IRAS Ethics -qualitative-protocol (017) VAMIS

The research protocol forms an essential part of a research project. It is a full description of the research study and will act as a 'manual' for members of the research team to ensure adherence to the methods outlined. As the study gets underway, it can then be used to monitor the study's progress and evaluate its outcomes.

The protocol should go into as much detail about the research project as possible, to enable the review bodies to fully understand your study.

The use of this collated consensus guidance and template is not mandatory. The guidance and template are published as standards to encourage and enable responsible research.

The document will:

- Support researchers developing protocols where the sponsor does not already use a template
- Support sponsors wishing to develop template protocols in line with national guidance
- Support sponsors to review their existing protocol template to ensure that it is in line with national guidance.

A protocol which contains all the elements that review bodies consider is less likely to be delayed during the review process because there will be less likelihood that the review body will require clarification from the applicant.

We would appreciate self-declaration of how you've used this template so we are able to measure its uptake.

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- **This protocol has regard for the HRA guidance and order of content; OR**
- **This protocol has regard for the HRA guidance; OR**
- **This protocol does not have regard to the HRA guidance and order of content**

FULL/LONG TITLE OF THE STUDY
Video analysis of errors and technical performance within minimally invasive surgery

SHORT STUDY TITLE / ACRONYM

Video Analysis in Minimally Invasive Surgery (VAMIS)

PROTOCOL VERSION NUMBER AND DATE

Version 17

Date: 10/1/2024

RESEARCH REFERENCE NUMBERS

IRAS Number:	309024
SPONSORS Number:	TGI 001
FUNDERS Number:	TGI-DS-001&2

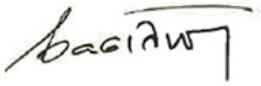
SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: 

Date:
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Name (please print): Mrs Vasiliki Kiparoglou

Position: Chief Executive Officer, The Griffin Institute

Chief Investigator:

Date:
..10../.1./..24.

Signature:

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Name: (please print): Professor Nader Francis

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STUDY SUMMARY

Study Title	Video analysis of errors and technical performance within minimally invasive surgery
Internal ref. no. (or short title)	VAMIS
Study Design	Observational
Study Participants	Patients undergoing minimally invasive surgical procedures
Planned Size of Sample (if applicable)	This project requires uploading a large number of video recorded cases in order to conduct the research and achieve all the primary and secondary end points. The type of cases will vary from generic laparoscopic procedures that will aid development initial phases of the project such as segmentation, to more advanced procedure segmentation e.g. laparoscopic cholecystectomy, robotic prostatectomy and robotic rectal cancer surgery and robotic hysterectomy. Since the methodology for technical performance analysis (Objective Clinical Human Reliability Analysis- OCHRA) was applied extensively in laparoscopic rectal cancer surgery, a comparison will also be made with robotic, hence, video recording of laparoscopic colorectal cases will be required. In order to achieve this number we will partner with a number of hospitals including Yeovil District Hospital NHS Foundation Trusts, University College London Hospitals, Queen Alexandra Hospital (Portsmouth), The Christie NHS Foundation Trust and Northwick Park & St Marks Hospitals and Central Middlesex Hospitals London North West University Healthcare NHS Trust, North East and North Cumbria Integrated Care System. There is no formal power calculation in this study but we aim to record as many procedures as possible within the time frame of the project and with a maximum 250 from each centre. We aim to conduct full OCHRA analysis including error annotation up to 50 videos per specialty. Additional study arm: real-time visualisation: A further aim is to gain additional consent from a subsample of patients (up to 20 cases) undergoing laparoscopic cholecystectomy procedures to assess the feasibility and usability of real-time visualisation on a secondary screen in the operating room, for training and education purposes.

	Additional study arm: real-time insights: A further aim is to gain additional consent from a subsample of patients (up to 20 cases) undergoing laparoscopic cholecystectomy procedures to assess the feasibility and usability of real-time insights through procedural time stamps, recorded on the system in the operating room, for training and education purposes that will be viewed post-operatively by the user.
Follow up duration (if applicable)	No direct patient follow-up or visits required in this study outside of standard care.
Planned Study Period	January 2022 – September 2025
Research Question/Aim(s)	This research project aims to assess/compare laparoscopic and robotic techniques for surgical phases and error detection that would permit the objective assessment of surgical performance, allowing for enrichened feedback and learning as well as certification of minimally invasive surgeons. The project will evaluate metrics for surgical performance and assess surgical procedural progression by analysing retrospective and prospective data, including pseudonymised patient data, including outcomes, and anonymized surgical video that is captured using the Touch Surgery EnterpriseTM. Additional robot kinematic (movement) data will be collected by dVLogger and analysed by computer scientists to further understand differences in skill and errors (novice vs expert). In the subsample of cases where real-time visualisation will be shown in the operating room on a secondary screen (that is separate to the main surgeon's operating screen), the project aims to understand the technical feasibility and surgeon opinions on the usability and utility of the technology. The overlays will highlight anatomical landmarks in lap chole procedures. The secondary screen and associated real-time visualisations will not be shown to the operating surgeon during the procedure. The long-term hypothesis is that the use of augmented visualization may help surgeons achieve Critical View of Safety through the identification of anatomical structures such as the Cystic Duct and Cystic Artery – further studies will follow this initial feasibility study. Similarly, the real-time insights arm will detect anatomical landmarks in real-time throughout the lap chole procedure, through a record of procedure time stamps, which will be available for the user to review post-operatively for education and review purposes. The study arm aims to test the feasibility and utility of a new real-time algorithm to detect

	critical structures in laparoscopic cholecystectomy procedures.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIAL SUPPORT GIVEN**
Digital Surgery, Medtronic **Karen.kerr@medtronic.com**	Full funding for PhD theses (Salaries for Mr Matt Boal and Dr Walaa Ghamrawi) (including annotation) in addition to standard analytics reporting.
The Griffin Institute Nader Francis **n.francis@griffininstitute.org.uk** Matt Boal **m.boal@griffininstitute.org.uk** Walaa Ghamrawi, w.ghamrawi@griffininstitute.org.uk Freweini Tesfai f.tesfai@griffinsintitute.org.uk Claudia Reali Claudia.reali@ydh.nhs.uk	Robotics training suite and national courses in minimally invasive surgery Employ PhD research fellows
WEISS Danail Stoyanov danail.stoyanov@ucl.ac.uk, Eddie Edwards **Eddie.edwards@ucl.ac.uk** Evangelos Mazomenos **E.mazomenos@ucl.ac.uk** **University College London/University College Hospitals London** John Kelly j.d.kelly@ucl.ac.uk Ashwin Sridhar Ashwin.sridhar@nhs.net Justin Collins justin.collins@ucl.ac.uk Dhivya Chandrasekaran d.chandrasekaran@nhs.net Georgia Zachou georgia.zachou@nhs.net	Access to expert computer scientists in robotics analysis including automated performance metrics Urology department Minimally invasive operative videos for analysis. Consultant gynaecologist, Gynaecology Oncology department O&G trainee and research fellow, supporting the gynaecology arm of the VAMIS trial.

