NON-INTERVENTIONAL/METHODOLOGICAL RESEARCH PROTOCOL

STUDY INFORMATION

- **Title of Project:**
  Comparison of surgeons' object discernment via their hands versus using a robotic surgical system that does not incorporate haptics

- **Sponsor:** The Valley Hospital

- **Principal Investigator**
  Patrick Culligan, MD, FACOG, FACS

- **Principal Investigator Dept.**
  Obstetrics & Gynecology / Urogynecology

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- **Protocol Version and Date: v1 06.24.23**

1.0 Research Design

1.1 Purpose/Specific Aims

A. Objectives

The objective of this study is to compare surgeons' discernment of 4 balloons filled with different materials when using their eyes and hands versus using the da Vinci robot.

B. Hypotheses / Research Question(s):

We believe that so called "visual haptics" derived from the high definition 3D optics associated with robotic surgery will allow for non-inferior object discernment compared to actual haptics of touching objects with surgeons' hands.

1.2 Research Significance (Briefly describe the following in 500 words or less)

Robotic surgery has emerged as a transformative technology in the field of medicine, revolutionizing surgical procedures across various specialties. The integration of advanced robotic systems, such as the da Vinci Surgical Systems, has provided surgeons with enhanced precision, improved dexterity, and greater visualization during complex surgical interventions. These advancements have been realized despite the lack any haptic feedback to the surgeon when using the da Vinci systems.

Robotic-assisted surgery is typically done through small incisions through which the surgeon places access points (ports) which are then connected to the robotic arms. The robotic arms hold the specialized robotic instruments and the high-definition 3D camera. After setting everything up, the surgeon sits at a console near the operating table and views the magnified, high-resolution 3D image of the surgical site. The surgeon's fingers are inserted into master controls on the console, which are designed to mimic the movements of the surgeon's hands. **Figure 1** depicts the most widely used robotic system – the da Vinci System (Intuitive Surgical, Sunnyvale CA) versus traditional laparoscopy.

Haptic feedback (i.e. the sense of touch) helps surgeons perceive the texture, resistance and consistency of various tissues and structures. This information helps surgeons maintain the optimal force during tissue manipulation. Ever since the first use of the da Vinci system in 1999, critics have bemoaned the lack of haptics as the Achilles heel of robotic surgery.

However, experienced robotic surgeons often report that they develop the sense of "visual haptics" that allows them to discern various properties of different tissue types as though they could actually feel them simply through a combination of manipulation and visualization.

To date, no studies have compared surgeons' ability to discern the nature of objects with their hands to robotic surgeons' ability to discern them while using only the robotic technology.

1.3 Research Design and Methods

A. Research Procedures

This will be a non-randomized parallel group study in which a group of surgeons (Group A) will make determinations as to the material within each of four visually identical balloons that contain air, water, petroleum jelly or a firm substance similar to the consistency of a non-ripe banana (Figure 2) using their hands and eyes while another group of experienced robotic surgeons (Group B) will do so using the da Vinci Xi System (Intuitive Surgical, Sunnyvale, CA). Only Board-certified surgeons will be recruited for the study. The study information will be obtained at Valley Hospital and the Intuitive Surgical training facility in Atlanta, Georgia.
Surgeon demographics will be recorded on Case Report Form #1

Before making their "hands on" determinations as to balloon contents, each surgeon will be asked to first determine whether they can visually determine the balloon contents without any manipulation. For the purposes of outcome measurement, only two possible outcomes will be considered – namely that the 4 balloons were ordered correctly or not. We will also record each "guess" for all surgeons in order to report any trends of mis-assortment that may occur.

B. Duration for Study and Each Subject

Each study participant will spend about 5 minutes doing study activities. We estimate that we will be finished with data collection by September 1st, 2023
All data collection will be performed by Dr. Patrick Culligan

1.3 Preliminary Data

Our balloon model was informally deemed plausible by myself and two other colleagues. (Figure 1)

1.4 Sample Size Justification

The probability of ordering all balloons correctly by chance is 1/24 or .0417.

The expectation is that group A will achieve 100% success. If so, we will require **35 surgeons in Group A and 18 surgeons in Group B** to achieve 80% power to make the determination that Group B was (or was not) "non-inferior" at discerning balloons (alpha = 0.05).

