Research Protocol

Project Title

Matched comparison of gastro-enterostomy construction: Quantify differences in technical proficiency and precision of robotic versus laparoscopic platform

HREA ID: 91593 (Local reference number: 89/23)

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7. Peninsula Private Hospital, Langwarrin
8. Epworth Eastern Hospital, Boxhill
9. St. Vincent's Private Hospitals, Fitzroy

New South Wales

1. St. George Private Hospital, Sydney
2. St. Vincent Private Hospital, Sydney

Queensland

1. John Flynn Private Hospital, Tugun
2. Pindara Private Hospital, Benowa

South Australia

1. Flinders Private Hospital, Bedford Park

Western Australia

1. St. John of God – Wexford Medical Centre, Murdoch

Sponsor:

The principal investigator (Dr.Yit Leang) is a Doctorate student of Monash University and a recipient of Australian Government RTP Scholarship. This project will contribute to part of his doctorate thesis.

Project Overview

The technical advantages of the robotic surgical platform have been embraced by surgeons but scientific quantification of the advantages when compared to conventional laparoscopic platform is scarce. Accurate measurement of such mechanical advantages in specific surgical procedures such as obesity surgery will be beneficial to assist surgeons in selecting the best surgical platform or tools to perform complex bariatric procedures with the aim of achieving the best surgical outcomes.

This project will analyse and compare surgical recordings of surgeons constructing gastro-jejunal anastomosis in gastric bypass surgery using the robotic surgical platform and conventional laparoscopic platform. The video analysis will be correlated against the difficulty of the procedure measured using the National Aeronautics and Space Administration Task Load Index (NASA TLX), a short survey regarding the performance of the gastrointestinal anastomosis and clinical outcome parameters.

The project will aim to recruit 50 patients in each group. A total of at least 42 patients in each group will provide the adequate volume to power the study to detect a difference in surgical proficiency between the two platforms.

Disclosure of Interests

The are no conflict of interests declared by any members on the project team.

Resources

The data collected will be entered to a password protected online database: Redcap, managed by Monash University.

The NASA TLX will be calculated using a free mobile software application developed by NASA, available on both iOS and Android platforms.

Funding

This is an investigator-initiated study supported by Department of Surgery, Central Clinical School, Monash University. This project is not funded by any external commercial entities or organisations.

Background

Robotic assisted surgery has more recently emerged as an alternative minimally invasive surgical approach due to its flexible, wristed instruments and magnified 3-dimensional vision. These features were said to facilitate surgical access, allows more precise dissection, facilitate intra-corporeal suturing and knot-tying with less physical stress on the surgeon (1–4). Such advantages may be particularly useful for technically challenging bariatric procedures which involves the construction of gastrointestinal anastomosis within the abdominal cavity such as gastric bypass. However, there is no consensus on the key advantages of disadvantages of such

promising technology when compared to conventional laparoscopic surgery (1,2,5,6). It would be important to understand how robotic technology provides a significant value in these cases and scientifically quantify the mechanical advantages provided by the robotic surgical platform.

At present, robotic assisted bariatric procedures have yet to demonstrate any superiority in clinical outcomes when compared to traditional laparoscopic technique on large scale database (5,7–9). This could be due a combination of data inclusion from novice robotic surgeons in their early learning curve, heterogeneity of case complexity and the well-established safety of bariatric procedures. Crude clinical outcomes such as length of stay, bleeding rate and complication rate are unlikely to be significant for straightforward bariatric procedures due the established safety of bariatric surgery. Hence, to prove superior clinical outcomes in robotic bariatric surgery will require a much larger volume of data. In addition, these reported outcomes do not consider the difference in surgical precision and proficiencies of the different surgical platforms.

Surgical proficiency has been established as having a close correlation with clinical outcomes as shown by Birkmeyer et al. in the bariatric population (10,11). As such, this would lead to the notion that the mechanical advantages of robotic assisted surgery with three-dimensional vision of the operative field, 7-axis motion of the robotic instruments and stabilisation of instruments with tremor cancellation (12,13) may improve procedural proficiency and hence improved surgical outcomes.

As such, the current conclusion regarding the advantages of robotic surgical systems in bariatric surgery are largely assumed rather than demonstrated. There are probably specific circumstances where using robotic surgical system is truly advantageous but has yet to be objectively measured or quantified. This is an important step and should be performed prior to more broadly assessing clinical outcomes. In addition, quantifying improvement in surgical proficiency can be a surrogate measure for clinical outcomes as proven by Birkmeyer et al. in his study (11). Surgical proficiency assessment has been proven to be feasible with the use of video technology and established surgical proficiency scores (14,15). This can be further correlated with the

National Aeronautics and Space Administration Task Load Index (NASA TLX) which has recently been validated as a marker of surgical difficulty (16,17) to investigate and compare the relationship of perceived surgical difficulty and technical proficiency on different surgical platforms.