ROLE OF STUDY SPONSOR AND FUNDER

MEDTRONIC

Touch Surgery™ Enterprise, (https://www.touchsurgery.com/) by Digital Surgery Limited, a Medtronic company, will record, process and provide analytics on video recordings of minimal-access surgical procedures. These are recorded through the standard operating stack and require no additional steps or changes to standard care. Currently, procedures are routinely recorded in the operating room, at the clinical sites, for training purposes to allow review and debrief after a procedure or to evaluate where improvements could be made. We do not anticipate that there will be any new material ethical issues associated with the recording system and surgical video feed. Medtronic will fund Dr Walaa Ghamrawi and Mr Matthew Boal's PhD thesis' looking into video analytics of minimally-invasive surgery initially radical prostatectomy and general colorectal cancer procedures which will be further extended to other operations.

The Griffin Institute (TGI)

TGI is a not-for-profit charitable research institute in Harrow, London, which employs Mr Matthew Boal and Dr Walaa Ghamrawi. Here there are many opportunities for research into training and evaluation of robotics and laparoscopic surgery pre-clinical simulation courses including dry, cadaver and live animal models.

Professor Nader Francis is the Director of Training at TGI and a Consultant Colorectal Surgeon with extensive experience within surgical training and education, including a key role in a UK wide laparoscopic training programme for consultant colorectal surgeons (LAPCO). As part of this programme, bespoke formative, Global Assessment Scale (GAS), and summative, Competency Assessment Tool (CAT), forms were developed and validated. These assessments inversely correlated to errors using Objective Clinical Human Reliability Analysis (OCHRA) and had predictive validity to patient outcomes.

Part of more recent work by Professor Francis has been applying OCHRA methodology to video analysis of laparoscopic colorectal procedures (TME in anterior resection), publishing the findings in JAMA. Using Professor Francis' and the research teams experience a protocol has been developed from previous work to analyse video data from minimally invasive surgery. OCHRA methodology will be further applied to robotic assisted radical prostatectomy (RARP) and anterior resection (rectal cancer excision). From this, any operation could have this methodology applied through the same process, defining phases and errors through a Delphi process with experts in that field.

TGI has established a partnership with Medtronic and Intuitive to support MIS training. Both companies have a laparoscopic and robotic training suite respectively at the TGI, with a goal to repatriate MIS work back to the UK. Traditionally advanced MIS training for British surgeons happened outside the UK in mainland Europe. Within this project, the organisations will work together in a partnership to support educational research that can generate and evaluate novel assessment tools, in the hopes of improving training in surgery and potentially patient safety and outcomes.

It is the aim to reproduce this transferable methodology to robotics assisted surgery, applying the same principles to further understand how surgical skill and error can potentially affect patient outcome, therefore, informing surgical training and credentialing.

Wellcome/EPSRC for Interventional and Surgical Sciences (WEISS)

WEISS provide specialists in computer science as a well as analysis of robotic performance metrics including kinematics and deep learning models/artificial intelligence (AI). This is hoped to ultimately allow automated feedback to surgeons including segmentation e.g., recognition of, and highlighting, an anatomical structure or instruments.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study management group:

Clinical team at The Griffin Institute: Professor Nader Francis, Mr Matt Boal, Dr Walaa Ghamrawi, Mrs Fiona Carter and Mr Jake Foad.

Funders: Dr Karen Kerr, Dr Lucy Culshaw and Ms Aimee Bambury from Digital Surgery- Medtronic, are appointed to the management committee as representatives of Digital Surgery Ltd. who will process the surgical video, provide access to data annotation platform, and provide advanced data analytics through Touch Surgery TM Enterprise.

PROTOCOL CONTRIBUTORS

The Griffin Institute: Mr Matthew Boal and Professor Francis have helped write the protocol and guide the research aims, providing the background and justification for it.

University College Hospitals London: Professor John Kelly, Professor Justin Collins, Mr Ashwin Sridhar additionally provided background knowledge and scientific justification for this research. They will provide video data for analysis from their senior trainees and consultant colleagues.

Medtronic: Dr Karen Kerr, Dr Aimee Bambury and Dr Lucy Culshaw will provide equipment (Touch Surgery Enterprise TM) to securely record, and store anonymised surgical video, and provide data analytics from this data set to the Sponsor. Medtronic has reviewed and contributed to the study protocol to ensure compliance with the research collaboration agreement pertaining to this submission and the technical capacities and terms of Medtronic products and services.

WEISS: Professor Danail Stoyanov, Dr Eddie Edwards and Dr Evangelos Mazomenos will aid in data analysis and interpretation of results of retrospective video data as well as additional kinematic data collected from dVLogger in da Vinci robot systems. WEISS will be responsible for sharing dVLogger data with Intuitive in anonymised form.

KEY WORDS:

Minimally Invasive or Minimal Access Surgery

Assessment and Evaluation

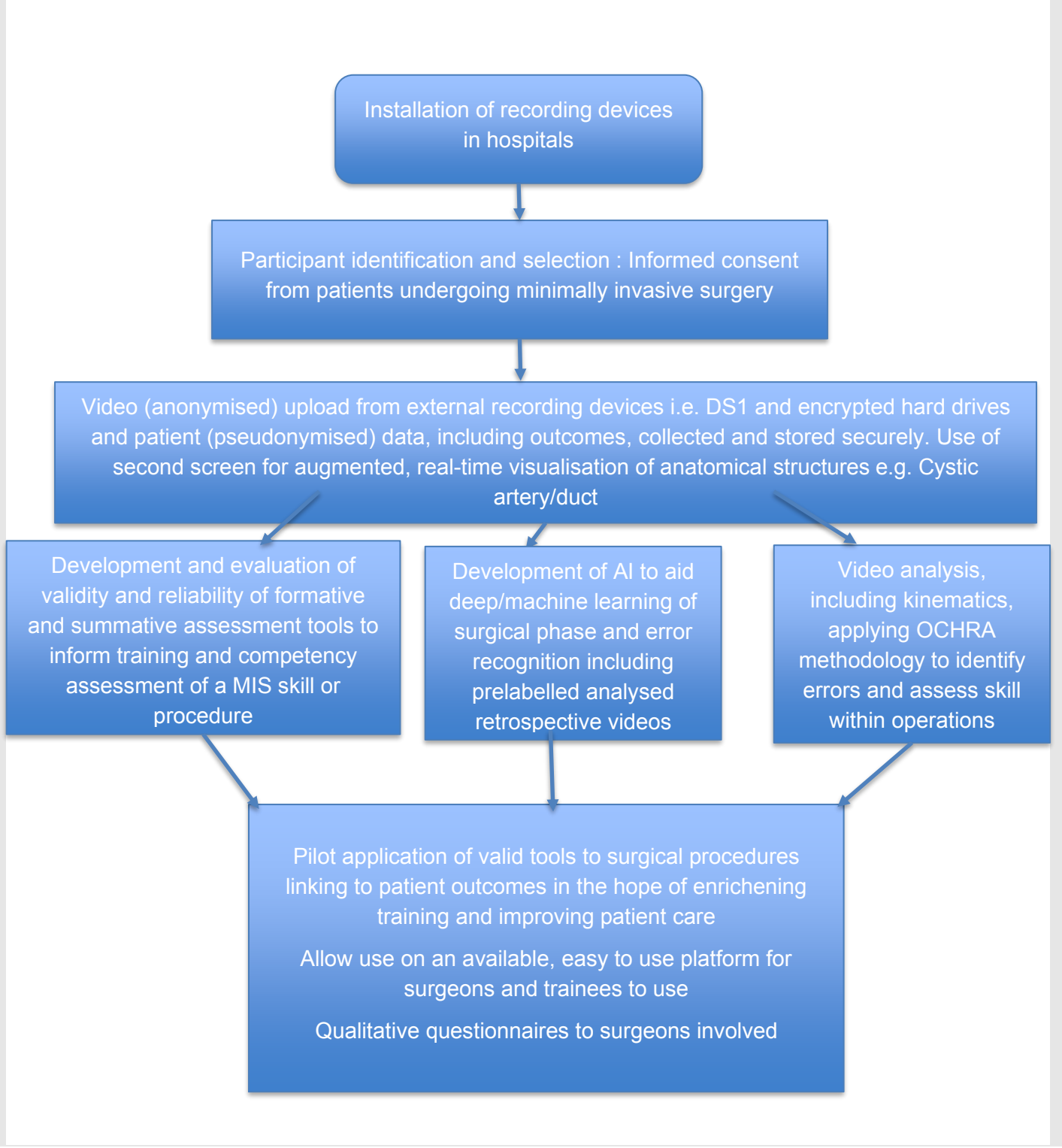
Clinical Competence/Credentialing

Artificial Neural Network

Video analysis

Objective Clinical Human Reliability Analysis (OCHRA)

STUDY FLOW CHART



STUDY PROTOCOL

Video analysis of errors and technical performance within minimally invasive surgery

1 BACKGROUND & RATIONALE

There are 2.5 million people who have cancer in the UK, projected to increase to 4M by 2030 [1]. Over the past three decades, there has been a rapid uptake of minimally invasive (keyhole) surgery i.e. laparoscopic and robotic techniques, to treat cancer across different specialties. Robotic surgery is a well-established modality; the most commonly used robot for surgery (da Vinci) has been used in more than 8.5 million procedures, 1.25 million of which were in 2020[2].

With an increasing use of robotic systems across different specialties, there is a need for standardization of training, assessment, testing and sign-off as a competent robotic surgeon in order to improve patient safety. Despite the high volumes, advanced minimally invasive surgery is not standardised and variations often occur in technique, performance, delivery, team communication, and surgical approach. Such variations can result in errors and complications that can potentially be avoided.

A study from the 1990s estimated that more than 250,000 people die in the USA every year from medical error[3]. Another study from the USA reported between 2000-2013 10,624 adverse events relating to robotic procedures [4]. Experts raised concerns over surgical curricula being random and insufficient to ensure patient safety[5]. In addition, an independent review by the Emergency Care Research Institute (ECRI) on health technology hazards identified a lack of robotic surgical training as one of the top 10 risks to patients[6,7]. Comparisons are frequently made between the aviation industry and surgery in terms of adverse event analysis and non-technical skills. The aviation industry, however, has mandatory, recurrent, reassessment and requalification throughout the career pathway and an internationally agreed standard for training, which robotic surgery does not[6].

This project aims to analyse surgical phases (stage of the operation), skill and errors to anonymised, surgical video data through Medtronic's Touch Surgery™ Enterprise DS1 Computer which can capture video data anonymously in any minimally invasive procedure in the operating room, allowing immediate, upload of data to a platform for immediate feedback and assessment to surgeons. Anonymised surgical video will be collected for any minimally invasive surgery, including but not exclusively robotic assisted radical prostatectomy (RARP), robotic rectal cancer operations, robotic gynaecology and laparoscopic general surgery. Additional minimally-invasive operations or specialties may be included, the list above is not exhaustive.

This project will apply the validated Objective Clinical Human Reliability Analysis (OCHRA) methodology for skill and error analysis to captured surgical video data. OCHRA was developed by this research group from the industrial model of Human Reliability Analysis to capture and analyse surgical performance, reporting errors enacted during rectal cancer surgery. This aided the development of a classification system to report on errors and operative events during surgical performance[8]. Additionally, it was able to link surgeons' technical skill, including errors made, to patient outcome i.e. those who scored better had better outcomes[9,10]. Additional objectives include use of automated assessment (artificial intelligence) to aid machine learning to assess its feasibility in operative phase and error recognition. Assessment tools can then be developed with the hope to improve feedback, learning and ultimately surgeons' performances. We also aim to validate these methods by correlating video "scores" of skill/errors to patient outcomes[9] e.g. complications, cancer outcome.

Kinematic robot movement data will be assessed from the dVLogger, which inserts to the robot system to record this, in combination with artificial intelligence and machine learning, in the hope to further develop our understanding of these data and the possible implications within surgery i.e., errors and outcomes. This will be accessible to WEISS for analysis and shared with Intuitive Surgical Inc. in an anonymised format.

Given the link between surgical skill and error counts to patient outcome, this research team aims to analyse surgical video within robotic (keyhole) surgery in different procedures to further understand the surgical process and errors made. We hypothesise that understanding and optimising surgical processes, and errors will reduce unwarranted variations and improve the performance of the entire surgical team that is ultimately hoped to enhance patient safety and outcomes.

3 THEORETICAL FRAMEWORK

Valid tools for formative and summative assessment exist both within laparoscopic and robotic surgery. Robot-assisted surgery is a growing area of minimal access surgery with great promise to improve surgical skill and reduce error through improved dexterity and vision.

