Greger Lønne

Surgical treatment of Lumbar Spinal Stenosis: X-stop vs Minimally Invasive Decompression

Image assessment, treatment effects and health economic evaluations

Thesis for the degree of Philosophiae Doctor

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Sammendrag på norsk

Denne avhandlingen er basert på en norsk randomisert og kontrollert multisenterstudie med fokus på diagnostikk og behandling av pasienter med lumbal spinal stenose (LSS). LSS er den vanligste årsaken til ryggkirurgiske inngrep hos eldre. Den medisinske og teknologiske utviklingen har bedret mulighetene for diagnostikk og behandling av denne pasientgruppen. Bildediagnostikk har endret seg fra røntgen, via CT-undersøkelse til MR, som brukes mest i dag. Behandlingen siste par tiår har endret seg fra større åpen laminektomi til mini-invasiv dekompresjon.

En ny behandlingsmetode er introdusert som "ekspanderende interspinøst implantat". I 2005 ble X-stop som den første implantatet godkjent av FDA i USA. Studier viste at den var mer effektiv enn konservativ behandling. Målet med vår studie var å sammenlikne X-stop med den operasjonsmetoden som må sies å være gullstandard nå, nemlig mini-invasiv dekompresjon. Vi ønsket å vurdere de preoperative MR-bildene, samt å finne ut hvilken metode som ga best effekt og å gjøre en helseøkonomisk sammenlikning to år etter behandling.

I denne studien ble 96 pasienter i alderen 50 til 85 år inkludert til randomisering. Preoperative bilder var tilgjengelig for vurdering fra 84 pasienter, mens 81 av pasientene ble behandlet og fulgt opp i 2 år etter å ha blitt randomisert til enten X-stop (n=40) eller mini-invasiv dekompresjon (n=41). Symptomer i bena ved gange kortere enn 250 meter, og varighet over 6 måneder var viktige inklusjonskriterier. Pasienten skulle ha forsøkt konservativ behandling. Lindring av symptomer ved framoverbøyning av ryggen var et inklusjonskriterium, siden det var essensielt for effekten av X-stop.

Den første studien sammenliknet to ulike måter å vurdere graden av lumbal spinal stenose ved axiale snitt på MR-bilder; arealmåling eller morfologisk gradering A-D. Vi fant at det var god samstemmighet mellom metodene vurdert av to uavhengige radiologer, og at begge metodene kan brukes til å vurdere lumbal spinal stenose på MR-bilder.

Den andre studien viste at begge metodene ga signifikant bedring av symptomer ved alle målinger fra 6 uker til 2 år etter operasjon. Det var ingen signifikante forskjeller i symptomer mellom metodene på noe måletidspunkt, men en midtveis interim analyse viste signifikant flere reoperasjoner i X-stop-gruppen. Inklusjon ble derfor stoppet ved 96 inkluderte pasienter og ikke etter 180 slik planen var. Risikoen for peroperative komplikasjoner var like høy i begge gruppene, men det var mer alvorlige komplikasjoner i mini-invasiv dekompresjonsgruppen.

I den helseøkonomiske analysen i den tredje studien fant vi en incremental cost-effektivitetsratio (ICER) på € 25 700,- (NOK 218 000,-). Det vil si at det er 50% sjanse for helseøkonomisk gevinst hvis man er villig til å betale dette beløpet ekstra for et kvalitetsjustert leveår ved å bruke av X-stop i steden for mini-invasiv dekompresjon. Det var en ikke-signifikant bedre effekt i X-stop gruppen, men X-stop var altså dyrere og hadde signifikant flere reoperasjoner.

Vi konkluderte med at begge behandlingsmetodene ga signifikant bedring av symptomene etter 2 år, men at X-stop hadde flere reoperasjoner og var dyrere.

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I am especially grateful to all those patients who participated in the study. By sharing your experiences, you have helped to add new knowledge to the science of spine surgery.

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At last, I want to express my deepest gratitude to the most important people in my life: my wife, very best friend, and the love of my life, Anne Merete, and to our wonderful children Vetle, Sindre, Brede, Eline, and Endre. This is teamwork!

