Stability and function of the Prodisc-C VIVO cervical disc replacement. A radiostereometric (RSA) study

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Primary Objective: To investigate the primary stability of the Prodisc-C Vivo cervical disc replacement in the intercorporal space with regard to the adjacent vertebrae in patients with cervical disc disease.Secondary Objective(s): To evaluate...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Interventional

Summary

ID

NL-OMON38907

Source
ToetsingOnline

Brief title
Prodisc-C Vivo RSA

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Bone and joint therapeutic procedures

Synonym
cervical disc disease; cervical disc degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: AO Technikal Kommittee (AOTK)

Intervention

Keyword: cervical disc disease, cervical total disc replacement, RSA

Outcome measures

Primary outcome

Primary outcome:

Stability of both the upper and lower end plates of the Prodisc-C Vivo cervical disc replacement with regard to the adjacent cervical vertebrae. Stability is defined as the absence of micro-motion or migration. Migration is defined as the amount of translation in mm along the x-, y-, and z-axis and rotation in degrees around the x-, y-, and z-axis. As the accuracy is only acceptable for the translational component of migration, this is will be the main focus in this study. Migration will be measured using model-based radiostereometric analysis (MB-RSA). At 6 weeks, double RSA-measurements will be performed to assess the precision of the measurement method and to assess the level of *migration* that is no migration.

Secondary outcome

Secondary outcomes

* Neck Disability Index (NDI)

* NRS pain (arm and neck)

* Maximal flexion and maximal extension mobility of the cervical spine using radiographic motion in the sagittal plane was measured according to the method described by Frobin et al.

Study description

Background summary

Anterior cervical discectomy and fusion (ACDF) has been regarded the *gold standard* of surgical intervention in the treatment of cervical disc diseases. However, in the last years several clinical trials in which cervical total disc replacement (CTDR) was compared with ACDF, reported results are in favour for CTDR 1,2. Very few complications or adverse events have been mentioned. Above all, as CTDR aims to preserve segmental motion and with that to prevent the incidence of adjacent segment disease (ASD)3, the results of these studies showed that the cervical disc replacement retained this segmental motion. Cohort studies evaluating the long-term performance of different types of cervical disc prostheses report maintenance of clinical motion and function outcomes1,4,5 . However, due to study limitations concern still exists for long-term heterotopic ossification at the index level, spontaneous fusion, and failure to maintain motion and function.
The Prodisc-C Vivo is a 3rd generation (after Prodisc C and Prodisc C nova) CE-marked disc replacement implant for patients with disc degeneration, soft disk lesions, or cervical HNP. So far, no adverse events have been reported. The Prodisc-C Vivo replaces the cervical intervertebral disc to restore disc height and to maintain cervical mobility. Because of this mobility, and because the implant will be inserted between two cervical vertebrae without additional instrumentation, it is necessary to investigate the stability of the implant with regard to the adjacent cervical vertebrae. Furthermore, because the endplates of the implant are smaller than the body of the adjacent vertebrae, a possibility exists that the implant subsides into the vertebra below the index level. This could be detrimental for the mobility of the cervical spine. As the implant enables mobility of the cervical spine, early return to functioning and activities are necessary for proper functioning of the implant. This could be achieved safely when the implant is in a primary stable position in the intervertebral space.

Study objective

Primary Objective:
To investigate the primary stability of the Prodisc-C Vivo cervical disc replacement in the intercorporal space with regard to the adjacent vertebrae in patients with cervical disc disease.

Secondary Objective(s):
To evaluate mobility, pain, and function of the cervical spine after implantation of the Prodisc-C Vivo.

Study design

This study is a single centre, single surgeon prospective cohort study. The primary endpoint of the study is the stability of the Prodisc-C Vivo as measured with model based radiosteriometric analysis (MB-RSA) at 6 months follow-up.

Intervention

All patients receive the Prodisc-C Vivo cevical disc replacement.

Study burden and risks

Patients participating in this study will not be barred by any additional risk other than the regular risks for a cervical disc replacement. Regular risks are migration, infection, heterotopic ossification, spontaneous fusion, risks associated with anterior decompression. These risks will be recorded.

The dose of the RSA measurement is reasonably low. The patients will visit the clinic at regular follow-up moments. The questionnaires of the cervical spine will take a bit more time but do not bring any extra burden. The risks associated with participation can be considered negligible and the burden can be considered minimal.

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

* Single level C3-7 radiculopathy due to herniated disc, degenerative disc disease or spondylosis (confirmed by MRI)
* Preserved motion at symptomatic level (confirmed by flexion/extension X-rays)
* Failure of conservative treatment for at least 6 weeks
* Age > 21 years
* Written informed consent

Exclusion criteria

* Cervical deformity (kyphosis or lordosis or congenital)
* Loss of lordosis
* Multilevel spondylosis
* Disc height less than 50%
* Cervical trauma and instability
* Facet arthritis
* Infections
* Previous surgery at index level
* Osteoporosis
* Pregnancy (or plans to become pregnant during the study)
* BMI > 30
* Metastases

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2014
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO

Date:	13-11-2013
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL46526.048.13

Study results

Date completed:	22-12-2017
Actual enrolment:	16