A Prospective Study of the Role and Accuracy of Consumer-Facing Wearable Technology in Gastrointestinal Endoscopy

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Study Title: A Prospective Study of the Role and Accuracy of Consumer-Facing Wearable Technology for Patient Monitoring in Gastrointestinal Endoscopy

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Protocol Investigator Signature Page

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PROTOCOL VERSION: 15/JUL/2021 Version (1.0)

STUDY CENTER: Mayo Clinic Rochester

I, the undersigned, have read and understand the protocol specified above and agree on its content. I agree to perform and conduct the trial as described in the protocol and in accordance with applicable laws and regulations. In addition, when applicable, I agree to enlist sub- investigators who also agree to perform and conduct the trial as described in the protocol.

_____

Date

Principal/Coordinating Investigator (Print Name)

_____

Principal/Coordinating Investigator (Signature) **Date**

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LIST OF ABBREVIATIONS

CFR	Code of Federal Regulations
CRF	Case Report Form
DSMB	Data and Safety Monitoring Board
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
PHI	Protected Health Information
PI	Principal Investigator
SAE	Serious Adverse Event/Serious Adverse Experience
SOE	Schedule of Events
SOP	Standard Operating Procedure
IQR/M	Interquartile Range/Median

Study Summary

Title	**A Prospective Study of the Role and Accuracy of Consumer-Facing Wearable Technology for Patient Monitoring in Gastrointestinal Endoscopy**
Running Title	Wearable Technology Endoscopy
Title Acronym	Wearable Tech
IRB Protocol Number	21-007738
Phase	Prospective study
Methodology	Subjects who are eligible will have two consumer-facing wearable smart devices placed before scheduled endoscopy. Data from the devices will be downloaded after the procedure and analyzed, Patients and providers will complete a survey regarding their experience.
Overall Study Duration	6 months Recruitment and Active study execution, 3 months analysis and 3 months publication. Total: 12 months
Subject Participation Duration	Up to 60 days screening prior to study procedure, duration of the procedure itself, and completion of a survey within 14 days of procedure date
Objectives	Measure the accuracy and safety of wearable technology in patients undergoing endoscopic gastrointestinal procedures with sedation. Assess patient and provider preferences regarding wearable technology.
Number of Subjects	Five hundred (500)
Diagnosis and Main Inclusion Criteria	Subjects over 18 years of age who are scheduled to undergo an endoscopic procedure with sedation
Study Device	Consumer-facing wearable smart devices(examples include Apple Watch Series 6, FitBit Versa, The QardioCore ECG ambulatory monitoring device)
Reference Modality	Sedation/Anesthesia record
Statistical Methodology	All continuous variables will be expressed as mean and standard deviation. Categorical variables will be expressed as percentages.

1 Introduction

This document is a clinical research protocol relating to a prospective study of the role and accuracy of consumer-facing wearable technology in gastrointestinal endoscopy. The described study will be conducted in compliance with this protocol, applicable United States government regulations and Mayo Clinic policies and procedures.

1.1 Background

The term wearable technology encompasses a wide spectrum of devices worn on or near a person. (1) Market research suggests that one in five Americans are users of wearable technology with the market currently valued at over 30 billion dollars annually. (2,3) These devices have the ability to record physical information, ranging from heart rate to pulse oximetry, as well as audio and video. These devices are often marketed to improve health and well-being, and there has been significant interest in their use to diagnose, monitor and treat disease. (4) However there remain significant issues regarding the use of wearable technology (5). Rigorous studies of consumer-facing products have shown significant issues with accuracy and reliability. (6,7) Beyond simply inaccurate data, there have also been reports of unintended interference from consumer wearables, resulting in disabled clinical devices. (8) This is in addition to questions regarding the medicolegal, ethical and practical implications of recording data, audio, and video during a clinical encounter.

1.2 Investigational Device

Consumer-facing wearable smart watches are the latest is wearable watch technology and have the ability to measure heart rate, respiratory rate, single-lead electrocardiography, and blood oxygen saturation. The devices are widely available in retail stores and often advertised as the future of health. The devices have been cleared by the FDA and are already permitted inside procedure procedural areas at Mayo Clinic.

Consumer-facing wearable smart watches are the latest is wearable watch technology and have the ability to measure heart rate, respiratory rate, single-lead electrocardiography, and blood oxygen saturation. The devices are widely available in retail stores and often advertised as the future of health. The devices have been cleared by the FDA and are already permitted inside procedure procedural areas at Mayo Clinic. Additional FDA-approved accessories are available to increase the monitoring capabilities of smart devices. The QardioCore is one such accessory that allows for more detailed ambulatory electrocardiography monitoring in addition to other vital signs like skin temperature and respiratory rate.

1.3 Clinical Data to Date

Currently there is no available literature that systemically evaluates the performance of these smart devices within a controlled healthcare environment. Our study would provide the first prospective evaluation of its use in this setting.

1.4 Study Rationale and Risk Analysis (Risks to Benefits Ratio)

1.4.1 Study Rationale

We hope to further characterize and define the role of consumer-facing technology in the clinical environment by focusing on device accuracy when compared to standard clinical monitoring in patients undergoing an endoscopic procedure. We will generate and answer questions related to these devices that have not yet been explored in the gastroenterology literature. We will provide a timely and much-needed framework that addresses both practical and theoretical considerations around a technology that has become increasingly relevant to patients.

This study will specifically address whether consumer facing wearable devices can serve as patient monitoring devices in a comparable manner to the current gold standard in the procedural suite. In addition to accuracy, we will assess whether certain procedural maneuvers interfere with device data collection. This information will be relevant to patients, providers and healthcare institutions and can help inform policy regarding these devices.

1.4.2 Anticipated Risks

Patients would be undergoing endoscopic procedure that was clinically indicated with inherent risk of the procedure but minimal additional risk with placement of a watch in the pre-operative area. Wearable technologies (e.g. smartphones, smart watches) are already permitted in the endoscopy suite, so this protocol would not significantly alter standard of care.

There is a minimal risk of allergic reaction to a component of the watch or band. The devices may be re-used for multiple procedures or handled by study personnel and therefore carries the risk of transmitting infection. Precautions will be taken to ensure that all devices are cleaned similarly to reusable devices in the procedural suite. As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk. As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

1.4.3 Potential Benefits

If successful and reliable, the use of mass-produced consumer devices could be used in locations where traditional cardiopulmonary monitoring devices are unavailable. Alternatively, inaccurate device readings would have medicolegal implications of which patients, providers and healthcare systems should be aware. This information can help inform institutional policy.

1.5 Anticipated Duration of the Clinical Investigation

The overall duration of the study is estimated to be twelve months. 6 months recruitment and active study execution, 3 months analysis and 3 months for publication.

2 Study Objectives

2.1 Primary Objective

Measure the accuracy of wearable technology for patient monitoring compared to currently used equipment in patients undergoing gastrointestinal endoscopic procedures with sedation

2.2 Secondary Objective

1. Assess patient and provider preferences regarding wearable technology
2. Outline current practices and policies regarding wearable devices at Mayo Clinic

3 Study Design

3.1 General Design

We will perform a prospective, non-blinded, exploratory study to assess the accuracy and safety of smart technology in the endoscopy suite for patients undergoing gastrointestinal endoscopic procedures with sedation. We will also simultaneously perform an assessment of patient and provider preferences using narrative-driven, qualitative evaluation.

Patients will be identified by reviewing daily procedure listings on endoscopy units on Alfred 6, Gonda 2 and Gonda 9. Recruitment will occur over the phone the day prior to a procedure, or the pre-procedure areas on the day of the procedure. Patients who meet inclusion criteria and consent to participation in the study will be provided the smart devices. The devices will be secured to the wrist and torso by study personnel prior to administration of sedatives. The smart watch will be programmed to record respiratory rate, heart rate, and oximetry using native, first party device applications. These applications include *Blood Oxygen* (measures oxygen saturation), *ECG* (records single lead ECG), *Heart Rate* (heart rate), and *Health* (which logs respiratory rate while sleeping). The QardioCore ECG device will measure a single-lead ECG, heart rate, skin temperature, and respiratory rate.

