East and North Hertfordshire Teaching NHS Trust

Ergonomic evaluation of microscopic ear surgery with exoskeleton: A single site non-blinded study

.

Short Title: Exoskeleton ear

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Study Chief Investigator: Mr A Vijendren
Study Sponsor: East & North Hertfordshire NHS Teaching Trust, Lister Hospital, Coreys Mill Lane, Stevenage, SG1 4AB
IRAS ID: 370819

This protocol has regard for the HRA guidance

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Ergonomic Evaluation of microscopic ear surgery with exoskeleton : a single site non-blinded study

Exoskeleton ear

Study Sponsor	East & North Hertfordshire NHS Teaching Trust Lister Hospital, Coreys Mill Lane, Stevenage, Hertfordshire, SG1 4AB United Kingdom Telephone: 01438 314333
Chief Investigator	Mr Ananth Vijendren ENT 01438288019 Email: Ananth.vijendren1@nhs.net
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Date:	*18.05.2026*
Amended:	

Protocol Signature Page

Ergonomic Evaluation of microscopic ear surgery with exoskeleton : a single site non-blinded study

Protocol version: 2.0
Version date: 18.05.2026

Approved by Chief Investigator:



Ananth Vijendren, BM MRCS MRCS (ENT) FRCS (ORL-HNS) PhD

Date: 18.05.2026

Investigator's Agreement

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor, East & North Hertfordshire NHS Trust.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.



Ananth Vijendren, BM MRCS MRCS (ENT) FRCS (ORL-HNS) PhD 18.05.2026

Trial Administration

Chief Investigator	Name : Ananth Vijendren Department : ENT Address : Lister Hospital, East and North Herts NHS Teaching Trust, Coreys Mill Lane, SG1 4AB, Stevenage Tel:01438288019 Email: Ananth.vijendren1@nhs.net
Co-Investigators	Name Dr Fabio Castro Department Lecturer, Institute of Sports Address : University of Hertfordshire Email: f.castro@herts.ac.uk
Co-Investigators	Name : Dr Anushka Ghosal Department : ENT Address : Lister Hospital, East and North Herts NHS Teaching Trust, Coreys Mill Lane, SG1 4AB, Stevenage Email: anushka.ghosal@nhs.net
Co-Investigators	Name : Mr Tobias Huckle Department: Institute of Sports Address : University of Hertfordshire Email: th23aar@herts.ac.uk
Co-Investigators	Name : Mr Panos Dimitriades Department : ENT Address : Lister Hospital, East and North Herts NHS Teaching Trust, Coreys Mill Lane, SG1 4AB, Stevenage Email: p.dimitriadis@nhs.net
Co-Investigators	Name : Ms Chloe Iliana Langston Department: Institute of Sports Address : University of Hertfordshire Email: chloe.langston@icloud.com

Co-Investigators	Name : Abigail Louise Ripper Department: Institute of Sports Address : University of Hertfordshire Email: abi.ripper@gmail.com
Co-investigators	Name : Dr Amit Pujari Department: Institute of Sports Address : University of Hertfordshire Email: a.pujari@herts.ac.uk
Trial Coordinator	Name : Toral Odedra Department : Research & Development Office Address : Lister Hospital, East and North Herts NHS Teaching Trust, Coreys Mill Lane, SG1 4AB, Stevenage Email: toral.odedra@nhs.net

Protocol contributors

[Idea and concept]	Name : Ananth Vijendren Department : ENT Address : Lister Hospital, East and North Herts NHS Trust, Coreys Mill Lane, SG1 4AB, Stevenage Tel:01438288019 Email: Ananth.vijendren1@nhs.net
[data recordings]	Name Dr Fabio Castro Department Lecturer, Institute of Sports Address : University of Hertfordshire Email: f.castro@herts.ac.uk

Protocol Synopsis

Abstract

Study Title	Ergonomic Evaluation of microscopic ear surgery with exoskeleton : a single site non-blinded study
Short Title	Exoskeleton Ear

