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Implementation and clinical evaluation of the Versius Robotic System in a multispecialty setting: an IDEAL 2a/b study.

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Abstract

Background: There has been a steady diffusion of robotic assisted surgery into practice in the United Kingdom. As robotic platforms enter the market, it is imperative that robust and standardised evaluations using recognised frameworks take place to ensure clinical efficacy and safety. The Versius robot (Cambridge Medical Robotics) gained CE mark in 2019 and is the first robotic platform.

Methods: An IDEAL 2a/2b study was designed assessing the development (2a) and exploration (2b) in a multispecialty CMR programme, consisting of colorectal, hepatobiliary and general surgery. All patients undergoing robotic surgery between February 2020 and November 2023 were included. Key robotic outcomes were reported in keeping with the RoboCOS core outcome set. Innovation outcomes were reported in keeping with the COHESIVE core outcome set.

Results: Ninety-three patients were included in this evaluation. There were 55 (59%) colorectal, 9 (10%) general surgery and 29 (31%) hepatobiliary procedures, with anterior resection (n=27, 29%) and cholecystectomy (n=24, 26%) as the most common procedures. The overall morbidity was 9% (n=8). There were no intraoperative complications. Seven patients (8%) required a return to theatre, with the predominant complication being anastomotic leak (n= 6, 6%). No complications were directly attributed to the robotic platform. In total, 77 (83%) of procedures were completed robotically. There were no reports of device malfunction, however expected disadvantages were encountered related to available instrumentation. Surgeons favourably reported on improved visualisation aiding with pelvic dissections.

Conclusions: This study demonstrates that Versius can be successfully implemented into a multispecialty setting. Clinical evaluations using recognised frameworks should be universally applied to develop best practice, highlighting benefits and disadvantages of innovations, and to enable better evaluation of robotic assisted surgery at patient, organisation and population level.

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Introduction

There has been a rapid adoption of Robotic Assisted Surgery (RAS) in the NHS with a steady increase in cases performed totalling over 10,000 procedures in 2019¹. Surgeons have been quick to embrace RAS, due to its increased visibility and perceived technical

and clinical benefits². The introduction of robotic surgery programmes into hospitals is associated with a broad and immediate increase in surgeries performed across a range of specialties and procedures, with trends showing a decrease in laparoscopic surgery in favour of the robotic approach³. In the UK in 2020, 6% of colorectal cancer resections were performed robotically, compared

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to only 0.3% in 2013⁴. This trend will continue to be driven by a culture of innovation in an increasingly competitive marketplace. Future robotic platforms will be responsive to competing and varied demands in surgery, leading to the development of smaller and smarter systems with improved economic and environmental profiles⁵.

Cambridge Medical Robotics (CMR) introduced Versius in 2019 following successful pre-clinical trials as the first robotic platform developed in the UK. The current evaluation status of the Versius system is limited and there are few reports of its implementation in a multispecialty setting.

It is imperative that existing and future robotic innovations are robustly evaluated to ensure both clinical efficacy and safety. Many frameworks currently exist to enable an appropriate and robust evaluation of innovative technologies into clinical practice and to ensure safety and transparency through consistent reporting. The Idea, Development, Evaluation, Assessment and Long-term monitoring (IDEAL) framework was first introduced in 2009 to describe the stages in development of surgical and interventional innovations. More recently the development of the COHESIVE and ROBO-COS core outcome sets have presented frameworks for the standardised evaluation of innovative surgical procedures and devices as they are introduced and evaluated⁶⁻⁸. The aim of this IDEAL 2a/b study is to report the safe implementation of the Versius robotic system (Cambridge Medical Robotics, UK) within a multispecialty programme.

Methods

This study was designed in keeping with the principles of the IDEAL (Idea, Development, Exploration, Assessment and Long-Term Monitoring) framework and maps to Stage 2a and 2b: Development and Exploration using updated guidelines⁶. Institutional ethical approval was waived for this study.

The Versius Robotic System

The Versius platform is a teleoperated, open console robotic system with modular design consisting of up to four free standing and adjustable bedside units (BSU). The BSUs have been designed to replicate the articulation of the human arm and wrist. All components including the console are mobile, allowing for easy transportation, movement and adaptation of the theatre environment. The surgeon uses hand controllers and receives three-dimensional (3D) high-definition feedback. The adaptable positioning of the robotic arms is designed to mirror laparoscopic surgery, offering easy access and familiar port placement with haptic feedback to laparoscopic surgeons new to the robotic system⁹⁻¹⁰. End user feedback has been integrated in the optimisation of the design of

Versius including the development of wristed instruments providing seven degrees of freedom, and an open console design to enable more effective communication between surgical teams during operation¹¹.

IDEAL Stage 2a: Development of Surgical approach

The development study was led by the participating surgeons to determine the optimal port placement and configuration of robot arm docking for each index procedure. Port placement with the Versius robot is principally based on the laparoscopic technique. A hybrid surgical approach was adopted for surgical procedures with steps required an energy device or stapling technology.

For anterior resections and abdominoperineal resections an open Hassan technique is used to achieve pneumoperitoneum with an 12mm umbilical port, with further 12mm right iliac fossa port, 2 further low right and left iliac fossa ports, 12 and 5mm respectively. Dissection of the colon is undertaken laparoscopically in a medial to lateral approach and the inferior mesenteric artery and vein is divided before the robot is docked. The robot is usually initially docked for rectal mobilisation in the TME plane to the pelvic floor. A laparoscopic energy device is selectively used to divide the mesorectum with laparoscopic stapling devices used to divide the rectum. For anterior resection a low colorectal or coloanal anastomosis is fashioned using a double stapled technique. Following division of the rectum, the specimen is extracted through a Pfannenstiel incision, the proximal colon is transected and prepared for anastomosis with insertion of the stapler anvil. This is returned to the abdominal cavity, pneumoperitoneum is re-established and an end to end anastomosis is performed.

For right hemicolectomy, an 12mm supraumbilical port is placed with further 5mm ports in the left upper quadrant and suprapubic space. A final 12mm port is placed in the left iliac fossa. The robot is docked and dissection begins medial to lateral in Toldt's plane. The ileocolic pedicle is isolated and divided between clips. Dissection is continued to the hepatic flexure until sufficiently mobilised. Depending on tumour anatomy, the middle colic vessels are preserved or isolated and divided robotically. A limited midline incision is performed and an extracorporeal double-stapled ileo-transverse anastomosis is performed.

For distal pancreatectomy, a 12mm umbilical port is placed with a further 12mm left upper quadrant, and three 5mm ports in the epigastrium and right and left upper quadrants. The gastrocolic ligament is opened laparoscopically with a Lotus ultrasonic scalpel device, the stomach is mobilised and the short gastric vessels are divided with the Lotus between haemolocks. The transverse mesocolon is separated and if necessary



the splenic flexure is mobilised before the Versius robot is docked and antegrade dissection of the pancreas is undertaken. The pancreas and splenic vessels are divided laparoscopically using a vascular stapling device. A left upper quadrant drain is placed at the end of the procedure.

Surgical team

All members of the extended surgical team attended a three-day training course which included dry lab technical skills exercises. This included an online programme consisting of 13 modules, with each module comprising an assessment with 80% pass mark. In total, four colorectal surgeons and two hepatobiliary surgeons completed an additional minimum 6 hours of simulator training and a two-day standardised wet lab simulation programme. An additional wet lab simulation course on distal pancreatectomies was organised for a hepatobiliary consultant. All surgeons had extensive prior laparoscopic experience, and one colorectal surgeon was a practising robotic surgeon on the Da Vinci X platform. Prior to commencement of the first cases, a half day implementation programme took place at the hospital. The first four live cases were performed under the supervision and guidance of a dedicated robotic proctor.

IDEAL Stage 2b: Exploration and evaluation

Eligibility: Adult patients aged >18 with ASA 1-3 were eligible for inclusion. Procedures included were colorectal resections, cholecystectomy, inguinal hernia repair and distal pancreatectomy. All cholecystectomies were performed by a hepatobiliary surgeon. All patients with colorectal cancer were included irrespective of rectal cancer height, T4 stage or previous abdominal surgery or radiotherapy. Benign colorectal resections were also included.

Patient Consent: Patients were counselled pre-operatively in clinic prior to undergoing a robotic procedure. All patients were counselled that procedures would be undertaken on a new surgical device by experienced minimally invasive surgeons who had undergone training on the Versius device but were either at the start or early in their learning curve on the Versius robot.

