

Using end-user feedback to optimize the design of the Versius Surgical System, a new robot-assisted device for use in minimal access surgery

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To cite: Hares L, Roberts P, Marshall K, *et al.* Using end-user feedback to optimize the design of the Versius Surgical System, a new robot-assisted device for use in minimal access surgery. *BMJ Surg Interv Health Technologies* 2019;1:e000019. doi:10.1136/bmjst-2019-000019

Received 01 August 2019
Revised 02 October 2019
Accepted 24 October 2019

ABSTRACT

Background Robot-assisted minimal access surgery (MAS) reduces blood loss, recovery time, intraoperative and postoperative complications and pain. However, uptake of robotic MAS remains low, suggesting there are barriers to its use. To overcome these barriers, a new surgical robot system, Versius, was developed based on the needs and feedback of surgeons and surgical teams.

Methods The surgical robot prototype was designed based on observations in the operating room (OR) and previous interviews with surgeons. Formative studies with surgeons and surgical teams were used to refine the prototype design, resulting in modifications to all components, including the arms, instruments, handgrips and surgeon console. Proof-of-concept cadaver studies were used to further optimize its design by assessing its usability during surgical procedures.

Results Feedback led to the development of a novel, mobile design with independent arm carts and surgical console, linked by supported serial or parallel connections, providing maximum flexibility in the OR. Instrument tips were developed based on surgeons' preferred designs and wristed at the tip providing seven degrees of freedom within the patient. Multiple handgrip designs were assessed by surgeons; of these, a 'game controller' design was rated most popular and usable. An open surgical console design allowing multiple working positions was rated highest by surgeons and the surgical teams.

Conclusions This surgical robot system has been developed using feedback from end users throughout the design process and aims to minimize barriers to robotic MAS uptake. Additionally, these studies demonstrate system success in the surgical procedures it was designed for. The studies reported here, and further studies of the Versius Surgical System, are intended to align with IDEAL (Idea, Development, Exploration, Assessment, Long-term study) Framework guidance.

INTRODUCTION

Minimal access surgery (MAS) was pioneered in the late twentieth century and is increasingly used for a range of surgical procedures, particularly prostatectomies, hysterectomies and partial nephrectomies.^{1,2} Research demonstrates multiple advantages of MAS over open surgery, including reduced blood loss³ and

Key messages

What is already known about this subject?

- ▶ Minimal access surgery (MAS) is associated with multiple benefits over open surgery but is difficult to perform and has a steep learning curve.
- ▶ Robot-assisted surgical devices can help overcome some of the challenges associated with performing MAS; however, the use of robotics is still relatively uncommon.

What are the new findings?

- ▶ The Versius Surgical System has been developed and aimed to address barriers to MAS uptake by incorporating feedback from end users throughout the design process.
- ▶ The system has a novel, mobile design with independent arm carts and surgical console, wristed instrument tips providing seven degrees of freedom within the patient and a 'game controller' handgrip design.

How might these results affect future research or surgical practice?

- ▶ By including the end users in device development, Versius has been designed to better meet their needs.
- ▶ It is hoped that by addressing end-user needs and reducing the barriers to MAS, there will be greater uptake of the technique, leading to improved patient outcomes.

reduced intraoperative and postoperative complications, such as incisional hernias,⁴ infections and pain; together these benefits lead to reduced average hospital stays and improved clinical outcomes.^{3,5,6}

MAS uptake has been lower than expected. Reasons for this are likely to be multifactorial.⁷ MAS is associated with a steep learning curve, meaning surgeons completing few surgical procedures are less likely to use MAS techniques.^{5,8} This is particularly likely to affect surgeons in smaller, rural hospitals where a lack of training opportunities will limit the number



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of surgeons performing MAS procedures.⁵ Low numbers of patients requesting MAS may also limit uptake, either because patients are unaware of MAS or that the technique is associated with improved outcomes.^{5,9}

Over the last 20 years, several robot-assisted surgical devices have been developed that overcome some of the challenges associated with performing MAS. Robot-assisted devices are now available to support many procedures, including laparoscopic, cardiovascular, orthopedic, and brain and spine surgery.¹⁰⁻¹³ Robotic-assisted MAS has the potential to bring the benefits of MAS to a wider population of patients, and research suggests it may provide benefits over standard laparoscopic surgery.¹⁴⁻¹⁷ However, the use of robotics is still relatively uncommon, accounting for ~5% to 10% of all MAS procedures performed,² and installed robotic surgical systems are rarely used to full capacity.

