Consent to Participate in a Research Study

Title of Research Study:

A Prospective, Post Market, Feasibility Study to Assess the Practical Utility of the OR BlackBox Platform When Used to Compare Surgical Technique During 2D Versus 3D Laparoscopic Bariatric Surgery – The Black Box Study

Study Principal Investigator:

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Study Sponsor

This study is sponsored by Olympus Corporation of the Americas (OCA). The study sponsor is providing funding as well as the 2 dimensional (2D) and 3 dimensional (3D) laparoscopic surgical equipment to conduct the study. All surgical equipment provided by the sponsor is commercially available for use and not considered investigational.

Conflict of Interest Declaration

This study is being conducted as Research in the field of Education in Surgery and Patient Safety.

The study Principal Investigator Dr. Grantcharov and his surgical team will also be involved in this study as participants.

The OR BlackBox® Platform is being provided by Surgical Safety Technologies (SST), a company owned by Dr. Grantcharov and in which St. Michael's Hospital has shares.

This project as was mentioned above is sponsored by OCA, and the data collected in this study will be co-owned by St. Michael's Hospital and the Olympus Corporation of America.

Introduction

Before agreeing to take part in this research study, it is important that you read the information in this research consent form. It includes details we think you need to know in order to decide if you wish to take part in the study. If you have any questions, please ask a study investigator or study staff. You should not sign this form until you are sure you understand the information. All research is voluntary. You may also wish to discuss the study with your family doctor, a family member or close friend.

Purpose of the Research

The purpose of this study is to compare the impact of 2D visualization to 3D visualization using the Operating Room (OR) Data Recorder or "Black Box" during laparoscopic roux-en-y gastric bypass surgery, with the objective to compare the surgical team´s technical and non-technical performance using these two video camera systems.

The concept of the "Black Box" was introduced in aviation (flight) several decades ago to record all relevant flight data, including voice recordings from the cockpit, to help analyze airplane crashes, accidents or critical situations, in order to improve safety. The "Black Box" for use in the OR follows the same ideas by recording video and audio (sound) data during an operation as well as vital signs of the patient and environmental factors such as the operating room temperature.

The video and audio data that is gathered will be reviewed to see how 2D and 3D imaging affect laparoscopic roux-en-y gastric bypass surgery

How Many People are Taking Part in this Study?

Approximately 50 patients and about 50 OR team members will participate in this study. All procedures will be performed in the department of General Surgery at St. Michael's Hospital (Toronto, Canada).

Description of the Research

You are being asked to consider participating in this study because you are scheduled for an elective laparoscopic roux-en-y gastric bypass surgery at St. Michael's Hospital. If you choose to participate in this study, you are agreeing to be video- and audio-recorded while your surgery is being performed. The view of the laparoscopic camera will be video-recorded throughout the procedure as per standard of care in this unit. In addition, panoramic (wide) views of the entire operating room will be video-recorded after you have been completely protected from the camera view by sterile drapes. The laparoscopic video recording will show the surgery as it is happening inside your body. The panoramic view camera will be affixed on a defined position in the operating room and will record the OR team as they perform their duties. Recording will be stopped before the sterile drapes are removed.

No identifiable part of your body will ever be visible or captured on the recordings. In the unlikely event that this happens due to unforeseen technical error the recording process will be stopped immediately and any video and audio material recorded up to that point will be securely deleted. Besides video, sound (audio) will also be recorded during the procedure. Environmental factors that are recorded will be room temperature and sound level.

If you choose to participate in this study you will be operated on using the 2D or 3D camera. You will not be able to request the type of camera used during the surgery. If you decided not to participate in this study your surgery will be performed using the 2D camera only; the 3D camera will not be used.

Before, During, and After Your Elective Laparoscopic Surgery

Your study doctor and/or a member of the study team will review your medical record and collect basic demographic information (e.g., age, gender) and relevant medical information, including information about your surgical procedure.

If you choose to take part in this study you will have laparoscopic roux-en-y gastric bypass surgery with either a laparoscopic camera with a 2D display or a laparoscopic camera with a 3D display. Twenty-five consecutive surgeries will be performed with each type of laparoscopic camera (25 2D and 25 3D). The type of camera used in your surgery will not have any effect on the success of your surgery. Both cameras are standard for this type of surgery and are approved by Health Canada. The standard of routine care at Saint Michael's Hospital is to use the 2D vision camera for this

procedure. The data we collect from your procedure will help us evaluate if there are any advantages to surgeons or patients when using 2D or 3D cameras.

