Using End-User Feedback to Optimize the Design of Versius, a New Robot-Assisted Device for Use in Minimal Access Surgery

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SUPPLEMENTARY MATERIALS

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Arm development studies

Formative Arms Study 1

This study aimed to assess the usability of the prototype Versius arms in the context of their set up, operation and tear down. Nine scrub nurses and one OR technician participated. The study involved a training session (all ten participants together) followed by an assessment session (involving two participants and more focused discussions). As this study was completed during the early stages of arm design it was not possible to use fully working arms, therefore, an arm that could be positioned and had removable instruments was used. Participant feelings and opinions regarding the arms were recorded and recommendations were made based on participant feedback.

Arm Usability Study 2

This usability study involved seven members of the surgical team from Addenbrooke's Hospital, Cambridge, UK, and built on the findings from the formative arm study 1. It aimed to explore workflows associated with arm set up and tear down. In addition, the need for arm status feedback during these activities (and during surgical procedures) was also explored. The study included demonstrations of the arm, arm mode and the surgical console, as well as set up role play and discussions on OR layout, workflow and sterility. Qualitative feedback from participants on the design and performance of the arm in these situations was recorded and further recommendations were developed based on this.

Workflow studies

Workflow Study 1

Each surgical team completed a four-hour session. Each team was introduced to the surgical system by an independent facilitator, before being walked through a practical session simulating the setup of the system for a pelvic procedure. Surgeons were trained on the system controls using a 'system emulator' before simulating surgical scenarios with the rest of the team. Observations on system use and qualitative feedback from the surgeons were recorded throughout the sessions.

Workflow Study 2

Each surgical team completed a six-hour session on Versius use. Each team was introduced to the surgical system by an independent facilitator, before being walked through a practical session simulating the setup of the system for a procedure. Intraoperative system tasks, emergency procedure and tear-down sessions were also completed. Surgeons were trained on the system controls using a 'system emulator' before simulating surgical scenarios using the full surgical system, with the rest of the team. Observations on system use and qualitative feedback from the surgeons were recorded throughout the sessions.

Instrument development studies

Instrument Tip Exploratory Study

Nine Robotic Surgeons and one Surgical Nurse Care Practitioner took part in this study exploring instrument tip preference. Images of different instrument tip prototypes were shown to the participants and they were asked to rate instrument tips from 1–5 (1: they would never use the instrument tip; 5: they would always use it). All interviews were recorded and transcribed in full. Transcripts were then analysed for common themes to aid further instrument tip development.

Handgrips development studies

Surgeon Handgrips Formative Study

Eight surgeons with different levels of laparoscopic and robotic surgery experience were recruited from Colchester Hospital, Guy's Hospital and St Thomas' Hospital. Interviews lasted one hour and were conducted by an independent moderator using a pre-approved discussion guide. All interviews were recorded and live-streamed to CMR Surgical via Skype. Participants were reimbursed for their time. Five different surgeon console hand grip prototypes (game controller; hybrid; palm ball; precision; scissors) were fixed to a dummy gimbal and participants were asked to handle each one in a randomized order. Photographs were taken to show participant handling of each handgrip.

Each participant's hand size was measured by asking all surgeons to close all their fingers and thumb together. Hand width was measure from the widest points (base of thumb to smallest finger knuckle), hand length was measure from the tip of the middle finger to the start of the wrist. The hand size and gender of the participants are shown in **Supplementary Table S6**.

Grips Study 2

The second handgrips formative study was run alongside the instrument tip exploratory study and included nine robotic surgeons and one Surgical Nurse Care Practitioner. The one-to-one interviews, each lasting 1.5 hours were audio recorded. Additionally, surgeons' hands were filmed to demonstrate specific actions while using the different handgrip models. Participants were shown three handgrip concepts in a randomised order and asked to indicate their preferred location for different controls and to rate each hand grip for preference from 1–7 (1: meets none of their surgical requirements, 7: meets all their surgical requirements). All transcripts were coded to look for common themes, preferences and usability.

