Official Title: Esophagogastric junction distensibility during hiatal hernia repair

NCT04450628

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ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**Atrium Health Department of Surgery / "Esophagogastric junction distensibility during hiatal hernia repair"**
Atrium Health Number:	**01-20-07**
Principal Investigator: (Study Doctor)	**Paul D. Colavita, M.D.**
Telephone:	[redacted] **(24 Hours)**
Address:	**Atrium Health** [redacted]

KEY INFORMATION

You are invited to take part in a research study. This research study is studying EndoFLIP as a possible predictor of post-operative dysphagia (trouble swallowing or feeling food stick) and post-operative results after hiatal hernia repair and fundoplication (anti-reflux surgery).

The study can potentially help you and/or people in the future by changing parts of the surgery for hiatal hernia repair that can play a role in reflux and difficulty swallowing after surgery. This study would follow the same work-up, treatment, and follow-up course as we standardly do for hiatal hernia repair, except we perform an EndoFLIP evaluation during your surgery. You will not be charged for the EndoFLIP procedure or the EndoFLIP catheter. You or your insurance company will be billed for the standard hiatal hernia procedure. This study also includes an office visit with your surgeon 6 months after surgery; this is a visit that we do not typically perform and you will not be charged for this additional office visit. In addition, at your initial appointment and your follow-up appointments, you will need to complete two surveys to assess your reflux symptoms and swallowing symptoms. We will be collecting your health information, the results of the EndoFLIP study, and your survey results, all of which will be stored appropriately. There are risks associated with EndoFLIP, such as injuring the esophagus, which will be detailed later in this form. EndoFLIP is used frequently, but has never been examined in people during an operation and followed up with ongoing data collection into the future until this study.

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Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you have a hiatal hernia. A hiatal hernia is when organs from your abdomen get pushed up into your chest through a widened opening in the diaphragm. Hiatal hernias are frequently repaired by repairing the widened defect that leads to your stomach or other organs moving up into your chest. Further, the repair is strengthened by performing a fundoplication, which is where the top of the stomach is wrapped around the esophagus, which also is designed to prevent or treat reflux disease. This wrap helps to anchor the stomach in place and prevent the hernia from recurring. Sometimes a stomach wrap, or fundoplication, can be performed too tight or too loose.

We would like to use a new technology called EndoFLIP to test the tightness of hiatal hernia repair and the wrap around the junction of your esophagus and your stomach. The EndoFLIP technology involves a balloon that can read the amount of pressure and diameter or surface area within your esophagus at different points. It is performed using an endoscope, or camera, that is placed in your esophagus via your mouth. This will be done in the operating room at the time of your surgery. By doing this, we hope to be able to determine the ideal tightness of a hiatal hernia repair and a stomach wrap. The tightness of either can affect post-operative reflux and swallowing.

The purpose of this research study is to:

- Assess the effect of hiatal hernia repair and fundoplication on the distensibility (how much the esophagus opens when pressure occurs inside the esophagus, such as with swallowing) of the esophagus and stomach junction using EndoFLIP technology.
- Assess for a correlation between this distensibility and post-operative gastroesophageal reflux and dysphagia (trouble swallowing).

A target of 50 subjects will participate in this study.

WHAT WILL HAPPEN DURING THE STUDY?

Your participation in this study will last approximately 6 months and will include three visits to the study center (Carolinas Medical Center) after surgery. Two of these follow-up visits are standard whether you are in the study or not. The third follow-up visit at 6 months is not standard, but you will not be charged for that visit. You will go through standard post-operative care and answer 2 surveys regarding your symptoms at each of these follow-up visits. You will also be asked to answer 2 surveys at your pre-operative visit.

