Long-term follow-up of movement of the cervical spine after anterior cervical discectomy (ACD) or anterior cervical discectomy with arthroplasty (ACDA)

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The primary objective of this study is to investigate the sequence of segmental contributions in the cervical spine in the long-term follow-up of surgery for CDDD. Specifically, the motion of the cervical spine after ACD and ACDA will be analyzed…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49700

Source
ToetsingOnline

Brief title
Cervical spine motion. Long term-follow up of ACDA and ACD.

Condition

- Other condition

Synonym
Cervical spine motion

Health condition

Wervelkolom aandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: IO 1604 Afdeling Neurochirurgie

Intervention

Keyword: anterior cervical discectomy (ACD), anterior cervical discectomy with arthroplasty (ACDA), Cervical Spine, Motion

Outcome measures

Primary outcome

The primary objective of this study is to investigate whether the sequence of segmental contributions in the cervical spine in the long-term follow-up of ACD and ACDF had changed compared to the short-term follow-up and if this correlates to clinical symptoms.

At the start of the cinematographic recording, one image will be saved as a lateral X-ray of the cervical spine to determine Kellgrens* Score (KS).
The KS will be determined by two neurosurgeons and is a scoring method to determine severity of degenerative disc disease, using five gradations:
* Grade 0: absence of degeneration in the disc.
* Grade 1: minimal anterior osteophytosis.
* Grade 2: definite anterior osteophytosis, possible narrowing of the disc space, some sclerosis of the vertebral plates.
* Grade 3: moderate narrowing of the disc space, sclerosis of the vertebral plates, osteophytosis.
* Grade 4: severe narrowing of the disc space, severe sclerosis of the

vertebral plates, multiple large osteophytes.

Cinematographic recordings: participants are seated on a crutch, adjustable in height, with their neck, shoulders and head free. Before recordings are made, participants will be instructed to perform the prescribed flexion and extension movement in about 10 seconds with 7 frames per second. . Participants are placed on the crutch with their shoulder*s perpendicular to the image intensifier to obtain sagittal images from the occiput till C7. As soon as the recording is started, the participant is instructed to move his head in the sagittal plane from maximal extension to maximal flexion, without moving the upper part of the body. It is important that the participants shoulders are kept as low as possible while making the recordings to ensure that all the cervical vertebrae are visible. The movement of the cervical spine should be as fluent as possible to prevent for sudden large rotations and translations between consecutive frames. The cinematographic recordings will be made once using the Philips Alura Xper FD20 X-ray system.

Secondary outcome

The secondary outcome will be to determine the radiological sROM on the cinematographic recordings. The amount of degeneration will be assessed on the lateral X-ray according to the Kellgren's Score (KS).

Clinical outcomes will be assessed according to the visual analogue score (VAS) score for neck and arm pain, the neck disability index (NDI), SF-36 and Odom Outcome Score. Patients will be asked to indicate whether they have been

diagnosed with new episodes of CDDD and how these were treated. All patients

will receive a clinical neurological exam to objectify clinical outcomes.

Study description

Background summary

Cervical degenerative disc disease (CDDD) results from degeneration of cervical intervertebral disc(s) and/or the adjoining vertebral bodies. This causes clinical symptoms of cervical myelopathy, radiculopathy or myeloradiculopathy. Surgical treatment can be an option if non-surgical treatment options provide insufficient relief. The standard surgical technique for treating single or multilevel CDDD is anterior cervical discectomy, either without (ACD) or with fusion (ACDF). Both ACD and ACDF have good short-term clinical results in 90-100% of patients. Both techniques also have a high rate of fusion, respectively 70-80% and 95-100% 1. After 7-20 years, patient satisfaction slowly drops to 68-96% 2. The reason for this decline is thought to be due to the development of adjacent segment disease (ASDis). This is defined as the development of new complaints of radiculopathy or myelopathy due to degeneration one level above or below the previously operated segment. This occurs in approximately 25% of patients during 10 years follow-up and more than 2/3 of these patients need additional surgery 3. The underlying mechanism is thought to be compensation of loss of motion in the fused segment, resulting in overstraining of the adjacent segments 4. Anterior cervical discectomy with arthroplasty (ACDA) is developed in an effort to reduce the incidence of ASD by preserving physiological motion in the operated segment.

Although the term *physiological motion* is commonly used, a proper definition has been lacking for a long time. Segmental range of motion (sROM, e.g. the amount of sagittal rotation in a segment between maximal flexion and maximal extension position of the entire cervical spine) is most commonly used to study motion. SROMs, however, suffer from large intra- and interindividual variability 5,6. Therefore, in the lower cervical spine, Boselie et al have recently described a consistent sequence of segmental contribution in sagittal rotation during flexion and extension in 20 healthy participants 7,8. This was based on historic reports by van Mameren et al 5,6. The mean age of the healthy participants was 23 years (SD 2.65, range 18-55 years). They showed that the sequence of segmental contributions in the lower cervical spine during the second half of extension of the entire cervical spine and head was uniform in 80-90% of the healthy participants. The sequence of segmental contributions was C4-C5 followed by C5-C6, and then C6-C7. Also, they described a group of ten single level cervical degenerative disc disease (CDDD) patients in which this sequence was present in only one patient (10%) 7. This is the first method

described which can reliably differentiate between normal or abnormal movement of the cervical spine in an individual subject.

Moreover, Boselie et al performed a randomized controlled trial (RCT) to compare the presence of this physiological motion pattern and clinical outcomes for ACDA (n=12) and ACD (n=12) patients. Before the randomization 3 patients were operated in a pilot group (all with ACDA), so in total 27 patients with CDDD and radiculopathy were operated. In both groups 10 patients were available for follow-up at one year and fusion rate was 0% in the ACDA group and 70% in the ACD group. The majority of patients in the ACDA group (80%) showed a normal sequence of segmental contribution of motion. There were no differences in patient reported outcome measures, however the study population was small. These data have been submitted but not been published yet since follow-up duration is considered to short for most journals. The primary goal at the moment was to analyze sequence of segmental contribution of motion for which a follow-up duration of one year seemed appropriate. It was also common for this type of study at the moment the study was started. However, the expected advantage of the ACDA lies in the long-term since it should lead to less ASD by preserving physiological motion in the operated segment. Therefore, longer follow-up is needed to be able to determine if this physiological pattern remains present in the majority of the ACDA group in the long term.

Several RCT*s have been published in the past 10 years to assess the effects of ACDA versus ACD or ACDF in the treatment of cervical radiculopathy/myelopathy due to single level CDDD. A Cochrane review of 9 studies with a total of 2400 included patients were analyzed, the results for the ACDA group were better than the ACDF group for all comparisons after 1-2 years. However, the actual differences in effect were small and not clinically relevant for any of the primary outcomes 9. More recently, long-term results of the previously mentioned RCT*s are being published. The ACDA group shows better results on neck complaints and a lower amount of re-operations at adjacent levels 10.

In the RCT performed by Boselie et al, the first patient was operated in December 2007 and the last one patient in September 2014. At this moment the follow-up duration is therefore 6 to almost 13 years. Our method for analyzing the sequence of segmental contribution of motion and to differentiate between normal or abnormal movement 8 has not been used before in long-term follow up of CDDD patients who underwent surgery. Therefore, we want to analyse the movement of the cervical spine in these 27 patients again in the long-term (at an average follow up of 9 years). We hope to be able to define a different movement pattern in patients undergoing ACD or ACDF. We expect to see an increase in motion on the levels adjacent to the operated segment. This might support our hypothesis of the development of ASD after fusion surgery.

Study objective

The primary objective of this study is to investigate the sequence of segmental

contributions in the cervical spine in the long-term follow-up of surgery for CDDD. Specifically, the motion of the cervical spine after ACD and ACDA will be analyzed compared to the short-term follow-up at one year after surgery.
The secondary objectives will be to correlate these motion patterns to the long-term clinical outcome of the long-term follow-up of these patients.
Clinical outcomes will be assessed according to the visual analogue score (VAS) score for neck and arm pain, the neck disability index (NDI), SF-36 and Odom Outcome Score.
Moreover, patients will be asked to indicate whether they have been diagnosed with new episodes of CDDD and if/how these were treated.
All patients will undergo a clinical neurological exam to assess clinical outcomes.
Moreover, the degree of degeneration will be determined on lateral X-rays of the cervical spine and scored according to the Kellgren classification.

Study design

This is a fundamental research project in which a cohort of previously operated patients will be included. All of these patients were previously operated in the setting of a randomized controlled trial. Initial flexion and extension cinematographic recordings of the cervical spine have been made before surgery, and at three months and one-year post-operatively. We will now make similar cinematographic recordings to assess the long-term changes in cervical segmental range of motion in this group of patients having undergone ACD or ACDF.
Participants have previously indicated that they are open to be contacted for follow-up studies. They will be asked to participate in this study through a phone call, after which an information letter will be sent to them. Informed consent will be signed after a reflection period of at least 7 days, if they are willing to participate.

Study burden and risks

Flexion- and extension cinematographic recordings are made using the Philips Allura Xper FD20 X-ray system. Radiation dose per cinematographic recording, determined by radiation experts, will be around 0.084 mSv. A lateral X-ray of the cervical spine will be made to asses fusion on the operated segment and degeneration at adjacent levels (according to the Kellgren*s classification), resulting in a radiation dose of 0.0096 mSv. Average radiation dose per participant will therefore be 0.0938 mSv.
This amount of radiation can be categorized in category IIa using the Neurocritial Care Society (NCS) guidelines about risk of radiation dosage (0.1-1mSv) [Dosimetry NCOr). This category includes moderate risk which can be justified if there is a potential health benefit for future patients.

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 will now be included according to the following criteria:
- All participants of previous RCT
- Able to perform flexion/extension movement of the cervical spine
- Signed informed consent

Exclusion criteria

Patients were excluded in the RCT based on the following criteria, and will now be excluded based on the same criteria:
- Ongoing or active infection
- Previous or actual tumorous processes in the cervical region

- Pregnancy
- Previous radiation therapy in the cervical region
- Not being able to speak Dutch

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2022
Enrollment:	27
Type:	Actual

Ethics review

Approved WMO

Date:	28-09-2020
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL74644.096.20