Console development studies

Surgeon Console Study

A mixture of laparoscopic and robotic surgeons, from a variety of UK hospitals, were interviewed to provide feedback on a range of console designs. Seven console designs had been produced to assess the importance of different aspects (e.g. option to sit/stand, presence of arm rests) of a robotic console to surgeons. Surgeons were asked some introductory questions about their experience of surgery generally, and their thoughts on current robotic systems. Console concepts were then presented on a large tablet in a randomized order to surgeons for assessment. Interviews were recorded and transcribed in full. CMR Surgical remained anonymous throughout the trial and watched all interviews via a Skype link. Specific questions could be asked via an instant messaging function.

Console Usability Study

One-to-one interviews were completed with 13 surgeons from a range of hospitals and experience levels. Surgeons used a console system set up to test the handgrip design and ergonomic set up when performing a range of simulated tasks. The console system included a prototype hand controller ("game controller" design) connected via a wired link and a gimbal. A crib sheet showing the functions on each of the controls was available for surgeons to reference. Adjustable arm rests were also included in the system. A 3D monitor was mounted onto the console, with adjustable height and tilt angle. Participants were asked to wear 3D glasses (over their own spectacles if necessary). A simulator showing virtual instruments and targets for the participants to work with was shown on the 3D monitor. Participants were asked to perform a range of tasks using this simulator. The movement of the virtual instruments corresponded with the movement of the hand controllers. Surgeons had a range of gloves sizes and adjusted the console to a variety of different heights and positions.

Proof of concept cadaver studies

After completion of the formative studies and development of an initial surgical robot prototype, six proof of concept cadaver studies (C1–6) were completed to test the prototype design in a surgical setting. Studies took place at the Evelyn Cambridge Surgical Training Centre. As each cadaver study was completed, recommendations for the design of the robot were given based on the challenges and successes of that specific study. Recommendations were implemented through an iterative process as Versius progressed through the proof of concept studies. Details of the methodology of each cadaver study can be found in **Supplementary Table S1**.

SUPPLEMENTARY RESULTS

Supplementary Table S1. Methodology of proof of concept cadaver studies

Proof of concept cadaver studies	Methods
C1 (A3 system)	No full single procedure Arm and instrument testing
C2a–c (A4 system)	8 surgeons, 3 parts (a: 2 days, b: 3 days, c: 3 days) Demonstrate use for surgery (cholecystectomy [x2], hysterectomy, nephrectomy [x2], sacrocolpopexy)
C3 (A5 system)	3 surgeons, 3 days investigating instrument performance in surgical tasks Gynaecological set up and tear down, reliability testing Colorectal surgery attempt and system configuration testing Usability testing, detailed notes on instrument and system performance, participant feedback recorded
C4 (A5 system)	5 surgeons and bedside team, 3 days investigating instrument and general system performance and cart setups for key procedures Usability testing, detailed notes on instrument and system performance, participant feedback recorded
C5 (A5 system)	4 surgeons, 2 days Set up for procedures in upper GI, colorectal and pelvic surgery, test motion control of 30-degree endoscope, compare instruments to standard laparoscopic instruments 2 cadavers: 1 for upper GI, 1 for colorectal and pelvic Detailed notes about instrument and system performance taken, surgeon feedback recorded
C6 (two A-model systems)	Determine bedside and port placement, and procedures for adjusting these in the event of reach problems Key surgical steps noted, data capture sheets with relative measurements to capture bedside and port placement Where feasible complete surgical procedures were performed