List of papers

I. Lønne G, Ødegård B, Johnsen LG, Solberg T, Kvistad KA, Nygaard ØP.
MRI evaluation of lumbar spinal stenosis: is a rapid visual assessment as good as area measurement? *Eur Spine J. 2014 Jun;23(6):1320-4.*

II. Lønne G, Johnsen L G, Rossvoll I, Andresen H, Storheim, K, Zwart JA, Nygaard OP.
Minimally invasive decompression versus X-stop in Lumbar Spinal Stenosis: A randomized controlled multicenter study. *In press, Spine.*

III. Lønne G, Johnsen LG, Aas E, Lydersen S, Andresen H, Rønning R, Nygaard ØP.
Comparing cost-effectiveness of X-stop to minimally invasive decompression in lumbar spinal stenosis: a randomized controlled trail. *Reviewed, addressing comments; Spine.*

Acronyms and abbreviations

CEAC	Cost effectiveness acceptability curve
CT	Computer tomography
DSCA	Dural sac cross-sectional area
EQ-5D	European quality of life - 5 Dimensions
FDA	Food and Drug Administration
HRQoL	Health-related quality of life
ICER	Incremental cost effectiveness ratio
IPD	Interspinous process decompression
ITT	Intention to treat
LSS	Lumbar spinal stenosis
MID	Minimally invasive decompression
MRI	Magnetic resonance imaging
NIC	Neurogen intermittent claudication
NRS	Numeric rating scale
ODI	Oswestry Disability Index
PP	Per protocol
PROM	Patient reported outcome measurement
QALY	Quality adjusted life year
RCT	Randomized controlled trail
SF-6D	Short form – 6 dimensions
SG	Standard gamble
TTO	Time trade off
VAS	Visual analogue scale
WTP	Willingness to pay

Summary

This dissertation is based on a randomized controlled Norwegian multicenter study and focuses on diagnosis and treatment of lumbar spinal stenosis (LSS), which is the most common reason for spinal surgery among the elderly. As new medical technology has improved, so has the diagnostic and treatment options. Imaging has gone from x-ray via CT scan to MRI, the trend within surgery over the last two decades has gone from laminectomy with larger incisions to minimally invasive decompression. A new treatment method has been introduced as interspinous process decompression (IPD). In 2005, X-stop became the first IPD device to be approved by the US Food and Drug Administration (FDA). The aims in this study were to compare X-stop to what is regarded as the gold standard, namely minimally invasive decompression. We wanted to assess the image evaluation done prior to the operative treatment and ascertain whether X-stop or minimally invasive decompression provides the best clinical outcome and health economic efficacy two years after treatment.

In this study 96 patients were included for randomization. Eligible patients were aged 50–85 years and exhibited symptoms of neurogenic intermittent claudication within 250 meters walking distance for at least six months. Symptom relief through spinal flexion was an inclusion criterion, since this was a necessary indication for the use of X-stop. Preoperative images from 84 patients were available for the first paper; 81 patients completed the two-year follow-ups and were randomized to either X-stop (n = 40) or minimally invasive decompression (n = 41). Due to the significant reoperation rate in the X-stop group, the study was terminated after a midway interim analysis.

In the first study, we compared two different ways of assessing LSS on preoperative axial view via MRI and found the inter- and intraobserver agreements of area measurement and morphological grading A–D to be acceptable. The intercorrelation between the methods was strong, and both methods may be used in the MRI evaluation of LSS.

The second study showed that both X-stop and minimally invasive decompression led to significant symptom improvements. There were no significant clinical differences in effect between the methods at any of the follow-up time points, yet X-stop had a significantly higher rate of secondary surgery. The risk of surgical complications was equal in both groups, but more severe for minimally invasive decompression group.

Comparing cost-effectiveness of X-stop to minimally invasive decompression in the third study revealed an incremental cost-effectiveness ratio (ICER) of € 25,700, which means that there was a 50% likelihood that X-stop is cost-effective at the additional price for a quality-adjusted life-year (QALY) compared to minimally invasive decompression. The difference in effect was insignificant. The significantly higher cost of X-stop is mainly due to implant cost and the significantly higher reoperation rate.

We concluded that both methods had significant effect at all follow-ups, and that there were no differences in effect between the methods. X-stop was significantly more expensive. High reoperation rate in the X-stop group is a clear disadvantage with this method, although minimally invasive decompression has a potential for more severe complications.