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

Primary outcome: (y/n) whether balloons were sorted correctly
Secondary outcome: Trends for any mis-assignments of balloons

De-identified surgeon demographics will be compared between groups

1.7 Data Collection

A. Primary Data Collection

- **Location**: The Valley Hospital and Intuitive Surgical Training Center in Atlanta GA. (Permission to conduct study at the Intuitive Surgical site obtained from Myriam Curet, MD , Intuitive Surgical CMO.
- **Process of Data Collection**: Case Report Forms (see attached) will be filled out and collected by Dr. Culligan
- **Timing and Frequency**: One time only per surgeon. Data collection will happen in 1 or 2 days at the Intuitive Surgical site – dates TBD
- **Procedures for Audio/Visual Recording**: N/A
- **Study Instruments**: The balloon model (Figure 2) is made of posterboard to which 4 balloons (Party City gold 5 inch) each containing 20 mL of material – either air, water, petroleum jelly, or water-absorbing crystals (LiquiLock, Oatey Inc) are affixed (Figure 1) The same model will be used for all data collection if possible, but in the event of balloon breakage or some other reason, identical replacement balloons may be created easily. The surgeons will be allowed to manipulate the balloons with their hands (Group A) or the robotic instruments (Group B) as they see fit, but they must leave the poster board laying flat with the balloons still attached. Surgeon Demographics (de-identified) and study data will be collected on Case Report forms 1 & 2. (Figures 3 & 4)
- **Ethnographic Studies, Interviews, Or Observation**: Surgeons will be allowed to manipulate the balloons as they see fit whether they are using their hands or the robotic instruments, but they will not be allowed to disconnect the balloons from the poster board. The poster board must lay flat at all times.

- **Subject Identifiers**: Dr. Culligan will hold the key indicating which substance is in each balloon. Each surgeon will be assigned a subject number sequentially.

B. Secondary Data Collection
N/A

1.9 Interviews, Focus Groups, Surveys, and/or Observations
N/A

B. Study Instruments
- **Evaluation Instrument Details – see above. The case report forms are Figures 3 & 4**

2.0 Project Management

2.1 Research Staff and Qualifications
Dr. Patrick Culligan (CV attached) has extensive clinical research experience and is up to date with his CITI training

2.2 Research Staff Training – N/A

2.3 Research Sites
The Valley Hospital & Intuitive Surgical Training Center, Atlanta, GA

3.0 Multi Center Research N/A

4.0 Research Data Source/s

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects
For the non-robotic surgeons, we will use any Board Certified surgeons on staff at The Valley Hospital. For the robotic surgeons, we will use any The Valley Hospital surgeons with unrestricted robotic privileges or any similarly credentialed robotic surgeons we encounter at the Intuitive Surgical Training Center.

B. Recruitment Details –
Dr. Culligan will approach surgeons to ask for their participation and guide them through the study process

C. Subject Screening –

Surgeons will review the below criteria and self-select whether they are eligible

- **Inclusion Criteria –**
  Group A (35 surgeons) Board Certified surgeons
  Group B (18 surgeons) Board Certified surgeons with unrestricted robotic privileges

- **Exclusion Criteria –** Surgeons unwilling to spend adequate time to participate in the study or those who are not Board Certified

4.2 Secondary Subjects

N/A

4.3 Number of Subjects

A. Total Number of Subjects

53

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**
  In lieu of signing traditional informed consent, each surgeon will be provided with a Study Information Sheet. Their participation in the study will serve as implied informed consent.

- **Consent Discussion Duration**
  5 minutes or less

- **Coercion or Undue Influence**
  N/A

- **Subject Understanding**
  Their participation will imply their understanding

B. Waiver or Alteration of Consent Process

- **Waiver or Alteration Details**
  This study does not involve any patient care or any other risky situations. In fact, this study carries the smallest possible risks to the study subjects. At the same time, the surgeons who agree to be subjects are very busy people. Keeping the enrollment process to a minimum will be critical for obtaining participation.

- **Destruction of Identifiers**
  No Identifiers will be collected (see Figure 3)

- **Use of Deception/Concealment**
  N/A
  a. **Minimal Risk Justification**
     No patient care of any kind will be included in the study. The only study activity will be manipulation of inanimate objects.

  b. **Alternatives**
     Use of human or animal tissue is not practical, because the study design calls for uniformity of the model objects. The materials within the balloons are similar to fluids that are present during surgical dissection.
  c. **Subject Debriefing**
     Each surgeon will be told whether or not they ordered the balloons correctly right after they do so, and they will be asked to keep this information to themselves.

C. Documentation of Consent

- **Documenting Consent**
  N/A

- **Waiver of Documentation of Consent (i.e., will not obtain subject's signature)**
  Each subject will receive a Study Information Sheet

B. Removing a Subject

If a subject decides to cease participation we will shred their forms and choose a subsequent study subject.

