ISRCTN34264292 https://doi.org/10.1186/ISRCTN34264292

Can special glasses called prismatic loupes improve surgeons' work and help them feel less uncomfortable while working in the operating room?

Submission date
22/08/2023

Recruitment status
No longer recruiting

Registration date
23/08/2023

Overall study status
Completed

Last Edited
23/08/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Neck pain is commonly reported among surgeons. The pain is often related to the awkward neck postures during operations. Prismatic loupes that infract light have been shown, in simulated tasks within a short training period, to improve neck posture for surgeons. However, little has been studied regarding the effects of prismatic loupes on surgeons' physical workload and discomfort in actual operations.
The primary aim of this study was to evaluate the effects of using prismatic loupes, when compared to conventional non-prismatic loupes, on surgeons intraoperative physical workload and musculoskeletal discomfort. The secondary aim was to evaluate the visual qualities and usability of prismatic loupes during actual operations.

Who can participate?
Experienced surgeons (experience of surgery>2 years) from an academic university hospital who actively perform open surgeries and have joined a test using prismatic loupes in a clinical training centre at the time of recruitment can volunteer to participate.

What does the study involve?
In this study, we evaluated surgeons' intraoperative physical workload and musculoskeletal discomfort using the prismatic loupes and non-prismatic lopes during real surgeries. Participants performed two similar operations on one day in a random order using prismatic and non-prismatic conventional loupes. Physical workload was evaluated with two set of sensors: the muscular activity of the upper trapezius and neck extensors using EMG electrodes, and the postures and movements of the head, trunk, and upper arms using IMU sensors. Questionnaires on body-part discomfort, perceived workload, visual qualities, and usability of the loupes were filled in.

What are the possible benefits and risks of participating?
The major possible benefits were hypothesised to reduce the physical workload and the risk of

developing neck-shoulder pain are reduced for surgeons by using these prismatic loupes. There is no health risk of participating in the study. The particapants are free to end their participation at any time.

Where is the study run from?
Karolinska University Hospital at Solna, Stockholm, Sweden

When is the study starting and how long is it expected to run for?
October 2019 to March 2023

Who is funding the study?
Afa Insurance (AFA) (Sweden)

Who is the main contact?
Prof. Mikael Forsman, miforsm@kth.se

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

Evaluation of prismatic loupes on surgeons' intraoperative physical workload and musculoskeletal discomfort compared to conventional loupes - A crossover randomized controlled trial

Acronym
PrismSurg2

Study objectives
1. Using prismatic loupes reduce surgeons' intraoperative physical workload compared to conventional loupes
2. Using prismatic loupes reduce surgeons' musculoskeletal discomfort after surgery compared to conventional loupes

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/02/2020, Swedish Ethical Review Authority (Etikprövningsmyndigheten Box 2110, Uppsala, 750 02, Sweden; +46 10-4750800; registrator@etikprovning.se), ref: 2020-02161

Study design
Randomized cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Work-related musculoskeletal disorders

Interventions
Each participating surgeon conducted two comparable procedures in the measurement day, using prismatic loupes and conventional loupes, interspersed by a standard break as per the hospital's routine schedule. The type of surgical loupes used in the first operation, whether conventional or prismatic, was randomly assigned, and then alternated for the subsequent procedure. The assignment of order is calculated in Excel with a randomization function.

Intervention Type

Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Two types of surgical prismatic loupes from Optergo AB, Mölnlycke, Sweden and HOYA Technosurgical Corporation, Tokyo, Japan.

Primary outcome measure
Physical workload was measured using two sets of sensors during the whole surgeries. First, bipolar surface EMG was recorded bilaterally from the neck extensors and upper trapezius. Second, upper arms, trunk, and head postures and movements were recoded using inertial measurement units (IMUs).

Secondary outcome measures
1. Perceived body-part discomforts of neck, both shoulders, upper and lower back, and fatigue were measured using Borg CR-10 scale before and after each surgery.
2. Perceived visual qualities of the loupes were measured using 5-point Likert-type scale scoring from very bad to very good after each surgery.
3. Potential physical symptoms related to loupes usage including double vision, headache and nausea were assessed on a 4-point scale scoring from severe to no symptoms after each surgery.
4. Self-rated surgical workload was assessed using a modified NASA-TLX scale, including dimensions of mental and physical demand, temporal demand, distractions, frustrations, task complexity, situational stress, and performance after each surgery.
5. The usability of the prismatic loupes, including easiness to use and intention for frequent future use, was measured using a 5-point Likert scale after all surgeries.
6. Subjective evaluations and experiences of the loupes were measured using semi-structured interview after all surgeries.

Overall study start date
01/10/2019

Completion date
17/03/2023

Eligibility

Key inclusion criteria
1. Currently actively working as surgeons.
2. Work experience as surgeons >= 2 years.
3. Work actively with open surgeries in vascular surgery or in otorhinolaryngology (endocrine surgery).

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
20

Total final enrolment
15

Key exclusion criteria
Surgeons who experienced severe physical symptoms when using the prismatic loupes.

Date of first enrolment
22/03/2022

Date of final enrolment
17/03/2023

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Universitetssjukhuset
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Funder(s)

Funder type
Industry

Funder Name
AFA Försäkring

Alternative Name(s)
AFA Insurance

Funding Body Type

Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Sweden

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
17/03/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof Mikael Forsman, miforsm@kth.se

IPD sharing plan summary
Available on request