GI: gastrointestinal

1 **Supplementary Table S2.** Demographics for each formative study

Study	Participants	Details
Formative Arm Study 1	10 Scrub Nurses/OR Technicians	
Arm Usability Study 2	7 members of the scrub team from Addenbrooke's Hospital	• 1 Senior Sister • 1 Surgical Care Practitioner: urology/robotics • 1 Operating Department Practitioner • 1 Clinical Team Lead; Surgical Care Practitioner • 3 Scrub Nurses
Surgeon Handgrips Formative Study	8 surgeons with varying laparoscopic and robotic surgery experience from Colchester, Guy's and St Thomas' hospitals	• Laparoscopic Surgical Registrar ST7: general surgery • Robotic and Laparoscopic Surgeon: colorectal and pelvic floor • Consultant Laparoscopic Surgeon: GI/colorectal • Consultant Laparoscopic Surgeon: trans-anal • Consultant Laparoscopic Surgeon: women's services • Laparoscopic Surgeon: gynaecological oncology • Senior Clinical Fellow: gynaecological oncology • Laparoscopic and Robotic Surgeon • Trainee Robotic Surgeon: urology
Grips Study 2 and Instrument Tip Exploratory Study	10 Robotic Surgeons from Guy's, The Wellington Hospital, St George's and UCLH	• SPR Urology • Consultant Urologist • Specialist Registrar: urology • Post CCT Fellow: urology • Consultant Urologist • Consultant Urological Surgeon • Consultant Surgeon: colorectal • Consultant Surgeon: uro-oncology (radical prostatectomy) • Specialist Registrar: urology • Surgical Care Practitioner: urology
Console Usability Study	13 surgeons from a range of hospitals and experience levels	
Surgeon Console Study	8 Laparoscopic/Robotic Surgeons with and without robotic experiences from Guys, St Thomas', Papworth and Colchester hospitals	• ST5 Registrar: general surgery • Robotic Surgeon • Consultant Laparoscopic Surgeon: women's services (PhD student at the Centre for Robotics Research at King's College London) • Laparoscopic Surgeon: gynaecological oncology • 2 Consultant Thoracic Surgeons • 2 Consultant Laparoscopic Surgeons
Workflow Study 1	4 different surgical teams	Each team comprised of the following: • Surgeon • Surgical Assistant • Scrub Nurse • Circulating Nurse • Healthcare Practitioner
Workflow Study 2	4 different surgical teams (2x urology, 1x colorectal, 1x gynaecology)	Each team comprised of the following: • Surgeon • Surgical Assistant • Scrub Nurse • Circulating Nurse

2 CCT: certificate of completion of training; OR: operating room; SPR: specialist registrar; ST5: speciality
3 training, year 5; ST7: speciality training, year 7; UCLH: University College London Hospitals.

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Supplementary Table S3. Demographics for each proof of concept cadaver study

Proof of concept study	Participants	Details	
C1	CMR Surgical employees and surgeons	• Technology Director, CMR Surgical • Senior Software Engineer, CMR Surgical • Senior Engineer, CMR Surgical • Chief Medical Officer, CMR Surgical • Laparoscopic Surgeon • Urogynaeocologic Surgeon	
C2	8 surgeons	• Consultant Surgeon: upper GI • Consultant Urogynaecologist • 2 Consultant Urologists • Consultant Gynaecologist	• Consultant Surgeon • Clinical Lead • Consultant Urologist
C3	2 surgeons and Luke Hares	• Luke Hares • Consultant Surgeon • Consultant Gynaecologist	
C4	5 surgeons, 2 non-technical CMR employees as bedside team, 1 Surgical Care Practitioner	• Laparoscopic Surgeon • General Surgeon: upper-GI specialism • Consultant Gynaecologist	• Consultant Gynaecological Surgeon and Oncologist • Consultant Surgeon
C5	4 surgeons	• General Surgeon: upper-GI specialism • Consultant Surgeon	• Consultant Surgeon • Consultant Gynaecologist
C6	20 surgeons and 1 surgical first assistant	• 3 Consultant Gynaecologist • 1 Consultant Urogynaecologist • 6 Consultant Urologist • 1 Consultant Hepato-Pancreato-Biliary and Transplant Surgeon	• 2 Consultant General and Colorectal Surgeon • 3 Consultant General Surgeon • 3 Consultant Colorectal Surgeon • 1 Academic Clinical Fellow: urology

GI: gastrointestinal.

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Supplementary Table S4. Key user feedback obtained during formative assessment of Versius