Outcomes

Data was collected from patient electronic health records including a review of the operation note and clinical admission summary from February 2020 to November 2023. Outcomes have been considered and reported according to RoboCOS and COHESIVE core outcome sets⁷⁻⁸. Relevant clinicopathological details were collected including age, sex, ASA grade, prior abdominal surgery, history of chemoradiation treatment, tumour staging, and post operative histopathology.

Robotic outcomes were reported in keeping with RoboCOS patient, surgeon and organisation level outcomes. Patient outcomes include overall measure of complications including mortality (or adverse events) and procedure effectiveness. Surgeon level outcomes report on precision, accuracy and visualisation. Organisation level outcomes include assessment of equipment failure and standardisation of operative technique.

Key outcomes related to surgical innovation were reported in keeping with the COHESIVE core outcome set to assess and measure the seamless, standardised evaluation of innovative surgical procedures and devices (7). The COS consists of eight innovation specific domains including; modifications, expected/unexpected disadvantages, intended benefits device problems, technical procedure success, whether the overall desired effect was achieved, surgeons'/patients' experience.

Post-operative complications were classified as adverse events within 30 days of the operation and were classified according to the Clavien-Dindo classification. Complications graded III-V were included and considered as major complications. Re-operative rates were reported as any unplanned re-operation within 30 days of the index operation. Length of stay was defined as the number of days following the day of surgery until medically fit for discharge.

Data analysis

Patient data was analysed using descriptive statistics. Categorical values have been presented as number and percentage. The reported median values were accompanied by their interquartile ranges.

Results

Between, February 2020 and November 2023, a total of 93 patients were included in this evaluation. There were 51 (55%) male and 42 (45%) female participants, with a median age of 61 (IQR 40-71). A total of 55 (59%) colorectal, 9 (10%) general surgery, and 29 (31%) hepatobiliary procedures were performed by six consultant surgeons. The most commonly performed procedures were anterior resection of rectum (n=27, 29%) and cholecystectomy (n= 24, 26%). Overall patient and procedure characteristics are summarised in Table 1a and 1b.

Overall Outcomes

Overall length of stay was 5 days (IQR 2-6). The complication rate was 9% (n=8). Reoperation rates were 8% (n=7) and the readmission rate was 2% (n=2). Overall innovation outcomes were acceptable. In total, 83% (n=77) of procedures were completed robotically



Table 1a: Patient characteristics

Characteristics	Overall (n=93)	Colorectal (n=55)	General Surgery (n=9)	Hepatobiliary (n=29)
ASA III	17	12	5	0
Gender M:F	51:42	29:26	7:2	15:14
ASA II	59	37	19	3
ASA I	17	6	9	2
Age (IQR)	61 (40–71)	62 (53–71)	53 (41–72)	31 (29–60)

Table 1b: Procedure characteristics

Specialty	Procedure	n
Colorectal	Anterior resection	27
Colorectal	APER	17
Colorectal	Appendectomy	2
Colorectal	Hartman's procedure	1
Colorectal	Left hemicolectomy	1
Colorectal	Right hemicolectomy	5
Colorectal	Sigmoid colectomy	2
General Surgery	Inguinal hernia	8
General Surgery	Incisional hernia	1
Hepatobiliary	Cholecystectomy	24
Hepatobiliary	Distal pancreatectomy	4

as planned. Modifications were made in 1% (n=1) of procedures. Expected disadvantages included lack of energy device and stapling technology. Overall, surgeon satisfaction was excellent. Specific RoboCOS and COHESIVE outcomes are reported in Table 2.

Colorectal

Colorectal resections were undertaken for malignancy (n=51, 92%), diverticular disease (n=2, 4%) and appendiceal lesions (n=2, 4%). Most resections were for rectal cancer (n=35, 64%). The R1 resection rate was 5% (n=3). The overall morbidity for all colorectal procedures was 15% (n=8). There were no intraoperative complications. There were 6 (11%) anastomotic complications, all requiring a return to theatre. Median length of stay was 5 days (IQR 4-11). 30-day readmission and re-operation rates were 4% (n=2) and 13% (n=7). The conversion rate was 13% (n=7), with four conversions to open due to difficult pelvic dissection and one conversion to a laparoscopic approach due to increased intraabdominal adiposity, making access to the ileocolic vascular pedicle difficult. One case was converted to a laparoscopic approach due to bleeding and the need for an energy device. One further case was converted to an open approach due to difficulty grasping the colon with available instrumentation.

