assessments of all the recovery pigs showed that the pigs had recovered well, the renal bed was unremarkable, port sites healed well, and surrounding organs macroscopically appeared healthy with no signs of injury, infection, or inflammation (Fig. 5).

4. Discussion

Overall, the cadaver studies demonstrated that the system can be used for robotic surgery in common renal and prostate MAS procedures. The system’s flexibility and portability enabled adequate surgical access to reach the important fields of work within the retroperitoneum and pelvis, even in specimens with a high BMI. The system’s user-led design (articulation of the instrument tip, ergonomic handgrip, and console) enables surgeons to complete procedures successfully within the confined space of the pelvis. All procedures were performed in a manner similar to how they would be performed in the clinical setting, from surgical set-up to the surgical steps performed. Moreover,
the ability to perform radical nephrectomy safely and effectively has been demonstrated in a live animal model, providing a good simulation of system performance expected in live humans and demonstrating that the instruments could be used for safe and effective manipulation of live tissue.

Port placement strategies for robot-assisted laparoscopic procedures with currently available robot systems usually require three or four ports for the robotic instrument arms, and one or two assistant ports in both nephrectomy and prostatectomy [21]. The attendant narrow range of port placement configurations may make access to the bedside difficult or uncomfortable. Findings from this study demonstrate one of the benefits of Versius: the versatility of the modular BSU design allows a variety of port placement to provide adequate surgical access and reach. This versatility enabled surgeons to effectively transfer their preferred laparoscopic port placements for use with the robotic system.

The da Vinci Surgical System (intuitive Surgical, Sunnyvale, CA, USA) was the first commercially available robotic laparoscopic MAS surgical system. The design of the key components of Versius differs significantly from that of the da Vinci Surgical System. The robotic arms of Versius are modular, providing increased arm positioning flexibility. With both systems, the surgeon may be seated at the remote surgeon console; however, the Versius surgeon console is open, and can be operated at either a standing or a seated position, while the da Vinci counterpart has a fixed, closed design. Finally, the entire Versius robotic device control has been placed on-board handheld control units, removing the need for foot pedal controls. A detailed comparison between Versius and da Vinci Xi has been reported by Atallah and colleagues [22].

### 4.1. Further development of Versius

The system tested in these studies is not the final production design. Incremental changes to instruments, hardware, and software were made throughout these studies to improve the design of the robot and the surgical set-up for each type of procedure tested. Port and base positions were initially chosen to try and mirror conventional laparoscopic port placements. In the course of the study, both port and base positions were modified to improve access and to avoid arm clashes. Although the safe and effective use of the instruments was demonstrated by successful procedure completion in the porcine study, further studies will be performed to quantitatively assess instrument functionality. In addition, procedures that have been performed a limited number of times in cadavers will be repeated to further optimise the use of the device for these surgeries.
4.2. **Study limitations**

Porcine models bear greater similarity to live tissue handling, dissection, surgical plane identification, and control of bleeding in live human surgery. On the other hand, clearly human cadavers provide much greater anatomical relevance and realism than pigs [23]. Testing in both human cadavers and pig models balances the limitations in each model. However, it is not possible to identically replicate the experience and performance of the robot for surgery in live humans. Although only radical nephrectomy was performed in pigs, this procedure was selected to provide a good simulation of system performance for renal surgery in live humans, as porcine kidneys are similar in size and vascularity to those of humans. The number of radical nephrectomies performed was deemed the minimum required to generate sufficient evidence for the safety of Versius to align with the 3Rs.

5. **Conclusions**

The studies presented here cover the preclinical assessment of Versius for renal and prostate extirpative surgery in cadaveric and porcine models. Several types of renal and prostate surgeries were tested in cadavers, with the lead surgeons evaluating a range of port and BSU positions. All surgeries were completed successfully. Radical nephrectomy was also performed safely and effectively in a live animal model. These promising early results support the progression of the new system to further phases of development and exploration in clinical studies of renal and prostate surgery as per the IDEAL-D framework [20].

**Author contributions:** Mark Slack had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Study concept and design:** Slack.

**Acquisition of data:** Stewart, Thomas, Hussain, Barber, Pradhan, Dinneen, Slack.

**Analysis and interpretation of data:** Stewart, Thomas, Hussain, Barber, Pradhan, Dinneen, Slack.

**Drafting of the manuscript:** Stewart, Thomas, Hussain, Barber, Pradhan, Dinneen, Slack.

**Critical revision of the manuscript for important intellectual content:** Stewart, Thomas, Hussain, Barber, Pradhan, Dinneen, Slack.

**Statistical analysis:** Stewart, Thomas, Hussain, Barber, Pradhan, Dinneen, Slack.

**Obtaining funding:** Slack.

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**Supervision:** None.

**Other:** None.

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**Appendix A. Supplementary data**

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