Formative Study	User Feedback
Formative Arm Study 1 and Usability Arm Study 2	P1: "*if I'm the Scrub Nurse or circulator lifting 4 of these arms, I'm going to have back pain by the end of the list*" P7: "*it's an expensive piece of equipment, you don't want to drop it!*" P5: "*if it [the cart] were slimmer, it would help a lot*" P10: "*it's in my way, that's why it would be more beneficial to have them individual, so you can get in-between if you need to"* P2: "*I'm more into lights than icons*" P7: "*I want an alarming sound to let us know something's not right*"
Workflow Studies 1 and 2	Circulator 1: "*One person has to do all three carts if they are to be draped all round – it would be better to have non-sterile handles – also useful in pulling the carts out of the sterile field in an emergency"* Circulator 1: *"Is there a click when it goes in? How do we know it's on right? We need audible feedback that it's on."* Assistant 2: *"You've got nice mobile pieces of equipment, so it's likely they won't be left in position, so you wouldn't have a purely robotic theatre with everything set up in place."* Surgeon 4: *"The advantage of this [system] is the flexibility, so, assuming that your range of operations is going to expand, you may want to move it around more"* Scrub Nurse 3: *"I want all the drapes in one pack, all on my trolley"* Assistant 1: *"The whole arm should turn red. The red light on the cart isn't enough."*
Instrument Tip Exploratory Study	P4: "*I quite like the curved scissors, I think they're safer. Particularly in robotics the problem is that you can overshoot the mark and if, for whatever reason, you're not precise enough and you don't want to poke through anything you just want to cut between the blades and not beyond the blades*" P10: *"curved scissors are lovely because your hand is curved, you want to follow your hand action. Any instrument that is curved is much more natural to use than a straight line. If you're cutting against an abdominal wall you don't want your scissors to go into it, you want them curved away from it so curved will always win in my opinion."*

Versius Design and Development – Supplementary Materials 02 October 2019

Supplementary Table S5. Recommendations resulting from arm formative studies

Study	Key recommendations	
Formative Study 1	• Changes to workflow terminology to better reflect the clinical task being performed by the end-user or more familiar terminology e.g. "Calibration" rather than "Port training" or "Docking" rather than "Instrument Adjust" • Consider simplification of status indication • Undertake further workflow evaluation with Surgical Assistants (Surgeons of Surgical Care Practitioners) to explore the broader workflow of mode changes (ideally on a fully working arm) • Undertake further setup workflow evaluation, exploring the time efficiencies and sterility challenges of draping the arms before bringing the cart to the patient • A higher fidelity system is required to better assess the higher ends of the workflow	• Consider how cart design can provide flexibility in layout and provide ease of working e.g. providing shelves • Consider smaller single arm carts • Explore ease of communication in future usability session • Drape design should accommodate the cart (front, top, sides at a minimum) although this does not specifically need to be part of the arm drape itself • Consider not making the carts replacements for the stack as it complicates sterility of the cart • Explore sterility in relation to arm exchange in future workflow studies
Usability Study 2	• Consider moving arm mode indication either more distally on the arm or onto the heads-up display • Trial the use of audio notifications to accompany state changes • Avoid red and green as identification colours if possible • Review the perceived commercial value in the 'hot swap' feature of the current system • If hot swap remains, work on reducing the weight of the arms to within manual handling limits • Ensure instruments are compatible with defibrillation • Ensure drape design considers handling by both sterile and non-sterile team members	• Explore the concept of single socket trolleys to improve patient access during the procedure • Consider cable management in future workflow studies • Explore team communications around the system in future workflow studies • Ensure critical information is not language dependant • Explore the concept of height adjustable carts to accommodate table height/tilt • Ensure cart braking activation is a single step operation • Consider delivering a formal surgical team training program • Ensure drape design clearly labels handling areas

1 **Supplementary Table S6.** Recommendations resulting from the proof of concept cadaver studies

Cadaver Study	Key recommendations			
	Arm design	Instrument design	Handgrips design	Console design
C1	• The trolleys need to be smaller with a couple of 45-degreee mounting points on them and 4 casters so that they are easier to move around • Recovering from joint faults needs to be able to be done gracefully without resetting the whole arm	• A method of making sure the instrument jaws are closed and the wrist is straight before trying to extract it through a port • A faster way of changing between articulated instruments and scissors is needed. The physical instrument switch should be faster when the instruments are no longer screwed into place	-	• Surgeon console needs to be more manoeuvrable and narrower for fitting through door ways
C2	• Further study should be considered for optimal cart placements based on the required working volume • The stability of the arm at different poses should be investigated further	• Consider raising the maximum panning speed of the endoscope • A basic self-collision avoidance measure should be considered	-	-

