Permission to Take Part in a Human Research Study

Title of Research Study: Feasibility Assessment of A Novel Wearable Skin Sensor for Post-Operative Monitoring Following Anterior Cervical Discectomy and Fusion (ACDF)

Investigator: Alpesh Patel, MD

Supported By: This research is supported by Northwestern University.

Financial Disclosure: Dr. Xu, an investigator on this study, is an inventor of the device being tested in this study and is a co-founder of the company, Sonica LLC that is sponsoring this study and could benefit from the results of this study. Dr. Xu is compensated for consulting activities performed in relation to this device. ***In addition, Northwestern University owns the invention being tested in this study and may benefit financially from it in the future.***

Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are over 18 years old and you are planning to have a procedure to remove the diseased disc between your neck vertebrae and fuse the bones together for stability in your upper spine, also known as anterior cervical discectomy and fusion (ACDF).

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Difficulty swallowing (dysphagia) and changes to your voice(dysphonia) in addition to a less flexible range of motion in your neck are common complications after anterior cervical spine surgery. Current ways of measuring dysphagia, dysphonia, and cervical range of motion are cumbersome and have not been widely tested. Wearable sensors are a non-invasive and easy-to-use way to monitor dysphagia, dysphonia, cervical range of motion, and overall recovery progress after surgery. We think that these sensors will help surgeons assess recovery as well, or better, than the current methods.

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How long will the research last and what will I need to do?

We expect that you will be in this research study for 2 weeks. You will be asked to wear a skin sensor for 2 weeks following discharge after surgery and complete a survey about your experience once you have returned to clinic for your 2 week post-operative visit.

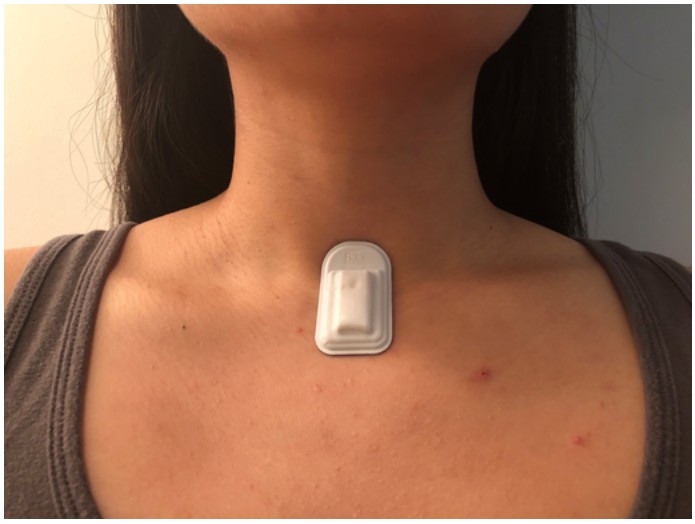

Fig.1 : The placement and size of the ADAM sensor can be seen above.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?

The primary risk associated with participation is discomfort from the skin sensor placed on the suprasternal notch following surgery. Any discomfort or irritation caused by the sensor that you deem excessive may lead the study team to remove the sensor prior to discharge or prior to the 2-week post-operative visit at your discretion.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include helping surgeons develop better ways of monitoring recovery after anterior cervical spine surgery

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled. Your alternative to participating in this research study is to not participate.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

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Whom can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 312-472-6024.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?
We expect about 30 people here will be in this research study.

What happens if I say "Yes, I want to be in this research"?
You will be scheduled for surgery the same way as if you were not in a research study. On the day of your surgery, your surgery will be done the same way as if you were not in a research study. After your surgery is complete, but before you are taken out of the operating room, your surgeon will place a wearable sensor on your suprasternal notch, the "dent" where your neck and torso meet. The sensor will be attached using an adhesive that is designed to be non-irritatingthat is commonly used in other adult and pediatric procedures. The sensor will measure heart rate, respiratory rate, swallow count, talking time, energy expenditure, neck specific motion, and body orientation.

You will wear the sensor all the time for approximately 2 weeks. The sensor is waterproof and should be worn without removal for any activities including bathing and sleeping. While wearing the sensor, you will be asked to replace the adhesive strip securing the sensor to your skin once every 24 hours for the first 14 days of the study. Adhesive strips will be provided to you prior to discharge from the hospital and a member of the study team will instruct you on how to replace the adhesive strip properly. Following this period, you will be asked to complete an online survey about your experience wearing the sensor. If you feel uncomfortable or unwilling to answer any question as a part of your experience, you may choose to skip the question at anytime and move on to the next one. At your 2-week postoperative visit your surgeon will conduct a standard-of-care physical exam & the sensor will be removed by gently pulling off the adhesive and removing any residue with an alcohol wipe.

During your participation in the study, an investigator may ask to record images or video of the device while it is placed on your body. The recordings will be used to demonstrate how the device performs while it is operating and to correlate visuals of certain actions (i.e. swallowing, coughing, rotation of the head) with anatomical data being recorded by the device. Investigators will take ample precautions to not include identifiable body features or markings as part of these recordings, and in the event that identifiable features are recorded they will be obscured before being shared with individuals outside the study team. The video recording component of this study is entirely optional and is not required for you to participate.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to tell your surgeon or research team if the sensor falls off prior to your 2 week clinic visit.

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What happens if I say "Yes", but I change my mind later?

You can leave the research at any time; it will not be held against you. If you decide to leave the research, contact the investigator so that the investigator can arrange for you to visit the clinic and have the sensor removed.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

Detailed Risks: Is there any way being in this study could be bad for me?

You may experience skin irritation at the site of the sensor placement. This may be uncomortable enough to require early removal of the sensor. You also may experience minor pain during sensor removal.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution

All data for this study will be stored on password-protected computers within the health system and will only be accessable to approved members of the study team. Video recordings obtained as part of this study, should you choose to authorize collection of this data, will be stored in the same password-protected location.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

If you choose to participate in the optional video recording portion of this study, you may choose to limit sharing of the video recordings obtained to members of the immediate study team only. You may also choose to authorize sharing these recordings with members of the scientific community, for which the study team will undertake every effort to insure identifiable features are obscured.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if you remove the sensor before your 2-week postoperative visit.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study devices
- Billing information

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH),

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Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.

- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Alpesh Patel, MD
Northwestern University
Department of Orthopaedic Surgery
676 N. St. Clait Street, Ste. 1350

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.

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I agree	I disagree	
_____	_____	The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent