Usability of the ADEPTH sensor for bore depth measurements in plate osteosynthesis procedures: a monocenter randomized pilot study (ADEPTH-Pilot)

Published: 04-07-2023
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Primary Objective: - To assess the usability score of the ADEPTH sensor for bore depth measurements during elective plate osteosynthesis procedures in adults.Secondary Objective: - To compare the duration of the fixation process per screw between...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON53499

Source
ToetsingOnline

Brief title
ADEPTH-Pilot

Condition

- Fractures
- Bone and joint therapeutic procedures

Synonym
Bone fracture, traumatic fracture

Research involving
Human

Sponsors and support

Primary sponsor: SLAM Orthopedics
Source(s) of monetary or material Support: Ministerie van OC&W,SLAM Ortho B.V.

Intervention

Keyword: Fracture, Osteosynthesis, Sensor, Usability

Outcome measures

Primary outcome

System Usability Score.

Secondary outcome

- Duration of the fixation process per screw, in seconds.

- Implant waste.

Study description

Background summary

During osteosynthesis operations, surgeons currently use a manual depth gauge (a hook) to manually measure the drilling depth after drilling in order to determine the correct screw length. Surgeons have indicated that the bracket is not always accurate enough and that using the bracket often takes a long time. To solve this, SLAM Orthopedics has developed the ADEPTH sensor that automatically measures the drilling depth during drilling. In this way, the manual measuring step is eliminated, which can save time. In addition, the ADEPTH sensor is more accurate than the hook, which reduces the chance of the wrong length of the screw. In this study we want to know how the surgeon thinks the ADEPTH sensor works, so we are curious about the usability of the ADEPTH. This first pilot study in the clinic is necessary to further develop the ADEPTH to meet the needs of the surgeon in the future and to improve patient care. This first in-clinic pilot study is necessary to further improve the ADEPTH sensor in order to improve future patient care and to provide in the surgeon's needs to replace the manual depth gauge.

Study objective

Primary Objective:

- To assess the usability score of the ADEPTH sensor for bore depth measurements during elective plate osteosynthesis procedures in adults.

Secondary Objective:
- To compare the duration of the fixation process per screw between the control group and intervention group.
- To compare implant waste between the control group and intervention group.

Study design

Monocenter, randomized pilot study.

Intervention

In the intervention group, the surgeon uses the ADEPTH sensor for depth measurements during the operation. The hook is always present as a backup should the sensor malfunction. After the operation, the surgeon and the OR assistant receive a short questionnaire (SUS survey) about the use of the ADEPTH sensor. There will be no further changes to the care or treatment for the patient.

Study burden and risks

Trauma surgeons will perform the plate osteosynthesis procedures according to standard of care. The ADEPTH sensor is tested on safety, performance and sterility before the start of the pilot study. The additional risk of using the ADEPTH sensor during plate osteosynthesis procedures is considered very low, since the workflow is not changed and the DG will always be available for backup. Surgeons and OR assistants will be trained before the start of the study and will be asked to fill in one survey after three plate osteosynthesis procedures. There is no extra burden, nor an increased risk for the patient. Possible benefits for the patient could be the higher accuracy of the ADEPTH sensor, causing less re-operations. In addition, the time saving component could reduce the duration of the procedures which could lead to a lower infection rate.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Elective plate osteosynthesis procedure (clavicula, humerus, radius, ulna, femur, tibia, fibula, malleoli)(incl. delayed union, nonunion and malunion)
Adults (>= 18 years)
Needed surgical instrument net: 2.4/2.7/3.5-4.0/4.5-5.0-6.5
Written informed consent by patient

Exclusion criteria

Bone disease (dysplasia's, sarcomas, chondroma's, osteolysis, osteomyelitis)
Variable angle plates
Corrective surgery after previous plate osteosynthesis procedure or hardware removal

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-08-2023
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	ADEPTH
Registration:	No

Ethics review

Approved WMO Date:	04-07-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	10-05-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
Other	komt nog
CCMO	NL83315.078.23