Most robotic assessment tools currently exist as summative rather than formative. Moreover, these tools are not used in everyday clinical life due to time constraints and availability of an easy-to-use tool. With the advent of digital platforms in recent years, it opens a huge opportunity to provide these tools on the smartphones of surgeons, allowing real time assessment and learning.

There is a lack of models in robotic surgery particularly to assess and analyse surgical technique and error. The most widely used validated tool for generic skills assessment within robotics is GEARS [11] which misses certain domains of assessment, such as robotic console control[12]. However, GEARS could be modified to address this, then piloted and evaluated for validity. If successful, it is reasonable to suggest that a modified GEARS form could be used as a more comprehensive formative and summative tool for generic robotic skills.

Development of robotic procedure-specific formative and summative forms is transferable from already validated laparoscopic tools. LAPCO developed, validated, and implemented the competency assessment tool (CAT). Construct validity was confirmed between those who passed and failed. Concurrent validity was tested by comparing CAT scores with error analysis using objective clinical human reliability analysis (OCHRA). The study developing the tool found that CAT scores were inversely proportional to OCHRA counts[10] i.e. a better surgical skill score equated to fewer errors. The CAT can reliably assess technical performance in laparoscopic colorectal surgery, which could be adapted by other specialties. In-training GAS and CAT forms had predictive validity in surgical performance after LAPCO when assessing patient outcomes

Further development of error and skills analysis through OCHRA methodology within robotics is transferable from video analysis research done in laparoscopy. This would allow development of further competency assessment tools within other specific procedures; the ultimate goal would be to have machine learning through artificial intelligence (AI) and have immediate feedback during and after any minimally-invasive case. AI is already widely used in industry and other healthcare systems, but there is a gap for its application in surgical training. OCHRA methodology currently is incredible time consuming and labour intensive, AI we hope will be able to address this in the future, although we appreciate that these are still in the initial steps within the time frame of this study.

4 RESEARCH QUESTION/AIM(S)

Aim

This research project aims to assess robotic techniques for surgical phases and error detection that would permit the objective assessment of surgical performance, allowing the assessment of surgeon and procedure specific proficiency gain curves (learning curves) and identifying training needs.

4.1 Objectives

1. Develop a standardised and agreed segmentation of the operations (Delphi system)
2. Video error analysis: Application of OCHRA into minimally surgical operations (benign and malignant)
3. Validation of assessment tool scoring, video analysis to patient outcomes i.e., morbidity, histopathological data
4. Development of formative assessment tools for generic and specific procedures
5. Video error analysis: Development, evaluation and application of automation and video error analysis (artificial intelligence and machine learning) in minimally-invasive surgery.
6. Qualitative data review of surgeons' perception of TSE after using the platform.
7. Qualitative data review of surgeons' perception of effect on learning curve.
8. Analyse kinematic data to further understand its role in errors and skill in minimally-invasive surgery
9. Development of summative assessment tools to aid certification and accreditation.
10. Application of artificial intelligence to previously analysed, anonymous retrospective video, to train recognition of skills and errors within minimally invasive surgery
11. Assess the technical feasibility and surgeon opinions on the usability and utility of real-time visualisation on a secondary screen in the operating room, on a subsample of patients undergoing laparoscopic cholecystectomy procedures
12. Assess the technical feasibility and surgeon opinions on the usability and utility of real-time visualisation on a secondary screen in the operating room, on a subsample of patients undergoing laparoscopic cholecystectomy procedures

4.2 Outcome

Primary outcome measure:

- Number of errors in an operation using OCHRA

Secondary outcome measures:

-Review operative factors: Age (years), ASA grade I-V (internationally accepted anaesthetic risk score), BMI (kg/m^2), neoadjuvant treatment (Type-chemotherapy/radiotherapy- Yes or No), Total operating time (minutes) Operative blood loss (millilitres), Conversion to open surgery (binary- Yes or No), length of post-operative stay (days) 30-day readmission rate (Yes or No), 30 day readmission reason (aetiology), histopathological outcomes (pTNM cancer staging), Postoperative complications using Clavien-Dindo classification (1-5 scale of severity and necessary corrective action), 30-day mortality (Yes or No), all cause mortality (Yes or No).

- To enhance training through formative assessment tools which will have been validated for generic and procedure-specific skills. Similarly, to standardise competency assessment through validated summative tools.

- Apply assessment tools and OCHRA to analyse defined surgical phases of a procedure in order to enhance understanding of surgical skill and error. The hope is to enhance training so that surgeons learn more effectively from operations and therefore, perform better intraoperatively, therefore, improving patient outcome.

- Apply initial results to understand the feasibility of machine learning to identify surgical phases and errors based on kinematic and video data, or video data alone.

Study arm: real-time visualisation and real time insights:

- Distribute surveys to clinical teams to understand surgeon opinion opinions on the usability and utility of real-time visualisation of anatomical structures on a secondary screen in the operating room.

- Assess technical feasibility and performance of the real-time visualisation during laparoscopic cholecystectomy procedures.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

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Study design: Observational study collecting anonymised video data and uploaded to Touch Surgery platform.

Recruiting sites and Principal investigators: University College London Hospitals (Mr Ashwin Sridhar, Dhivya Chandrasekaran), Yeovil District Hospital NHS Foundation Trust (Professor Nader Francis), Queen Alexandra Hospital, Portsmouth (Professor Jim Khan), The Christie NHS Foundation Trust (Mr Chelliah Selvasekar) and Northwick Park & St Marks Hospitals and Central Middlesex Hospitals, London North West University Healthcare NHS Trust (Mr Danilo Miskovic), North Tees & Hartlepool NHS Trust (Mr Talvinder Gill), The Royal Cornwall NHS Hospital (Mr James Clark), HCA Wellington Hospital (Miss Adeola Olaitan),The Royal Surrey NHS Trust (Miss Hersha Patel), Gemelli Hospital, Rome, Italy (Dr Valentina Lacobelli), Leiden University Medical Center (LUMC), Leiden, The Netherlands (Dr Jogchum Beltman). Interested international sites will be eligible to join the VAMIS study

Prospective data upload:

Patient identification: The local team will identify patients in clinic/ team meetings based on adherence to inclusion criteria. The patient will be approached by a GCP trained member of the research team, we will aim to give 24 hours to consider the information before providing informed consent. However, from a pragmatic and feasible standpoint we may recruit participants on the day of surgery as it is a low risk study with low risk of coercion and without change to the patient care pathway.

Any surgeon willing to contribute their video data for analysis will be given access to the Touch Surgery Platform to review their own videos and annotate, these videos will also be added to a shared group with the clinical research team for analysis. The surgeon will be consented to allow their data to be analysed and results disseminated, which will be anonymised. If they wish, they can ask for analysis feedback.