Aims

1. To objectively compare the technical proficiency, efficiency, and precision of constructing a gastrojejunal anastomosis using robotic and laparoscopic platform.
2. To objectively assess the difficulty and operative workload of constructing a gastrojejunal anastomosis intra-corporeally using the NASA-TLX index on the robotic and laparoscopic platform.

Methods

This study will involve the surgeon digitally recording themselves performing a handsewn gastrojejunal anastomosis during a gastric bypass procedure (Roux-en-Y gastric bypass or one anastomosis gastric bypass) on either the laparoscopic or robotic platform. Laparoscopic gastric bypass is offered at all participating sites. Robotic gastric bypass is offered at selected sites with robotic equipment.

Immediately after the procedure, the operating surgeon will complete a short 1-minute survey (refer Appendix 3) assessing the difficulty of the anastomosis and completing the NASA TLX score.

Participating surgeons will complete an initial surgeon experience statement (years of practice as a bariatric surgeon and number of primary cases performed using the surgical platform: laparoscopic vs. robotic)

There is no limit on the number of submissions per surgeon. Each recording will be identified with a unique study number and basic patient demographic data (age, sex, height, weight, medical comorbidities, primary or revision). No patient identifiers will be collected in this study.

There is no expected deviation of routine pre-operative, intra-operative or post operative surgical care provided by the surgeon and their team to the patients in this study. All participating surgeons not restricted in the selection of their surgical assistant, surgical instruments, and energy devices familiar to their routine surgical practice.

Inclusion criteria:

1. Adult (≥18 years old)
2. Laparoscopic OR Robotic gastric bypass procedure
    a. Roux-en-Y gastric bypass (RYGB)
    b. One anastomosis gastric bypass (OAGB)

Exclusion criteria

1. Emergency or urgent surgery
2. Patient or next of kin with no capacity to provide consent for video recording

NASA TLX

The NASA TLX is calculated using the mobile application (on iOS or Android mobile devices). The NASA TLX was developed by Human Performance Group at NASA's Ames Research Centre (18) as a multi-dimensional scale to estimate workload. This has been validated for in use for the field of surgery by various studies (16,17,19).

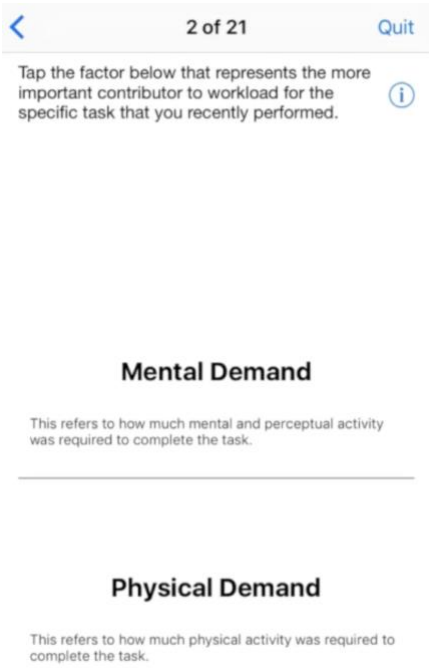
How to complete NASA TLX:

This process is completed shortly after the surgery by the operating surgeon involving a paired scale selection and a rating scale selection.

The evaluation starts with a **weighting score** by choosing between 2 paired items out of the 6 categories listed below depending on which category is more important to the surgeon's experience of workload during the operation.

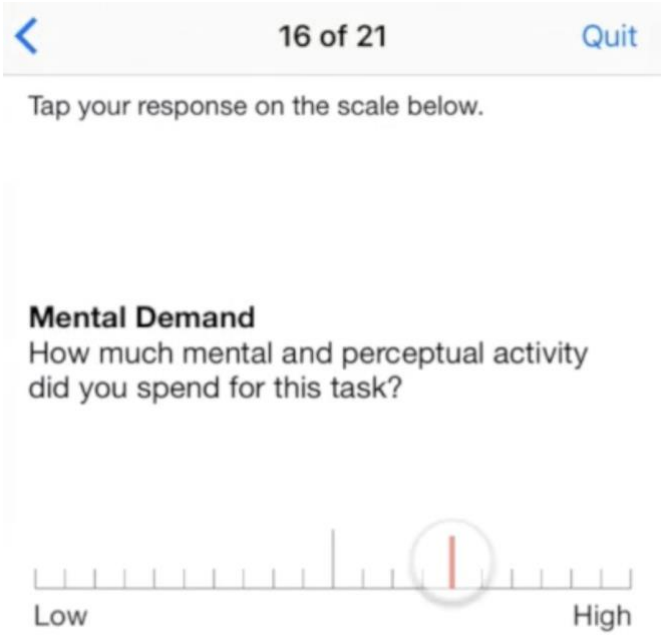
1. Mental Demand
    a. How much mental and perceptual activity was required? Was the task easy or demanding, simple or complex?
2. Physical Demand
    a. How much physical activity was required? Was the task easy or demanding, slack or strenuous?
3. Temporal Demand
    a. How much time pressure did you feel due to the pace at which the tasks or task elements occurred? Was the pace slow or rapid?
4. Overall Performance
    a. How successful were you in performing the task? How satisfied were you with your performance?
5. Effort
    a. How hard did you have to work (mentally and physically) to accomplish your level of performance?
6. Frustration Level
    a. How irritated, stressed, and annoyed versus content, relaxed, and complacent did you feel during the task?