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Screening

Before any study-related tests and procedures are performed, you will be asked to read, sign and date this consent document. The following screening tests and procedures will then be performed to determine if you qualify to take part in this study:

- Must be at least 18 years of age
- Must be undergoing elective surgery
- If you have a pre-operative esophageal manometry (a test used to identify problems with movement and pressure in the esophagus), you cannot have signs of as spastic esophageal disorders or specific cases of poor motility (ability to move) of your esophagus.
- If there is insufficient esophageal length in which case a standard fundoplication (stomach wrap) cannot be performed or a Collis gastroplasty (esophageal lengthening surgery) is required, you would not be able to continue in the study.
- The other study requirements are our standard work-up prior to hiatal hernia repair and would have already been performed (endoscopy, x-ray studies, possible pH testing, and possible manometry).

If you qualify to take part in this study and go on to receive the study treatment, then the following will happen:

Study Treatment

This study has two phases. If you are in the first phase, your surgeon will not be able to see the results of your EndoFLIP assessment, but the data will be collected to be compared to your postoperative symptoms. If you are in the second phase, your surgeon will be able to see the results of the EndoFLIP assessment and make any adjustments to the hiatal hernia repair or the stomach wrap that are felt to be necessary. The study is blinded to subjects, which means you will not know which group you were in, but the surgeon will know. If you are in the first phase (whose data is not being analyzed by the surgeon in the operating room), your data will be blinded from the surgeon as well until your 6-month office visit. In case of an emergency, however, the study doctor can get this information.

You will have the following study visits and undergo the following procedures:

- Initial consultation with completion of 2 pre-operative surveys
- Surgery with additional EndoFLIP assessment in the operating room
- 2-week follow-up appointment with completion of 2 surveys
- 6-week follow-up appointment with completion of 2 surveys
- 6-month follow-up appointment with completion of 2 surveys

After Study Treatment

There are no further study treatments planned after your participation in the study.

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EXPECTATIONS

If you participate in this study, you will be expected to:

- Attend all follow-up visits
- Complete all study surveys

RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

Risks associated with EndoFLIP:

- Sore throat
- Allergic reaction (including life-threatening reaction)
- Bleeding
- Cardio-respiratory (heart and lung) complications
- Dental (tooth) trauma
- Infection
- Pain
- Hole in esophagus (perforation)
- Stomach contents entering the lung (pulmonary aspiration)
- Fainting (vasovagal response)
- Rarely, injury to the esophagus

Allergic Reaction Risks

As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms, or any other side effects, during the study.

Other study risks:

- Questionnaires: The questionnaires used in this study may be upsetting. You do not need to answer any questions that you are not comfortable with.

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- Confidential health information: It is possible that your private health information could be breached. All health information is stored securely, with all dates studied and reported in a de-identified manner.

UNFORESEEN RISKS

There may be other risks that are unknown or unforeseeable. Tell the study doctor or study staff right away if you have any problems.

BIRTH CONTROL RESTRICTIONS

There are no specific birth control or pregnancy restrictions. However, we would not perform elective surgery if you were pregnant.

ALTERNATIVES TO PARTICIPATION

You do not have to be in this study to receive treatment for your hiatal hernia. If you do not wish to participate you can undergo the same planned surgery without partaking in the study. Your pre-operative work-up and post-operative follow-up will be the same except for the 6-month follow-up visit.

Please talk to the study doctor about your options before you decide whether you will take part in this study.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

BENEFITS

You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Information learned from the study may help other people in the future.

COMPENSATION FOR PARTICIPATION

You will not be paid for being in this study.

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STUDY STAFF PAYMENT/FINANCIAL DISCLOSURE

None of the doctors asking you to participate in this study has received or will receive money or other benefits for personal use due to this study from Medtronic, the company that sells EndoFLIP. However, Medtronic has provided support with money and equipment for this study to a research fund, foundation, educational institution, or other organization with which the study doctor or study staff is associated.

Medtronic may give the participating doctors or study staff money or other benefits for personal or professional use not related to this study. You may ask the doctor any questions necessary to assure yourself that these benefits have not overly influenced the doctor's request for you to take part in this study. The decision whether to enroll in the study is yours alone. You should have all the information you need to be comfortable with your decision.