Surgeons will be recruited by their local Principal Investigator at each site, who will be working closely with the research team at The Griffin Institute.

Retrospective data upload:

Analysed, anonymised video from a previous study (IRAS no: 195969) can be further used with artificial intelligence and its application to start recognition of skills and error within minimally invasive surgery. With our colleagues at WEISS, we can initiate research into an area poorly studied but at the forefront of research questions. It is hypothesised as our understanding and training of AI develops to automatically recognise and warn surgeons of “poor” technique or errors, we will likely improve patient safety, with the ultimate goal of an early warning system to prevent errors. This suggested research we believe is a step towards that.

Data capture and analysis

Surgical videos will be recorded via an encrypted hard drive or The Touch Surgery™ Enterprise DS1 Computer.

The Touch Surgery™ Enterprise DS1 Computer is connected to the operating room's video imaging system with a HDMI cable (or other compatible wired connectivity). A member of the operating room staff uses the Touch Surgery™ Enterprise DS1 Wireless Controller to select the procedure and surgeon name. A custom file name and notes can also be added, and users are prompted with a reminder not to input any patient personal information. Throughout the case, and whilst the recording is in process, the video passes through our AI-powered safeguard, RedactOR™, before it is saved to the Touch Surgery™ Enterprise DS1 Computer. RedactOR™ works on the video in real-time to determine when the scope has exited the patient. The algorithm then pixelates the video frames, and will continue to do so, until the scope re-enters the patient. All videos will be uploaded to TSE and therefore be processed through RedactOR™. This redaction is irreversible, thereby giving additional confidence that visual information that could identify a patient is transmitted, processed or stored. Upon direction by the authorised user, the video is uploaded from the Touch Surgery™ Enterprise DS1 Computer to our secure cloud provided by Amazon Web Services (AWS). AWS complies with ISO 9001, ISO 27001, ISO 27017, and ISO 27018, and audited against HDS (France).

Touch Surgery™ Enterprise DS1 Computer will record, process and provide analytics on video recordings of minimal-access surgical procedures. These are recorded through the standard operating stack and require no additional steps or changes to standard care. Currently, procedures are routinely recorded in the operating room for training purposes to allow review and debrief after a procedure or to evaluate where improvements could be made.

The dVLogger box additionally records endoscope video in stereo and robotic movement data. No audio will be recorded. This data is collected by an encrypted hard drive and used by WEISS who will anonymise the data sent to Intuitive Surgical Inc. WEISS will have access to the study ID to link analysis to patient data, Intuitive will not.

We do not anticipate that there will be any new material ethical issues associated with the recording system and surgical video feed.

Operative steps will be closely analysed using this software, applying machine learning and OCHRA methodology techniques to identify phases and errors of minimally-invasive surgical operations.

Researchers trained in these methodologies will be observing and analysing the data. Data upload to TSE will be anonymised with no patient identifiable data, but the clinical research team will pseudonymise patient data and outcomes including demography, identifiers to follow up outcome, surgeons' grade/level of expertise. Video editing software will be used to annotate and highlight surgical video data to categorise phases and errors.

Study arm: real-time visualisation:

For a subsample of laparoscopic cholecystectomy procedures, a secondary screen with a computing unit will be deployed in the operating room to augment visualization of anatomical structures such as the Cystic Artery and Cystic Duct. The video feed of a laparoscopic cholecystectomy procedure will be processed in real-time and the system will detect anatomical structures such as the Cystic Duct and Cystic Artery. The secondary screen will display a visual overlay by highlighting the identified structures when they are in the field-of-view. This additional feature aims to support surgical training and the

sharing of best practices. The secondary screen and associated real-time visualisations will not be shown to the operating surgeon during the procedure. However, hospital staff who are not directly involved with the procedure will be given the opportunity to view the secondary screen. The purpose of introducing this feature is to initially assess the technical feasibility and surgeon opinions on usability and utility. This is in line with the study aims to support training and best practice through the use of innovative technology. Participation in this study arm is optional for participants, as detailed in the Participation Information Sheets. Participants do not have to agree to this in order to participate in the study. It is hoped that this feature could be expanded to other minimally invasive surgical procedures in the future, for the purpose of supporting surgical training and sharing best practice.

In the 'real time insights' optional study arm, the real-time algorithm will detect lap chole critical structures (Cystic Duct, Cystic Artery) that will run in the background of computer system in the form of timestamps. There is no additional equipment such as secondary screen, or intraoperative outputs such as visual overlays. A record of timestamp outputs will then be visible to the user on upload of the video to Touch Surgery™ Enterprise for review post-operatively. This requires the software product feature 'Preview mode' to be enabled that offers faster surgical video upload to the cloud to support training and education. The end-user (healthcare professional) will be provided with training, and remote support (initially in-person) by Medtronic. The end-user will be able to select to upload the video on the day of the procedure or later, at a date of their choosing.

The real time insights study arm aims to test the feasibility and utility of a new real-time algorithm, in development, to detect critical structures in laparoscopic cholecystectomy procedures. In order to test this, the RedactOR™ algorithm (which is run over surgical video feed in real time to blur the environment outside of the patient's abdomen to reduce the likelihood of inadvertent personal data collection in the operating room) needs to be disabled temporarily, to enable the critical structures algorithm to run in real time. The likelihood of capturing personal data in the operating room is considered to be low because the system captures the laparoscopic video feed in the patient's abdomen. However, as a failsafe, to support patient confidentiality, Medtronic will run the RedactOR™ algorithm over the surgical videos in the cloud following upload. Both cohorts, patients and end-users (healthcare professionals) will be informed of this feature, and the details of the study arm, through the participant information sheets.

The 2 sub studies will not be available to participating sites at the same time.

6 STUDY SETTING

Data will be collected at multiple centres that have the capability to capture minimally-invasive surgery videos in the following procedures initially: patients undergoing a robotic-assisted cancer procedures including prostatectomy, cystectomy and anterior resection (rectal cancer operation), but can incorporate any minimally invasive surgical procedure. Patients will be approached during the consent process at participating research sites: University College London Hospitals, Queen Alexandra Hospital (Portsmouth), The Christie NHS Foundation Trust, Northwick Park & St Marks Hospitals and Central Middlesex Hospitals, London North West University Healthcare NHS Trust, Newcastle upon Tyne Hospitals NHS Foundation Trust, North Tees & Hartlepool NHS Trust and Yeovil District Hospital NHS Foundation Trust. However, it will expand to any NHS site performing minimally-invasive surgery and willing to participate.

It is appropriate to have multiple sites, as this will provide the most data and ensure a richer data set to address the research objectives
Site requirements; to perform minimally-invasive surgery and have video capturing devices installed.