1: Introduction to study

This dissertation focuses on diagnosis and treatment of lumbar spinal stenosis (LSS). First, it compares two different ways of assessing stenosis on preoperative MRI. Second, it compares the effect of two different operation methods, namely X-stop and minimally invasive decompression, in a randomized controlled Norwegian multicenter study. And third, through a health economic evaluation, it assesses the cost-effectiveness of the two different treatments.

1.1: Rationale

LSS is the most common reason for spinal surgery among the elderly.[1] It is important to evaluate and improve the diagnostic and treatment of this condition, including evaluation of MRI images, which is essential in the diagnostic process. Decompression surgery is the gold standard for surgical treatment. The trend has gone from laminectomy with larger incisions a few decades ago, to minimally invasive decompression today. A new treatment method has been introduced as interspinous process decompression (IPD). In 2005, X-stop became the first IPD device to be approved by the US Food and Drug Administration (FDA) in the US.[2] It demonstrated better outcomes than conservative treatment[3], but could it be better than the present standard treatment—i.e. minimally invasive decompression? And would the device be cost-effective? When we began planning this randomized trial, these questions were important issues in assessing this new treatment method.

1.2: Background

In anatomical or imaging terms, LSS refers to a reduction in the cross-sectional area of the spinal canal.[4] MRI shows an hourglass-shaped narrowing of the spinal canal at disc level in sagittal

view, and limited area available for the nerve structures in axial view.[5 6] When symptomatic, LSS causes variable symptoms of gluteal and/or lower-extremity such as pain and/or fatigue, which may occur with or without back pain.[7] Neurogen intermittent claudication (NIC) can be defined as claudication accompanied by pain and paresthesias in the back, buttocks, and lower limbs that is relieved by flexion. It is caused by mechanical disturbances resulting from compression or by ischemia of the cauda equina, usually in association with LSS.[8] Symptomatic LSS has certain characteristic provocative and palliative features. Provocative features include upright exercise such as walking or positional-induced neurogenic claudication. Palliative features commonly include symptomatic relief with forward flexion or sitting.[9]

Since Verbiest in the fifties first described the probable cause of LSS[10], and the pathoanatomic basis later was further clarified[11 12], new medical technology has improved both diagnostic and treatment options for LSS. Imaging has changed from x-ray to CT scan to MRI, and treatment has shifted from large open laminectomy to minimally invasive techniques.

Still, there are many unanswered questions. Significant narrowing of the spinal canal on MRI scans may be asymptomatic[13], and patients with classical symptoms of LSS may have minor stenostic changes on MRI.[14] The indication for operation is relative, based partly on the individual patients' condition and preferences and partly on the surgeons' expert advice. The results from surgical treatment vary[15-17], and there is no strict consensus on which treatment to use, when to fuse, and the role of other techniques, such as IPD devices.[18] For the decision-makers, new methods have to be evaluated in light of cost-effectiveness to ensure that resources are used optimally when treating this growing patient group.

1.3: Pathogenesis

LSS can cause symptoms early in life among patients with a congenitally narrow spinal canal which can, but the vast majority acquires LSS after the age of fifty. The spinal canal's diameter can be reduced as a consequence of a normal aging process. The most important morphological changes are enlargement of the facet joints, thickening of the ligaments, and bulging of the intervertebral disc, often described as spondylosis (Figure 1).[6 19 20] These are slow processes and gradually seem to yield symptoms that have their origin from the level where compression of the neural structures is greatest.[21]

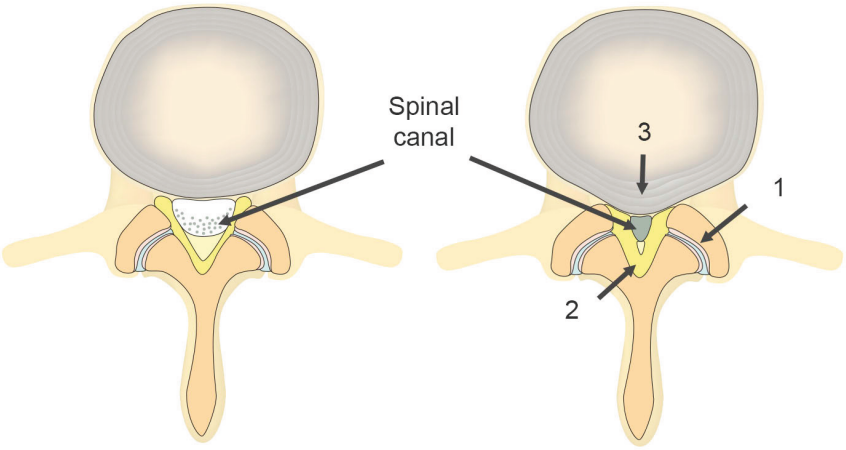

Figure 1. Left: Axial view of a normal spine at disc level. Right: Enlargement of the facet joints (1), thickening of the ligamentum flavum (2), and bulging of the intervertebral disk (3) causing lumbar spinal stenosis.

