**Research Protocol**

**Project Title**

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

**Principal Investigator**

Yit Leang1,2

**Chief Investigator**

Paul Burton1,2,3,4

**Associate Investigators**

Wendy Brown1,2,3

Joseph Kong1,2,4

Chrys Hensman1,5

Sites

1. Monash University Department of Surgery
2. Alfred Health, Melbourne
3. The Avenue Private Hospital, Melbourne
4. Cabrini Hospital, Melbourne
5. The Valley Private Hospital (Mulgrave Private), Melbourne

**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 be open to all bariatric surgeons in Australia with the aim of recruiting 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 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 project and not funded by any 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 rates and complicates rates 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. Immediately after the procedure, the operating surgeon will complete a short 1-minute survey (refer Appendix 7) 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
   1. Roux-en-Y gastric bypass (RYGB)
   2. 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
   1. How much mental and perceptual activity was required? Was the task easy or demanding, simple or complex?
2. Physical Demand
   1. How much physical activity was required? Was the task easy or demanding, slack or strenuous?
3. Temporal Demand
   1. 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
   1. How successful were you in performing the task? How satisfied were you with your performance?
5. Effort
   1. How hard did you have to work (mentally and physically) to accomplish your level of performance?
6. Frustration Level
   1. How irritated, stressed, and annoyed versus content, relaxed, and complacent did you feel during the task?

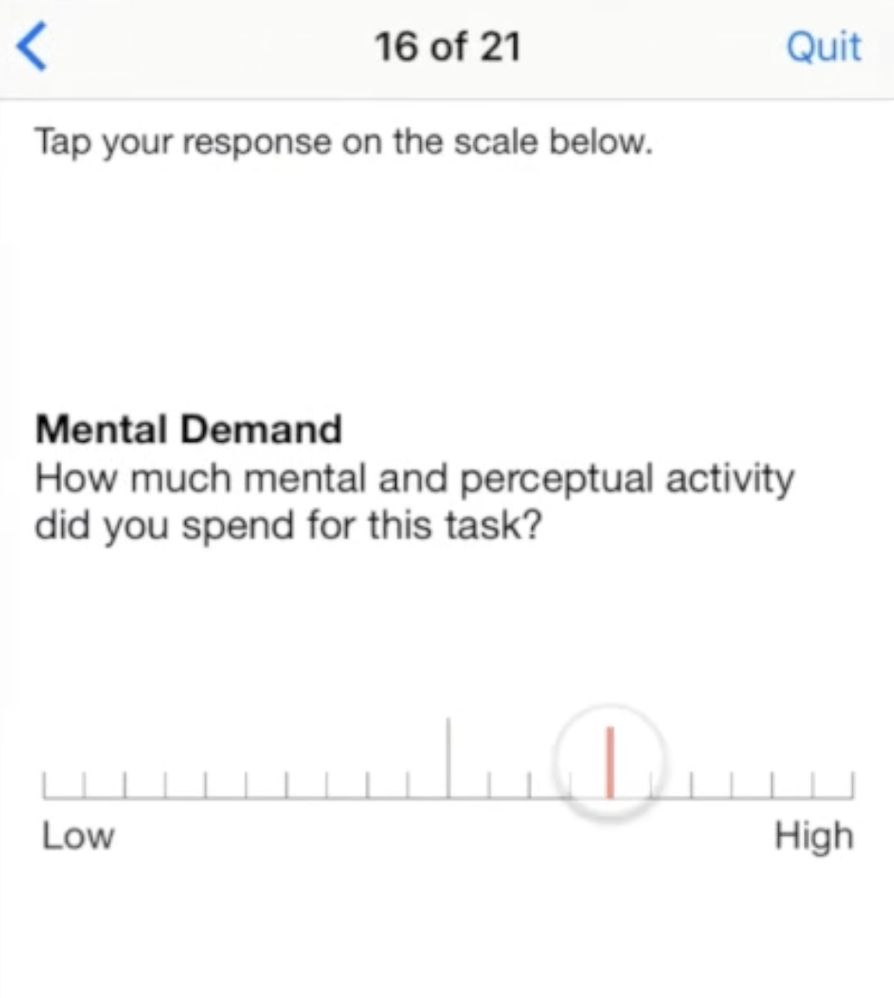
**For example:**

**Graphical user interface, text, application

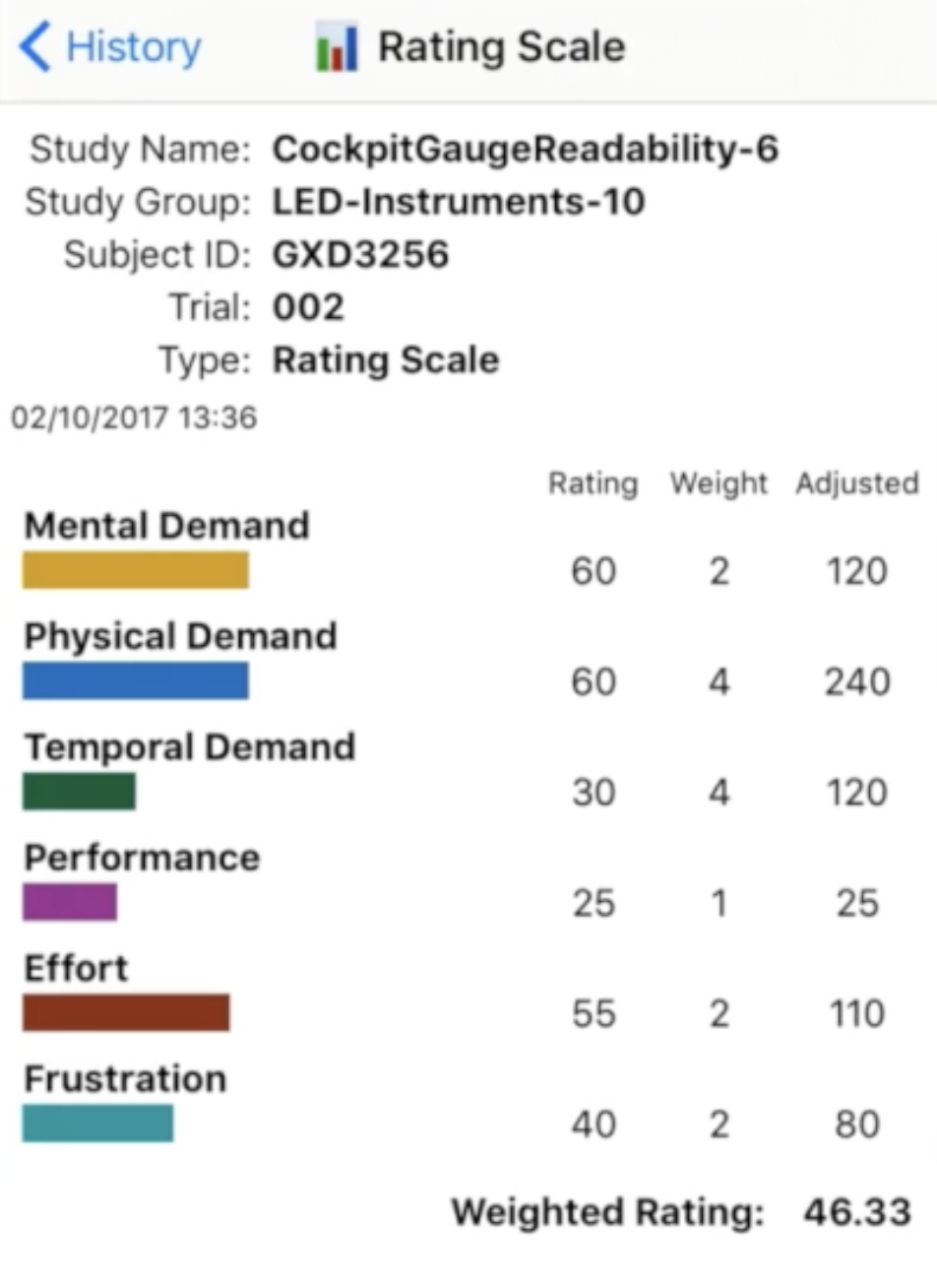
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The weighting of importance of each of the items is created following the paired selection.