Versius Design and Development – Supplementary Materials 02 October 2019

C3	• Consider correlated torque readings for collision avoidance • Need to manage cables to keep clear of brake descending • Ensure arm buttons are easier to locate under drapes • The trolley needs to be easily rolled over cables	• In compliant mode it would also be useful to be able to straighten the instrument • Suture material is recommended as a future test material for scissor evaluation	-	• The roll up indicator should be enabled when in full compliance mode so the user can tell whether they are rolling up joints or unrolling joints • A matching sticker on both cable connector and console connector could help connect cables and console quicker • Feedback to surgeon to indicate when a limit reached required
C4	-	• Optimise instrument use with software system	• Thumbstick click to straighten instruments only when engaged	-
C5	-	• Improve performance of scissors and quality of camera	-	-
C6	-	-	-	-

1

Versius Design and Development – Supplementary Materials 02 October 2019

Supplementary Table S7. User feedback from formative assessments of the instruments

	Concept	User feedback
	**Needle Driver (s/n 2875)**	• Manipulating needles is one of the most difficult laparoscopic techniques • Many successful knots using needle driver in combination with the grasper • Suturing thread did not easily slide over instrument wrist and sometimes caught on the pitch-yaw pins • This may be resolved by redesigning outside of instrument to prevent thread from snagging
	**Fenestrated Grasping Forceps (s/n 2885)**	• Used to support an organ or other tissue to access the area underneath • Important for jaws to be wide opening to support the organ across more of its surface and reduce the chance of it dropping • Felt too loose and could be pushed/rotated out of the way as the cable is low tension • Increasing the initial set tension should minimise this problem • Also ensure ball fitting fits well in the recess of the jaw to further improve the issue • Found permanent deformation of the instrument after use – increased strength required
	**Scissors (s/n 2866)**	• Size and profile look good for laparoscopic surgery • Software for scissors not yet able to be used fully so unable to demonstrate technique used by a surgeon • Cutting usually uses multiple small snips rather than long strokes of the whole blade • Tips of the blade need to be robust enough to perform most of the cutting • Also used to separate layers of tissue using the outside edge of the blades – this should be considered in the design

1 **Supplementary Table S8.** Hand sizes of participants in the handgrips study

Participant number	Age	Gender	Left/right handed?	Right hand length (mm)	Right hand width (mm)
1	39	M	Right	202	113
2	35	M	Right	187	109
3	45	M	Right	198	115
4	44	M	Right	187	105
5	43	M	Right	200	107
6	38	F	Right	166	92
7	34	M	Right	192	114
8	35	M	Right	180	105

2 F: female; M: male.

Supplementary Table S9. User feedback on the five handgrip prototypes used in the Surgeons' Handgrips Formative Study

Concept	User feedback
1. Game controller	**This was well received and was the most comfortable and usable for most of the participants.** P2 "I totally like it. Definitely. Probably it would be necessary to have more buttons because then you wouldn't need a foot pedal." P3 "Now, we've got an Xbox and I'm rubbish at it but this automatically feels comfortable." P8 "Yeah. It's just like a Wii, this is good."
2. Hybrid	**Participants liked that they could fit their whole hand around the controlled to aid stability.** P3 "It's safe because you have to make a purposeful movement. You won't fire inadvertently if you're doing something." P8 "perhaps my thumb is not very flexible. It's not quite… it's difficult to reach the button on this side" P6 "the button the on the lower platform is probably just a bit too far away."
3. Palm ball	**The majority of participants spontaneously held this incorrectly, when participants were shown how to use it correctly, there were mixed reviews.** P2 "Hmm, carpal tunnel disease. It's definitely the worst… in my opinion, this is absolutely a dumb position". P3 "It feels good but it's perhaps too much of a point pressure there, I wonder what would happen after five years." P5 "when I'm operating it prevents me from using my arm, my hand to the full extent."
4. Precision	**Surgeons with extensive experience in robotic surgery were very happy with this design, those with limited experience held the rings incorrectly.** P4 "Well I personally prefer to use my index finger and my thumb. I think that that's a stronger, more deliberate, purposeful movement and it's a movement you use when you're writing so the muscles in the finger and thumb would be stronger in that position." P1 (naïve to robotic surgery) "My hand aches. It hurts my hand. I think because those [gestures at previous handgrips] were done with my handgrip; these are more like finger grips. It's almost like trying to drink a mug of tea; you hold the mug with your hand and if you hold it with two fingers all the time it's going to be much more effort."
5. Scissors	**Most participants felt comfortable with the scissors, however, there was confusion over how the design could be used on the robot.** P2 "This is closer to the laparoscopic approach, but I think this is really a wrong approach for a robotic approach… there's no advantage in this control. It's awful to move, it's difficult to give the right movement. A precise movement is totally impossible with this. It's the worst." P3 "I like these grips. And I've learned to, over the years, change my position on the grips... I don't mind this, it's quite versatile. It's interesting because this is thin and doesn't fit in the hand snugly, but it feels better than the previous one I was using [the Hybrid]." P8 "I know for a fact that if I had to use this to do a retraction or something my thumb is usually numb just because it's so tight, rigid; not really fluid like the other designs."

