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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20795

Bron
Nationaal Trial Register

Verkorte titel
TedTrial

Aandoening

Not applicable

Ondersteuning

Primaire sponsor: Prof. M.P. Schijven, department o Surgery, Amsterdam UMC, location AMC.
Overige ondersteuning: Olympus

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2019
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	08-07-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7857
CCMO	NL68185.018.19

Resultaten