# Using the best wearable sensor in facilitating hands-free, sterile control in the operating room

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON20795

**Source**
Nationaal Trial Register

**Brief title**
TedTrial

**Health condition**

Not applicable

### Sponsors and support

**Primary sponsor:** Prof. M.P. Schijven, department o Surgery, Amsterdam UMC, location AMC.
**Source(s) of monetary or material Support:** Olympus

### Intervention

### Outcome measures

**Primary outcome**

Quantification of disruptions of workflow using the MDR in both the intervention and control group

**Secondary outcome**

- Comparing the quantified delay between a command and complete execution of the command in both intervention groups and the control group as detected in a MDR augmented OR
- Comparing the error rate of the execution of a command when using direct human-computer interaction using inertial wearable sensors with the error rate in the control group as objectified in a medical data recorder augmented OR. An error is defined as the incorrect execution of a command, execution of the wrong command (misinterpretation), or incapability to execute the command (lack of proficiency in using the equipment).
- Assessing the self-reported frustration on a three-item frustration scale, comparing frustration between both intervention groups and control group and correlate frustration to the number of reported errors, the delay and the number of disruptions of workflow.
- Assessment of changes in communication in relation to the disruptions of workflow, quantified delay and error rates.
- Assessment of NASA TLX scores, comparing intervention and control group and correlation with the number of reported errors, delay and the number of disruptions of workflow
- Assessment of body metrics (HR, HRV and RPM) in the Myo™ Armband, Plantronics headset and control group, comparison between intervention and control group and correlation with reported frustration and reported NASA TLX scores.
- Evaluation of satisfaction with the use of the TedCube© system and associated sensors or third person interaction using a self-developed questionnaire.

# Study description

**Background summary**

Rationale: Interaction with electronically controlled operating room (OR) systems embedded in modern surgical environments such as the ‘STORZ OR 1’ and ‘Olympus ENDOALPHA’ is everyday practice for surgeons performing Minimally Invasive Surgery (MIS) in our hospital. While there is a non-sterile operating nurse available in the OR, capable of interacting with these systems upon request by the surgeon, this indirect control is mostly slow, prone for error and disrupting surgical workflow. Facing an unanticipated and unwanted outcome may result in frustration and eventually even anger, both examples of distress emotions. Distress emotions are undesirable when performing surgery, since they may impact available cognitive workload. Furthermore, they may result in negative communication, hampering OR-team empowerment and effective leadership. Both factors are known to negatively influence quality and safety in the OR.
The TedCube© system is a plug and play device enabling wearable sensors to act as a wireless alternative for a regular computer mouse, therefore enabling direct hands-free and sterile control of the OR.
Objective: The aim of the TedTrial is to investigate what setup best enables surgeons to interact with the endoscopic operation room setup during surgical procedures. As a result, delays, errors and disruptions of workflow may be reduced. Outcome parameters are time

from a command until complete execution of said command, number of delays, number of workflow disruptions, OR communication, distress and satisfaction. Outcome parameters will be objectified using medical data recorder (MDR) derived output. Distress will be objectified using both biometric analysis and questionnaires. Satisfaction with the hands-free system will be evaluated using a questionnaire.
Study design: This study is an observational trial with three different arms: Intervention group 1) direct interaction by surgeon with OR environment using TedCube© and Myo™ armband, Intervention group 2) direct interaction of surgeon with OR environment using Tedcube© and Plantronics© wireless microphone headset. The third arm is the control group using indirect interaction of surgeon with OR environment using third-person computer interaction. All study procedures will be performed in a MDR augmented OR, in order to objectify communication patterns, workflow disruptions, errors and delays. Surgeons in both intervention groups and the control group will wear a special t-shirt equipped with multiple sensors registering biometric parameters to objectify symptoms of distress (frustration and anger). All surgeons will be asked to complete a questionnaire post-operatively about experienced levels of frustration. In parallel, any system failure or not-executed command during control-procedures is registered. Satisfaction with the way of interaction is evaluated with a questionnaire after each surgical procedure. Subjectively reported parameters on frustration are compared between groups and correlated to objectively measured biometric parameters. Satisfaction is evaluated using a self-developed questionnaire and correlated with errors occurring during surgery.
Study population: The study population consists of volunteering gastro-intestinal MIS surgeons, since anticipated interaction with the ENDOALPHA operating system is the highest in procedures performed in this subspecialty.
Intervention: The TedCube© will be set-up prior to every surgical procedure by researcher. No software needs to be installed on the hospital computer for the system to work, as it is a ‘plug&play’ device. The TedCube© simulates a remote controlled USB-mouse or -keyboard, and has the same technical functionalities as a normal computer mouse, except the input may come from wearable sensors such as armbands or microphones. TedCube© has already been tested for integration in the Olympus ENDOALPHA operating rooms and has shown to be both feasible and reliable, not breeching computer software nor AMC data protocol (pilot feasibility test).
Main study parameters/endpoints: Main endpoint of study is the number of workflow disruptions due to the operation of laparoscopic OR equipment. Secondary endpoints are error rate, delay, team communication, subjectively reported frustration and satisfaction with the system and objectively measured stress as symptom of frustration and anger as distress emotions.
Results: Primary and secondary endpoints of study are compared among groups. It is anticipated that reduction of miscommunication, error and delay may result in a reduction of distress emotions.

## Study objective

OR workflow for surgeons needing to interact with the laparoscopic equipment during surgery is optimized using TedCube© in combination with the Myo™ gesture control armband and/or a wireless headset.

**Study design**

05-07-2019: approval METC
01-08-2019: start first inclusion
31-12-2019: study closed

**Intervention**

The TedCube© (TedCas Systems S.L., Navarra, Spain) enables touchless interaction with any PC or computer system that can be controlled using USB-mouse and keyboard input. In this case, allowing for hands-free and sterile interaction with the Olympus ENDOALPHA panel. This study has three arms. Intervention arm 1 uses the TedCube sysem in combination with the plantronics headset to enable hands-free interaction using voice control, Intervention arm 2 uses the TedCube system in combination with Myo armband using gesture control. The third arm is the control group using third person interaction.

# Contacts

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# Eligibility criteria

## Inclusion criteria

Elective procedures, Procedures with repetitive actions, in this study limited to:
- diagnostic laparoscopy
- laparoscopic lymph node resection
- laparoscopic appendectomy
- laparoscopic cholecystectomy
- laparoscopic Heller myotomy
- laparoscopic hernia diaphragmatica repair
- laparoscopic fundoplication

- laparoscopic stoma formation
- laparoscopic oesophageal surgery
- laparoscopic adrenal gland surgery
Procedures performed on patients aged >18 years
Informed consent of the patient to be operated on in a medical data recorder augmented OR

### Exclusion criteria

Emergency Surgery, Absence of a circulation nurse, Surgerin In OR's other than OR 20 in the Amsterdam UMC, location AMC

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-08-2019 |
| Enrollment: | 30 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Positive opinion

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|---|---|
| Date: | 08-07-2019 |

Application type: First submission

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL7857 |
| CCMO | NL68185.018.19 |

# Study results