The clinical and radiological outcome of patients with recurrent radiculopathy after hernia surgery and lytic spondylolisthesis treated with posterior lumbar interbody fusion and percutaneous sextant pedicle fixation

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To investigate differences in clinical outcome between patients with lytic spondylolisthesis and residual hernia surgery pain undergoing minimal invasive spinal fusion surgery. Beside this clinical outcome we investigate the radiological outcome of...

Ethical review	Approved WMO
Status	Pending
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON37902

Source
ToetsingOnline

Brief title
Outcome of lumbar interbody fusion with Sextant technique

Condition

- Tendon, ligament and cartilage disorders

Synonym
radiculopathy, spinal nerve entrapment

Research involving

Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Interbody fusion, recurrens radiculopathy, Sextant, spondylolisthesis

Outcome measures

Primary outcome

Is the outcome of patients undergoing 1- or 2-level posterior lumbar interbody

fusion in combination with minimally invasive pedicle screw placement

(MIP-PLIF technique) the same for patients who had residual hernia surgery pain

as for patients with lytic spondylolisthesis?

Secondary outcome

Does significant subsidence of the cage occur two years after surgery in these

80

patients? If there is significant subsidence, is there a significant difference

between the groups?

Study description

Background summary

Minimally invasive lumbar fusion surgery is in his infancy. Magerl first reported the use of percutaneous pedicle screws for spinal fusion in 1982. Foley et al subsequently advanced the design of percutaneous pedicle screws, combined with the tubular retractor system. This led to the development of minimally invasive percutaneous posterior lumbar interbody fusion (MIP-PLIF). The first MIP-PLIF using the Sextant system (Medtronic) was performed in 2001 (7). The first results of this new technique are promising and in our hospital

we have performed lumbar fusion with the Sextant system in over 300 patients with lytic spondylolisthesis and patients with recurrent radiculopathy after hernia surgery. Our experience is that patients with a lytic spondylolisthesis undergoing minimally invasive interbody fusion have a better outcome than patients with recurrent radiculopathy after hernia surgery. To our knowledge there is no study comparing the outcome of lumbar fusion surgery in these patient groups.

Study objective

To investigate differences in clinical outcome between patients with lytic spondylolisthesis and residual hernia surgery pain undergoing minimal invasive spinal fusion surgery. Beside this clinical outcome we investigate the radiological outcome of the lumbar fusions.

Study design

Retrospective study with prospective follow-up. Two cohorts of an equal number of 40 patients. One cohort with diagnosis lytic spondylolisthesis and one with diagnosis recurrent radiculopathy after hernia surgery. All 80 patients underwent 1-level or 2-level lumbar spine fusion in our hospital between 2002 and 2010, using the MIP-PLIF technique (Sextant system, Medtronic). The cohorts will be matched for age, gender and follow-up time. Data will be collected after a minimal follow-up time of two years after surgery. Enrolment criteria included available demographic, surgical and clinical outcome data.

Study burden and risks

One single X-ray. (X lumbal spine lateral)

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

Adults (>18 yrs)
Patients who underwent 1-level or 2-level lumbar spine fusion with new sextant technique (performed in St Elisabeth hospital between 2002 and 2010)

Exclusion criteria

No spondylodesis prior to the spinal fusion with sextant technique
Age <18 yrs

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-10-2011
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO Date:	16-03-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL38113.008.11