Type of Trial	Single-site non-blinded cross-over prospective cohort study
Study Period	12 months
Objectives	1. To investigate the effects of the exoskeleton system on musculoskeletal strain during live microscopic ear operations. 2. To compare subjective pain scores and object surface EMG muscle data in neck, back and shoulder in microscopic ear operations with and without the exoskeleton
Outcome measures	Objective outcome measure sEMG data from neck, shoulder and back muscles Subjective outcome measure 1. Visual analogue scale scores at 5 minute intervals
Study Design and Methodology	*Comparison between objective and subjective outcome measure during microscopic ear operations with and without the exoskeleton*
Indication	-
Planned Trial sites	*Single site*
No of Participants	30 participants: performing 60 operations (30 in each arm)
Eligibility Criteria	• ENT surgeons who perform a range of microscopic ear surgery including tympanomastoid surgery and hearing implants. • Willing to participate with surface EMG (sEMG) monitoring and utilise the Ottobock exoskeleton
Treatment	*N/A*
Assessment Schedule	*N/A*
Statistical Methodology and analysis	*SPSS to assess data conformity. Wilcoxon signed rank test for likely non-parametric data comparisons.*

Study Glossary

Commonly used abbreviations [**add/delete as applicable, NB – this is <u>not</u> an exhaustive list]**

AE	Adverse Event
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
DMC	Data Monitoring Committee
GAfREC	Governance Arrangements for NHS Research Ethics
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials Number
Main REC	Main Research Ethics Committee
NHS R&D	National Health Service Research & Development
NIHR	National Institute for Health Research
NIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SDV	Source Document Verification
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
TMG	Trial Management Group
TSC	Trial Steering Committee
WHO	World Health Organisation
sEMG	Surface Electromyography
SENIAM	Surface electromyography for non-invasive assessment of muscles
VAS	Visual analogue scale

DRAFT

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1 INTRODUCTION

1.1 Background

Microscopic surgery is currently considered the gold standard for middle ear, mastoid and lateral skull base surgery (1). There are however several limitations associated with the operating microscope. They are bulky with limited maneuverability and can be awkward to manipulate whilst maintaining sterility. Furthermore, microsurgeons may well be particularly susceptible to musculoskeletal symptoms due to long periods of neck flexion and static posture (2–5). Indeed, Babar-Craig et al reported a 72% prevalence, amongst UK otolaryngology surgeons, of neck and back pain with otologists primarily affected. These findings were attributed to the frequency of microscope use (6).

1.2 Preclinical/Clinical Data

The exoskeletal system (7) has been developed as an ergonomic solution to reduce musculoskeletal strain during work. It has the benefit of being a lightweight postural support tool that has been shown to maintain full freedom of movement during physical activity in various industries (8,9). While there is some evidence amongst Orthopaedic surgeons (10) and Rhinologists (11) there is no publications looking at the effect of the exoskeleton during ear surgery or microscopic procedures.

1.3 Rationale

We feel that the exoskeleton system can help reduce the physical strain experienced by surgeons while operating using a microscope.

2 STUDY OBJECTIVES AND DESIGN

2.1 Objectives

2.1.1 Primary objective:

1. To investigate the effects of the exoskeleton system on musculoskeletal strain during live microscopic ear operations.
2. To compare subjective pain scores and object surface EMG muscle data in neck, back and shoulder in microscopic ear operations with and without the exoskeleton

2.1.2 Secondary objectives:

1. To investigate the timing and duration taken to put on the exoskeleton during live surgery
2. To determine if the exoskeleton has any effect and bearing on operating capacity of the surgeon

2.2 Endpoints/outcomes

2.2.1 Primary Endpoints/outcomes:

The study will continue for 20 minutes or recording or when the surgeon feels that he / she is unable to complete the surgery secondary to the use of the exoskeleton

2.2.2 Secondary Endpoints/outcomes:

The same as primary endpoint

2.3 Study Design

This will take the form of a prospective observational study. Collaboration has been set up between the ENT Department of East and North Herts NHS Teaching Trust and the Institute of Sport Sciences at the University of Hertfordshire. The study and participants would be recruited and conducted at the Lister Hospital, Stevenage. The University of Hertfordshire will loan the EMG machine and provide expertise analyzing the EMG results. The Ottobock Exoskeleton system (7) will be purchased using funding from Research Capacity Funding.

2.3.1 Number of subjects

30 participants (ENT surgeons) performing in total 60 operations (30 in each arm).

2.3.2 Study Duration

1 year

2.3.3 End of Study

The sponsor will inform the REC within 90 days of the 'end of trial' that the study has closed.

Following the submission of end of trial notification to the REC, the sponsor should ensure that end of trial report is submitted within 12 months of this notification.

In circumstances of early termination of the trial or temporary halt by the sponsor, the sponsor will notify the REC within 15 days of the decision and a detailed, written explanation for the termination/halt will be given.

3 SUBJECT SELECTION AND RECRUITMENT

3.1 Inclusion Criteria

- ENT surgeons who perform a range of microscopic ear surgery including tympanomastoid surgery and hearing implants.
- Willing to participate with surface EMG (sEMG) monitoring and utilise the Ottobock exoskeleton

3.2 Exclusion Criteria

- Pre-existing musculoskeletal problems that limits procedures under microscope and tympanomastoid surgery
- Unable to perform surgery using the exoskeleton

3.3 Subject Recruitment and Screening

Clinicians within the ENT and Audiology department will be invited through email via trust communications to voluntarily participate in the study. Participants will then be screened by the PI to ensure they meet the inclusion criteria with no exclusion criteria present.

4 SUBJECT WITHDRAWAL

- Participants can withdraw for any reason. This would include
  - Unduly musculoskeletal strain during surgery
  - Unable to operate using the exoskeleton
  - Clinical / intraoperative complications

5 STUDY PROCEDURES AND SCHEDULE OF ASSESSMENTS

5.1 Informed consent

Participants will be provided briefed about the study and what it entails (see Appendix A). A timeframe of 24 hours will be provided to ensure their understanding of the study and should they have any questions that would need clarifying before informed written consent is taken (see Appendix B). This process may be done by any member of the project research team. It is the responsibility of the Investigator, or a person delegated by the Investigator to obtain written informed consent from each subject prior to participation in the trial, following adequate explanation of the aims, methods, anticipated benefits and potential hazards of the study. “Adequate time” must be given for consideration by the patient before taking part. The PI must record when the patient information sheet (PIS) has been given to the patient. [If the amount of time between the PIS being given and the date of consent is less than 24 hours, the PI needs to explain the rationale for this]. The Investigator or designee will explain the patients are under no obligation to enter the trial and that they can withdraw at any time during the trial, without having to give a reason. No study procedures will be conducted prior to taking consent from the participant. Consent will not denote enrolment into trial. A copy of the signed Informed Consent form will be given to the participant. The original signed form will be retained at the study site. If new safety information results in significant changes in the risk/benefit assessment, the consent form will be reviewed and updated if necessary and subjects will be re-consented as appropriate. Where the participant population is likely to include a significant proportion of participants who cannot read or write, require translators or have cognitive impairment, appropriate alternative

methods for supporting the informed consent process should be employed. Details of alternative methods for supporting informed consent should be provided. This may include allowing a witness to sign on a participant's behalf (in the case of problems with reading or writing), or allowing someone to date the form on behalf of the participant, or providing Participant Information Sheets in other languages or in a format easily understood by the participant population (in the case of minors or cognitive impairment). Where a participant is able to consent but later becomes incapacitated, the management of these participants must also be stipulated in the protocol; in all such cases the original consent given endures the loss of capacity, providing that the trial has not significantly altered (there may be clinical justification under such circumstances for cessation of any further clinical intervention while data collection for follow-up purposes continues).

5.2 Trial Procedures by Visit

Please see schedule of assessment below

Procedure	**Study period**	
	Screening	**[Visit 1]**
Informed consent	X	
Eligibility criteria	X	
Baseline information		X
Data recordings		X

5.3 Screening and Baseline assessments

Data will be collected on the following

- Microscope use experience (months) :
- Previous musculoskeletal injuries:
- Any existing musculoskeletal strain / pain:

5.4 Study assessments and procedures

After informed consent is obtained, the recruited ENT surgeons will have the Ottoblock exoskeleton placed on them based on manufacturing advice (7). The surgeons will prepare for tympanomastoid surgery using existing standard operating protocols. They will have their skin cleaned with alcohol gel and allowed to dry as per SENIAM guidelines (12,13) and have the electrodes placed on their neck, shoulder and back as outlined above prior to scrubbing. The surgeon will then position him or her on a standard operating chair in the operating theatre and be asked to adjust the height of the chair and bed as well as their positions prior to starting to ensure any initial strain is minimized. The operating microscope will be set up and draped as usually done for any standard tympanomastoid surgery. The sEMG recordings will start at the beginning of surgery and a member of the study team will take the subjective measurements every 5 minutes. Data collection ends at the end of surgery. Measurements will be done using a standard operating microscope for 30 cases. The same protocol will be then repeated in 30 different cases without the use of the exoskeleton. A total of 60 major ear-operating cases will be recorded. There are no patient exclusion criteria.

5.5 End of study procedures

The study ends at the end of each individual surgery.

Data collection and entry.

1. Subjective measurements

A data collection proforma (Appendix C) will be filled in for each participant with a random unique participant number with the affix of S for study patients (eg. S1, S2, S3), ENT experience, pre-existing musculoskeletal injuries, strain and pain as well as visual analogue measurement of strain sustained during the recordings. The details of the corresponding unique participant number and patient name, date of birth and address will be stored onto a pseudo-anonymised Excel spreadsheet stored in the Trust ENT shared drive and password protected so it is only accessible by the research team. The hard copies of consent forms and original data collection sheets will be filed within the Research Team office according to GDPR and trust data storage requirements. This would mean that no identifiable data would be present in any data collection sheets.

2. Objective measurements

Recordings obtained from the sEMG will be stored on an encrypted USB drive with reference to each participants unique number. No identifiable patient data will be uploaded. The anonymised sEMG recordings will then be sent to the team based at the University of Hertfordshire for analyses via encrypted email (eg NHSmail or EGRESS). All results will be stored on Excel in the form of amplitude % change from rest sEMG and max sEMG.

Primary Outcome Measures:

- Differences in VAS and motor unit firing (via sEMG) of participants with and without the exoskeleton during microscopic tympanomastoid surgery

Secondary Outcome Measures:

- Differences in baselines characteristics of participants
- Differences in time of set up for exoskeleton

6 SAFETY REPORTING

6.1 Definitions

6.1.1 Adverse Event (AE)

An adverse event (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Inter-current illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality:

- results in study withdrawal
- is associated with a serious adverse event
- is associated with clinical signs or symptoms
- leads to additional treatment or to further diagnostic tests
- is considered by the investigator to be of clinical significance

6.1.2 Serious Adverse Event (SAE)

A serious adverse event is any AE that is:

- Fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

6.1.3 Disease related Events/outcomes NOT qualifying as SAEs

An event which is part of the natural course of the disease under study (i.e., disease progression) should not be reported as an SAE. However, if the progression of the underlying disease is greater than that which would normally be expected for the subject, or if the investigator considers that there was a causal relationship between treatment with study intervention or protocol design/procedures and the disease progression, then it must be reported as an SAE.

Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardise the subject, and may require intervention to prevent one of the other serious outcomes noted above.

6.1.4 Pre existing conditions

A pre-existing condition is one that is present at the start of the study. A pre-existing condition should be recorded as an adverse event if the frequency, intensity, or the character of the condition worsens during the study period.

At screening, any clinically significant abnormality should be recorded as a pre-existing condition. At the end of the study, any new clinically significant findings/abnormalities that meet the definition of an adverse event must also be recorded and documented as an adverse event**.**

6.2 Investigator Assessments

6.2.1 Seriousness

When an AE/AR occurs the investigator responsible for the care of the patient must first assess whether the event is serious using the definitions given above. If the event is serious and not exempt from expedited reporting, then an SAE form must be completed.

6.2.2 Causality

The Investigator must assess the causality of all adverse events in relation to the trial therapy using the definitions in the table below. There are 5 causality categories: unrelated, unlikely, possible, probable and definitely related. If the causality assessment is unrelated or unlikely to be related then for reporting purposes the event will not be regarded as an adverse reaction

to trial therapy. If the causality is assessed as possible, probable or definitely related then for reporting purposes the event is classified as an adverse reaction.

