

Can light-bending glasses improve surgeons' neck posture and reduce neck pain?

Submission date 19/01/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/01/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 28/02/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Surgeons often suffer from work-related musculoskeletal disorders (MSDs) in the neck and shoulders. These MSDs impact surgical productivity and may shorten the work life of the surgeons. The occurrence of MSDs is partially due to high physical workload such as long-term neck bending, which is common among surgeons. The usage of traditional surgical loupes not only increase the bending angle of the surgeon's neck, but also increase the load that the neck of the surgeon bears. This study aims to investigate whether prismatic loupes can reduce surgeons' physical workload and improve their perceived discomfort without compromising performance.

Who can participate?

All experienced surgeons (experience of surgery over 2 years) from an academic university hospital who actively perform open surgeries

What does the study involve?

This study compares three types of surgical loupes: the surgeons' own non-prismatic loupes (own), low-tilt prismatic loupes (LT), and high-tilt prismatic loupes (HT). Participants perform three surgical tasks with one of the three types of loupes at a time, and repeat with the other two types of loupes. Each participant is given a specific order of loupes from the following four options: 1) own, HT, LT; 2) own, LT, HT; 3) HT, LT, own; 4) LT, HT, own. Each time, participants perform the three surgical tasks in a fixed order: peg transfer (PT), basic suture (BS), and precision cutting (PC).

During the experiment, the researchers measure several outcomes for each participant in each task with each type of loupes, and compare the differences among the three types of loupes. These outcomes include the inclination angle and the velocity of the head, trunk and upper arm, muscle activity, as well as surgical errors and the completion time for each task. The researchers also ask participants how the visual quality of each type of loupes, if they experienced any discomfort in any body parts, and their comments, thoughts and preference of the three types of loupes.

What are the possible benefits and risks of participating?

The major possible benefits are reduced physical workload and a reduced risk of developing

neck and shoulder pain by using prismatic loupes. All participants may keep one pair of prismatic loupes at the end of the study. There is no health risk of participating in the study, and during the laboratory study there is a minor, temporary risk of nausea, motion sickness, and double vision. The participants are free to end their participation at any time.

Where is the study run from?

Karolinska University Hospital at Solna (Sweden)

When is the study starting and how long is it expected to run for?

October 2019 to October 2021

Who is funding the study?

Afa Insurance (AFA)

Who is the main contact?

Prof. Mikael Forsman

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Contact information

Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Non-prismatic and prismatic loupes in simulated surgical tasks among surgeons – a controlled, randomized cross-over laboratory trial

Acronym

PrismSurg1

Study objectives

Can prismatic loupes reduce surgeons' physical workload and reduce surgeons' perceived discomfort without compromising performance?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/07/2020, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; +46 (0)10 4750800; registrator@etikprovning.se), ref: Dnr 2020-02161, an extension of Dnr 2014/1120-31

Study design

Randomized cross over study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Work-related musculoskeletal disorders

Interventions

This randomized cross-over study enrolled eligible surgeons in an academic hospital in Sweden from September to December 2021, to compare two prismatic loupes (new) and one non-prismatic loupes (conventional) in three simulated surgical tasks, i.e., peg transfer (PT), basic suture (BS) and precision cutting (PC), in a surgical training room.

Each participant performs three simulated surgical tasks, peg transfer (PT), basic suture (BS) and precision cutting (PC), in a fixed order with one of three types surgical loupes, i.e., their own non-prismatic loupes (own), low-tilt prismatic loupes (LT) with an angulation angle of 15° in the prism, and high-tilt prismatic loupes (HT) with an angulation angle of 48° in the prism. Each participant is randomized, balanced, and assigned to one of the following four orders of loupes: own->LT->HT, own->HT->LT, LT->HT->own, and HT->LT-> own. The assignment of order is calculated in Excel with a randomization function and announced on site.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Physical workload including:
 - 1.1. Inclination angle and velocity of head, trunk and both upper arms measured using inertial measurement units during each task with each type of surgical loupes
 - 1.2. Muscle activity of cervical erector spinae, trapezius and lumbar erector spinae measured using electromyography during each task with each type of surgical loupes

Key secondary outcome(s)

1. Perceived visual quality measured using 5-point Likert-type scale or 4-point scale depending on questions with each type of surgical loupes at the end of each task
2. Perceived body-part discomfort measured using a Borg CR-10 scale with each type of surgical loupes at the end of each task
3. Surgical performance, including task completion duration measured using a timer, and number of errors evaluated by two independent surgeons with each type of surgical loupes at the end of each task
4. Subjective evaluations and preferences of loupes measured using a semi-structured interview on the same day at the end of the study

Completion date

21/10/2021

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)
4. Never used prismatic surgical loupes
5. No age limitations (due to sufficiency of other criteria)

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

19

Key exclusion criteria

1. Experienced severe discomfort when using any surgical loupes during the experiment
2. Experienced severe discomfort due to the technical measurement of ergonomic exposure

Date of first enrolment

03/04/2020

Date of final enrolment

15/01/2021

Locations

Countries of recruitment

Sweden

Study participating centre

Karolinska Universitetssjukhuset, Solna
Karolinska vägen, Solna

Stockholm
Sweden
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Sponsor information

Organisation

Karolinska Institute

ROR

<https://ror.org/056d84691>

Funder(s)

Funder type

Industry

Funder Name

AFA Försäkring

Alternative Name(s)

AFA Insurance, AFA Insurance (Sweden)

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Sweden

Results and Publications

Individual participant data (IPD) sharing plan

All the raw data are available on request from Xuelong Fan (Xuelong.fan@ki.se) and Mikael Forsman (Mikael.forsman@ki.se).

Primary analysed data will be available after the publication of the manuscript for 10 years for research groups in relevant fields in worldwide-recognized universities and/or hospitals for meta-analyses and musculoskeletal disorder research.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/01/2024	28/02/2024	Yes	No