For example:

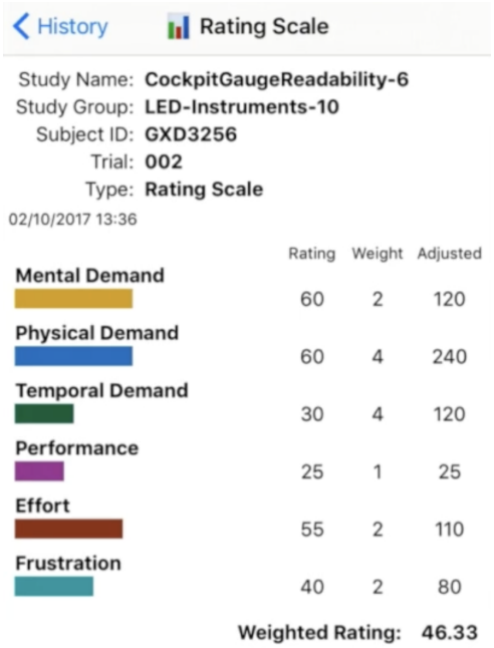


The weighting of importance of each of the items is created following the paired selection.

This is followed by a **rating score** which assesses the workload experience of the surgeons during the procedure which gives a numerical score (0-100) on each of the six visual analogue scale that best matches their experience.



The final score is then calculated by multiplying the **rating score** by the **weighting score** adjusted to a total of 100.



Surgical video assessment

Segment of the surgical videos consisting of the gastrojejunal anastomosis construction will be assessed using validated a **procedure specific rating scale**, a **general rating scale** and **surgical component rating** by 2 independent blinded assessors.

1. **Procedure specific scale:** Bariatric Objective Structured Assessment of technical skills (BOSATS) (20)

   This scale was developed and validated in 2013 to assess operative skill in laparoscopic gastric bypass using a hierarchical task analysis, a Delphi questionnaire and a panel of international experts in bariatric surgery. The specific component of gastro-jejunal anastomosis within the scale will be utilised for this study.

2. **General rating scale**

a. Laparoscopic – Global Operative Assessment of Laparoscopic Skills (GOALS)

This is a 5-item global rating scale developed in 2005 and has been used to evaluate laparoscopic surgical proficiency on different procedures such as cholecystectomy, inguinal hernia and fundoplications (21–26).

OR

b. Robotic – Global Evaluative Assessment of Robotic Skills (GEARS) (27)
   This is a 5-item global rating scale developed in 2012 and independently validated tool (28) to evaluate surgical proficiency in robotic skills modelled after GOALS.

3. Surgical Component rating

The video recordings will be assessed and scored against following components:

a. Number of times suture needle was dropped during the anastomosis construction
b. Number of times the angle of suture needle had to be repositioned (repositioned being defined as attempts after the first positioning)
c. Number of times suture needle was inaccurately placed (Inaccurate placement being defined as suture being removed and replaced)
d. Number of times suture was fractured during anastomosis construction
e. Number of times a knot throw was missed in tying the sutures
f. Number of times camera lens had to be withdrawn for cleaning (withdrawn being defined as endoscope being removed from abdominal cavity)

<u>Surgical assistant and scrub nurse survey</u>

It is foreseeable that blinded assessors may not readily appreciate surgical complexities based on segments of video recording. Therefore, additional short surveys for correlation to the video analysis from the scrub nurse and surgical assistant (Refer appendix 4 and 5) regarding the difficulty and performance of the anastomosis construction will be gathered from the following institutions:

1. The Avenue Private Hospital, Melbourne
2. Cabrini Hospital, Melbourne

Selection of assessors

A pool of 4 surgeons from The Alfred's upper gastrointestinal surgical unit will function as assessors.

Hypotheses

1. Performing an intra-corporeal gastrojejunal anastomosis procedure with the robotic platform increases proficiency and precision by 20% or more.
2. Performing an intra-corporeal gastrojejunal anastomosis procedure with the robotic platform reduces the surgeon workload.

