

# 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...

|                              |  |
|------------------------------|--|
| <b>Ethical review</b>        | Approved WMO                             |
| <b>Status</b>                | Pending                                  |
| <b>Health condition type</b> | Tendon, ligament and cartilage disorders |
| <b>Study type</b>            | 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**

### **Public**

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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 |