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.

1. **General rating scale**
2. 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**

1. 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.

1. **Surgical Component rating**

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

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

**Surgical assistant and scrub nurse survey**

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 8 and 9) 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

Additional institutions may be added with the participation from other bariatric surgeons practising at other centres.

**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.

1. 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**

All data will be stored securely in an online database 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.

**Consent**

Each patient will provide consent to involvement in the study when they provide consent to their operation. Refer Appendix 2

Each surgeon, scrub nurse and surgical assistant will provide consent to involvement in the study at the start of the study. Refer Appendix 3,4 and 5.

Patients and surgeons 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**

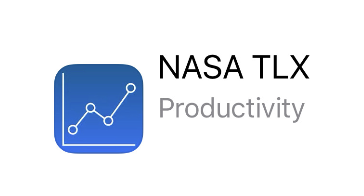
Results from this study will be submitted for presentation at national and international conferences and written up for publication in a peer reviewed journal. The surgeons involved in the study are all associate investigators and will be involved in the data analysis and manuscript writing. Patients 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.

**Appendix 1:**

NASA TLX instructions:

The NASA TLX application can be found in the App store as a free download.



The study name is: Gastro-enterostomy matched comparison

For “study group”: Please enter your hospital name

For “subject ID”: Please enter YOUR initials

For “trial”: The app will automatically assign a study ID for your cases.

Press “start”, then read each of the instruction and definitions pages. This clearly explains how to complete each section of the assessment. The assessment should only take you 1-2 minutes.

Having completed the assessment please tap the “history” icon and select the “ratings scale” file for the case just completed. This will present a summary results page. Please DO NOT share this via the “share” button as it will only send some of the data, and NOT the final NASA TLX score.

Please take the final “weighted rating” number and enter that into the Redcap database as the NASA TLX score.

Privacy:  
NASA has an End User Licence Agreement (EULA) embedded within the application which states that the End User owns and controls the content.

The instructions above create a data file that is only stored on the surgeon’s own device, and not on any external server. This data is not identifiable as it is only recorded as a study ID number. The final NASA TLX score (“weighted rating”) is recorded separately in the Redcap database and is therefore also only identifiable by a unique study ID number.

**Appendix 2:**

PICF - Patient:

**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

*[Insert site name]*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify technical proficiency and precision advantages of robotic versus laparoscopic platform. |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Protocol Number** | 1.1 |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/ Principal Investigator** | Yit Leang |
| **Associate Investigator(s)** | Paul Burton (The Alfred, The Avenue, Cabrini), Wendy Brown (The Alfred, The Avenue), Chrys Hensman (The Valley Private Hospital) |
| **Location** | The Alfred Hospital (Melbourne), The Avenue Hospital (Melbourne), Cabrini Hospital (Melbourne), The Valley Private Hospital (Melbourne) |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you will be having a minimally invasive operation (laparoscopic or robotic) by one of the surgeons involved in the trial. The research project will compare the technical advantages and disadvantages of the newer robotic platform against the well-established, widely available and safe conventional laparoscopic platform for minimally invasive surgery. This will not alter your treatment or operation at all but will involve the surgeon and his/her team completing a survey AFTER your operation is completed.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to have the tests and treatments that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Currently, minimally invasive operation is performed using conventional laparoscopic platform comprises of a 2-dimensional camera and long straight surgical instruments with 4-axis of motions. While this has been proven to be a very safe and effective way of performing minimally invasive surgery and widely adopted worldwide by many surgeons, newer technology such as the robotic platform which has 3-dimensional camera and surgical instruments with 7-axis of motions has been introduced. This may reduce the difficulty of performing complex minimally invasive procedures such as bariatric surgeries.

This newer robotic technology cost more and published surgical results on the use of robotic platform for bariatric procedures have not been conclusive to justify the cost of this technology. This is because conventional laparoscopic surgery is very safe and hence proving a superior clinical outcome will require a lot of study and research data.

Other ways to compare the 2 platforms is to evaluate and compare the technical advantages and disadvantages using established surgical proficiency and difficulty tools. The aim of this study is to scientifically measure if robotic platform makes a complex laparoscopic procedure easier to perform and how it does so to help surgeons understand and choose the best tools to perform your operation to achieve the best possible outcome.

*Where the research is for the purpose of obtaining a degree or other educational qualification:*

The results of this research will be used by the study doctor Dr. Yit Leang to obtain a Doctor of Philosophy degree.

*Where the research project is investigator-initiated:*

This research has been initiated by the study doctor, Dr Yit Leang.

*Where the research project is funded by a grant:*

This research has no external funding.

*Where the research is being coordinated outside the institution:*

This research is being conducted by the investigators listed above, at the hospitals listed above.

*Where commercial sponsorship is available:*

This research is being conducted without commercial sponsorship.

**3 What does participation in this research involve?**

⮞ Consent form will be signed prior to any study assessments being performed.

⮞ Initial steps

• Screening for eligibility: Patients undergoing laparoscopic or robotic bariatric gastric bypass procedure being performed by a study surgeon will be eligible for the trial.

• There will be no randomisation or blinding for this study. The laparoscopic group will be used as a control for this study.

⮞ Procedures

• Procedures: Laparoscopic or robotic bariatric gastric bypass

• Involvement in the trial will not alter your treatment in any way. The trial involves your surgeon recording your procedure. Your surgeon and surgical team completing a survey of how difficult or easy the operation was to perform AFTER your procedure is completed. The video of your procedure will be reviewed by 2 surgeons and difficulty of the procedure evaluated using developed tools.

• Follow-up: You will be followed up by your surgeon and team in the normal manner. Involvement in the trial will not alter your routine care.

• Duration of participant’s involvement will only be during performance of the operation. It is expected that it will take 6-18 months to complete the trial.

⮞ Reimbursement and costs – There will be no additional costs. There will be no reimbursement.

⮞ How the research will be monitored: The Human Research Ethics committee will monitor the research project.

⮞ The commitment required by the participant: Allowing the intra-abdominal component of the procedure to be video recorded (you will be not identified on the video as only the internals are being recorded), allowing the surgeon and team to complete the survey at completion of the operation, allowing your demographics details (excluding identifiable information) to be recorded for the trial.

*Bias (to be used in all research projects)*

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

*Additional costs*

There are no additional costs associated with participating in this research project, nor will you be paid.

*Reimbursement*

You will not need to be reimbursed for any costs as there will be no additional expenses associated with the research project beyond your normal care.

**4 What do I have to do?**

The study will not change your procedure or normal care. You do not need to do anything extra to be involved in the study. You will provide consent to:

1. The surgeon and surgical team completing a survey about the difficulty of your surgery after completing your procedure.
2. Capturing and storing an internal video of your procedure being performed where you are not being identified in any way.
3. Obtaining and storing your general demographic data and some basic surgical outcome measurements.

**5 Other relevant information about the research project**

This is a national study and will involve other surgeons at other hospitals enrolling their patients into this study. All surgeons will be working in collaboration.

**6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with your treating hospital.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. If you do not take part in this study, your operation and care will proceed as normal.

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include progressing our understanding on the use of the new robotic surgical platform and achieve better surgical outcomes in the future.

There will be no clear benefit to you from your participation in this research.

**9 What are the possible risks and disadvantages of taking part?**

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

The potential side effects of your surgery will not be increased or decreased by your involvement in the study as this study will not alter your treatment.

We are aware of the importance of patient privacy and will take every precaution to protect your important personal information. This includes the internal surgical recording of your procedure along with your basic de-identified demographic and basic surgical outcome data. This data will be recorded on a password protected database.

These days, whilst anaesthesia is generally very safe there are some risks associated with anaesthesia. The most common problems associated with anaesthesia are feeling unwell or vomiting, bruising at the site of injections, sore throat or hoarse voice. Most patients do not have these problems. If these problems do happen, they usually get better very quickly. Damage to teeth may occur, but this is rare. The risk of brain damage or death due to anaesthesia is very rare.

The risk of problems from anaesthesia increases for patients who are having more major surgery, those with medical problems and those that require difficult anaesthetic procedures. If you have any concerns about these issues, you should discuss them with the study team.

**10 What will happen to my internal video?**

This will be stored securely and analysed for the study.

**11 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

**12 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you can have all appropriate treatments that relate to your routine surgical care.

**13 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

**14 Could this research project be stopped unexpectedly?**

It is not expected that this study will stop between you consenting to the trial and then undergoing surgery.

**15 What happens when the research project ends?**

The results will be analysed, published and presented at surgical meetings to report the results of this research. It is hoped that this study will better inform surgeons on the technical advantages of robotic surgical platform in bariatric surgery and the information help develop future studies to validate this result.

Participants can request the results and publications be made available to them within 12 months of the study being completed.

**Part 2 How is the research project being conducted?**

**16 What will happen to information about me?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. The internal video recorded during your surgery will not be able to identify you and will only be identifiable by your unique study number. Your demographic data and information on surgery will be recorded in a password protected database. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. No personal information will be attached to the study outcomes data or internal video recording. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project and for the future research described in Section 16 that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**17 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**Compensation**

The avenue that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:

• You may be able to seek compensation through the courts.

**18 Who is organising and funding the research?**

This research project is being conducted by Yit Leang

This research project is not being sponsored or externally funded.

You will not benefit financially from your involvement in this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**19 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of The Alfred Hospital.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**20 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on 03 9903 0190.

**Clinical contact person**

|  |  |
| --- | --- |
| Name | *Yit Leang* |
| Position | *Principal Investigator* |
| Telephone | *03 9903 0190* |
| Email | *Yit.leang@monash.edu* |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | *Yit Leang* |
| Position | *Principal Investigator* |
| Telephone | *03 9903 0190* |
| Email | *Yit.leang@monash.edu* |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

*This person should be someone independent of the research, such as the Executive Officer of the reviewing HREC that approved the project (if a multi-centre clinical trial). Contact your local HREC administrator (single site trial) for the requirements at your institution.*

|  |  |
| --- | --- |
| Reviewing HREC name | *[Name of HREC]* |
| HREC Executive Officer | *[Name]* |
| Telephone | *[ HREC Executive Officer Phone number]* |
| Email | *[ HREC Executive Officer Email address]* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site - Research Governance Officer)**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify technical proficiency and precision advantages of robotic versus laparoscopic platform. |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Protocol Number** | 1.1 |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Yit Leang |
| **Associate Investigator(s)** | Paul Burton (The Alfred, The Avenue, Cabrini), Wendy Brown (The Alfred, The Avenue), Chrys Hensman (The Valley Private Hospital) |
| **Location** *(where CPI/PI will recruit)* | The Alfred Hospital (Melbourne), The Avenue Hospital (Melbourne), Cabrini Hospital (Melbourne), The Valley Private Hospital (Melbourne) |

**Consent Agreement**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Monash Universityconcerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

**Declaration by Participant – for participants who have read the information**

|  |
| --- |
| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| Declaration - for participants unable to read the information and consent form  See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness\*.  Witness to the informed consent process  Name (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older. |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project; its procedures and risks and I believe that the participant has understood that explanation.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

***Consent via telehealth or telephone***

*Where the consent has been obtained by telehealth or telephone, once the PICF is signed and dated by the participant and Investigator, the participant is to tick the statement identifying that consent was obtained by telehealth or telephone with the name of the Investigator. Similarly, the Investigator is to tick the statement identifying that consent was obtained by telehealth or telephone with the name of the participant.*

*Examples of additional statements:*

* Consent was obtained using telehealth with *[Name of Participant]* whose photographic identification was sighted by the Investigator who observed the Participant’s signature being written
* Consent was obtained via telephone with *[Name of Participant]* on [DD/MMM/YYYY].
* Participant’s signed consent form received by the Investigator on [DD/MMM/YYYY].
* Consent was obtained using telehealth with *[Name of Investigator]* whose photographic identification was sighted by the Participant who observed the Investigator’s signature being written
* Consent was obtained via telephone with *[Name of Investigator]* on [DD/MMM/YYYY].
* Discussed with *[Participant]* via telephone on *[insert date]* and received signed consent form on *[insert date]*. Signed by *[Investigator].*

**Form for Withdrawal of Participation -** *Adult providing own consent*

*It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary. Note that a participant’s decision to withdraw their separate consent to the use and storage of tissue will need to be documented separately and linked to the PICF used for that purpose.*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify technical proficiency and precision advantages of robotic versus laparoscopic platform. |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Protocol Number** | 1.1 |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Yit Leang |
| **Associate Investigator(s)**  *(if required by institution)* | Paul Burton (The Alfred, The Avenue, Cabrini), Wendy Brown (The Alfred, The Avenue), Chrys Hensman (The Valley Private Hospital) |
| **Location** *(where CPI/PI will recruit)* | The Alfred Hospital (Melbourne), The Avenue Hospital (Melbourne), Cabrini Hospital (Melbourne), The Valley Private Hospital (Melbourne) |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

|  |
| --- |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

**Appendix 3**

PICF - Surgeon:

**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

*[Insert site name]*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify technical proficiency and precision advantages of robotic versus laparoscopic platform. |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Protocol Number** | 1.1 |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/ Principal Investigator** | Yit Leang |
| **Associate Investigator(s)** | Paul Burton (The Alfred, The Avenue, Cabrini), Wendy Brown (The Alfred, The Avenue), Chrys Hensman (The Valley Private Hospital) |
| **Location** | The Alfred Hospital (Melbourne), The Avenue Hospital (Melbourne), Cabrini Hospital (Melbourne), The Valley Private Hospital (Melbourne) |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you will be performing a minimally invasive operation (laparoscopic or robotic) bariatric gastric bypass surgery. The research project will compare the technical advantages and disadvantages of the newer robotic platform against the well-established, widely available and safe conventional laparoscopic platform for minimally invasive surgery. This will not alter the treatment or operation of your patient but will involve you recording the procedure and completing a survey AFTER operation is completed.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to video record the internal component of the procedure, complete a short survey after each operation and collect some basic patient demographic and outcome data.

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Currently, minimally invasive operation is performed using conventional laparoscopic platform comprises of a 2-dimensional camera and long straight surgical instruments with four axis of motions. While this has been proven to be a very safe and effective way of performing minimally invasive surgery and widely adopted worldwide by many surgeons, newer technology such as the robotic platform which has 3-dimensional camera and surgical instruments with 7-axis of motions has been introduced. This may reduce the difficulty of performing complex minimally invasive procedures such as bariatric surgeries.

This newer robotic technology cost more and published surgical results on the use of robotic platform for bariatric procedures have not been conclusive to justify the cost of this technology. This is because conventional laparoscopic surgery is very safe and hence proving a superior clinical outcome will require a lot of study and research data.

Other ways to compare the 2 platforms is to evaluate and compare the technical advantages and disadvantages using established surgical proficiency and difficulty tools. The aim of this study is to scientifically measure if robotic platform makes a complex laparoscopic procedure easier to perform and how it does so to help surgeons understand and choose the best tools to perform your operation to achieve the best possible outcome.

*Where the research is for the purpose of obtaining a degree or other educational qualification:*

The results of this research will be used by the study doctor Dr. Yit Leang to obtain a Doctor of Philosophy degree.

*Where the research project is investigator-initiated:*

This research has been initiated by the study doctor, Dr Yit Leang.

*Where the research project is funded by a grant:*

This research has no external funding.

*Where the research is being coordinated outside the institution:*

This research is being conducted by the investigators listed above, at the hospitals listed above.

*Where commercial sponsorship is available:*

This research is being conducted without commercial sponsorship.

**3 What does participation in this research involve?**

⮞ Consent form will be signed prior to any study assessments being performed.

⮞ Initial steps

• Screening for eligibility: Patients undergoing laparoscopic or robotic bariatric gastric bypass procedure being performed by a study surgeon will be eligible for the trial.

• There will be no randomisation or blinding for this study. The laparoscopic group will be used as a control for this study.

⮞ Procedures

• Procedures: Laparoscopic or robotic bariatric gastric bypass

• Involvement in the trial will not alter your patients treatment in any way. The trial involve you recording the procedure. You and your surgical team completing a survey of how difficult or easy the operation was to perform AFTER the procedure is completed. The video of the procedure will be reviewed by 2 surgeons and difficulty of the procedure evaluated using developed tools.

• Follow-up: You will follow up your patient in the normal manner. Involvement in the trial will not alter your patient’s routine care as you prescribed.

• Duration of participant’s involvement will only be during performance of the operation. It is expected that it will take 6-18 months to complete the trial.

⮞ Reimbursement and costs – There will be no additional costs. There will be no reimbursement.

⮞ How the research will be monitored: The Human Research Ethics committee will monitor the research project.

⮞ The commitment required by the participant: Allowing the intra-abdominal component of the procedure to be video recorded (you will be not identified on the video as only the internals are being recorded), allowing the surgeon and team to complete the survey at completion of the operation, allowing your demographics details (excluding identifiable information) to be recorded for the trial.

*Bias (to be used in all research projects)*

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

*Additional costs*

There are no additional costs associated with participating in this research project, nor will you be paid.

*Reimbursement*

You will not need to be reimbursed for any costs as there will be no additional expenses associated with the research project beyond your normal care.

**4 What do I have to do?**

The study will not change your patient’s procedure or normal care. You will provide consent to:

1. Completing a survey about the difficulty of the surgery after completing the procedure.
2. Capturing and storing an internal video of the procedure being performed where you and your patient are not being identified in any way.
3. Obtaining and storing your patient’s general demographic data and some basic surgical outcome measurements.

**5 Other relevant information about the research project**

This is a national study and will involve other surgeons at other hospitals enrolling their patients into this study. All surgeons will be working in collaboration.

**6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with your treating hospital.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. If you do not take part in this study, your operation and care will proceed as normal.

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include progressing our understanding on the use of the new robotic surgical platform and achieve better surgical outcomes in the future.

There will be no clear benefit to you from your participation in this research.

**9 What are the possible risks and disadvantages of taking part?**

We are aware of the importance of patient privacy and will take every precaution to protect your patient’s important personal information. This includes the internal surgical recording of the procedure along with basic de-identified demographic and basic surgical outcome data. This data will be recorded on a password protected database.

**10 What will happen to the internal video?**

This will be stored securely and analysed for the study.

**11 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw.

**12 Could this research project be stopped unexpectedly?**

It is not expected that this study will stop between you consenting to the trial and then undergoing surgery.

**13 What happens when the research project ends?**

The results will be analysed, published and presented at surgical meetings to report the results of this research. It is hoped that this study will better inform surgeons on the technical advantages of robotic surgical platform in bariatric surgery and the information help develop future studies to validate this result.

Participants can request the results and publications be made available to them within 12 months of the study being completed.