Table 3. Definitions of Causality

Relationship	Description
Unrelated	There is no evidence of any causal relationship
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial intervention). There is another reasonable explanation for the event (e.g. the patient's clinical condition, other concomitant treatment).
Possible	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial intervention). However, the influence of other factors may have contributed to the event (e.g. the patient's clinical condition, other concomitant treatments).
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely	There is clear evidence to suggest a causal relationship

6.2.3 Expectedness

Expected SAEs for the disease and trial intervention should be listed in the protocol. Investigators must file the current version of the Expected Adverse Events list in the safety reporting section of their Investigator File.

6.2.4 Grading

Insert relevant grading information including version of CTCAE to be used.

6.3 Reporting of AEs and SAEs

At each contact with the subject, the investigator must seek information on adverse events by specific questioning and, as appropriate, by examination. Information on all adverse events should be recorded immediately in the source document, and also in the appropriate adverse event module of the case report form (CRF). All clearly related signs, symptoms, and abnormal diagnostic procedures results should recorded in the source document, though should be grouped under one diagnosis. Methods to detect the presence of adverse events may take one or more of the following:

- Information volunteered by the patient or carer.
- Open-ended and non-leading verbal questioning of the patient at every visit such as the following: "How are you feeling? Have you had any (other) medical problems since your last visit?"
- Observation by the investigational team, other care providers or relatives.

All adverse events occurring during the study period must be recorded. The clinical course of each event should be followed until resolution, stabilisation, or until it has been determined

that the study treatment or participation is not the cause. Serious adverse events that are still ongoing at the end of the study period must be followed up to determine the final outcome. Any serious adverse event that occurs after the study period and is considered to be possibly related to the study interventnion or study participation should be recorded and reported immediately.

A serious adverse event must be reported to the study sponsor within 24 hours of the event. A Serious Adverse Event (SAE) form must be completed by the investigator and faxed to the study sponsor within 24 hours. The investigator will keep a copy of this SAE form on file at the study site. Report serious adverse events by phone and facsimile to:

Ananth Vijendren, Ananth.vijendren1@nhs.net

At the time of the initial report, the following information should be provided:

• Study identifier • Study Center • Subject number • A description of the event • Date of onset • Current status	• Whether study treatment was discontinued • The reason why the event is classified as serious • Investigator assessment of the association between the event and study treatment

This should include a copy of the completed Serious Adverse Event form, and any other diagnostic information that will assist the understanding of the event. Significant new information on ongoing serious adverse events should be provided promptly to the study sponsor.

6.3.1 Pregnancy

Pregnancy itself is not regarded as an AE unless there is a suspicion that the intervention under study may have interfered with the effectiveness of a contraceptive medication. However, the outcome of all pregnancies (spontaneous miscarriage, elective termination, normal birth or congenital abnormality) must be followed up and documented even if the patient was discontinued from the study. All reports of congenital abnormalities/birth defects are SAEs. Spontaneous miscarriages should also be reported and handled as SAEs. Elective abortions without complications should not be handled as AEs. All outcomes of pregnancy must be reported on the pregnancy outcomes report form.

Pregnancy of the patient's partner is not considered to be an AE. However, the outcome of all pregnancies (spontaneous miscarriage, elective termination, normal birth or congenital abnormality) must be followed up and documented. The outcomes of any conception occurring during the study must be followed up and documented. All outcomes of pregnancy must be reported on the pregnancy outcomes report form.

6.3.2 Notification Procedure

- The SAE form must be completed by the Investigator (consultant named on the signature list and delegation of responsibilities log who is responsible for the patient's care), with due care being paid to the grading, causality and expectedness of the event as outlined above. In the absence of the responsible investigator the form should be completed and signed by a member of the site trial team.
- All unexpected SAEs not defined in protocol or related documents in ENHT sponsored trials (including non-ENHT patients) must be reported to the R&D Office using the ENHT Adverse Event Report Form and a copy of the local/ trial specific form used for REC/HRA notification.