Overall innovation outcomes for colorectal surgery were acceptable with no modifications to surgical approach (Table 2). Perceived expected disadvantages related to the lack of an energy device and stapling technology and inadequate grip strength of the graspers in select cases i.e., obese patients. Technical procedural success was 87% (n=48). There were no reports of device malfunction. Surgeons favourably reported on the advanced 3D visualisation which aided difficult pelvic dissections.

General Surgery

Of the 9 general surgery cases included, indications were incisional hernia (n=1, 11%) and inguinal hernia (n=8, 89%). Seven (88%) inguinal hernias were repaired using a totally extraperitoneal approach. There were no complications, 30-day readmissions or return to theatre episodes. The median length of stay was 0 days (IQR 0-1). In total, 89% (n=8) of procedures were completed robotically as planned.

The overall conversion rate was 11% (n=1), with a robotic totally extraperitoneal inguinal hernia repair converted to a laparoscopic transabdominal approach due to difficulties with access. Overall innovation outcomes for general surgery were acceptable with one modification to surgical approach. There were no expected or unexpected disadvantages. Technical procedural success was 89% (n=8). There were no reports of device malfunction.

Hepatobiliary

Hepatobiliary procedures included were cholecystectomy (n=24, 83%), distal pancreatectomy (n=4, 14%) and distal pancreatectomy and splenectomy (n=1, 3%). The majority of cholecystectomies were performed for gallstones (n=21, 72%), one for gallbladder polyp (n=1, 3%) and one for previous cholecystitis (n=1, 3%). Indications for pancreatectomy included neuroendocrine tumour (n=2, 40%), insulinoma (n=1, 20%), ductal adenocarcinoma (n=1, 20%) and solid pseudopapillary lesion (n=1, 20%).

There were no complications, 30-day readmissions or return to theatre episodes. The median length of stay was 0 days (IQR 0-1). Twenty-seven cases (93%) were completed robotically as planned. The overall conversion



Table 2: RoboCos and COHESIVE outcomes

Core area	Outcome	Overall (n=93)	Colorectal (n=55)	General (n=9)	Hepatobiliary (n=29)
RoboCOS, Patient Level	Complications	9% (n=8)	15% (n=8)	0%	0%
	Mortality	0%	0%	0%	0%
	30-day readmissions	2% (n=2)	4% (n=2)	0%	0%
	Return to theatre episodes	8% (n=7)	13% (n=7)	0%	0%
	Procedures completed robotically	83% (n=77)	87% (n=48)	89% (n=8)	93% (n=27)
	Length of stay	5 (IQR 2-6)	5 (IQR 4-11)	0 (IQR 0-1)	0 (IQR 0-1)
RoboCOS, Surgeon Level	Precision/accuracy	No issues	No issues	No issues	No issues
	Visualisation	Excellent visualisation for pelvic dissection	Excellent visualisation for pelvic dissection	No issues	No issues
RoboCOS, Organisational Level	Equipment failure	No equipment failure	No equipment failure	No equipment failure	No equipment failure
	Operative standardisation	Operative approaches standardised	Operative approach standardised	Operative approach standardised	Operative approach standardised
COHESIVE, Innovation outcomes	Modifications	Unplanned in one case	No modifications	Unplanned in one case	No modifications
	Procedure completion success	83% (n=77)	87% (n=42)	% (n=9)	100% (n=9)
	Problems with device	No device problems	No device problems	No device problems	No device problems
	Expected/unexpected disadvantages	Lack of dedicated energy device; Lack of stapling technology	Lack of dedicated energy device. Lack of stapling technology	None	None
	Overall desired effect	Yes	Yes	Yes	Yes
	Surgeon's experience	Favourable	Favourable	Favourable	Favourable

rate was 7% (n=2). One cholecystectomy was converted laparoscopically due to an impacted stone in an inflamed Hartman's pouch and one pancreatectomy required laparoscopic conversion due to bleeding from the splenic vein. All pancreatic lesions were completely excised. Overall innovation outcomes for hepatobiliary surgery were acceptable with no modifications. There were no expected or unexpected disadvantages. There were no reports of device malfunction.