**Part 2 How is the research project being conducted?**

**14 What will happen to information about me?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify your patient will remain confidential. The internal video recorded during the surgery will not be able to identify your patient and will only be identifiable by a unique study number. The demographic data and information on surgery will be recorded in a password protected database. The information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about your patient may be obtained from health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. No personal information will be attached to the study outcomes data or internal video recording. In any publication and/or presentation, information will be provided in such a way that your patient cannot be identified, except with their permission.

Information about the study patients participation in this research project may be recorded in your health records.

In accordance with relevant Australian and Victorian privacy and other relevant laws, the patient has the right to request access to their information collected and stored by the research team. They also have the right to request that any information with which they disagree be corrected. Please contact the study team member named at the end of this document if they would like to access their information.

Any information obtained for the purpose of this research project and for the future research described in Section 16 that can identify your patient will be treated as confidential and securely stored. It will be disclosed only with their permission, or as required by law.

**15 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**Compensation**

The avenue that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:

• You may be able to seek compensation through the courts.

**16 Who is organising and funding the research?**

This research project is being conducted by Yit Leang

This research project is not being sponsored or externally funded.

You will not benefit financially from your involvement in this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**17 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of The Alfred Hospital.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**18 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on 03 9903 0190.

**Clinical contact person**

|  |  |
| --- | --- |
| Name | *Yit Leang* |
| Position | *Principal Investigator* |
| Telephone | *03 9903 0190* |
| Email | *Yit.leang@monash.edu* |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | *Yit Leang* |
| Position | *Principal Investigator* |
| Telephone | *03 9903 0190* |
| Email | *Yit.leang@monash.edu* |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | *[Name of HREC]* |
| HREC Executive Officer | *[Name]* |
| Telephone | *[ HREC Executive Officer Phone number]* |
| Email | *[ HREC Executive Officer Email address]* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site - Research Governance Officer)**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify technical proficiency and precision advantages of robotic versus laparoscopic platform. |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Protocol Number** | 1.1 |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Yit Leang |
| **Associate Investigator(s)** | Paul Burton (The Alfred, The Avenue, Cabrini), Wendy Brown (The Alfred, The Avenue), Chrys Hensman (The Valley Private Hospital) |
| **Location** *(where CPI/PI will recruit)* | The Alfred Hospital (Melbourne), The Avenue Hospital (Melbourne), Cabrini Hospital (Melbourne), The Valley Private Hospital (Melbourne) |

**Consent Agreement**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Monash Universityconcerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

**Declaration by Participant – for participants who have read the information**

|  |
| --- |
| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| Declaration - for participants unable to read the information and consent form  See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness\*.  Witness to the informed consent process  Name (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older. |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

***Consent via telehealth or telephone***

*Where the consent has been obtained by telehealth or telephone, once the PICF is signed and dated by the participant and Investigator, the participant is to tick the statement identifying that consent was obtained by telehealth or telephone with the name of the Investigator. Similarly, the Investigator is to tick the statement identifying that consent was obtained by telehealth or telephone with the name of the participant.*

*Examples of additional statements:*

* Consent was obtained using telehealth with *[Name of Participant]* whose photographic identification was sighted by the Investigator who observed the Participant’s signature being written
* Consent was obtained via telephone with *[Name of Participant]* on [DD/MMM/YYYY].
* Participant’s signed consent form received by the Investigator on [DD/MMM/YYYY].
* Consent was obtained using telehealth with *[Name of Investigator]* whose photographic identification was sighted by the Participant who observed the Investigator’s signature being written
* Consent was obtained via telephone with *[Name of Investigator]* on [DD/MMM/YYYY].
* Discussed with *[Participant]* via telephone on *[insert date]* and received signed consent form on *[insert date]*. Signed by *[Investigator].*

**Form for Withdrawal of Participation -** *Adult providing own consent*

*It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary. Note that a participant’s decision to withdraw their separate consent to the use and storage of tissue will need to be documented separately and linked to the PICF used for that purpose.*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify technical proficiency and precision advantages of robotic versus laparoscopic platform. |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Protocol Number** | 1.1 |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Yit Leang |
| **Associate Investigator(s)**  *(if required by institution)* | Paul Burton (The Alfred, The Avenue, Cabrini), Wendy Brown (The Alfred, The Avenue), Chrys Hensman (The Valley Private Hospital) |
| **Location** *(where CPI/PI will recruit)* | The Alfred Hospital (Melbourne), The Avenue Hospital (Melbourne), Cabrini Hospital (Melbourne), The Valley Private Hospital (Melbourne) |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

|  |
| --- |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

**Appendix 4**

PICF – Scrub Nurse:

**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

*[Insert site name]*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify technical proficiency and precision advantages of robotic versus laparoscopic platform. |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Protocol Number** | 1.1 |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/ Principal Investigator** | Yit Leang |
| **Associate Investigator(s)** | Paul Burton (The Alfred, The Avenue, Cabrini), Wendy Brown (The Alfred, The Avenue), Chrys Hensman (The Valley Private Hospital) |
| **Location** | The Alfred Hospital (Melbourne), The Avenue Hospital (Melbourne), Cabrini Hospital (Melbourne), The Valley Private Hospital (Melbourne) |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you will assist the participating surgeon in performing a minimally invasive operation (laparoscopic or robotic) bariatric gastric bypass surgery. The research project will compare the technical advantages and disadvantages of the newer robotic platform against the well-established, widely available and safe conventional laparoscopic platform for minimally invasive surgery. This will not alter the treatment or operation of the patient but will involve you completing a survey AFTER operation is completed.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to complete a short survey after each operation

• Consent to the use of your personal information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Currently, minimally invasive operation is performed using conventional laparoscopic platform comprises of a 2-dimensional camera and long straight surgical instruments with four axis of motions. While this has been proven to be a very safe and effective way of performing minimally invasive surgery and widely adopted worldwide by many surgeons, newer technology such as the robotic platform which has 3-dimensional camera and surgical instruments with 7-axis of motions has been introduced. This may reduce the difficulty of performing complex minimally invasive procedures such as bariatric surgeries.

This newer robotic technology cost more and published surgical results on the use of robotic platform for bariatric procedures have not been conclusive to justify the cost of this technology. This is because conventional laparoscopic surgery is very safe and hence proving a superior clinical outcome will require a lot of study and research data.

Other ways to compare the 2 platforms is to evaluate and compare the technical advantages and disadvantages using established surgical proficiency and difficulty tools. The aim of this study is to scientifically measure if robotic platform makes a complex laparoscopic procedure easier to perform and how it does so to help surgeons understand and choose the best tools to perform the operation to achieve the best possible outcome.

*Where the research is for the purpose of obtaining a degree or other educational qualification:*

The results of this research will be used by the study doctor Dr. Yit Leang to obtain a Doctor of Philosophy degree.

*Where the research project is investigator-initiated:*

This research has been initiated by the study doctor, Dr Yit Leang.

*Where the research project is funded by a grant:*

This research has no external funding.