The patient will undergo his or her scheduled procedure. Patients, proceduralists and anesthetists will not be blinded to their enrollment as the devices will be visible. On completion of the procedure, the devices will be removed by the study coordinator and data downloaded onto a central device for analysis. Procedural information will be extracted from the operative note, sedation record, and anesthesia encounter in EPIC. The day after the patient's procedure, a survey will be submitted to them electronically which will remain open until 14 days after

the procedure. A en electronic reminder will be sent if uncompleted at 7 days, followed by a telephone reminder if not completed at 13 days. There will be no additional patient follow up after completion of the survey. At study completion, a survey will be sent to involved proceduralists and anesthetists.

3.2

Figure 1: Study Design

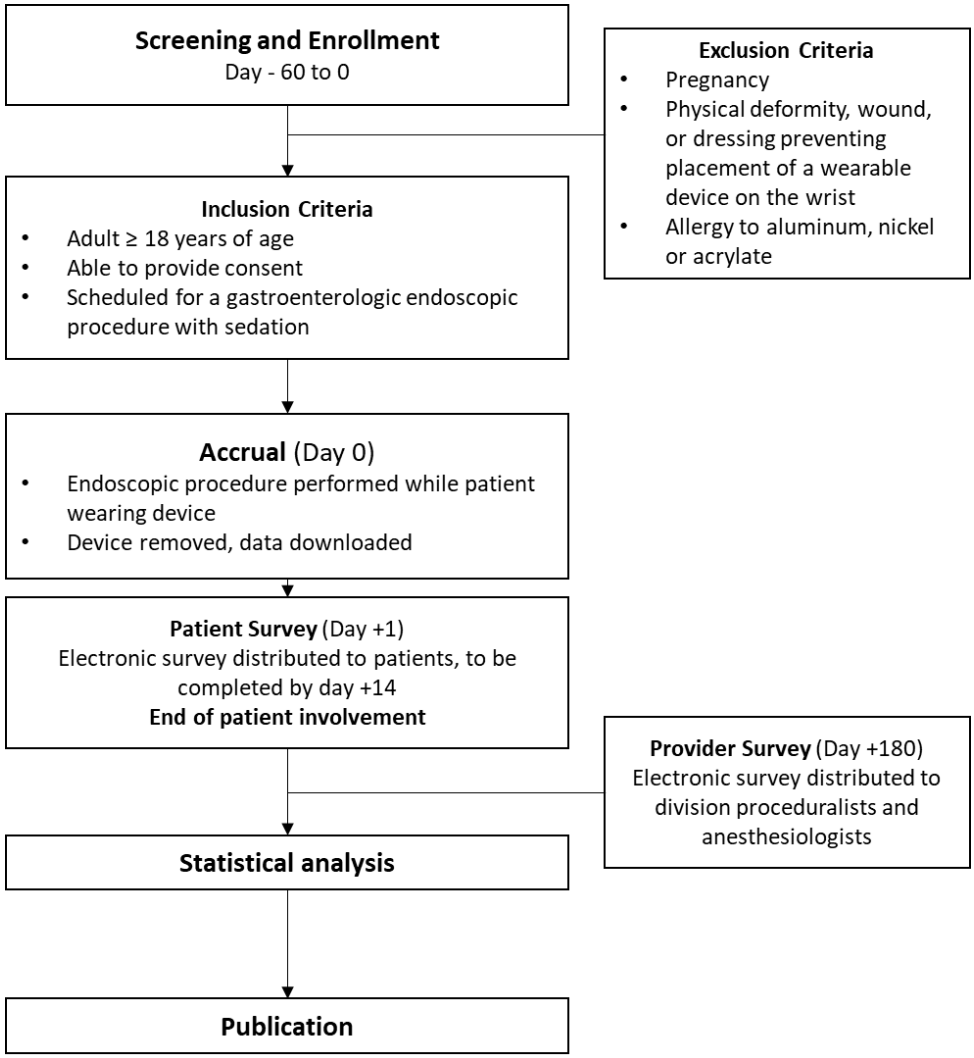

Table 1. Schedule of Events

	Baseline Screening & Enrollment Visit 1 Days -60 to 0	**Accrual: Study Intervention** Visit 2 Day 0	**Patient Survey** Visit 3 Day +1 to +14	**Provider survey** Days 0 to 180
Inclusion/ Exclusion	X	X (if not performed earlier)		
Device(s) Placement/ Recording		X		
Patient Survey			X	
Provider Survey				X

3.3 *Visit Descriptions*

3.3.1 Baseline Screening & Enrollment (Visit 1)

Eligible study participants will be screened, approached, and consented for the study. The screening and enrollment process may be performed remotely via telephone prior to the procedure date, or performed in the pre-procedure area on the day of procedure. Relevant study material will be provided to the patient at this time.