    - Initial SAE reports must be faxed within one working day of the investigator's knowledge of the event.
    - Follow-up Patients must be followed-up until clinical recovery is complete and laboratory results have returned to normal or baseline, or until the event has stabilised. Follow-up should continue after completion of protocol treatment if necessary. Follow-up information should be noted on a further SAE form by ticking the box marked 'follow-up' as information becomes available. Extra, annotated information and/or copies of test results may be provided separately. The patient must be identified by trial number, date of birth and initials only. The patient's name should not be used on any correspondence.

6.3.3 Medical Monitoring

It is the responsibility of the Principal Investigator to oversee the safety of the study at his/her site. This safety monitoring will include careful assessment and appropriate reporting of adverse events as noted above, as well as the construction and implementation of a site data and safety-monitoring plan. Medical monitoring will include a regular assessment of the number and type of serious adverse events and suspected unexpected serious adverse events.

6.3.4 Hospitalisation, Prolonged Hospitalisation or Surgery

Any adverse event that results in hospitalisation or prolonged hospitalisation should be documented and reported as a serious adverse event unless specifically instructed otherwise in this protocol. Any condition responsible for surgery should be documented as an adverse event if the condition meets the criteria for an adverse event.

Neither the condition, hospitalisation, prolonged hospitalisation, nor surgery are reported as an adverse event in the following circumstances:

- Hospitalisation or prolonged hospitalisation for diagnostic or elective surgical procedures for a pre-existing condition. Surgery should not be reported as an outcome of an adverse event if the purpose of the surgery was elective or diagnostic and the outcome was uneventful.
- Hospitalisation or prolonged hospitalisation required to allow efficacy measurement for the study

- Hospitalisation or prolonged hospitalisation for therapy of the target disease of the study, unless it is a worsening or increase in frequency of hospital admissions as judged by the clinical investigator.

Examples where an AE is NOT to be reported:

- Medical or surgical procedure (e.g., endoscopy, appendectomy). Note, the condition that leads to the procedure is an AE.
- Situations where an untoward medical occurrence did not occur (social and/or convenience admission to a hospital).
- Anticipated day-to-day fluctuations of pre-existing disease(s) or condition(s) present or detected at the start of the study that do not worsen.
- The disease/disorder being studied or expected progression, signs, or symptoms of the disease/disorder being studied unless more severe than expected for the subject's condition.

6.3.5 Post study AEs

All unresolved adverse events should be followed by the investigator until the events are resolved, the subject is lost to follow-up, or the adverse event is otherwise explained. At the last scheduled visit, the investigator should instruct each subject to report any subsequent event(s) that the subject, or the subject's personal physician, believes might reasonably be related to participation in this study. The investigator should notify the study sponsor of any death or adverse event occurring at any time after a subject has discontinued or terminated study participation that may reasonably be related to this study. The sponsor should also be notified if the investigator should become aware of the development of cancer or of a congenital anomaly in a subsequently conceived offspring of a subject that has participated in this study.

6.3.6 Abnormal Laboratory values

A clinical laboratory abnormality should be documented as an adverse event if <u>any one of the following</u> conditions is met:

- The laboratory abnormality is not otherwise refuted by a repeat test to confirm the abnormality
- The abnormality suggests a disease and/or organ toxicity
- The abnormality is of a degree that requires active management; e.g. modification of intervention, more frequent follow-up assessments, further diagnostic investigation, etc.

Abnormal laboratory findings (e.g., clinical chemistry, haematology, urinalysis) or other abnormal assessments that are judged by the investigator as clinically significant will be recorded as AEs or SAEs if they meet the definition of an AE or SAE.

Clinically significant abnormal laboratory findings or other abnormal assessments that are detected during the study or are present at Baseline and significantly worsen following the start

of the study will be reported as AEs or SAEs. However, clinically significant abnormal laboratory findings or other abnormal assessments that are associated with the disease being studied, unless judged by the investigator as more severe than expected for the subject's condition, or that are present or detected at the start of the study and do not worsen, will not be reported as AEs or SAEs.

6.3.7 Lack of efficacy

When there is a deterioration in the condition for which the study treatment is being used, there may be uncertainty as to whether this is lack of efficacy or an AE. In such cases, unless the reporting physician considers that study treatment contributed to the deterioration or local regulations state to the contrary, the deterioration would be considered a lack of efficacy.

6.3.8 Deaths

All deaths that occur during the study, or within the protocol defined follow up period after the administration of the last intervention, must be reported as follows:

- Death clearly the result of disease progression should be reported to the study monitor at the next monitoring visit and should be documented in the CRF but should not be reported as an SAE.
- Where death is not due (or not clearly due) to progression of disease under study, the AE causing the death must be reported to the study monitor as an SAE within 24 hours. The report should contain a comment regarding the co-involvement of progression of disease, if appropriate, and should assign main and contributory causes of death.
- Deaths with an unknown cause should always be reported as an SAE and a post-mortem may be helpful in the assessment of the cause of death.

There will be no use of medications or invasive physical intervention on volunteers. The surface elecromyelogram electrodes used as purely sensory and will not provide any stimulus to the surgeon to distract them from the surgery. Should the surgeon / participant experience any allergic reaction to the electrodes, these will be immediately removed and treated as per the trust allergy and anaphylaxis protocol. Surgeons may choose to stop wearing the exoskeleton if it is interfering with the surgery or causing them strain.

7 STATISTICS AND DATA ANALYSIS

7.1 Sample Size determination

A priori power analysis was based on data from Tetteh et al. (14), which reported reductions in lumbar erector spinae activity from ~5.7%MVC to 3.8%MVC with exoskeleton use. Standard deviations were estimated at 35% of the mean, yielding a conservative effect size of d ≈ 0.6 for intraoperative conditions. Using a paired design (α = 0.05, 80% power), 24 participants were required. To account for potential data loss and variability, the final target sample size was set at 30 surgeons, each performing procedures with and without exoskeleton support. In conclusion, there will be 60 independent surgical recordings in total.

7.2 Subject Population(s) for Analysis

A priori power analysis was conducted using data from Tetteh et al. (14), which demonstrated a reduction in lumbar erector spinae activity from approximately 5.7% MVC to 3.8% MVC with the use of an exoskeleton. Standard deviations were conservatively estimated at 35% of the mean, resulting in an effect size of approximately d = 0.6 under intraoperative conditions. Based on a paired study design (α = 0.05, power = 80%), a sample size of 24 participants was required. To allow for potential data loss and inter-individual variability, the target sample size was increased to 30 surgeons, each performing procedures both with and without exoskeleton assistance. In total, 60 procedures will be conducted.

7.3 Statistic Methods

Data will be assessed for parametric conformation. Based on a previous study comparing effects of standard operating chair vs ergonomic chair during simulated microscopic procedures[4] where parametric assumptions were not met, we would then employ Wilcoxon signed-rank test for continuous data assessment of the difference in %rest sEMG and % max sEMG between microscopes and exoscopes and between VAS of strain.

8 DATA HANDLING AND RECORD KEEPING

8.1 Confidentiality

Information about study subjects will be kept confidential and managed according to Trust requirements. These require a signed subject authorisation informing the subject of the following:

- 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 authorisation.

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

8.2 Source Documents

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

The source data for each study should be decided depending on the type of study and Trust policy. This should then be detailed in the protocol. If the case report form (CRF) is to be considered source data this should be clearly documented in the protocol.

8.3 Case Report Form

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, write "ND". If the item is not applicable to the individual case, write "NA". All entries should be printed legibly in black ink. If any entry error has been made, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. DO NOT ERASE OR WHITE OUT ERRORS. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it.

8.4 Data handling and record keeping

The Investigator and other personnel will keep confidential any information provided by East and North Hertfordshire NHS Teaching Trust (including this protocol) related to this study and all data and records generated in the course of conducting the study, and will not use the information, data, or records for any purpose other than conducting the study. These restrictions do not apply to: information which becomes publicly available through no fault of the investigator or study site personnel; information which it is necessary to disclose in confidence to an Ethics Committee solely for the evaluation of the study; information which it is necessary to disclose in order to provide appropriate medical care to a study subject, or study results which may be published. If a written contract for the conduct of the study, which includes confidentiality provisions inconsistent with this statement, is executed then that contract's confidentiality provisions shall apply rather than this statement. The responsibility for this rests with the Chief investigator.

8.5 Records Retention

- Archiving for this study will be carried out according to gSOP-17
- Destruction of essential documents will require authorisation from the Sponsor
- Archiving will be authorised by the Sponsor following submission of the end of study report
- Which trial documents the sponsor will be responsible for archiving and which trial documents the site(s) will be responsible for archiving
- The location and duration of record retention for essential documentation and databases.
- All essential documents will be archived for 5 years after completion of trial.

9.0 STUDY MONITORING, AUDITING AND INSPECTING

9.1 Study Monitoring Plan

This study will be monitored according to the monitoring plan. The investigator will allocate adequate time for such monitoring activities.

The Investigator will also ensure that the monitor or other compliance or quality assurance reviewer is given access to all the above noted study-related documents and study related facilities and has adequate space to conduct the monitoring visit.

The monitoring plan will depend on the type of trial and the Sponsor will be provide some monitoring assistance as detailed in gSOP-12, but it is important that the Investigator ensures that the data in relation to this study is accurate and verifiable and that patient safety is maintained throughout the trial duration regardless of sponsor monitoring activities.

9.2 Auditing and Inspecting

The investigator will permit study-related audits, and inspections by the IEC, the sponsor, government regulatory bodies, and R&D Compliance and Quality Assurance groups of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data etc). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g. diagnostic laboratory)

Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and R&D Compliance and Sponsor Quality Assurance offices.

9.3 Trial Management Group (TMG)

This will be comprised of the members stated above between East and North Herts NHS Teaching Trust and University of Hertfordshire.

10. REGULATORY OBLIGATIONS AND COMPLIANCE

This study is to be conducted according to EU and international standards of Good Clinical Practice and International Conference on Harmonisation guidelines, applicable government regulations and Ethics policies and procedures.

This protocol and any amendments will be submitted to a properly constituted Independent Ethics Committee (IEC), in agreement with local legal prescriptions, for formal approval of the study conduct. The decision of the IEC concerning the conduct of the study will be made in writing to the investigator and a copy of this decision will be provided to the sponsor before commencement of this study. The investigator should provide a list of IEC members and their affiliate to the sponsor.

- Before any site can enroll patients into the trial, the Chief Investigator/Principal Investigator or designee will apply for NHS confirmation of capacity and capability from the site's Research & Development (R&D) department.

10.1 Protocol compliance

Protocol deviations, non-compliances, or breaches are departures from the approved protocol. Detail how protocol compliance will be managed

The protocol should state that:

- prospective, planned deviations or waivers to the protocol are not allowed and must not be used e.g. it is not acceptable to enroll a subject if they do not meet the eligibility criteria or restrictions specified in the trial protocol
- accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.
- deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

10.2 Notification of Serious Breaches to GCP and/or the protocol

A “serious breach” is a breach which is likely to effect to a significant degree –
(a) the safety or physical or mental integrity of the subjects of the trial; or
(b) the scientific value of the trial

- the sponsor will be notified immediately of any case where the above definition applies during the study conduct phase

11. STUDY FINANCES

11.1 Funding Source

We have secured a small grant from the trust through research capability framework to purchase the exoskeleton. The University of Hertfordshire will loan their sEMG equipment and perform sEMG analyses.

11.2 Conflict

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management plan that has been reviewed and approved by the study sponsor prior to participation in this study.

11.3 Subject Stipends or Payments

None

12 INDEMNITY

The East and North Hertfordshire NHS Teaching Trust will provide indemnity. Details of insurance cover will be forwarded to the NRES recognised Ethics Committee for review

13 PUBLICATION PLAN

The project will either be published in an ENT or ergonomic journal upon completion. Examples include Otology Neurotology, Clinical Otolaryngology, Laryngoscope or Applied Ergonomics.

14 REFERENCES

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APPENDICES

Appendix A Participant information sheet

Appendix B Participant consent form

Appendix C Data collection sheet