*Where the research is being coordinated outside the institution:*

This research is being conducted by the investigators listed above, at the hospitals listed above.

*Where commercial sponsorship is available:*

This research is being conducted without commercial sponsorship.

**3 What does participation in this research involve?**

⮞ Consent form will be signed prior to any study assessments being performed.

⮞ Initial steps

• Screening for eligibility: Patients undergoing laparoscopic or robotic bariatric gastric bypass procedure being performed by a study surgeon will be eligible for the trial.

• There will be no randomisation or blinding for this study. The laparoscopic group will be used as a control for this study.

⮞ Procedures

• Procedures: Laparoscopic or robotic bariatric gastric bypass

• Involvement in the trial will not alter your patients treatment in any way. The trial involve the surgeon recording the procedure. You and your surgical team completing a survey of how difficult or easy the operation was to perform AFTER the procedure is completed. The video of the procedure will be reviewed by 2 surgeons and difficulty of the procedure evaluated using developed tools.

• Follow-up: The patient will be followed up by the participating surgeon in the normal manner. No follow up is required after you complete the survey.

• Duration of participant’s involvement will only be during performance of the operation. It is expected that it will take 6-18 months to complete the trial.

⮞ Reimbursement and costs – There will be no additional costs. There will be no reimbursement.

⮞ How the research will be monitored: The Human Research Ethics committee will monitor the research project.

⮞ The commitment required by the participant: Completing a short survey AFTER completion of the procedure and allow some basic information about your career experience to be collected.

*Bias (to be used in all research projects)*

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

*Additional costs*

There are no additional costs associated with participating in this research project, nor will you be paid.

*Reimbursement*

You will not need to be reimbursed for any costs as there will be no additional expenses associated with the research project beyond your normal care.

**4 What do I have to do?**

The study will not change your patient’s procedure or normal care. You will provide consent to:

1. Completing a survey about the difficulty of the surgery after completing the procedure.

**5 Other relevant information about the research project**

This is a national study and will involve other surgeons at other hospitals enrolling their patients into this study. All surgeons will be working in collaboration.

**6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the participating surgeon or your employer hospital.

**7 What are the alternatives to participation?**

If you do not take part in this study, the operation and care for the patient will proceed as normal.

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include progressing our understanding on the use of the new robotic surgical platform and achieve better surgical outcomes in the future.

There will be no clear benefit to you from your participation in this research.

**9 What are the possible risks and disadvantages of taking part?**

We are aware of the importance of patient privacy and will take every precaution to protect your important personal information. This includes the internal surgical recording of the procedure along with basic de-identified demographic and basic surgical outcome data. This data will be recorded on a password protected database.

**10 What will happen to the internal video?**

This will be stored securely and analysed for the study.

**11 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw.

**12 Could this research project be stopped unexpectedly?**

It is not expected that this study will stop between you consenting to the trial and then undergoing surgery.

**13 What happens when the research project ends?**

The results will be analysed, published and presented at surgical meetings to report the results of this research. It is hoped that this study will better inform surgeons on the technical advantages of robotic surgical platform in bariatric surgery and the information help develop future studies to validate this result.

Participants can request the results and publications be made available to them within 12 months of the study being completed.

**Part 2 How is the research project being conducted?**

**14 What will happen to information about me?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. The internal video recorded during the surgery will not be able to identify you and will only be identifiable by a unique study number. The demographic data and information on surgery will be recorded in a password protected database. The information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about the patient may be obtained from health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. No personal information will be attached to the study outcomes data or internal video recording. In any publication and/or presentation, information will be provided in such a way that your patient cannot be identified, except with their permission.

In accordance with relevant Australian and Victorian privacy and other relevant laws, the patient has the right to request access to their information collected and stored by the research team. They also have the right to request that any information with which they disagree be corrected. Please contact the study team member named at the end of this document if they would like to access their information.

Any information obtained for the purpose of this research project and for the future research described in Section 16 that can identify your patient will be treated as confidential and securely stored. It will be disclosed only with their permission, or as required by law.

**15 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**Compensation**

The avenue that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:

• You may be able to seek compensation through the courts.

**16 Who is organising and funding the research?**

This research project is being conducted by Yit Leang

This research project is not being sponsored or externally funded.

You will not benefit financially from your involvement in this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**17 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of The Alfred Hospital.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**18 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on 03 9903 0190.

**Clinical contact person**

|  |  |
| --- | --- |
| Name | *Yit Leang* |
| Position | *Principal Investigator* |
| Telephone | *03 9903 0190* |
| Email | *Yit.leang@monash.edu* |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | *Yit Leang* |
| Position | *Principal Investigator* |
| Telephone | *03 9903 0190* |
| Email | *Yit.leang@monash.edu* |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | *[Name of HREC]* |
| HREC Executive Officer | *[Name]* |
| Telephone | *[ HREC Executive Officer Phone number]* |
| Email | *[ HREC Executive Officer Email address]* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site - Research Governance Officer)**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify technical proficiency and precision advantages of robotic versus laparoscopic platform. |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Protocol Number** | 1.1 |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Yit Leang |
| **Associate Investigator(s)** | Paul Burton (The Alfred, The Avenue, Cabrini), Wendy Brown (The Alfred, The Avenue), Chrys Hensman (The Valley Private Hospital) |
| **Location** *(where CPI/PI will recruit)* | The Alfred Hospital (Melbourne), The Avenue Hospital (Melbourne), Cabrini Hospital (Melbourne), The Valley Private Hospital |

**Consent Agreement**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

**Declaration by Participant – for participants who have read the information**

|  |
| --- |
| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| Declaration - for participants unable to read the information and consent form  See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness\*.  Witness to the informed consent process  Name (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older. |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

***Consent via telehealth or telephone***

*Where the consent has been obtained by telehealth or telephone, once the PICF is signed and dated by the participant and Investigator, the participant is to tick the statement identifying that consent was obtained by telehealth or telephone with the name of the Investigator. Similarly, the Investigator is to tick the statement identifying that consent was obtained by telehealth or telephone with the name of the participant.*

*Examples of additional statements:*

* Consent was obtained using telehealth with *[Name of Participant]* whose photographic identification was sighted by the Investigator who observed the Participant’s signature being written
* Consent was obtained via telephone with *[Name of Participant]* on [DD/MMM/YYYY].
* Participant’s signed consent form received by the Investigator on [DD/MMM/YYYY].
* Consent was obtained using telehealth with *[Name of Investigator]* whose photographic identification was sighted by the Participant who observed the Investigator’s signature being written
* Consent was obtained via telephone with *[Name of Investigator]* on [DD/MMM/YYYY].
* Discussed with *[Participant]* via telephone on *[insert date]* and received signed consent form on *[insert date]*. Signed by *[Investigator].*