After your laparoscopic surgery is finished any complications or bad reactions you have will be documented. Within 30 days of your surgery you will receive a phone call from a clinical team member as post procedure follow-up. During this call you will be asked about any complication or bad reactions you have had since your surgery.

Video and Audio Recordings

The video and audio recordings captured during your surgery will be assessed by expert personnel who will rate performance of the OR team using a standard questionnaire. The video recordings will only be linked to you by a unique study code so your name will NOT be on the video recordings or on any data that is gathered in addition to it. As per standard medical practice any technical deviations or incidental findings during your surgery will be recorded in the operative note. In cases where these findings may be relevant to your health and future treatment these will be discussed with you in person by your treating team as per standard medical practice.

Educational Library

Educational library is a collection of video materials created strictly for the purpose of future education and training of the operating room team members. All video material will be completely anonymized. Additional video and audio filters will be applied in order to ensure full identity protection of all persons appearing in the recorded materials. Processed educational clips will be rendered completely anonymous by combining video blurring and voice altering technology.

If you do not want anonymized procedure used for the educational library, you can opt out within 48 hours of your procedure by contacting the research team

The laparoscopic camera view will be stripped of all identifying patient information (including patient name, time and day of the procedure) and stored on a secure St. Michael's hospital server. Since the laparoscopic video is anonymized, there is no way of linking the video to you or any member of the OR team.

Potential Harms and Risks

Your participation, or choice to not participate, will not have any effect on your surgery or any other part of your treatment or on the quality of medical care at St. Michael's Hospital for you or other members of your family. There are no known harms related to your participation in this study, apart from some potential risks related to your personal health information/identifying information (which are discussed in further detail in the 'Confidentiality and Privacy' section below).

Potential Benefits

There are no direct benefits from participation in this study. This study will not give you any improved treatment of any kind. There is however a potential benefit for future patients and operating room teams. Results from this study may further medical or scientific knowledge.

Confidentiality and Privacy

All persons involved in this study, including the study doctor and study team members (hereby referred to as "study personnel") are committed to respecting your privacy. All records will be held strictly confidential unless required by law. Any records, documentation, or information related to you will be coded by a unique study number. Additionally, in the video recordings of the operating room, your face and body will always be protected from the camera view. No identifying information about you will be allowed off site. All information that identifies you, both paper copy and electronic information, will be kept confidential and stored and locked in a secure place that only the study personnel will be able to access. Electronic files will be stored securely on a fire-wall protected, on-site server or securely on any encrypted portable electronic devices.

The data collected during this study will be shared with the study sponsor; Olympus Corporation of the Americas located at, 136 Turnpike Road, Southborough, MA 01772 USA as well as SST, a company owned by Dr. Teodor Grantcharov and St. Michael's Hospital. This company is physically located at St. Michael's Hospital; Toronto Ontario.

By signing this document, you agree to the use and transfer of your de-identified study data, outside of Canada where data protection laws differ from those of Canada. Once personal information is transferred outside Canada, it is subject to the data privacy laws of that country where it is stored. There are laws that allow government authorities access to personal information under certain circumstances. In the USA, for example, lawful disclosure of personal information to the government is permitted for certain national security purposes under the USA PATRIOT Act.

There are people who may need to review or audit your study information to make sure the study is done correctly and that the data collected is correct. These people include your study doctor and study staff, the study sponsor (Olympus Corporation of the Americas) or its representatives, the St. Michael's Research Ethics Board. These people may have direct access to your original medical record as a result of study related information that may be stored there. All information that may identify you will be kept confidential and will remain on-site. The review or audit would be co-ordinated by St. Michael's Hospital study personnel.

The video recording of the laparoscopy will only capture the details on the instruments and performance of the laparoscopic surgery. Since the laparoscopic video is

anonymized, there is no way of linking the video to patient or any member of the OR team.

The video recordings and study information collected about you will be identified only by a unique study number If it happens that any identifying information does get video/audio recorded (for example, your identity printed on any documents or if your name is spoken during the recording), this information will be removed as soon as discovered.