4.6 Risks and Benefits to Subjects

A. Description of Subject Risk And Benefits

There are no risks to being in this study. The benefits consist of the contribution each study subject will have made to further our knowledge of this topic.

Existing Condition/Disorder
N/A

- **Minimizing Risks**
  N/A
- **Certificate of Confidentiality (CoC)**
  N/A

- **Risks to Non-Subjects**
  N/A
- **Potential Benefits**
  The benefits consist of the contribution each study subject will have made to further our knowledge of this topic.

5.0 Data Management Plan

5.1 Data Analysis

Continuous variables will be compared via T-tests or Mann-Whitney test as applicable; Categorical data will be compared via chi square test. Power calculation / sample size estimate information as above.

5.2 Data Security

Dr. Culligan will keep the completed Case Report Forms in a folder in a secured briefcase until they can be entered into the electronic study database. The case report forms will be preserved to allow for potential further analysis, but no personal identifiers will have been collected. All study documents will be stored in the investigator's locked and secured office at The Valley Hospital.

5.3 Reporting Results

A. Subject Results Reporting
Our plan calls for data to be will be published in a peer reviewed journal. We will share our information with all study subjects at their request.

B. Professional Reporting We plan to present our findings at a national meeting (such as SGS, AUGS or AAGL, and we intend to publish our findings in a peer-reviewed journal.

5.4 Secondary Use of the Data

N/A

Figure 1.

Conventional laparoscopic surgery (which inherently includes haptic feedback to the surgeon) versus robotic-assisted surgery (which does not)

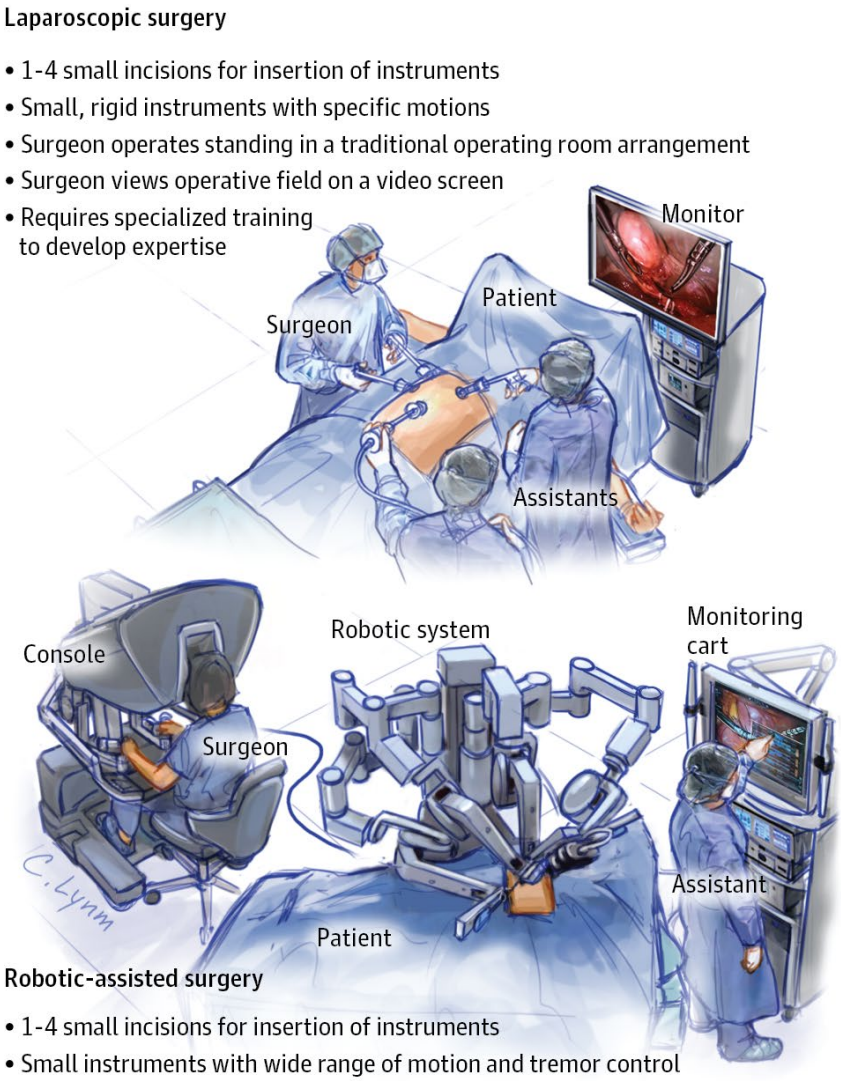

Figure 2.

The balloons - each filled with 20 mL of either air, water, petrouleum jelly or water absorbing crystals (consistency of a non-ripe banana)

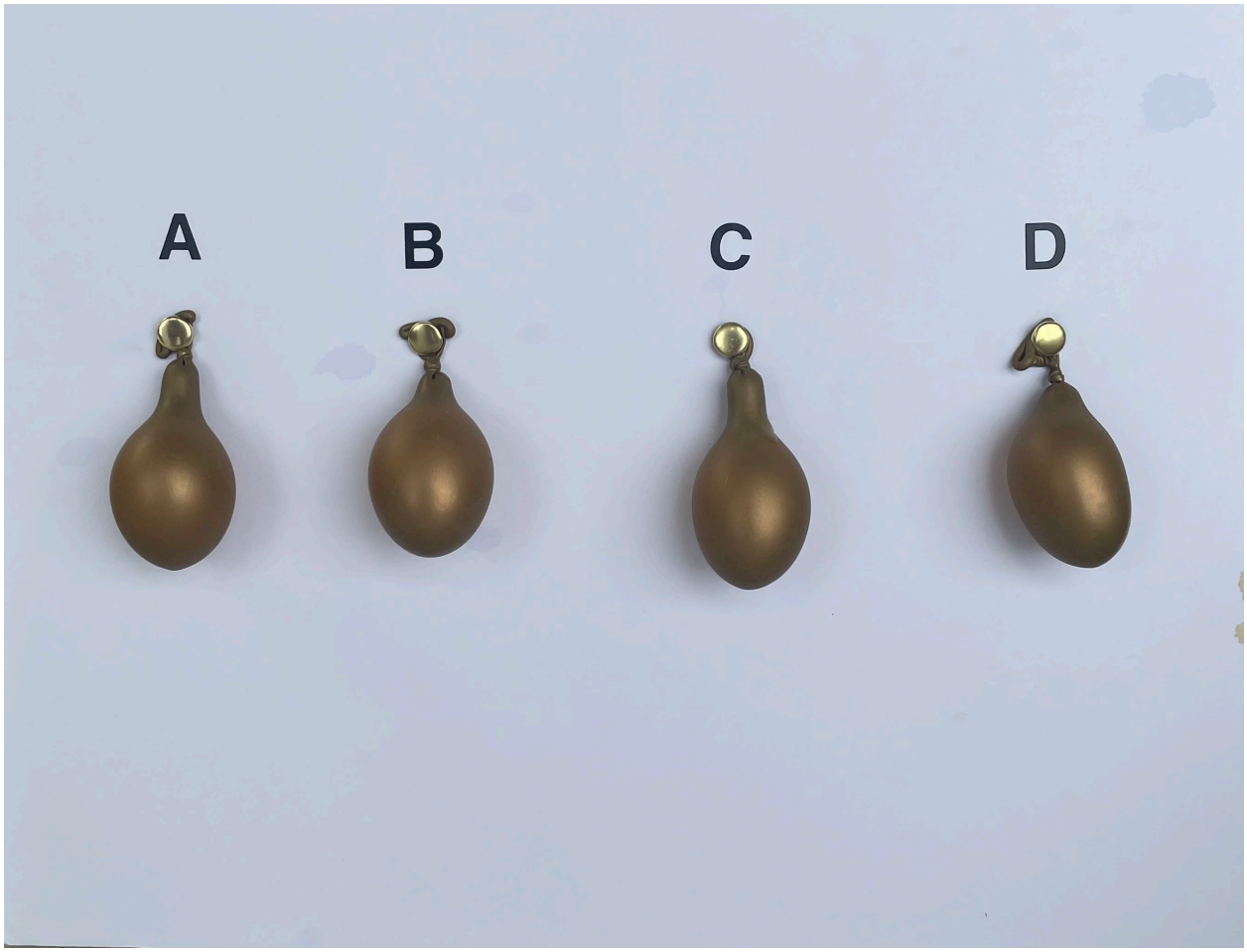

Figure 3.
Case Report Form 1
Surgeon Demographics

Subject # _____

Board Certification (circle all that apply) FACS FACOG FPMRS
Other _____

Age _____

Male Female non-Bianary

Years since residency _____

Years since fellowship _____

Credentialed for robotic surgery Y N

Approximate total number of robotic cases performed _____

Figure 4.

Case Report Form 2

Study Data Collection

Subject # _____

Surgeon felt as though they could discern balloon contents using only sight? Y N

Balloon discernment via manipulation HANDS ROBOT

AIR WATER JELLY CRYSTALS

Correct? Y N Y N Y N Y N

If No, which did they think it was?

_____ _____ _____ _____