3.3.2 Clinical Procedure/Accrual (Visit 2)

The devices will be secured to the wrist and torso by study staff prior to administration of sedatives. The devices will be programmed to record respiratory rate, heart rate, oximetry, skin temperature as well as single-lead ECG. The patient will undergo his or her scheduled procedure. On completion of the procedure, the devices will be removed by the study staff will download data onto a central device for analysis.

3.3.3 Survey (Visit 3)

The day after the patient's procedure, a survey will be submitted to them electronically which will remain open until 14 days after the procedure. An electronic reminder will be sent if uncompleted at 7 days, followed by a telephone reminder if not completed at 13 days. There will be no additional patient follow up after completion of the survey. At study completion, a survey will be sent to involved proceduralists and anesthetists. will be provided electronically to patients to assess their satisfaction and opinions regarding their experience.

3.4 Primary Safety Endpoints

There are no specific primary safety endpoints pertaining to the study given the non-invasive intervention. Wearable technology like smart watches and smart phones are already permitted within the procedural area.

4 Subject Selection, Enrollment and Withdrawal

All patients who are undergoing gastrointestinal endoscopic procedures with sedation may be eligible for the study. It is anticipated that we will screen up to 1000 subjects and enroll 500 subjects to the study.

4.1 Inclusion Criteria

1. Adults over 18 years of age
2. Undergoing gastrointestinal endoscopic procedures with sedation
3. Able to give appropriate consent to the study or have an appropriate representative to do so.

4.2 Exclusion Criteria

1. Pregnancy
2. Physical deformity, wound, or dressing preventing placement of a wearable device on the wrist or torso
3. Allergy to aluminum, nickel or acrylate

4.3 Subject Recruitment, Enrollment and Screening

Potential study subjects will be screened, recruited and enrolled by the principal and co-investigators, along with trained research personnel who are able to gain consent. Relevant material regarding the study will be handed to the subject for review.

4.4 Early Withdrawal of Subjects

4.4.1 When and how to Withdraw Subjects

The subjects will undergo the clinically indicated procedure with the wearable devices. Early withdrawal would include removal of the devices prior to procedure completion, which can be performed at the discretion of the patient or clinical providers at any point.

4.4.2 Data Collection and Follow-up for Withdrawn Subjects

Withdrawn subjects will be recorded in the study record in order to calculate the withdrawal rate. There will be not further utilization of any subject related data.

5 Statistical Plan

5.1 Sample Size Determination

Power analysis not performed as this study is descriptive and we do not plan to perform any statistical testing.

5.2 Statistical Methods

Descriptive Statistics
Baseline values for demographic, clinical, and outcome will be tabulated for the study subjects. Continuous variables will be expresses as mean and standard deviation. Categorical variables will be expressed as percentages.

We will measure the rate of concordance between device detection and documentation in anesthesia record (# of events recorded on wearable device / events noted on anesthesia record). Events to be recorded include tachycardia (HR > 100), bradycardia (HR < 60), desaturation (peripheral O2 saturation < 88%), any arrythmia, and tachypnea (RR > 18).

We will also calculate the difference in maximum and minimum heart rate, respiratory rate, and oxygen saturation recorded by the watch compared to the sedation record.

Handling of Missing Data
Subjects with missing or incomplete data will be noted but will not include in the final analysis. Available information regarding these patients will be reported separately to allow for evaluation of external validity

5.3 Subject Population(s) for Analysis

All subjects who wore the device for the duration of procedure will be included in the analysis.