Available robot-assisted surgical devices have limitations that may reduce surgeon uptake. Current devices often struggle to provide the same degrees of freedom as the human arm, reducing surgical access, especially when operating across multiple quadrants.¹⁸ MAS robots are large and difficult to move, requiring specifically designed operating rooms (ORs), increasing cost and reducing flexibility of use.¹⁹ The use of surgical robots is often associated with communication challenges, particularly when the device employs a closed console design in which the surgeon places their head.²⁰ Finally, ergonomics do not always provide optimal surgical experience, for example, robots do not cater to a wide range of grip sizes, and surgeons often maintain a single operating position for extended periods, which can result in back and neck pain, two common causes of sickness and early retirement for surgeons.²¹⁻²³

Here we describe the development of the Versius Surgical System, a teleoperated robotic surgical system designed to assist surgeons in performing MAS and to overcome challenges associated with currently available systems. Versius is designed to aid surgical procedures, increase team communication, and improve surgeons' work environment and career longevity. The system comprises an open surgeon console with hand controllers that the surgeon uses to control the arms and instruments. The surgeon receives three-dimensional (3D), high-definition video feedback from the endoscope camera via the head-up display. The display also has an overlay showing active instruments, system warnings and system function. The visualization bedside unit (BSU) supports the endoscope arm and has an auxiliary display that provides a two-dimensional, high-definition version of the endoscope feed for the surgical team. The team and surgeon are able to access controls and feedback on up to four individual BSUs, each supporting an instrument arm (online supplementary figure S1). These studies were designed considering IDEAL (Idea, Development, Exploration, Assessment, Long-term study) Framework guidelines and recommendations for surgical innovation.^{24,25} The studies aligned with Stage 0 of the framework and

aimed to ensure end-user feedback was incorporated into all steps of the design process and that the resulting design meets surgeon and surgical team needs.

METHODS

The concept of Versius was developed by Luke Hares to address a number of identified surgeon needs, confirmed through discussions with surgeons, that were unaddressed by available surgical robots. The first prototype was designed by the authors with the aim of addressing challenges associated with current surgical robots. Iterative formative studies were used to refine the prototype. Studies recruited potential users of robot-assisted laparoscopic MAS devices to gain feedback on different design features (arms, instruments, handgrips and console). Following completion of each component-focused study, the prototype was modified to incorporate end-user feedback. The updated version of each component prototype was tested again in further formative studies, and any feedback was used to further improve the design. Following final prototype development, Versius was used to perform multiple surgical procedures on cadavers during six separate studies (online supplementary table S1). Feedback obtained from surgeons during these procedures was used to further refine the design of Versius. Full study methods can be found in the online supplementary methods. The formative study methods leading to the development of the final prototype are briefly described further below.

CMR Surgical manufactures Versius in conformity with the essential requirements and provisions of Council Directive 93/42/EEC concerning medical devices (class IIb) and with Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, which applies to them (including but not limited to compliance with the harmonized standards IEC/EN 60601-1 and EN ISO 10993). The Company achieved the registration of its Quality Management System to ISO 13485:2016 by Underwriters Laboratories LLC (UL), and the status as a UL Registered Firm, in September 2015.

Arm development studies

Arm design was refined through two formative studies: formative arms study 1 and arm usability study 2. In both studies, surgical team participants were trained on arm use and were asked to provide qualitative feedback on the design and usability of the arm and cart prototypes. Recommendations were used to improve and align them with user needs.