CONFIDENTIALITY

The records of this study will be kept private. If any report about this research is published, we will not include any information that will make it possible to identify you. However, there is some risk that de-identified data might be re-identified. Also, your record for this study may be reviewed and/or photocopied by Atrium Health or by representatives of the Food and Drug Administration or other government agencies.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

COMPENSATION FOR INJURY

In the event that you are harmed as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner. You do not waive any legal rights by signing this consent form.

If you become ill or are hurt while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need.

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



COSTS

There will be no additional charge to you for your participation in this study. The EndoFLIP procedure and additional 6-month follow-up study visit will be provided at no charge to you or your insurance company.

FUTURE RESEARCH STUDIES

Identifiers might be removed from your identifiable private information collected during this study and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

CLINICALLY RELEVANT RESULTS

Research results that are clinically relevant, including individual research results, will be disclosed to you under these conditions: at your 6-month visit, you can be told if your surgeon was blinded or not blinded and if it impacted your hiatal hernia repair or fundoplication.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the Study Subject Adviser: Pro00040539.

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VOLUNTARY PARTICIPATION / WITHDRAWAL

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not in any way harm your relations with your doctors or Atrium Health. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Atrium Health.

However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or Atrium Health can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.



AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

If you wish to participate in this research study, you

_____

Printed Name of Research Subject

must sign this Authorization. By signing this Authorization, you give all healthcare providers, including Atrium Health, permission to use or disclose (release) your protected health information, both past and present, for the research study described here:

Esophagogastric junction distensibility during hiatal hernia repair

The protected health information that we may use or disclose (release) for this research may include all information in your medical record, such as results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.

The health information listed above may be used by and/or disclosed (released) to:

- Study investigator and research staff
- Regulatory or other governmental authorities of the United States or other countries based on this study
- Other persons or agents authorized by the study sponsor
- Atrium Health employees
- Other persons or agencies as required by law or allowed by federal regulations, and/or;
- Advarra Institutional Review Board (Advarra IRB).

Atrium Health is required by law to protect your protected health information. By signing this Authorization, you authorize Atrium Health to use and/or disclose (release) your protected health information for this research study. Those persons who receive your protected health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your protected health information with others without your permission, if permitted by laws governing them. Your protected health information may then no longer be protected by the Privacy Rule.

Please note that you do not have to sign this Authorization, but if you do not, you may not receive research-related treatment through this study. However, Atrium Health may not condition (withhold or refuse) your other Atrium Health providers treating you on whether you sign this Authorization. You may change your mind and withdraw (take back) this Authorization at any time, except to the extent that Atrium Health has already used or disclosed your protected health information based on

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this Authorization. To withdraw this Authorization, you must write to the Study Doctor at the address listed on the first page of this form.

No publication or public presentation about the research described above will reveal your identity without another Authorization from you. If all protected health information that does or can identify you is removed, the remaining information will no longer be subject to this Authorization or federal rules (such as the Privacy Rule) and may be used or disclosed for other purposes.

When the research for which the use or disclosure is made involves treatment and is conducted by Atrium Health: To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete.

At the conclusion of the research study and at your request, you generally will have access to your protected health information. Access to your protected health information in a medical record is described in the Notice of Privacy Practices provided to you by Atrium Health.

When conducting research, the data and results may be used or disclosed for further treatment outcomes research or to research a secondary result. This Authorization will remain in effect after the end of the current study, and any future related secondary study unless it is revoked by the you in writing as described above.

_____

Signature of Research Subject

_____

Printed Name of Research Subject

_____

Date

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PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

❒ **YES** (If yes, please complete the information below)

❒ **NO**

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____

Signature of Research Subject Date Time

_____

Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____

Signature of Person Explaining Consent Date Time

_____

Printed Name of Person Explaining Consent

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