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Impact of minimally invasive surgery on surgeon health

Submission date 04/01/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/03/2022	**Overall study status** Completed	
Last Edited 15/10/2024	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Minimally invasive surgery (MIS) has a significantly shorter recovery and lower complication rate compared to open surgery and is the preferred route for the surgical management of many conditions. However, the impact of MIS on surgeons has been largely forgotten and many are reporting work-related musculoskeletal symptoms (WMS). The concern is that these symptoms (pain, stiffness and fatigue) have the potential to reduce the working life and productivity of surgeons. Optimising surgeons' working conditions is vital for their own health but may also affect patient safety by affecting their surgical performance. The aim of this study is to develop and validate a multi-component assessment tool that can objectively capture the real-time physical and psychological impact performing surgery has on the surgeon.

Who can participate?
Consultant surgeons and gynaecologists at the participating hospital who are performing major abdominal surgery.

What does the study involve?
The assessment tool includes: pre/during/post procedure salivary cortisol; continuous heart rate monitoring and upper-arm/back motion sensor monitoring during the procedure; and pre/during /post procedure questionnaires. The study involves the surgeons wearing light, unobtrusive sensors that monitor motion as well as a heart monitor for the duration of the surgical procedure. Cortisol swabs will be taken before the start of the procedure, at the time of removal of the specimen, and immediately after completing the procedure. The consultants will complete questionnaires before and after the surgical procedure. Patients will be consented for their surgeon to be monitored whilst performing their surgical procedure.

What are the possible benefits and risks of participating?
Participating in the study is not associated with any further risks in addition to the risk associated with performing surgery. The equipment used to monitor the surgeon's movements has been checked by the medical physics department to ensure that it does not interfere with equipment within the operating theatre. All the surgeons will have undergone testing and familiarization with the equipment on a simulator to demonstrate that wearing the equipment does not affect their movements.

Where is the study being conducted?
University Hospitals of Leicester (UK)

When is the study starting and how long is it expected to run for?
November 2021 to August 2024

Who is funding the study?
Intuitive Surgical (USA)

Who is the main contact?
1. Dr Esther Moss, em321@le.ac.uk
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
300580

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
0823, IRAS 300580, CPMS 49943

Study information

Scientific Title
Impact of minimally invasive surgery on surgeon health: a feasibility study

Acronym
ISSUE

Study objectives
The physical/psychological impact on surgeons is less with robotic-assisted surgery compared with straight-stick laparoscopy and open surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/09/2021, East Midlands - Leicester Central Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)2071048138; leicestercentral.rec@hra.nhs.uk), REC ref: 21/EM/0174

Study design
Non-randomized feasibility study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgeons performing live surgical procedures (open/laparoscopic/robotic).

Interventions
This study aims to develop and validate a 5-point assessment tool to objectively measure both the physical and psychological impact of complex surgical cases on a surgeon, in order to give a single categorisation of impact: high, intermediate or low. Data will be collected from surgeons performing live surgical procedures: continuous heart rate monitoring; salivary cortisol; continuous movement sensor monitoring; State Trait Anxiety Inventory questionnaire; and musculoskeletal symptoms questionnaire. Patients will be consented for their surgeon to undergo monitoring during their surgical procedure.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The proportion of surgical procedures where all five variables of the assessment tool are captured (continuous heart rate [HR] monitoring; salivary cortisol (taken pre-, intra- and post-operatively); continuous movement sensor monitoring; State-Trait Anxiety Inventory (STAI) questionnaire and modified Nordic work-related musculoskeletal symptoms (WMS) questionnaire), taken pre- and post-operatively

Key secondary outcome(s))
1. A single value of ‘impact’ (high/intermediate/low) per procedure calculated by combining the five recorded variables will be calculated on completion of participant recruitment to the feasibility cohort
2. Validation of the calculated ‘impact’ values by comparison of surgeon’s subjective assessment

of case complexity with objective measures will be calculated on completion of participant recruitment to the validation cohort
3. Analysis of the impact on surgeons of supervising surgical trainees measured using heart rate monitoring and salivary cortisol levels intraoperatively
4. Willingness of recruitment of patients and surgeons and sample size calculations for a future multi-centre study comparing the impact of the route of surgery on the surgeon, measured using recruitment and retention rates on completion of participant recruitment to the feasibility cohort
5. Primary/secondary outcomes for a future definitive multi-centre study comparing the impact of the route of surgery on the surgeon, identified using qualitative interview data on completion of participant recruitment to the feasibility cohort
6. Optimisation and validation of patient data recording measures to capture anaesthetic /operative/clinical events and outcomes using analysis of collected quantitative data on completion of participant recruitment to the feasibility cohort
7. Safety of measurement tools and recording devices in the theatre environment assessed using a Medical Physics assessment before commencing participant/surgeon recruitment
8. Optimisation of surgeon continuous heart rate monitoring during the procedure, quality and completeness of data collection and analysis, assessed using interview and quantitative data on completion of participant recruitment to the feasibility cohort
9. Optimisation of positioning and recording of muscle movement/activity sensors and streamlining of data-analysis using interview and quantitative data at on completion of participant recruitment to the feasibility cohort
10. Optimisation and validation of WMS and State-Trait Anxiety Inventory (STAI) questionnaires and data analysis using interview and quantitative data at on completion of participant recruitment to the feasibility cohort
11. Optimisation of salivary cortisol collection pre-, intra-, and post-operatively and utility of results assessed using interview and quantitative data at on completion of participant recruitment to the feasibility cohort

Completion date
31/08/2024

Eligibility

Key inclusion criteria
Surgeons:
1. Consultant Surgeons and Gynaecologists
2. Able to consent
3. Patient consents to their surgeon participating in the study

Patients:
1. All patients
2. Able to consent
3. Undergoing intra-abdominal surgery with a procedure expected to last less than 2 hours in duration
4. Aged >18 years

Participant type(s)
Mixed

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patients who do not consent for their surgeon to participate

Date of first enrolment
10/01/2022

Date of final enrolment
31/08/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Industry

Funder Name
Intuitive Surgical

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as there is patient data as well as personal information relevant to the participants, including their anthropometry, and this will be stored safely in an anonymised manner on the research drive of the University of Leicester.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 5	24/09/2022	05/04/2024	No	No