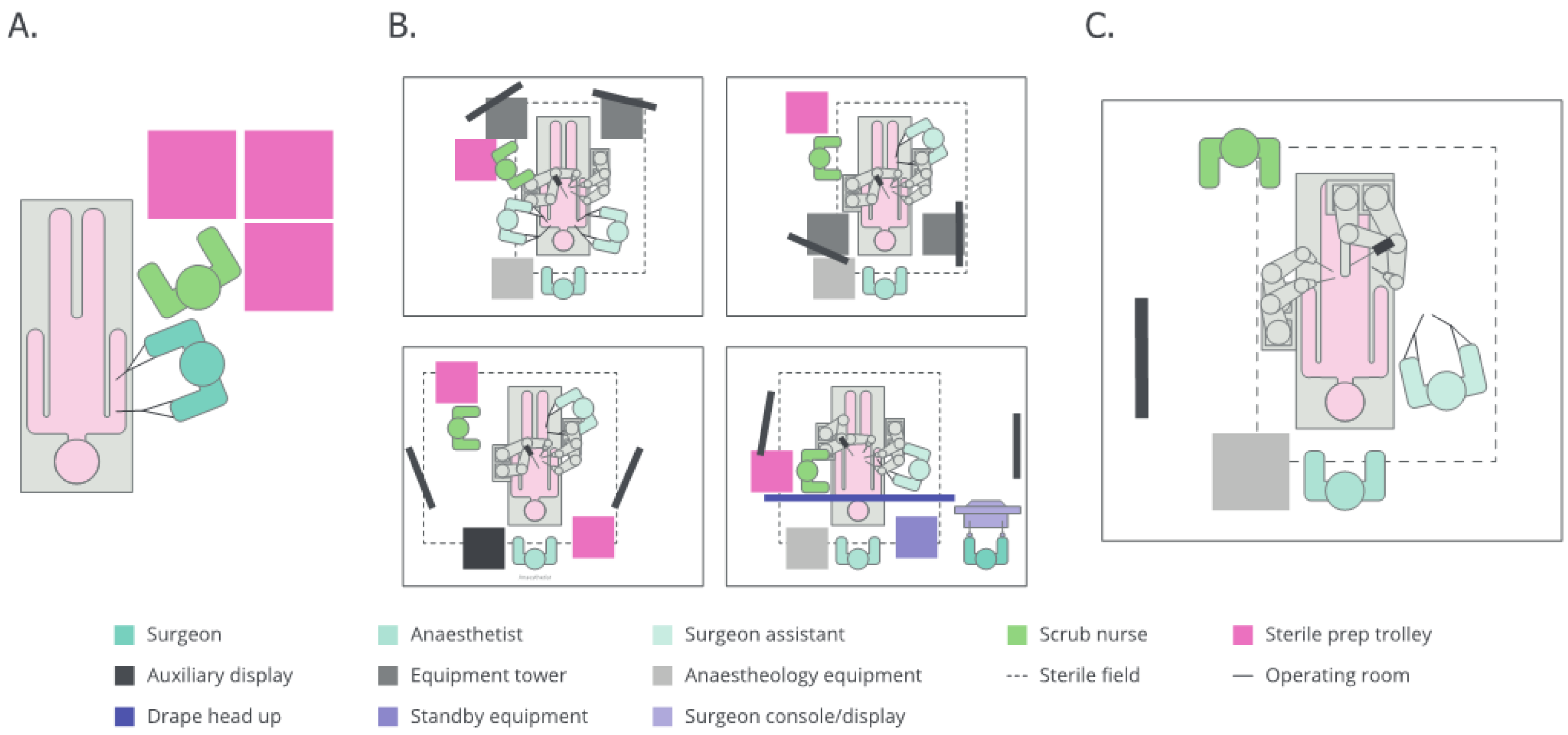
Supplementary Table S10. Formative results and participant quotes from Surgeon Console Study

