**PROTOCOL TITLE:**
Feasibility Assessment of A Novel Wearable Skin Sensor for Post-Operative Monitoring Following Anterior Cervical Discectomy and Fusion (ACDF)

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## 1.0 Purpose of the Study:

The purpose of this study is to assess the function and reliability of a non-invasive, skin-like electronic sensor. We hypothesize that this skin sensor will address an unmet need to wirelessly and noninvasively monitor and characterize the recovery process in post-operative patients who have undergone anterior cervical discectomy and fusion (ACDF). Specifically, we will validate the use of the sensor in this patient population through monitoring of key physiological signals in the recovery process, including heart rate, respiratory rate, swallow count, talking time, energy expenditure, neck specific motion, and body orientation.

## 2.0 Background / Literature Review / Rationale for the study:

Dysphagia, dysphonia, and loss of cervical range of motion (ROM) are common complications after anterior cervical spine surgery, specifically anterior cervical discectomy and fusion (ACDF). Despite their clinical importance, studies on the treatment and/or prevention of these complications are limited due to the lack of valid and reliable outcome measures. The majority of research is found in the otolaryngology literature and has focused on disease pathophysiology, diagnosis, and therapy.

Dysphagia and dysphonia are widely measured by patient self-reported questionnaires, including the MD Anderson Dysphasia Inventory and SWAL-QOL. However, these validated outcome tools are cumbersome to complete and, therefore, have not been widely accepted into clinical practice, including in post-operative ACDF patients. The Bazaz score, a subjective questionnaire that has not been validated in the literature, has also been used to evaluate dysphagia after ACDF. Assessment using the Bazaz score is based on clinical examination, with the surgeon listening to the patient's voice and documenting hoarseness in

the post-operative period. Recently, new patient-centered outcomes, the Eating Assessment Tool (EAT-10) and Voice Handicap Index (VHI-10) have been developed. Both EAT-10 and VHI-10 have excellent validity and reliability in evaluating dysphagia and dysphonia, respectively, in post-operative ACDF patients and can be used to document the initial dysphagia or dysphonia severity and monitor the treatment response in people with a wide array of swallowing and voice disorders. However, these methods of evaluating dysphagia and dysphonia alone offer limited information about the severity and characteristic of dysphagia or dysphonia and do not provide continuous monitoring of swallowing or speaking function throughout the post-operative period.

The wearable sensors under investigation in this study offer a novel, non-invasive, and easy-to-use way to monitor dysphagia, dysphonia, cervical ROM, and overall recovery progress in post-operative ACDF patients. Previous testing has demonstrated the ability of our sensors to monitor vital signs (including heart rate and respiratory rate), swallow count, talking time, energy expenditure, cervical neck movement, and body orientation. Sensor-measured swallow count and talking time, in conjunction with EAT-10 and VHI-10 scores, can provide a comprehensive view of the progression of dysphagia and dysphonia. Cervical neck movements measured by the sensor can enable continuous assessment of cervical ROM. Other general metrics captured by the sensors, including heart rate, respiratory rate, energy expenditure, and body orientation can provide other meaningful measures of recovery in post-operative ACDF patients. Our sensors have also received positive feedback from patients and physicians on their comfort, ease of use, and application, further demonstrating the potential value of these sensors in improving the quality of post-operative care for ACDF patients.

## 3.0 Inclusion and Exclusion Criteria:

**Inclusion criteria**:

- Patients who have undergone anterior cervical discectomy and fusion (ACDF) for one or more levels for a diagnosis of cervical radiculopathy or myelopathy
- Scheduled to return to the MSK orthopaedic clinic for a post-operative appointment
- Over 18 years of age at the time of consent

**Exclusion criteria**:

- Patients that underwent a revision of previous ACDF surgery at one or more operative levels
- Surgeries performed for a traumatic or oncologic etiology
- Members of vulnerable populations (i.e. prisoners, pregnant women)
- Patients unable or unwilling to consent to participate in the study

## 4.0 Sample Size:

We anticipate 30 individuals will participate at Northwestern Memorial Hospital in this study and will take approximately 6 months to recruit.

## 5.0 Research Locations:

The enrollment and data collection for this study will take place in the MSK orthopaedic clinic at 259 E. Erie, Ste. 1300 and participants will wear the skin sensor during the intervening week between discharge and post-operative follow up visit with their surgeon.

## 6.0 Multiple sites:

N/A

## 7.0 Reliance Agreements/Single IRB:

N/A

## 8.0 Procedures Involved:

Once eligible participants have endorsed the informed consent and HIPAA authorization, they will undergo their planned ACDF procedure at NMH. During closeout of the procedure the attending surgeon will then place the skin sensor into position on the suprasternal notch. Collection of the physiological data elements expanded below will begin as the participant is transferred to the post-anesthesia care unit:

- Heart rate
- Respiratory rate
- Cervical axis range of motion
- Talking time
- Swallowing frequency
- Caloric consumption
- Body positioning

The participant will continue to wear the skin sensor during the intervening 2 weeks until they return to clinic for their standard-of-care visit with the attending surgeon. Upon returning to clinic the surgeon will perform their assessment of the participant's progress in recovery and the skin sensor will be removed for download of the data elements collected between discharge and the participant's return to clinic.

An optional component for video recording of the sensor device functioning once applied will be offered to participants in order to assist with data analysis and development of figures and/or diagrams mapping the data obtained by the sensor to physiological behavior recorded in real time. This component will not

be obligatory for participation and individuals wishing to enroll in the study without consenting to video recording will be instructed to indicate their refusal on the relevant section of the consent form.

The participant will then be asked to complete a brief questionnaire within the study associated REDCap project regarding their experience/satisfaction wearing the sensor following their surgery. The sensor data and qualitative surveys will be compared to the clinical report provided by the attending surgeon as part of the terminal analysis.

## 9.0 Incomplete Disclosure or Deception:

N/A

## 10.0 Recruitment Methods:

Potential participants for this study will be identified by Dr. Alpesh Patel and Dr. Wellington Hsu using the surgical schedule to monitor for upcoming candidates for ACDF surgery. Once the surgery has been confirmed for the schedule, eligible participants will be approached prior to surgery to introduce the study and gauge interest to participate, where after those patients who agree to participate will be asked to sign a copy of the informed consent and HIPAA authorization form.

## 11.0 Consent Process:

Eligible participants identified by the study team and attending surgeon will be approached in the pre-operative holding area on the day of surgery to be introduced to the study and have any questions regarding participation answered. Risks, benefits, and alternatives of participation in the study as well as the ability to withdraw participation at any time will be discussed with the participant. Once they have agreed to participate in the study, they will be provided with an electronic copy of the informed consent and HIPAA authorization form via the REDCap application to review and endorse. All participants will be offered the opportunity to have a PDF copy of the endorsed consent emailed to the address on file at any time.

## 12.0 Financial Compensation:

There is no payment for participating in this study and the risks of the study are minimal.

## 13.0 Audio/Video Recording:

N/A

## 14.0 Potential Benefits to Participants:

There may be no benefit from being in this research, but there is hope that what we learn may be helpful to future patients or society in general.

## 15.0 Risks to Participants:

The risks of the study are minimal. 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 the participant deems excessive may lead the study team to remove the sensor prior to discharge or prior to the 2-week post-operative visit at the participant's discretion.

An additional risk is a potential loss of participant privacy from the data collected during the conduct of the study. The study team has taken measures described below to minimize this risk and all study data will be de-identified at the earliest possible opportunity to further protect the participants.

## 16.0 Provisions to Protect the Privacy and Confidentiality of Participants and the Research Data:

All data elements that are PHI identifiers will be stored separately from randomly generated participant ID numbers on a secure, encrypted NU SharePoint site and/or a REDCap project. Access to participant information will be restricted only to the PI, co-I, and members of the IRB approved authorized personnel list for the study. Participants will be able to ask any questions regarding the research before consent & the research staff will be transparent with explaining the study and explaining the timeline for participants.

The importance for confidentiality of the participant's protected health information (PHI) is recognized. PHI will be collected and transferred only where necessary. Where possible, participants will be identified only by generic ID's. SSL encryption will be used with all internet web pages to ensure confidential form submission. For data files that need to be transferred electronically, the information will be encrypted prior to transport. The web servers and associated database servers will be housed on dedicated housed with NU SharePoint. These will be physically protected from intrusion as well as natural disasters. The secure facilities are protected electronically by hardware and software firewalls, intrusion detection software, anti-virus scans, and 24x7 monitoring by onsite professionals.

## 17.0 Data Monitoring Plan to Ensure the Safety of Participants:

N/A

## 18.0 Data, and if applicable, Specimen Banking:

Confidentiality of patient information will be maintained using the REDCap database and NU SharePoint site associated with this study. Access to this database will only be available to the PI, co-I, and members of the IRB approved authorized personnel list. All study data will be maintained in a de-identified manner for a period of no less than 3 years following completion of data collection per NU policy. The data will thereafter be destroyed in its entirety via electronic deletion.

## 19.0 Data Sharing:

N/A

## 20.0 Qualifications to Conduct Research and Resources Available:

The PI, Dr. Alpesh Patel, and the Co-I, Dr. Steven Xu, are among the foremost experts in their field and have decades of experience in their respective practices of orthopaedic surgery and biomedical engineering. The study team and research staff to be enlisted for this project have considerable experience with all aspects of study conduct and a history of successful publication.

All components of the study intervention will be supported by the PI, co-I, research staff, and clinical staff in facilities at Northwestern Memorial Hospital.