Workflow assessment studies

Insights into surgical team use of the Versius system were obtained from two studies, workflow formatives 1 and 2. Feedback on the ease of use of the system was solicited throughout simulated OR sessions. Observations of room layout, preferences, errors, handling of the system and

coping mechanisms were recorded and used to further refine Versius.

Instrument development studies

A range of instrument tip designs were selected after consultation with senior surgeons. Surgeon feedback on instrument prototypes was collected through the instrument tip exploratory formative study. Surgeons were presented with images of different designs of needle drivers, scissors and grasper/forceps and rated each on a scale of 1–5 (1, they would never use the instrument tip; 5, they would always use it). Surgeons were asked their opinions on the design of each instrument. Prototype designs were then tested for usability by two surgeons. Based on their feedback, the instrument tips were further updated.

Handgrip development studies

Handgrip design was developed through two formative studies: surgeon handgrips formative study and grip study 2. In the first study, surgeons handled and provided qualitative feedback on five different handgrip prototype designs. Based on surgeon feedback, three further prototypes were produced.

Grip study 2 recruited surgeons to test and provide preference ratings on the three handgrip prototypes (1–7: 1, meets none of their surgical requirements; 7, meets all their surgical requirements). Participants were also asked to indicate their preferred location for different controls on the handgrip.

Console development studies

The initial console prototype was designed based on the surgeon console study, which asked surgeons for feedback on seven images of different console concepts, including options for sitting and standing during procedures. The console usability study then recruited surgeons to test a prototype by completing a range of simulated tasks.

Participants provided feedback on the design that was used to refine the console.

Patient and public involvement

Patients were not involved in the design of this study or the drafting of this manuscript as these studies describe the technical development and preclinical testing of a robotic surgical system.

RESULTS

Details of the participants involved in each formative study and proof-of-concept cadaver study can be found in online supplementary tables S2 and S3, respectively.

Robotic arm design and development

Figure 1 shows the arm and cart development process from the initial prototype (used in formative arm study 1) to the final design. Key feedback from participants and resulting recommendations from the two formative arm studies and the two workflow studies (online supplementary tables S4 and S5) focused on four main areas.

Workflows for arm set up

Participants commented that the device may be more intuitive to use if changes were made to the workflow terminology to better describe the tasks completed by the user. Communication of arm identity with the surgical team using descriptions instead of assigned arm colors, or including a statement in training explaining that arm colors are the correct way to identify arms, was also recommended.

Arm lifting, docking and draping

Arms were originally designed to be docked into ‘sockets’ either on a cart positioned by the side or on the bed. However, participants were concerned about the manual handling associated with the weight of the bed and that

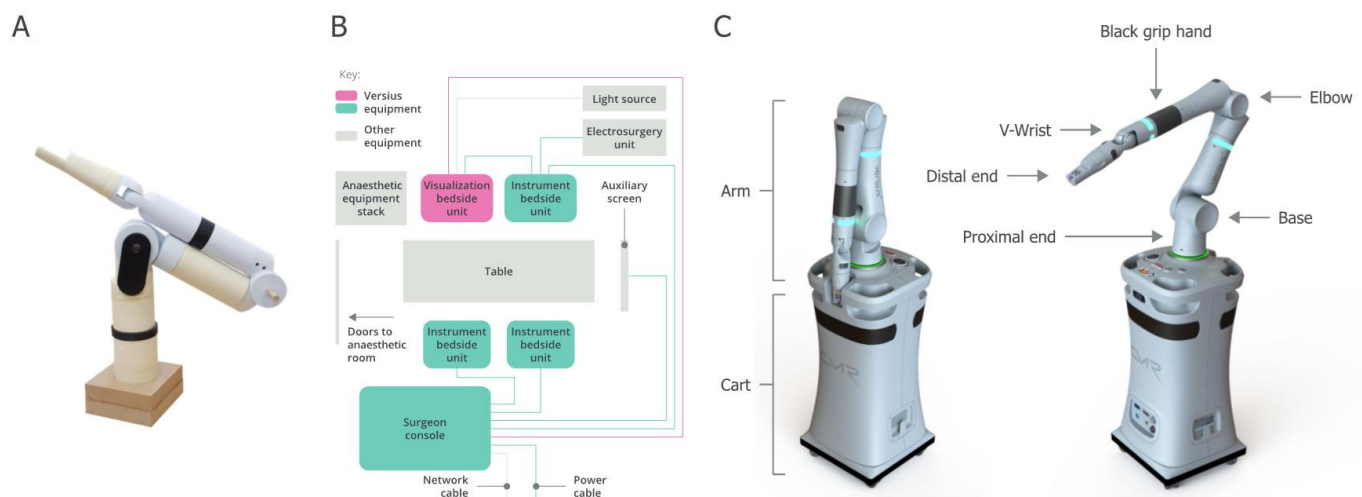


Figure 1 Arm development from initial prototype to final design. (A) Initial arm prototype used for formative arm study 1. (B) Layout of Versius equipment in a standard operating room. Versius can support up to four instrument BSUs and one visualization BSU. (C) Final Versius arm design. BSU, bedside unit.

they may be liable if they dropped and damaged the arms. Additionally, participants highlighted concerns about 'hot swapping' if an arm was faulty. As a result, arms were redesigned to attach to mobile carts to avoid lifting and moving arms.

Participants were happy with the draping process but recommended that draping include the cart, considered handling by both sterile and non-sterile team members, and that clips holding the drapes be refined to allow easier application (online supplementary table S4).

OR layout flexibility

Several recommendations focused on maximizing flexibility and ease of use within the OR layout. Multiple participants suggested that arms be placed on individual, smaller carts and wheeled around individually (online supplementary table S4). This aligned with the findings from the lifting and docking studies. Specific workflow options discussed in both the formative arm study and the arm usability study demonstrating scenarios that lend themselves to single-arm and cart configurations are shown in online supplementary figure S2.

Clear feedback of arm status

Simplification of arm status indication, through lights and sound, and the importance of critical information being language independent were highlighted by users (online supplementary table S5). It was recommended that all arm feedback be in the same area to allow easy checking of arm status.

Arm use during the proof-of-concept cadaver studies resulted in several key recommendations for the arm and cart design (online supplementary table S6). Cart size and placement were refined to ensure easy movement of both carts and the surgical team around the OR and to increase flexibility of arm and cart use. Additionally, communication of arm state and errors (including feedback designed to reduce arm collisions) was improved and arm buttons were made easier to locate after draping. Final arm design allows for maximum flexibility in an OR layout (figure 1B), optimizing robot use for each surgical procedure; the final arm design is shown in figure 1C.

Instrument tip design and development

Figure 2A–C shows the mean surgeon ratings of prototype tip designs alongside images of the three highest rated tips for each design from the instrument tip exploratory study. To maximize flexibility, each instrument incorporates a wristed design providing seven degrees of freedom at the tip.

Online supplementary table S7 summarizes user feedback on the prototypes developed based on the instrument tip exploratory study results. Several recommendations were implemented based on feedback: the outside of the needle driver was redesigned to prevent thread from snagging when suturing. The pitch cable was tightened, and the ball fitting was improved on the grasping forceps to prevent unintentional rotation. During extended

use of instrument tips in the proof-of-concept cadaver studies, several small iterative design changes were made to improve ease of use of all instrument tips (online supplementary table S6). The final design of each tip is shown in figure 2D.

Handgrip design and development

Measurements of participant hand sizes demonstrated a wide range from 202 mm (length) by 115 mm (width) to 166 mm (length) by 92 mm (width). The gender and hand size of participants (online supplementary table S8) were considered during the development of subsequent prototypes, with the aim of ensuring the controller could be held comfortably by hand sizes within the 5th and 95th percentiles for both genders.