Console Concept	User feedback
1	P1: *"It looks a perfectly workable concept… It seems a pretty natural position".* P2: *"I think I prefer configuration 1 to 2. I find that's a more natural focused posture, instead of the reclined position".* P5: *"This looks fine too, I think 1 and 2 personally for me are the best".* P5 preferred Concept 1 over Concept 2 due to manoeuvrability around the hospital. P2: *"I think that would work"* P1 thought that it would be useful to have the option to stand up during the operating and felt this concept could be used for that, as you could just extend the middle piece on the screen and stand up. Surgeons like to have the flexibility to move the screen towards them or further away (mentioned for other concepts).
2	P7: *"That's quite good actually… I think that's the best one. I mean the only thing is, you know, if that screen could move on a pivot. It supports the back and the neck".* P8: *"I think if you could get the gaming chair right so that it could accommodate tall, fat, thin, short surgeons and the scaling is correct, then I think I would go for Option 2".* P5: *"For some surgeons different things are important, different levels of comfort… it's like that when you drive isn't it".* P2, P3 and P6 did not like the recline. P3 and P6 commented that the recline would feel unnatural as you are normally bent forward for operating. P2 liked this concept the least out of all the concepts, as he thought he might feel like he is locked in. All the surgeons spoke about the need to have arm rests, so this was a very favourable aspect of Concept 2.
3	This concept was well received. There was a lot of discussion surrounding the arm linkages, vs other set ups. Most participants liked the idea of being able to move the screen wherever they wish, with P8 commenting that this is an absolute must. P8 felt that the image looks like the surgeons' arms are slightly forward *"you'd want your elbows by your sides really… to be continually reaching forward is tiring... what you want is small movements with your elbows at your sides".*
4	A few surgeons liked the thought of standing, and many thought it would be nice to have the option to stand during an operating, P7 and P8 commented that they would like the screen to be larger and separated. All surgeons disliked the lack of arm rests.
5	This concept did not gain a significant response except from P4 who concluded that this was her least favoured concept due to the posture required. She would prefer to be seated and felt that that is one of the main advantages of robotic surgery. The separate screen seemed appealing to participants. The lack of arm rests would cause a problem.
6	Most participants thought the perch stool was a great idea; P7 commented that he is going to integrate this into his current laparoscopic surgery. P3 and P5 said this was their preferred concept because it mimics the surgery they do. The lack of arm rests would pose a problem. P3 spoke about urologists having a special stool with padded arms on the side. She thinks that this could be adapted for this robot. P1: *"I mean being perched, I hate being perched, it's just bus shelter seating, it's really uncomfortable. I'd say 6 would be the worst I think".*
7	This concept would be unacceptable for laparoscopic and robotic surgeons. It was almost always rated as the least preferred concept. P4, P5 and P6 did not like the fact that the arms are concealed under the screen. P4 did state an advantage to this concept in the fact that it replicates the vision in open surgery, however she was the only surgeon who made this connection. P8: *"I really don't like 7. It looks really uncomfortable, very bad for your neck".* P1: *"I think the idea of looking down makes less sense than looking dead ahead".* P5: *"No, this one I don't like. No, no, no. I like to see in front of me".* P7: *"I just worry about tennis elbow, and the arms don't appear to be supported at all".*

Supplementary Figure S1. The Versius system in use

Versius Design and Development – Supplementary Materials 02 October 2019

Supplementary Figure S2. Workflow options discussed in arm formative and usability studies leading to the development of a single arm configuration



A. Typical OR layout for robotic procedure; **B.** Workflows proposed by participants during Formative Arm Study 1 with prototype two arm cart; **C.** Example OR configuration from Arm Usability Study 2 demonstrating an example where a single arm configuration would be preferred. OR: operating room.