Discussion

In this IDEAL 2a/b evaluation we have demonstrated the safe implementation of the Versius robotic platform in a multispecialty programme consisting of colorectal, general and hepatobiliary surgery, thus supporting previous works in this arena¹²⁻¹³. We have demonstrated the

versatility of the Versius platform in enabling established laparoscopic surgeons to transition seamlessly into a safe and effective robotic practice.

The clinical outcomes associated within our programme are in keeping with the current evidence base for the Versius system, demonstrating overall short length of stay, with low rates of post-operative morbidity and low conversion rate¹⁴⁻¹⁵. This is in keeping with the broader outcomes reported within the Versius surgical registry, reporting on outcomes across 2083 patients across a range of surgical specialities¹⁶. Our IDEAL evaluation includes 55 (59%) colorectal, 9 (10%) general surgery, and 29 (31%) hepatobiliary procedures. The largest operative group in the Versius surgical registry was cholecystectomy (n=539, 25.8%), followed by hysterectomy (n=324, 15.5%), inguinal hernia (n=178,



8.5%) and anterior resection (n=162, 7.7%). In keeping with the Versius registry, we report low rates of morbidity and conversion associated with cholecystectomy and inguinal hernia. Similarly, our colorectal related data is in keeping with the current reported literature, with an overall morbidity rate of 15% and conversion rate of 13%¹⁷⁻¹⁸. The higher conversion rate observed in colorectal surgery is in part due to the increased complexity of the underlying procedures, and some of the current robotic device related limitations, including, lack of energy device and stapling technology. These perceived disadvantages are likely to be overcome with future hardware updates.

Beyond the traditional patient level outcomes, this IDEAL study reports on unique surgeon level and organisational level outcomes in keeping with RoboCoS and innovation outcomes in keeping with the COHESIVE core outcome set. Overall, surgeons value the precision, accuracy and visualisation afforded by the Versius system. There were no device-related failures, with procedural success in 83% (n=77) of patients overall. These are important key outcomes in ensuring that the Versius robotic system delivers the same patient and technological outcomes as traditional laparoscopic surgery, as well as current established robotic systems. As RAS becomes increasingly disruptive, and newer platforms enter the market, it is incumbent that clinical and technical reporting details are standardised. Improved understanding of the current limitations of novel platforms will inform future development and more effective integration into clinical practice. As such, future studies reporting on robotic platforms should consistently use these frameworks to ensure relevant and comparable reporting of RAS.

The key strength to our work is the adoption of robust frameworks such as IDEAL in combination with core outcome sets. This ensures a standardised approach to device evaluation and facilitates accurate and relevant outcome reporting. This approach will enable future comparisons with new and emerging works in this arena, thus strengthening and advancing the evaluation of robotic assisted surgery. The key limitation of our work is the lack of outcome reporting across all domains of RoboCoS, specifically in the domains of organisation and population level outcomes. We have not reported on the cost-effectiveness of our programme or on equity of access for our population base. This work focuses on the early implementation of our multispecialty programme, and as this evolves, we will report these important, broader based outcomes. A further key limitation of our work is the lack of reporting on learning curves. These were not reported due to the relatively small number of patients included per each surgeon and speciality, leading to a lack of meaningful learning curve data. We acknowledge that this is an important process metric, especially for a new robotic platform, however,

it is essential that learning curves are appropriately constructed, based on prior experience, total number of cases performed, case-mix and complexity¹⁹. This is unlikely to be realised within our dataset. Furthermore, learning curve data, within the Versius registry was only calculated for robotic cholecystectomy due to the volume of cases (n=539), case-mix and complexity.

We have demonstrated that Versius can be safely implemented into practice in a multispecialty setting and allows a seamless transition into robotic practice in a group of experienced laparoscopic surgeons. Our reported clinical outcomes align with existing evidence for the Versius programme, indicating its efficacy and safety across a diverse range of procedures. We have applied robust evaluation frameworks, which has enabled standardised and relevant reporting of key outcomes. These frameworks should be readily adopted in future evaluations of robotic technology to enable comparison between current and emerging platforms and to ensure more effective integration of robotic systems into clinical practice.

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