Data will be collected at each site and analysed by the clinical research team.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

Patients must be:

- Patient undergoing elective minimally-invasive surgery
- 18 years old or over
- Have capacity to provide informed consent

7.1.2 Exclusion criteria

- Surgery performed with palliative intent or under unplanned/emergency settings
- Under 18 years old
- Cannot consent

7.2 Sampling including size of sample

Sampling will be from a clinical setting during the consent process.

Participant number:
This project requires uploading a large number of video recorded cases in order to conduct the research and achieve all the primary and secondary end points.
The type of cases will vary from generic laparoscopic procedures that will aid development initial phases of the project such as segmentation, to more advanced procedure segmentation e.g. Robotic prostatectomy and robotic rectal cancer surgery.
Since OCHRA was applied extensively in laparoscopic rectal cancer surgery, a comparison will also be made with robotic, hence, video recording of laparoscopic colorectal cases will be required. In order to achieve this number, we will partner with a number of hospitals including Yeovil District Hospital NHS Foundation Trusts, University College London Hospitals, The Christie NHS Foundation Trust, Queen Alexandra Hospital (Portsmouth) and Northwick Park & St Marks Hospitals and Central Middlesex Hospitals, London North West University Healthcare NHS Trust.
There is no formal power calculation in this study, but we aim to record as many procedures as possible within the time frame of the project and with a maximum 250 from each centre.
We aim to conduct full OCHRA analysis including error annotation up to 50 videos per specialty.

For the study arm: real time visualisation, up to 20 cases will be recruited from each participating site.

For the study arm: real time insights, up to 20 cases will be recruited from each participating site.

7.3 Recruitment

Patients at sites contributing to video analysis will be identified before surgery and consented using a standardised form and information leaflet.

Patients will be identified and clinic or multidisciplinary team meetings and approached by the local research team by a GCP trained healthcare professional. They will explain the study and provide a patient information sheet which they can read at home. Over 24 hours after the first approach they will then be asked if they would consent to the study, this can be easily done on the day of the operation, using a separate consent form to the procedure consent form.

There is minimal risk of coercion as it is a low risk, observational study, with no intervention or change to standard care.

7.3.1 Sample identification

Healthcare professionals such as doctors, clinical nurse specialists or research nurses can identify patients who may be eligible for the study. Similarly, if trained appropriately, any of the above could take consent as it is low risk. If any healthcare professional not involved in the study is asked questions about it, they could let the research team know to contact the patient.

Patients will be identified before surgery and will be provided with a patient information sheet and consented using a standardised form stating that the data will be anonymised and used for video analysis only. Clinical data and patient participants will be pseudonymized with a unique study identification number. Study ID numbers will be assigned with a local trust code e.g. UCL-001 and in order of upload to Touch Surgery, there is no need to randomise the numbers.

There will be no advertisements or external recruitment, patients will only be approached if they are undergoing a minimally-invasive surgical procedure and have capacity and time to consent. A Participant Information Sheet will be provided to the identified patient to describe the study and what their involvement means explaining they can withdraw at any time, that it is anonymous and that we believe ultimately through their involvement they will improve patient care through improving knowledge of surgical skill.

7.3.2 Consent

Participants will be informed of the study and will be provided with 24 hours to consider participation before we invite them to consent, if they wish. It's anticipated participants will be approached and informed in clinic, then consented on the day of the operation. Participants will be allowed to ask questions, withdraw without reason at any time and it will not affect their care.

Research entry and consent would take place at the same time as procedure consent. The use of translators (friends/relatives or professional services) would be at the discretion of the PI or co-investigator taking consent. Research entry is not possible without informed written consent.

Where possible, translation for the PIS and consent form will be provided through the Trust translational services. If it is not available or there is not enough time pre-operatively, non-English speakers will be excluded from the study if they do not have the fluency to read & comprehend PIS and ICF.

During the sub study involving real-time visualisation on a secondary screen, and real time insights sub study, participation will remain optional, and participants can withdraw at any time. Participants do not have to agree to this in order to participate in the study.

8 ETHICAL AND REGULATORY CONSIDERATIONS

Patient confidentiality

Patient confidentiality will be maintained. Surgical videos will be stored securely on Touch Surgery™ Enterprise (TSE; https://www.touchsurgery.com/). No patient identifying information will be attached to the videos that are uploaded to the Touch Surgery™ Enterprise platform, which will be monitored at the point of capture, using a real-time safeguarding algorithm, to ensure confidentiality. No audio is collected to maintain confidentiality. Clinical data will be collected and accessed by only the clinical research team, who all have employment or honorary contracts at the clinical sites. All clinical data will be kept

on NHS password-protected computers, on a password-protected Microsoft Excel spreadsheet on Trust premises, accessible only by the clinical research team. Digital Surgery Ltd team cannot access clinical data and patient participants will be assigned with a unique study identification number, so the identity of the patient is not known to them, to preserve patient confidentiality.

The data from dVLogger data sent to Intuitive is anonymised and sent on an encrypted hard drive.

Data protection

To capture the surgical videos, a video cable non-intrusively connects the standard video outputs of the surgical video monitor, surgical robotic device, or stack into the Touch Surgery™ Enterprise encrypted computing equipment, the DS1. The DS1 is not a medical device. The DS1 runs Digital Surgery Limited's proprietary, in-situ AI safeguarding algorithm (RedactOR™), which redacts, via automatic pixelation, out-of-body surgical video footage, to remove identifiable personal data, in real-time. The encrypted computing equipment then transfers the anonymised videos to Touch Surgery™ Enterprise platform; built upon a secure cloud server provided by Amazon Web Services in Europe, operated by Digital Surgery Limited. All anonymised data handling will be performed by designated, trained members of the clinical research team at TGI and technical research team at Digital Surgery Limited. All clinical data handling will be performed only by designated, trained members of the clinical team at The Griffin Institute. Digital Surgery Limited products and services (Touch Surgery ™ Enterprise) are compliant with the General Data Protection Regulation of 2018 (GDPR) and UK Data Protection Act of 2018 (UK GDPR).

The data custodian will be the Chief Investigator Professor Nader Francis. Personal data will be stored in line with respective trust data retention standard procedures. This will remain for up to 5 years.

In the 'real time insights' optional study arm, the real-time algorithm will detect lap chole critical structures (Cystic Duct, Cystic Artery) that will run in the background of thecomputer system in the form of timestamps. This requires the software product feature 'Preview mode' to be enabled that offers faster surgical video upload to the cloud to support training and education. The end-user (healthcare professional) will be provided with training, and remote support (initially in-person) by Medtronic. The end-user will be able to select to upload the video on the day of the procedure or later, at a date of their choosing. The RedactOR™ algorithm (which is run over surgical video feed in real time to blur the environment outside of the patient's abdomen to reduce the likelihood of inadvertent personal data collection in the operating room) needs to be disabled temporarily, to enable the critical structures algorithm to run in real time. The likelihood of capturing personal data in the operating room is considered to be low because the system captures the laparoscopic video feed in the patient's abdomen. However, to support patient confidentiality, Medtronic will run the RedactOR™ algorithm over the surgical videos in the cloud following upload.