**Form for Withdrawal of Participation -** *Adult providing own consent*

*It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary. Note that a participant’s decision to withdraw their separate consent to the use and storage of tissue will need to be documented separately and linked to the PICF used for that purpose.*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify technical proficiency and precision advantages of robotic versus laparoscopic platform. |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Protocol Number** | 1.1 |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Yit Leang |
| **Associate Investigator(s)**  *(if required by institution)* | Paul Burton (The Alfred, The Avenue, Cabrini), Wendy Brown (The Alfred, The Avenue), Chrys Hensman (The Valley Private Hospital) |
| **Location** *(where CPI/PI will recruit)* | The Alfred Hospital (Melbourne), The Avenue Hospital (Melbourne), Cabrini Hospital (Melbourne), The Valley Private Hospital |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

|  |
| --- |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

**Appendix 5**

PICF – Surgical Assistant:

**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

*[Insert site name]*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify technical proficiency and precision advantages of robotic versus laparoscopic platform. |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Protocol Number** | 1.1 |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/ Principal Investigator** | Yit Leang |
| **Associate Investigator(s)** | Paul Burton (The Alfred, The Avenue, Cabrini), Wendy Brown (The Alfred, The Avenue), Chrys Hensman (The Valley Private Hospital) |
| **Location** | The Alfred Hospital (Melbourne), The Avenue Hospital (Melbourne), Cabrini Hospital (Melbourne), The Valley Private Hospital (Melbourne) |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you will assist the participating surgeon in performing a minimally invasive operation (laparoscopic or robotic) bariatric gastric bypass surgery. The research project will compare the technical advantages and disadvantages of the newer robotic platform against the well-established, widely available and safe conventional laparoscopic platform for minimally invasive surgery. This will not alter the treatment or operation of the patient but will involve you completing a survey AFTER operation is completed.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to complete a short survey after each operation

• Consent to the use of your personal information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Currently, minimally invasive operation is performed using conventional laparoscopic platform comprises of a 2-dimensional camera and long straight surgical instruments with 4-axis of motions. While this has been proven to be a very safe and effective way of performing minimally invasive surgery and widely adopted worldwide by many surgeons, newer technology such as the robotic platform which has 3-dimensional camera and surgical instruments with 7-axis of motions has been introduced. This may reduce the difficulty of performing complex minimally invasive procedures such as bariatric surgeries.

This newer robotic technology cost more and published surgical results on the use of robotic platform for bariatric procedures have not been conclusive to justify the cost of this technology. This is because conventional laparoscopic surgery is very safe and hence proving a superior clinical outcome will require a lot of study and research data.

Other ways to compare the 2 platforms is to evaluate and compare the technical advantages and disadvantages using established surgical proficiency and difficulty tools. The aim of this study is to scientifically measure if robotic platform makes a complex laparoscopic procedure easier to perform and how it does so to help surgeons understand and choose the best tools to perform the operation to achieve the best possible outcome.

*Where the research is for the purpose of obtaining a degree or other educational qualification:*

The results of this research will be used by the study doctor Dr. Yit Leang to obtain a Doctor of Philosophy degree.

*Where the research project is investigator-initiated:*

This research has been initiated by the study doctor, Dr Yit Leang.

*Where the research project is funded by a grant:*

This research has no external funding.

*Where the research is being coordinated outside the institution:*

This research is being conducted by the investigators listed above, at the hospitals listed above.

*Where commercial sponsorship is available:*

This research is being conducted without commercial sponsorship.

**3 What does participation in this research involve?**

⮞ Consent form will be signed prior to any study assessments being performed.

⮞ Initial steps

• Screening for eligibility: Patients undergoing laparoscopic or robotic bariatric gastric bypass procedure being performed by a study surgeon will be eligible for the trial.

• There will be no randomisation or blinding for this study. The laparoscopic group will be used as a control for this study.

⮞ Procedures

• Procedures: Laparoscopic or robotic bariatric gastric bypass

• Involvement in the trial will not alter your patient’s treatment in any way. The trial involve the surgeon recording the procedure. You and your surgical team completing a survey of how difficult or easy the operation was to perform AFTER the procedure is completed. The video of the procedure will be reviewed by 2 surgeons and difficulty of the procedure evaluated using developed tools.

• Follow-up: The patient will be followed up by the participating surgeon in the normal manner. No follow up is required after you complete the survey.

• Duration of participant’s involvement will only be during performance of the operation. It is expected that it will take 6-18 months to complete the trial.

⮞ Reimbursement and costs – There will be no additional costs. There will be no reimbursement.

⮞ How the research will be monitored: The Human Research Ethics committee will monitor the research project.

⮞ The commitment required by the participant: Completing a short survey AFTER completion of the procedure and allow some basic information about your career experience to be collected.

*Bias (to be used in all research projects)*

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

*Additional costs*

There are no additional costs associated with participating in this research project, nor will you be paid.

*Reimbursement*

You will not need to be reimbursed for any costs as there will be no additional expenses associated with the research project beyond your normal care.

**4 What do I have to do?**

The study will not change your patient’s procedure or normal care. You will provide consent to:

1. Completing a survey about the difficulty of the surgery after completing the procedure.

**5 Other relevant information about the research project**

This is a national study and will involve other surgeons at other hospitals enrolling their patients into this study. All surgeons will be working in collaboration.

**6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with the participating surgeon or your employer hospital.

**7 What are the alternatives to participation?**

If you do not take part in this study, the operation and care for the patient will proceed as normal.

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include progressing our understanding on the use of the new robotic surgical platform and achieve better surgical outcomes in the future.

There will be no clear benefit to you from your participation in this research.

**9 What are the possible risks and disadvantages of taking part?**

We are aware of the importance of patient privacy and will take every precaution to protect your important personal information. This includes the internal surgical recording of the procedure along with basic de-identified demographic and basic surgical outcome data. This data will be recorded on a password protected database.

**10 What will happen to the internal video?**

This will be stored securely and analysed for the study.

**11 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw.

**12 Could this research project be stopped unexpectedly?**

It is not expected that this study will stop between you consenting to the trial and then undergoing surgery.

**13 What happens when the research project ends?**

The results will be analysed, published and presented at surgical meetings to report the results of this research. It is hoped that this study will better inform surgeons on the technical advantages of robotic surgical platform in bariatric surgery and the information help develop future studies to validate this result.

Participants can request the results and publications be made available to them within 12 months of the study being completed.

**Part 2 How is the research project being conducted?**

**14 What will happen to information about me?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. The internal video recorded during the surgery will not be able to identify you and will only be identifiable by a unique study number. The demographic data and information on surgery will be recorded in a password protected database. The information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about the patient may be obtained from health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. No personal information will be attached to the study outcomes data or internal video recording. In any publication and/or presentation, information will be provided in such a way that your patient cannot be identified, except with their permission.

In accordance with relevant Australian and Victorian privacy and other relevant laws, the patient has the right to request access to their information collected and stored by the research team. They also have the right to request that any information with which they disagree be corrected. Please contact the study team member named at the end of this document if they would like to access their information.