Online supplementary table S9 details user feedback from surgeon assessment of five initial handgrip prototypes. The game controller grip was reported as the most comfortable and easy to use; however, a smaller size controller was suggested as more usable, even by surgeons with larger hands. The palm ball controller was least liked and was often held incorrectly. The remaining prototypes received positive feedback alongside minor concerns or questions (online supplementary table S9).

Three handgrip prototypes were developed based on feedback received on these five prototypes (figure 3A). On average, participants rated Concept X most highly (mean rating: 4.9/7; figure 3A). Figure 3B shows participant location preferences for different buttons/controls included in the Concept X design. Greatest consensus was found regarding the endoscope control (most popular location: thumbstick) and electrocautery (most participants agreed this should be easily accessible, but in a position unlikely to be accidentally activated). The preferred location of the clutch was at the back of the handgrip, or back left, in parallel with the pinch. Finally, all but one participant preferred the mode change button to be on the top surface of the handgrip. The final handgrip design, based on user feedback from both grip studies, is shown in figure 3C. The positions of the controls were further assessed in workflow study 2; only the position of the electrosurgery controls divided opinion, with one participant stating a preference for foot pedal control and two preferring the handgrip position.

Participants found the handgrip easy to use during proof-of-concept cadaver studies, resulting in very few challenges or comments from surgeons (online supplementary table S6). However, minor refinement to the design of the controls was made to prevent accidental instrument movement.

Console design and development

There were mixed opinions about the seven console designs presented to participants in the surgeon console study (figure 4A and online supplementary table S10). Concept 7 was least preferred due to the neck angle and the arms being concealed under the screen. Surgeons reported that all designs without armrests would lack

