

Accuracy Of Patient-Specific 3D-Printed Drill Guides For Spine Surgery Compared With Computer Assisted Surgery

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In this non-inferiority trial, we aim to demonstrate that 3D-printed guides are just as good as CAS, regarding the postsurgical radiological screw-insertion accuracy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON47979

Source

ToetsingOnline

Brief title

3D-printed Spine Guides compared with Computer Assisted Surgery

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym

Spinal Instability

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 3D-printing, Drill Guides, Patient Specific, Spine Surgery

Outcome measures

Primary outcome

The radiological accuracy will be measured as the deviation (i.e. error) from planned trajectory, with the continuous variables; (1) entry point deviation (mm), and (2) angular deviation (degrees °). These parameters will be measured and compared between both techniques.

Secondary outcome

As secondary endpoint the accuracy results of both techniques will be compared within specific spinal regions: (1) Atlanto-Axial spine, (2) the sub-axial spine, (3) the cervical spine, and (4) the thoracic spine.

For pedicle screws, mutual techniques will also be compared according to the Rampersaud safety classification

Study description

Background summary

Accurate screw insertion is essential for safe and optimal spinal fixation surgery. Screw misplacement may lead to damage to vital structures or failure of the fixation. Traditionally, screws are inserted free-hand, based on anatomical landmarks and with the aid of fluoroscopy. There are however numerous studies reporting high rates of screw misplacement by freehand screw insertion.

Technical developments in spinal surgery have led to the implementation of Computer Assisted Surgery (CAS) navigation systems in complex spine surgery. Initially, CAS was based on preoperative planning, but current systems use an intraoperatively acquired CT and, therefore, require the surgeon to plan the screws during surgery. There is a consensus based on clinical experience that

CAS improves the accuracy of screw placement, but unfortunately screw malposition still occurs. Since modern CAS systems are considered highly accurate but lack integrated preoperative planning, optimizations of screw insertion can mainly be achieved by improving the screw planning using preoperative planning techniques.

Advancements in Computer-Aided Design and Manufacturing have led to 3D virtual surgical planning techniques and the use of patient specific 3D-printed drill guides. This technique consist of preoperative virtual screw planning including screw direction, length and thickness. The corresponding 3D-printed guides are applied per vertebra and therefore independent to intervertebral motion. Recently, our research team developed an optimized spinal 3D guide design during a cadaveric study, which allowed the surgeons to pass through the learning curve. Nowadays, guides have been implemented into clinical practise in addition to CAS, to assist in complex cases.

At present, no systematic comparison between guides and CAS has been conducted. Therefore, the current study will provide a randomized systematic comparison between guides and CAS by means of a uniform radiological 3D analysis.

Study objective

In this non-inferiority trial, we aim to demonstrate that 3D-printed guides are just as good as CAS, regarding the postsurgical radiological screw-insertion accuracy.

Study design

This non-inferiority study will be a prospective, split-spine randomized, controlled trial.

Intervention

The intervention in this study is the 3D virtual surgical planning and the use of patient specific guides for spinal screw insertion in one half of the patient*s spine.

Study burden and risks

Research-related burden includes Randomisation of two screw insertion techniques and the CAS measurements, together resulting in approximate surgery prolongation of 15 minutes.

The surgical procedure will not be subject to changes for the patient. The guides are produced under ISO 13485 and ISO 9001:2008, and the printed material (nylon) is bio-compatible according to the ISO 10993-1 classification. A risk

analysis and approval of Medical Technique UMCG was obtained (DAD17.00001).

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

- * Patients are awaiting surgical fixation of the cervical and/or thoracic spine.
- * Preoperative CT has to be available
- * Surgery must be elective or semi-elective.
- * Surgery must involve the placement of pedicle- or lateral mass screws
- * The patients are at least 16 years of age.

Exclusion criteria

- * Urgent cases that require surgery within 5 days
- * Presence of osteosynthesis material in the vertebrae planned for screw insertion.
- * Revision surgery, or laminectomy performed in earlier stage.
- * Vertebrae levels are planned for unilateral screw insertion
- * Scoliosis cases

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	3D-printed spinal drill guides
Registration:	No

Ethics review

Approved WMO	
Date:	03-04-2019
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	09-09-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL68406.042.18