Any information obtained for the purpose of this research project and for the future research described in Section 16 that can identify your patient will be treated as confidential and securely stored. It will be disclosed only with their permission, or as required by law.

**15 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**Compensation**

The avenue that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:

• You may be able to seek compensation through the courts.

**16 Who is organising and funding the research?**

This research project is being conducted by Yit Leang

This research project is not being sponsored or externally funded.

You will not benefit financially from your involvement in this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**17 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of The Alfred Hospital.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**18 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on 03 9903 0190.

**Clinical contact person**

|  |  |
| --- | --- |
| Name | *Yit Leang* |
| Position | *Principal Investigator* |
| Telephone | *03 9903 0190* |
| Email | *Yit.leang@monash.edu* |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | *Yit Leang* |
| Position | *Principal Investigator* |
| Telephone | *03 9903 0190* |
| Email | *Yit.leang@monash.edu* |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | *[Name of HREC]* |
| HREC Executive Officer | *[Name]* |
| Telephone | *[ HREC Executive Officer Phone number]* |
| Email | *[ HREC Executive Officer Email address]* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site - Research Governance Officer)**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify technical proficiency and precision advantages of robotic versus laparoscopic platform. |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Protocol Number** | 1.1 |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Yit Leang |
| **Associate Investigator(s)** | Paul Burton (The Alfred, The Avenue, Cabrini), Wendy Brown (The Alfred, The Avenue), Chrys Hensman (The Valley Private Hospital) |
| **Location** *(where CPI/PI will recruit)* | The Alfred Hospital (Melbourne), The Avenue Hospital (Melbourne), Cabrini Hospital (Melbourne), The Valley Private Hospital |

**Consent Agreement**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

**Declaration by Participant – for participants who have read the information**

|  |
| --- |
| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| Declaration - for participants unable to read the information and consent form  See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness\*.  Witness to the informed consent process  Name (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older. |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

***Consent via telehealth or telephone***

*Where the consent has been obtained by telehealth or telephone, once the PICF is signed and dated by the participant and Investigator, the participant is to tick the statement identifying that consent was obtained by telehealth or telephone with the name of the Investigator. Similarly, the Investigator is to tick the statement identifying that consent was obtained by telehealth or telephone with the name of the participant.*

*Examples of additional statements:*

* Consent was obtained using telehealth with *[Name of Participant]* whose photographic identification was sighted by the Investigator who observed the Participant’s signature being written
* Consent was obtained via telephone with *[Name of Participant]* on [DD/MMM/YYYY].
* Participant’s signed consent form received by the Investigator on [DD/MMM/YYYY].
* Consent was obtained using telehealth with *[Name of Investigator]* whose photographic identification was sighted by the Participant who observed the Investigator’s signature being written
* Consent was obtained via telephone with *[Name of Investigator]* on [DD/MMM/YYYY].
* Discussed with *[Participant]* via telephone on *[insert date]* and received signed consent form on *[insert date]*. Signed by *[Investigator].*

**Form for Withdrawal of Participation -** *Adult providing own consent*

*It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary. Note that a participant’s decision to withdraw their separate consent to the use and storage of tissue will need to be documented separately and linked to the PICF used for that purpose.*

|  |  |
| --- | --- |
| **Title** | Matched comparison of gastro-enterostomy construction: Quantify technical proficiency and precision advantages of robotic versus laparoscopic platform. |
| **Short Title** | Gastro-enterostomy matched comparison |
| **Protocol Number** | 1.1 |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Yit Leang |
| **Associate Investigator(s)**  *(if required by institution)* | Paul Burton (The Alfred, The Avenue, Cabrini), Wendy Brown (The Alfred, The Avenue), Chrys Hensman (The Valley Private Hospital) |
| **Location** *(where CPI/PI will recruit)* | The Alfred Hospital (Melbourne), The Avenue Hospital (Melbourne), Cabrini Hospital (Melbourne), The Valley Private Hospital |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

|  |
| --- |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

**Appendix 6**

**Patient Demographics Data Collection**

Age:

Sex: Male/Female

Height: (cm)

Weight: (kg)

\*on day of surgery

Medical comorbidities Type 2 Diabetes / Hypertension / Dyslipidaemia

Smoking status Active smoker or stopped within 3 months

or

Never smoked

or

Stopped > 3 months

Surgery status Primary / Revision

NASA-TLX weighted rating -

**Appendix 7 – Surgeon Rated Experience**

Case identification number :

Date of procedure :

For the following questions, please select ONE most appropriate answer.

1. How would you rate the difficulty of the anastomosis you have just performed?
   1. Very easy
   2. Easy
   3. Moderate
   4. Difficult
   5. Very difficult
2. How well do you think you done the anastomosis?
   1. Very poorly
   2. Poorly
   3. Adequate
   4. Well
   5. Very well

If you have performed the anastomosis LAPAROSCOPICALLY, please answer question 3 and 4.

If you have performed the anastomosis ROBOTICALLY, please skip to question 5.

1. Based on your experience, do you think the robotic surgical system would make the procedure easier?
   1. Yes
   2. No, it makes no difference
   3. Robotic platform will make it harder
2. If you are proficient with the robotic surgical system and it is available to you, would you have performed this procedure robotically?
   1. Yes
   2. No

1. Based on your experience, do you think performing the case laparoscopically would make the procedure harder?
   1. Yes
   2. It makes no difference
   3. Laparoscopic platform will make it harder

**Appendix 8 – Scrub Nurse Rated Experience**

Case identification number:

Date of procedure:

1. What is your experience level as a scrub nurse?
   1. Between 1 to 20 case experience in bariatric surgery
   2. Between 21 to 100 case experience in bariatric surgery
   3. >100 case experience in bariatric surgery
2. Based on your observation, how would you rate the difficulty of the gastro-jejunal anastomosis construction?
   1. Very easy
   2. Easy
   3. Moderate
   4. Difficult
   5. Very difficult
3. Based on your observation, how well do you think the surgeon has performed the anastomosis?
   1. Very poorly
   2. Poorly
   3. Adequate
   4. Well
   5. Very well

**Appendix 9 – Surgical Assistant Rated Experience**

Case identification number:

Date of procedure:

1. What is your experience level as a scrub nurse?
   1. Between 1 to 20 case experience in bariatric surgery
   2. Between 21 to 100 case experience in bariatric surgery
   3. >100 case experience in bariatric surgery
2. Based on your observation, how would you rate the difficulty of the gastro-jejunal anastomosis construction?
   1. Very easy
   2. Easy
   3. Moderate
   4. Difficult
   5. Very difficult
3. Based on your observation, how well do you think the surgeon has performed the anastomosis?
   1. Very poorly
   2. Poorly
   3. Adequate
   4. Well
   5. Very well

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