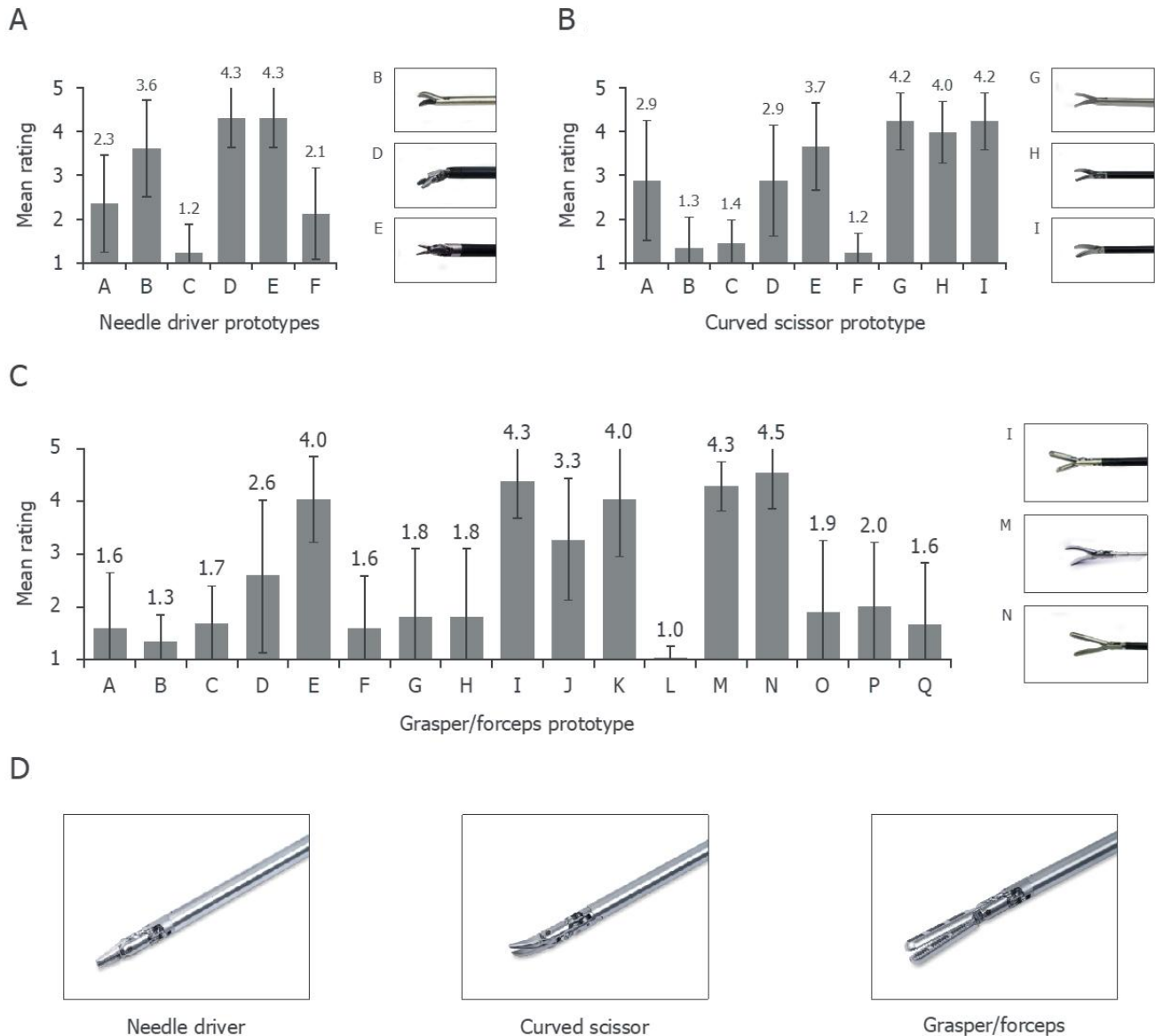


Figure 2 Instrument tip development from initial prototypes to final design mean participant ratings of (A) needle driver prototypes, (B) curved scissor prototypes, and (C) grasper/forceps prototypes and images of the three most popular prototypes of each instrument tip. Error bars indicate SD. (D) Final design of each instrument tip. All designs were rated 1–5, where 1 is ‘I would never use the instrument tip’ and 5 is ‘I would always use it’.

support. Feedback received recommended that the console design include arms rests with horizontal or back linkages (rather than front-to-back linkages), a seating position with the ability to recline or the option of operating standing up if desired, a separate screen, and comfortable 3D glasses.

Formative feedback from multiple surgeons’ assessment of the selected prototype console design suggested an open console could aid team communication and enable surgeons to adopt a low-risk posture during use. Most participants liked the option of a standing position but stated that most of their work would be completed sitting down. Standing was likely to only be used as a break from sitting. Console testing by surgeons of varying heights indicated that the console did not accommodate for small surgeons when seated (“you could not lower it

far enough”) or very tall surgeons when standing (unable to position the console high enough for P8, who was 6 ft 4 inches).

Figure 4B presents the final design of the console, showing the influence of formative study results on console design. Minor changes were made to the console following the proof-of-concept cadaver studies (online supplementary table S6), these focused on increasing ease of set-up and mobility of the console unit. Additionally, indication of arm and instrument statuses on the console was improved.

DISCUSSION

Versius was designed to address identified end-user needs. The formative and usability studies described here aided