The audio and room video recordings will be securely deleted after they have been evaluated by the expert assessors and are no longer required for study purposes. This will take place within 30 days after your surgery. The log linking the study data to your identity will also be securely destroyed.

It is important to understand that despite these protections being in place, there continues to be the risk of unintentional release of information. The chance that this information will accidentally be given to someone else not mentioned in this section is small. All the information collected as part of this study will be analyzed using technology provided by SST (a company physically located at St. Michael's Hospital).

By signing this form, you are giving permission for the review and/or use of your protected health information as discussed in this form. You are also authorizing direct access to your original medical records for the purpose of verifying the authenticity and accuracy of the information collected for the study, without violating your confidentiality to the extent permitted by applicable laws and regulations.

In no way does signing this consent form waive your legal rights nor release the study investigators or involved institutions from their legal and professional responsibilities.

Study Registration and Results

A description of this clinical trial will be available on www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of study results. You can search this website at any time.

We may present the results of this study at a scientific conference and we intend to write an article about this study for publication in a scientific journal. Your identity will remain confidential. You can ask us to send you a copy of the article upon publication by contacting our principal investigator, Dr. Grantcharov or one of our research personnel.

Potential Costs and Reimbursement

You will not be paid or reimbursed for your participation in this study. Your surgery is

considered routine care for your condition and would be recommended whether you take part in this study or not

New technology may be developed through the use of aggregate data generated during the study. In the event of commercialization of such technology, you will not be entitled to receive any personal payment or recognition.

Participation and Withdrawal

Your participation in this study is voluntary. You can choose not to participate or you may withdraw within the first 48 hours following the procedure. Your participation, or choice to not participate, will not have any effect on your surgery or any other part of your treatment or on the quality of medical care at St. Michael's Hospital for you or other members of your family. If you wish to withdraw early from the study (and do so within 48 hours of your surgery) the video recordings of your surgery will be securely destroyed and no evaluation of the recordings will be conducted. The other study participants from your surgery (the OR team members) may also withdraw from the study at any time and request that the video be deleted if it has not yet been analyzed. If analysis is already completed or after this 48-hour time point, the information gathered from the video analysis will be retained and included in the study, as well as the information collected up to the point of withdrawal. However no further information will be collected about you for the study. The study investigator may also withdraw you from the study at any time without your consent. This can happen if:

- Your study doctor decides that continuing in the study would be harmful to you
- Your study doctor cannot collect the data from you in the proper way or feels for any reason the data is not collected properly
- You are not able to follow the study procedures or attend the required appointments
- The St. Michael's Research Ethics Board decides to end the study
- The sponsor (Olympus Corporation of the Americas) decides to end the study

If this happens, the study doctor will tell you.

New Findings or Information

We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information in a timely manner.

Compensation for Injury

If you suffer a physical injury from the medical devices, procedures or participation in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form waive your legal rights nor release the study doctor(s), sponsors or involved institutions from their legal and professional responsibilities.

Study Contact

If you have any questions about the study, or if you wish to withdraw from the study at any time, please contact our Research Personnel at 416-864-6060, extension 77584 (8am-5pm Monday to Friday).

Research Ethics Board Contact

If you have any questions about your rights as a research participant, please contact Dr. David Mazer, Chair, Research Ethics Board at St. Michael's Hospital, at 416-864-6060 ext. 2557, during business hours. The Research Ethics Board is required to do periodic review of ongoing research studies. As part of this review, someone may contact you from the Research Ethics Board to discuss your experience in the research study.

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Declaration of Consent

The research study has been explained to me, and my questions have been answered to my satisfaction. I have been informed that I have the right not to participate and the right to withdraw without affecting my treatment or the quality of medical care at St. Michael's Hospital for me and for other members of my family. As well, the potential harms and benefits (if any) of participating in this research study have been explained to me.

I have been told that I have not waived my legal rights nor released the investigators or involved institutions from their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that records relating to me and my care will be kept strictly confidential and that no information will be disclosed without my permission or unless required by law. I have been given sufficient time to read the above information.

I consent to participate in this study. I will be given a signed copy of this consent form.

Name of Participant (print)	Signature of Participant	Date

I, the undersigned, have fully explained the study to the above-named participant.

Name and Position of Person Conducting Consent Discussion (print)	Signature of Person Conducting Consent Discussion	Date