1.4: Epidemiology

The presence of a narrow spinal canal found on radiological images in asymptomatic individuals is higher, from 10–50% depending on age and imaging definition and type.[13 22 23] This can be misleading in diagnosing LSS.[24] While there are no gender differences in incidence of LSS, the prevalence of symptomatic LSS is approximately 10% and normally starts after the age of fifty.[25] With the growing number of elderly[26] and greater demands on quality of life, the number of operations will probably increase in the future, thus rendering the present research especially important.

1.5: Diagnosis

Although classical symptoms and signs described as NIC are predominant features for LSS, diagnosing LSS sometimes can be challenging. Symptoms may vary in character and intensity.[27 28] The condition frequently coexists with other common problems in elderly, including osteoarthritis of the hips, trochanteric bursitis, polyneuropathy, vertebral osteoporotic fractures, nonspecific lower-back pain, and vascular claudication.

There is no single clinical test that gives the diagnosis. Walking or treadmill tests can sometimes confirm the suspicion[29], but they are usually too time consuming to be performed in a normal outpatient clinic. Neurological findings, such as wide-based gait, abnormal Romberg test, positive extension test, and neuromuscular deficits are associated with LSS diagnosis.[30] However, neurological tests are usually negative since symptoms often do not appear until the patient has been walking for a certain distance.[9]

Hence, the anamnestic information is crucial for the diagnosis. Careful attention to the patient's story and asking the right questions are important factors for establishing a correct diagnosis and evaluating symptom severity, i.e. impact on activities of daily living and health-related quality of life. It is likewise important to rule out other conditions, such as poor blood circulation in the legs and neurological conditions like polyneuropathy.

1.6: Imaging

X-ray with myelography was for many years the only standard imaging method of LSS. This is an invasive investigation where contrast fluid is injected into the spinal canal, giving a good visual impression of the number of affect levels and the degree of stenosis.[31] The use of CT scan myelography improves the imaging and gives further details in the affected area.[32 33] MRI has further improved the imaging and is today the method of choice.[34] But there are still challenges in using MRI.

Evaluation with MRI today is usually based on a quantification of the stenosis at the narrowest place in axial view, either by anterioposterior diameter or by the dural sac cross-sectional area (DSCA). There is no strong consensus on the criteria of diagnosing LSS in radiology. In two different systematic literature reviews, different quantitative[35] and qualitative[36] radiologic criteria are demonstrated. They found great variability in definitions of LSS and in intra- and interobserver agreement of these criteria.

In the mid-eighties Schönström et al., using a CT scan, concluded that the critical DSCA to yield symptoms is below 100 mm^2.[20] Some studies show a linear relationships between symptoms and degree of stenosis[5], other studies show no relationship between area and symptoms.[14 37]

MRI is taken when the patient is lying in supine position, but symptoms appear when walking or standing. Biomechanical tests demonstrate that the spine's posture affects the structures surrounding the spinal canal.[38 39] MRI machines that are able to scan the patient in the upright position show more bulking of the disc and a higher degree of stenosis compared to supine position.[40-42] It also shows that spine by bending forward enhances the space available for the nerves[43] and thus can relieve the pain temporarily. But this kind of MRI is not available in Norway.

The stenosis can also be evaluated via MRI on qualitative criteria. Schizas et al. introduced a morphological grading A–D based on the amount of cerebrospinal fluid (CSF) surrounding the nerves in axial view.[44] Later he also found that clinicians preferred this direct assessment of the image to DSCA measurement.[45] In everyday practice clinicians often make their decisions based on a morphological assessment of the image.

In addition, LSS can also be classified by anatomically different kinds of stenosis and are usually divided into central, lateral recess, or foraminal stenosis.[46] Central stenosis affects the central part of the spinal canal. Lateral recess stenosis affects the lateral part under the facet joint, and foraminal stenosis affects the nerve on the way out of the nerve root canal under the pedicle. This study addresses central stenosis only.