6 Safety and Adverse Events

Patients will be undergoing endoscopic procedures that are clinically indicated with inherent risk of the procedure itself. There will be minimal additional risk with placement of a smart device in the pre-operative area. Wearable technologies (eg. smartphones, smart watches) are already permitted in the endoscopy suite, so this protocol would not significantly alter standard of care. Therefore, this study will not track any adverse events.

Definitions

Adverse Effect (Event)

Any untoward medical occurrence in a subject involved in clinical study of an investigational device; regardless of the causal relationship of the problem with the device or, if applicable, other study related treatment(s).

Life-threatening adverse effect: Any adverse effect that places the subject, in the view of either the investigator or the sponsor, at immediate risk of death from the effect **as it occurred**. It does not include a reaction that, had it occurred in a more severe form, might have caused death.

Serious adverse effect: An adverse effect is considered "serious" if, in the view of either the investigator or the sponsor, it results in any of the following outcomes:

- death
- a life-threatening AE
- inpatient hospitalization or prolongation of existing hospitalization
- a persistent or significant disability/incapacity
- a congenital anomaly/birth defect.

Unanticipated adverse effect: Any adverse effect, the nature, specificity, severity, or frequency of which is not consistent with the risk information in the clinical study protocol or elsewhere in the current IDE application.

All inclusion and exclusion criteria are set out and there will be no protocol deviation.

7 Data Handling and Record Keeping

7.1 Confidentiality

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study?
- Who will have access to that information and why?
- Who will use or disclose that information?
- The rights of a research subject to revoke their authorization for use of their PHI.

In the event that a subject revokes authorization to collect or use PHI, the investigator, by regulation, retains the ability to use all information collected prior to the revocation of subject authorization. For subjects that have revoked authorization to collect or use PHI, attempts should be made to obtain permission to collect at least vital status (long term survival status that the subject is alive) at the end of their scheduled study period.

7.2 Source Documents

Source data comprise all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.

Source data are contained in source documents. Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial. When applicable, information recorded on the CRF shall match the Source Data recorded on the Source Documents.

Data Management
All data points gathered for the study will remain confidential and only available to designated research personnel. The data will be managed using Excel Subject Tracking.

Data Security and Confidentiality

All collected data points and information will be securely stored in Mayo Clinic issued laptops, desktops or tablets with password encryption. Only study personnel will have access to the study data and information.

7.3 Records Retention

The study team will maintain records and essential documents related to the conduct of the study. These will include subject case histories and regulatory documents.

The study team will retain the specified records and reports during the study and for the longer of the following.

1. As outlined in the Mayo Clinic Research Policy Manual –"Retention of and Access to Research Data Policy" http://mayocontent.mayo.edu/research-policy/MSS_669717,

   OR

2. A period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

8 Study Monitoring, Auditing, and Inspecting

8.1 Study Monitoring Plan

The investigator will allocate adequate time for such monitoring activities. Data safety monitoring plan (DSMP) will be completed after the first subject, then at 3 months and then

annually if required. Delegated study staff will conduct the review. The review will be written up as reports and submitted to IRB for further review if required. The Investigator will also ensure that the monitor or other compliance or quality assurance reviewer is given access to all the study-related documents and study related facilities (e.g., pharmacy, diagnostic laboratory, etc.), and has adequate space to conduct the monitoring visit.

8.2 Auditing and Inspecting

The sponsor-investigator will permit study-related monitoring, audits, and inspections by the IRB, the monitor, and government regulatory agencies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The sponsor-investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

9 Ethical Considerations

This study is to be conducted according to United States government regulations and Institutional research policies and procedures.

This protocol and any amendments will be submitted to a properly constituted local Institutional Review Board (IRB), in agreement with local legal prescriptions, for formal approval of the study. The decision of the IRB concerning the conduct of the study will be made in writing to the sponsor-investigator before commencement of this study.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. This consent form will be submitted with the protocol for review and approval by the IRB for the study. The formal consent of a subject, using the Approved IRB consent form, must be obtained before that subject undergoes any study procedure. The consent form must be signed and dated by the subject or the subject's legally authorized representative, and the individual obtaining the informed consent.

10 Study Finances

10.1 Funding Source

This is an investigator-initiated and investigator-funded study.

11 Publication Plan

The results of the study will be written up and submitted to gastroenterology/endoscopy journals for publication.

12 References

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