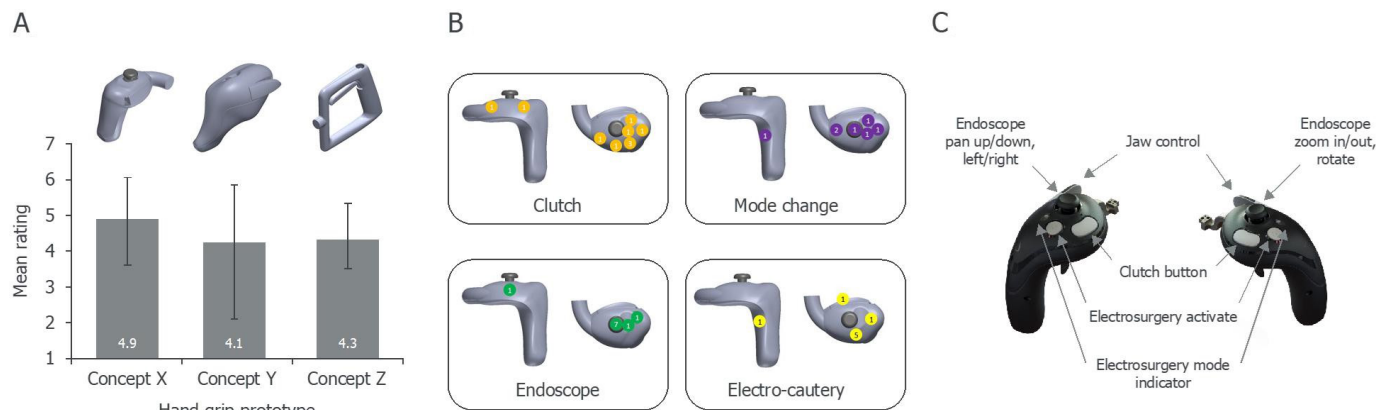


Figure 3 Handgrip development from early prototypes to final design. (A) Mean participant ratings of the three handgrip prototypes tested in grips study 2 (error bars indicate SD). All designs were rated 1–7, where 1 is ‘meets none of my surgical requirements’ and 7 is ‘meets all of my surgical requirements’. (B) Preferred control positioning for the most popular handgrip prototype (concept X); the number in the colored circle indicates the number of participants who placed the sticker in that position on the preferred handgrip design. (C) Image of the final controller.

development and ensured user feedback was incorporated during each stage of the design process.

MAS and robot-assisted MAS is underused despite the clear patient benefits provided by the techniques.⁵ Previous studies suggest that MAS underuse may partly be due to the technical challenges presented to the surgeon. Using straight instruments with limited motion and few degrees of freedom increases the challenges presented by some robot systems.¹⁸ The wristed instruments used with Versius provide seven degrees of freedom at the instrument tip, allowing surgeons to manipulate the instruments as they would in open surgery.

Poor communication during robotic surgery may lead to poor surgical outcomes.²⁰ With a closed console system, the surgeon is physically separated from the both the patient and the surgical team. Extensive communication between the surgeon and the surgical team is vital but may

be difficult to manage, especially in an emergency.²⁶ The open console of Versius allows surgeons and their teams to communicate more easily throughout procedures, which is more reflective of their normal surgical experience. It is hoped that improved communication will be reflected in improved surgical outcomes with Versius.

Neck and back pain is a well-documented occupational hazard for surgeons and is responsible for a high number of sick days and early retirement.^{21–23} Evidence indicates that surgical robots that provide the option for surgeons to be seated with armrests while operating reduce the muscular strain on surgeons’ legs, shoulders and back and cuts surgeon energy consumption during simulated MAS.^{27 28} The feedback from surgeons using Versius supports this and suggests ergonomics are further improved by providing the option to stand midprocedure. By using surgeon input and feedback to help design

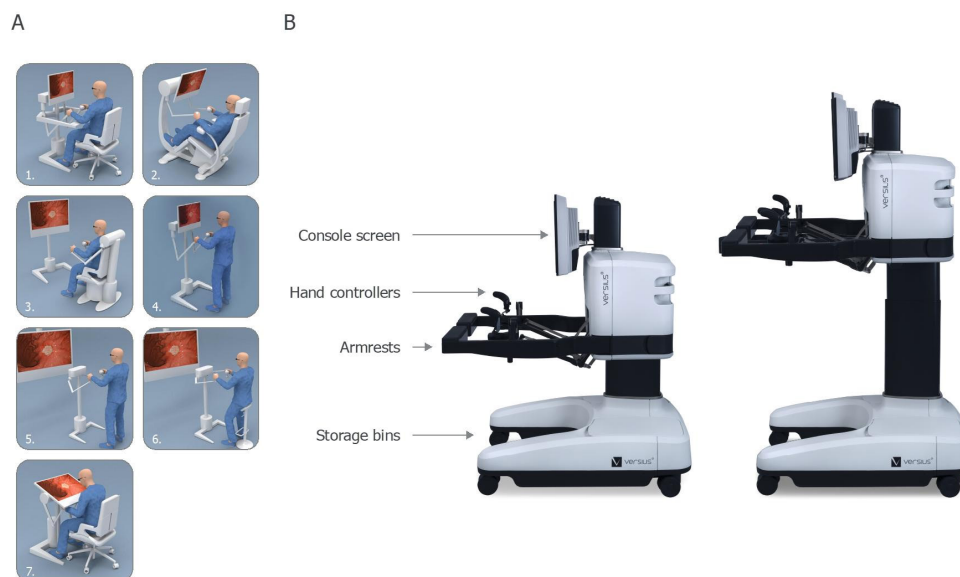


Figure 4 Console development from early to final prototype. (A) Console concepts tested in the surgeon console study. (B) Final design of Versius console.

the surgeon console, Versius aims to improve the surgical work environment, reduce surgeon pain and increase career longevity.

Currently available surgical robots are disadvantaged by their large size requiring large ORs and making maneuvering equipment challenging.¹⁹ Furthermore, the size and restricted mobility prevent the movement of robots between theaters, and so surgical robots often require a dedicated OR.¹⁹ Many hospitals do not have the available space or resource to build extra ORs^{5,29} and will use available theater space, restricting this theater space when the robot is not in use. Additionally, the large size and immobility of some surgical robots may make emergency conversions to open or manual laparoscopic surgery more challenging as physical space and access are restricted by the size and location of the robot over the patient.³⁰ The modular design of Versius aims to reduce these issues and increases potential for flexible use, as it is small enough to be used in a standard OR and can easily be moved within a single OR or between ORs.

Limitations

Many of the formative studies that influenced the design of Versius used interviews and image rating to collect user feedback. These methods are limited as participants cannot fully know their feelings about a device until they have used it for full surgical procedures. Additionally, the numbers of participants involved in these studies were relatively small, so their opinions may not reflect those of other laparoscopic and robotic surgeons. Most participants in the handgrip studies were male surgeons and, as a result, may not represent all female hand sizes. An additional study has been commissioned to address this limitation, which may result in further refinement of the handgrips.

The proof-of-concept studies were limited by the use of cadavers to test robotic surgical ability. Porcine models were rated by general surgical residents to have better tissue handling and ability to dissect and identify planes than cadaver models, when comparing to live human tissue.³¹ As a result of these limitations, it may be possible that the surgical instruments behave differently when used to operate on live human or animal tissue. This will be assessed during the next stages of testing in both cadavers and porcine models; any learnings will be used to further refine Versius' design before progressing to clinical trials.

CONCLUSIONS

Through the studies presented here, a new surgical robot, Versius, has been developed. Design of the robot was based on testing by, and feedback from, end users (surgeons and the surgical team). By including the end users in device development, Versius has been designed to better meet their needs. The positive response from surgeons on the performance of Versius in the proof-of-concept cadaver studies demonstrates it can be successfully used for MAS. Versius will now be tested further in preclinical studies in

human cadavers and porcine models, and the results of these studies will inform further development and refinement of the design of the system. These future studies are intended to continue Versius development in alignment with the IDEAL Framework guidelines.²⁵

Acknowledgements The authors thank the individuals who donated their bodies to medical research, the investigators and their teams who took part in this study. The authors also acknowledge Emma Phillips, PhD, and Simon Foulcer, PhD, from Costello Medical, UK, for medical writing and editorial assistance based on the authors' input and direction.

Contributors All authors made substantial contributions to the study conception and design, analysis and interpretation of the data, drafting the article or revising it critically for important intellectual content and final approval of the version of the article to be published.

Funding This study was sponsored by CMR Surgical. Support for third-party writing assistance for this article was funded by CMR Surgical in accordance with Good Publication Practice (GPP3) guidelines (<http://www.ismpp.org/gpp3>).

Competing interests All authors were founders of CMR Surgical.

Patient consent for publication Not required.

Ethics approval 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 12 603. 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.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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