Sample size calculation

A power calculation is performed a priori based on earlier work performed by Vassiliou et al. in the development of GOALS scale. (29) The mean score of attending surgeons was 16.95 points with a standard deviation of 4.75 points. Based on our projected hypotheses of 20% increase in the proficiency score, using a power of 0.9, and alpha of 0.05, the minimum required number of videos for each group is 42.

Therefore, at least 42 videos in each group will be statistically powered to prove our hypotheses.

Risk and management

Patient risk

1. Clinical risk

There is no deviation to the routine surgical care of the patients as prescribed by their surgeons pre-operatively, intra-operatively or post-operatively. The surgical approach (laparoscopic or robotic) is determined by the operating surgeon and patient.

2. Privacy risk

All data will be entered and stored in a password protected Redcap online database maintained by Monash University. All data will be de-identified with each patient identified by a unique study number.

The digital recording will only record intra-abdominal images and hence no identifiable information will be obtained. The confidentiality of the patients will be maintained as the surgical recordings are stripped of identifiable information.

Surgeon risk

1. The surgical recordings gathered will be used for research purposes in this project or subsequent relevant project only.
2. The identity of the operating surgeon will be blinded to the surgeon assessors to maintain neutrality and privacy.

Security and management of research data

A research assistant will be responsible for the data collection. All participating surgeons will be provided with a unique Redcap login to record data related to the case. Video recordings will be recorded from the endoscopic computer system into a solid-state hard drive provided by the study. All hard drives will be collected at an appropriate regular interval determined by the investigators depending on case volumes to facilitate distribution of videos to blinded assessors. Video recordings from participating sites outside of Victoria state will be posted by participating surgeons to the

coordinating principal investigator (Dr. Yit J Leang) using secure registered post with ID verification at the collection point.

All data will be stored securely in an online database (Redcap) managed by Monash University with password protected access by the investigative team. Surgical recordings containing the intra-abdominal images will be stored securely by the operating surgeon identifiable by the unique study number and uploaded to a specified and password protected drive set up by the Principal investigator.

The surgical videos will be stored in a password protected computer within the Department of Surgery of Central Clinical School, Monash University. Access to the area is only via Monash approved swipe access and access to the computer requires a Monash affiliated ID. Surgical video will be stored for a total of 7 years and deleted from the drive permanently.

Consent

a. Consent from participating surgeon:

At present, all participating surgeons are the associated investigator of this project and have agreed to participate in this study.

b. Consent from patient:

Consent will be obtained by the participating surgeon from their patient by providing a signature on the PICF form (Appendix 2). Alternative would be a phone consent (also provided on PICF-Appendix 2) which will be unusual under these circumstances as patients are being assessed and consented for a moderate to high risk surgical treatment for obesity.

The information sheet and consent form will be provided by participating surgeon to their respective patients.

A clear explanation will be provided by the surgeon to the patient explaining the fact that the surgical procedures being performed are routinely recorded by the surgeon for medical record and documentation purposely. The consent provided will allow the

surgical recording to be used for this research. Withdrawal from the study does not affect the planned obesity treatment.

c. Consent from Scrub Nurse and Surgical Assistant

If the patient consent to participate in this project, the research assistant of the project will be notified.

The research assistant will then brief and obtain consent from the scrub nurse and surgical assistant involved with the case and be invited participate in this study.

Participation is voluntary and consent will be obtained from the scrub nurse and surgical assistant by signing the PICF form (Appendix 4 and Appendix 5) to participate.

The survey will be completed online and the responses will be blinded to the participating surgeon. This process of consenting and completing the survey will mitigate the unequal relationship of doctor and nurse/surgical assistant to the project. The patients, nurse and surgical assistant can withdraw from the study at any time.

Anticipated outcomes

1. Objectively demonstrate robotic surgery improves surgical precision and efficiency compared to laparoscopic surgery when performing a routine procedure of moderate technical complexity.
2. Objectively demonstrate reduced surgeon workload using the robotic platform in performing a moderate to difficult surgical tasks.

Results, outcomes and future plans

Data will be de-identified and analysed along with manuscript preparation for reporting. All participating surgeons in the study will be offered co-authorship if they decide to contribute to review the final manuscript. This process will ensure participating surgeons who wish to remain anonymous remains so. Results from this study will be submitted for presentation at national and international conferences and written up for publication in a peer reviewed journal.

Patients will be able to access the study results by request but not surgical videos.

If this study achieves its aim of objectively quantifying the surgical proficiency, efficiency and surgeon workload of the robotic surgical platform, it is expected that the results will justify larger comparative studies to further evaluate the clinical advantages of robotic surgical platform to enhance surgical outcomes.

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