Potential risks

We expect no difference between those patients in the trial or not. All patients require the operation as part of their routine care and this study does not alter the way the surgeon performs the case in any way, routinely surgeons will record operations, there is no change to standard care nor are additional patient visits required. Any potential risk to patient confidentiality has been addressed and sufficiently

mitigated by the study protocol. There are no additional risks to the staff as part of this study. It will not impact surgical rotas; theatre lists or scheduled operations.

The only possible potential risk with this study is identification of significant errors on the video analysis that are not detected by the operating team and therefore no corrective action taken. However, the nature of this project involves reviewing the videos a significant period of time after the operation. Any sequelae from this event would have been apparent in the post operative period well before video analysis is conducted. If there are any learning points, however, these will be communicated with the PI at each site.

For the sub study, real-time visualisation, there is no anticipated change to standard care or the duration of the surgery. The secondary screen and surgical video overlay will be tested in the operating room ahead of any use where a patient is present. Deployment and training from Medtronic will include teaching the OR staff how to stop visual overlays at their discretion, at any time during the procedure. Any potential risk associated with this study arm has been sufficiently mitigated, due to the overlays being presented on a secondary screen only and not being viewable by the operating surgeon. Participation from the surgeon and patient is optional on the informed consent form and detailed in the participant information sheet.

Surgeons will use the main surgical screen to operate as per normal. The information provided on the secondary screen is entirely separate and the surgeons who are operating will not be able to view the real-time visualisations. However, hospital staff who are not directly involved with the procedure will be given the opportunity to view the secondary screen if they choose to.

For the sub study, real-time insights, there is no anticipated change to standard care or the duration of the surgery. There is no additional hardware or equipment in the operating room, instead the computer records timestamps throughout the procedure that are available for user to review post operatively. The end-user (healthcare professional) will be provided with training, and remote support (initially in-person) by Medtronic. Participation from the surgeon and patient is optional on the informed consent form and detailed in the participant information sheet. To support patient confidentiality, Medtronic will run the RedactOR^{TM} algorithm over the surgical videos in the cloud, post operatively.

Potential benefits

We hypothesise that understanding and optimising surgical processes, and errors will reduce unwarranted variations and improve the performance of the entire surgical team that will ultimately enhance the patient's surgery and outcomes. We do note that there is no direct benefit to the individual patient taking part other than potentially helping to improve the safety of standard routine surgical procedures in future operations.

We hope that this technology (including the real-time visualisation study arm and real time insights) will be used to improve surgical training and preparation of the entire operating theatre team and optimise performance and standardisation. It is hypothesised that the implementation of this technology may benefit patients by reducing surgical variations and errors and may also enable monitoring and assessment of surgical competence based on reliable, actionable data.

The real time insights sub study, in addition, will provide review of timestamps of specific anatomical structures following upload of surgical video upload to the cloud to support training and education,

enabled through the product feature 'Preview mode' that allows faster upload of video and algorithm outputs

If patient loses capacity to consent during study

If the patient loses capacity before consent then they will not be invited to participate (in accordance with inclusion criteria). In the event that the research team are informed that the participant has lost mental capacity then their consent and participation will be withdrawn from the project.

Physical security arrangements for storage of personal data

Videos will be in electronic format and retained in encrypted storage. Procedural data will be directly uploaded from the device to a secure cloud server provided by AWS (Ireland, Europe), which is GDPR compliant. AWS will be used to store all media and data, which conforms to the ISO 27001 security management standard and is a member of the Cloud Security Alliance. Any transfer between the study sites would be in encrypted storage formats or through a secured internet connection.

Data from the video recordings of surgery will be extracted, transferred and analysed using computerised software based at Digital Surgery Ltd. in London, UK. No patient data will be shared with Digital Surgery Limited in the duration of this study. Only Yeovil District Hospital NHS Foundation Trust/TGI (restricted to the clinical research team) will access and retain identifiable information such as study files. Yeovil District Hospital NHS Foundation Trust will only collect the minimum required information for the purposes of the study.

Recruitment Arrangements and informed Consent

Following informed consent to participate, the study patient participants will be assigned with a unique study identification number. This identifier is pseudonymised to the clinical research team. Patient consent forms will be securely stored in locked cupboards and password protected NHS equipment, NHS sites, with access restricted to the only authorised members of the clinical research team.

How will you ensure the confidentiality of personal data? / Who will have access to participants' personal data during the study?

The surgical video and associated metadata on Touch Surgery™ Enterprise cannot identify the participant. Participant personal data (any data that may identify a participant) is not necessary for the service Touch Surgery™ Enterprise provides to the study site.

Only the clinical research team has access to identifiable information about the participant. Access restrictions are in place to mitigate any risk to confidentiality of participant personal data.

Data will be used, stored and transferred in an encrypted format, and handled in accordance with the UK Data Protection Act of 2018 (UK GDPR).

Where will the data generated by the study be analysed and by whom?

Data generated will be analysed by the clinical research team. Only anonymised data will be transferred to Touch Surgery™ Enterprise (UK) and analysed by authorised members of the Digital Surgery Limited team for the purpose of the study, to identify key markers such as surgical phases and associated variations.

Intuitive Surgical Inc. will receive anonymised data from the dVLogger via an encrypted hard drive.

Pseudonymised data will be analysed by the research team at TGI and WEISS. This will be stored on secure servers with access limited to the team.

Based on previous similar uses of OCHRA errors in colonic surgery (Miskovic D, Surg Endosc 2011), we expect error count results to be normally distributed (however, this will be confirmed using detrended QQ statistical plots prior to analysis). Task and type specific error counts can be compared with Mann-Whitney U test.

OCHRA as previously described is a validated methodology to manually, accurately and reliably assess errors in a minimally invasive procedure. Data from this can then be statistically analysed and linked to patient data including demography and outcome

Digital Surgery data science team will be involved in video analysis through analytic reporting.

Qualitative questionnaires will be used at the end of the study to evaluate surgeons' opinion and gain insights on the use of surgical video and novel analytics. This will be done using thematic analysis.

SPSS will be used for all data analysis.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Regulatory Review & Compliance

Local sites submitting participant video data will all gain local approval from local research team, theatre manager and IT for any installation of video recording equipment.

