

# Cervical split laminectomy vs conventional cervical laminectomy for treatment of cervical myelopathy

Published: 15-09-2015

Last updated: 19-04-2024

The purpose of this study is to evaluate the long-term results of the split laminectomy and compare these results to the long-term results of the conventional laminectomy. The prevalence of kyphosis and segmental instability is being investigated...

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Head and neck therapeutic procedures
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON42752

### Source

ToetsingOnline

### Brief title

Cervical split laminectomy for treatment of cervical myelopathy

### Condition

- Head and neck therapeutic procedures

### Synonym

spinal canal narrowing

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Sint Lucas Andreas Ziekenhuis

**Source(s) of monetary or material Support:** geld vanuit het SLAZ zelf

## Intervention

**Keyword:** Cervical, laminectomy, myelopathy, split

## Outcome measures

### Primary outcome

Baseline and short-term functional status was scored via a questionnaire, the Nurick outcome scale. Long-term follow-up functional status was scored by means of a set of questionnaires: The Nurick outcome scale, the adjusted JOA scale and Neck disability index.

Preoperative fluoroscopy and MRI of the cervical spine were evaluated. The fluoroscopy was used to determine the presence of kyphosis and segmental instability using the methods of, Matsumoto and Knopp respectively.

The preoperative MRI was evaluated to confirm the diagnosis of spondylotic myelopathy, to count the number of stenotic levels and to assess the presence of any lesions in the spinal cord. Moreover, the compression ratio of all cervical levels was measured by dividing the sagittal diameter of the medulla by the transverse diameter

### Secondary outcome

At long-term follow-up a lateral and a flexion-extension fluoroscopy was obtained and evaluated for the presence of kyphosis and segmental instability. Anteroposition of more than 2 mm of two adjacent corpora occurring upon motion was considered as segmental instability.

In addition, prospective data of the perceived recovery were retrieved from a questionnaire at long-term follow-up, at least 3 year postoperatively

# Study description

## Background summary

Degenerative changes in the cervical spinal column leads to compression of the spinal cord and causes cervical spondylotic myelopathy (CSM). Patients with CSM often have severed neurological deficits such as sensory complaints, disturbance of fine motor skills and disability in walking. If these neurological symptoms become invalidating, surgical decompression of the spinal cord can be performed by either an anterior or a posterior approach. Both approaches have been commonly used but have several important drawbacks. Because of these drawbacks no real consensus has been reached. The decision-making and applied type of surgery still depends greatly upon the surgeon's preference and familiarity with the type of surgery. Posterior decompression by laminectomy or laminoplasty is often performed for the treatment of cervical spondylotic myelopathy (CSM). However, the posterior approach is associated with postoperative neck pain, frequent wound problems, decreased range of motion and high risk of late kyphosis with swan-neck deformity. These problems are putatively due to stripping of muscular and ligamentous attachments causing denervation and devascularization of the dorsal cervical musculature. To avoid such complications, without losing the benefits of decompression, Shiraishi et al. developed the so-called \*skip\* laminectomy technique with the idea to minimize the drawbacks. The short-term postoperative results compared to the conventional laminectomy techniques were promising. Similar degree of decompression of the cervical spinal cord was found while minor complications occurred. We modified Shiraishi's \*skip\* laminectomy technique and conducted this new \*split\* laminectomy technique in patients with CSM since 2004. In the period between 2004 and 2013 over 100 patients were treated with this modified technique.

## Study objective

The purpose of this study is to evaluate the long-term results of the split laminectomy and compare these results to the long-term results of the conventional laminectomy. The prevalence of kyphosis and segmental instability is being investigated, as well as the functional outcome and the patient's perceived recovery. Furthermore, correlations will be evaluated between radiological and clinical outcome. In addition, predisposing variable will be investigated. Hereby we hope to find new insights in the safety and effectiveness of the split laminectomy.

## Study design

Retrospective database research with follow-up

## Study burden and risks

Nature and extent of the burden and risks associated with participation are considered very low.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)  
Elderly (65 years and older)

### Inclusion criteria

all patients who underwent a cervical split laminectomy because of cervical myelopathy between the first of januari 2004 and 31 december 2013 in the SLAZ (Sint Lucas Andreas Hospital).

## Exclusion criteria

No medical data available  
pre-operative MRI of fluoroscopy not available  
Cervical operation in patients history  
Operation because of other reason then cervical spondylotic myelopathy  
Applying cervical spondylodesis during operation  
Additional neurological impairment  
congenital misformed cervical spine  
Patient is deceased  
patient is not available  
patient gave no informed consent

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Will not start

Enrollment: 0

Type: Anticipated

## Ethics review

Not approved

Date: 15-09-2015

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## 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	NL54661.100.15