Amendments

Any amendments to the protocol will be submitted to the REC for consideration.

8.3 Peer review

Peer review of the study protocol will be performed by specialists in video analysis and OCHRA methodology.

8.4 Patient & Public Involvement

There is no impact on the patient pathway, all data is anonymised or pseudonymised to link video analysis to outcomes. This is an observational, prospective study without active patient follow up/involvement.

Patient groups have been consulted on their opinions on recording and analysing their surgical video as part of another study in laparoscopic rectal cancer surgery with almost identical methodology.

Study results will be forwarded to patients upon request only. Should a large proportion of the patient wish to hear results, we would invite them to attend the results presentation given at each study site.

8.5 Protocol compliance

Protocol deviations will be managed by an internal review management and steering group, with root cause analysis, cause, and effect. Steps aiming to prevent any further deviations will be discussed and implemented.

8.8 Access to the final study dataset

Only the clinical research team has access to identifiable information about the participant. Access restrictions are in place to mitigate any risk to confidentiality of participant personal data.

The anonymity and confidentiality of the information provided for this study will be ensured by de-identification wherein a study ID will be allocated to the patient; only the Chief Investigator and Principal Investigator will be able to link the study ID to the patient identity and health information,

once the data set has been populated the code to the patient ID will be destroyed. This will leave a fully anonymised dataset. Only this dataset will be used in analysis. All electronic information relating to the study will be stored on a secure password protected database and all hardcopy information will be stored under lock and key.

9 DISSEMINATION POLICY

9.1 Dissemination policy

The study will generate a final report and additional smaller projects which will be published in peer reviewed journals, presented at meetings and conferences.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The researchers will work to find suitable journals for publication and meetings for presentation. As this is not a clinical trial the trial will not be registered on a database however, a summary will be publicly available on the HRA website.
Any significant finding from the study will be made available to the medical community. In the interested of public interest, presentation and international publication in peer reviewed journals will be sought as quickly as possible.
All researchers who have been involved in the project will have authorship of the paper and responsibility for the review and dissemination of the results

11. APPENDICIES

11.1 Appendix 1- Required documentation

Patient information sheet, patient consent form, surgeon information sheet, surgeon consent form, organisation information document, schedule of events, signature and delegation log, inclusion/exclusion criteria and excel data collection sheet linked to secure cloud will be provided by this research team

11.2 Appendix 2 – Schedule of Procedures (Example)

11.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1.0	Version 11	20.6.22	M Boal	Allowing approach to participant for consent within 24 hours if needed.
2.0	Version 12	25.7.22	M Boal	Retrospective analysis (OCHRA and application of artificial intelligence) of videos with previous ethical approval from other studies of this research group
3.0	Version 13	30.9.22	M.Boal and Aimee Bambury	Change 1: add new sites: North East and North Cumbria Integrated Care System, Newcastle upon Tyne Hospitals NHS Foundation Trust (Mr Richard Brady), and North Tees & Hartlepool NHS Trust (Mr Talvinder Gill). Change 2: revise patient inclusion criteria from elective minimally invasive urological/gastrointestinal surgery to elective any minimally invasive procedures including gynaecology. Change 3: added optional study arm: real time visualisation (overlay)
4.0	Version 14	19.1.23	Aimee Bambury F. Tesfai M. Boal	Change 1: add new sites and PI HCA Wellington Hospital, Royal Cornwall Hospital, Removed Newcastle Upon Tyne Hospital. Change 2: Added co investigators: Dr Tesfai on behalf of The Griffin Institue and added her as study co-ordinator. We have added Miss Chandrasekaran as co-investigator on behalf of University College of London Hospital NHS trust.

				Change 3: Established new optional study arm for real time insights (instead of visualisation (overlay)- changes to participant and surgeon consent form + information sheets Change 4: Minor amendment surgeon consent form highlighted in yellow (age, handedness, email)
5.0	Version 15	9.3.23	M. Boal A. Boydell F.Tesfai	Change 1:New Names on documents: New CEO at The Griffin Institute, Mrs Vasiliki Kiparoglou, reviewed the protocol and signed. Contact details inserted page 5 protocol and both surgeon/participant information sheets. New study co-ordinator added Ms Claudia Reali, as another PhD fellow on minimally invasive colorectal video analysis. Details inserted on protocol, both information sheets and consent forms, please note she is part of The Griffin Institute as a PhD fellow of Professor Francis' but without an email there yet, hence using her consultant NHS email. New study protocol contributor from medtronic for this amendment Anna Boydell. Change 2: Page 8 Protocol, inclusion criteria is any minimally-invasive surgery, therefore deleted urological/gastrointestinal surgery. It is stipulated elsewhere in the protocol (Page 2) we will include other specialties. No change to ethics. On both PIS forms: Change 3: Participant Information Sheet inserted area for PALS/Local research team details to be inserted, or section deleted, depending on local site preference, as requested by a local research team. Change 4: Surgeon Consent form, original text at point 4 was August 2024, and in amendment 4 had been changed erroneously to August 2022, I have corrrected this to August 2024. Change 5: Phone number standardised for all The Griffin co-investigators, changing it from Dr Tesfai's personal number on information sheets and consent form. Change 6: Both consent forms for version number and date of the Information sheets to be written on the consent form, as requested by a local research team, highlighting this is

				standard of practice Change 7: Surgeon consent form grammar error in order of words changed to "will store my". This refers to the normal information name and email to have an account with Touch Surgery. Change 8: Participant/surgeon information sheet and IRAS protocol- clarity provided in protocol in regards who is able to view secondary screen in the optional study arm “real time visualisation”. Change 9: Addition of new research site: The Royal Surrey NHS Trust
6.0	16	18.09.2023	F. Tesfai	Change 1:Addition of two new sites: Gemelli Hospital, Rome, Italy with PI: Dr Valentina Lacobelli and Leiden Univeristy Medical Center (LUMC), Leiden, The Netherland with PI: Dr Jogchum Beltman. Furthermore, we are stating in the protocol that international sites are eligble to join the study. Change 2: Dr Georgia Zachou (Gynaecology Research fellow) has been added to the protocol for the gynaecology arm.
7.0	17	10/01/2024	F. Tesfai M. Boal	Change 1: Study date extended due to additional research fellows' time period of study and due to delayed initial recruitment to obtain enough videos for analysis (page ix).Change 2: Objective point 2 & 3 have merged as multiple surgical specialities are now recruiting for vamis and this generic explanantion covers all operations. As a note this has been changed on the advice of other sites not performing previously defined operations within these objectives (i.e. prosatectomy and rectal cancer surgery) (page 4). Change 3 as per change 2 we are ensuring inclusivity of any minimally invasive surgical procedure (page 7).

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