Spondylolisthesis, where one vertebra slides anteriorly or posteriorly compared to the level below, is sometimes the cause of LSS. This may be considered as a different condition, and in some cases decompression is not enough, but has to be accompanied by instrumental or non-instrumental fusion due to instability. If this is suspected, a lateral x-ray of lumbosacral spine in standing position is important in addition to MRI to evaluate the degree of listhesis and stability.

The diagnostic evaluation and the decision whether or not to operate are usually based on anamnestic information given by the patient. MRI can confirm LSS as a cause of the symptoms but cannot alone give the diagnosis.

1.7: Treatment

LSS treatment depends on symptom intensity and the duration and the patient's general health. Non-operative treatment options are physical therapy, pharmacotherapy, or epidural injections. A systematic review of the literature yielded insufficient evidence to draw conclusions regarding the effectiveness of physical therapy or medical treatment as standalone treatments for LSS.[47 48] There is also no strong evidence in the literature supporting the use of epidural steroids in managing LSS.[49]

Current recommendations in conservative treatment are mainly based on expert opinions that incorporate available evidence into existing clinical and biologic paradigms.[18] Nevertheless, the main guidelines recommend conservative treatment first and then perhaps surgical treatment in patients who do not improve.

Research shows that surgery is more effective than conservative treatment.[15 50-52] The basic principle of surgical treatment is decompression of the nerves structures. The indication for operation is relative, and the patients' quality of life is important when making the treatment decision. Thorough information and shared decision-making between the physician and the patient is the basic principle in this process. LSS is neither a life threatening nor a rapidly deteriorating condition. Amundsen found in his study that an initial conservative approach seems

advisable for many patients, and those with an unsatisfactory result can be treated surgically later with good results.[21]

Laminectomy has been the surgical treatment since Verbiest introduced LSS diagnosis and treatment.[10] The principle of this operation is to remove the back wall of the spinal canal, including lamina with the spinal processes, medial part of the facet joint, and the ligamentum flavum.[53] This is an efficient and relatively safe procedure, but has the potential for some major complications, like hematoma and nerve injury. Approximately 30–40% of patients will experience chronic lower-back pain after laminectomy, probably because of prolonged muscle retraction that may lead to ischemic damage or some kind of instability.[54 55]

One way to deal with the instability problem has been to fuse in addition to decompress.[56] Fusion can either be instrumental with pedicle screws and rods, or non-instrumental with a bone fusion between the affected vertebrae. Meta-studies show that fusion has an uncertain role in plain LSS, but increases the complication rate.[16] Compared to decompression, simple fusion and complex fusion are associated with increased risk of major complications and 30-day mortality. In spite of this, the fusion rate seems to increase in some countries.[16]

Minimally invasive decompression has been predominant the recent years.[57 58] The operation uses smaller incisions and a type of retractor or tubular system and is performed with a microscope. The benefit is that soft tissue and bony structures are saved, yielding faster recovery, less instability problems, and fewer complications.[55 59]

According to Whitesides, Knowles introduced the principle of IPD already in the fifties.[60] But the success was limited and the method did not meet expectations.[61 62] Some IPD device systems have already been in use for several years.[63 64] With the introduction of X-stop in 2005, a new

device was available in spinal surgery. X-stop is installed between the spine processes to provide an unloading distractive force to the stenotic part of the motion segment, thus having the potential to relieve NIC symptoms associated with spinal stenosis.[65] The first randomized control trial (RCT) comparing X-stop to conservative treatment showed promising results.[3 66] Some later studies, mainly cohort studies[67-69], revealed a high failure rate and substantial risk of secondary surgery. While planning the study in 2007, we found no RCT studies comparing X-stop to other operation methods. Later, Strömqvist et al. compared X-stop to decompressive surgery with laminectomy and found that both methods are appropriate procedures. Similar results were achieved in both groups in the intention to treat analysis, but with a higher number of reoperations in the X-Stop group.[70]

1.8: Rationale for a randomized controlled multicenter trial

RCTs are considered the most reliable form of trials in medicine and are widely influential in healthcare policy and practice. They reduce spurious causality and bias because the patients being studied are randomly allocated to one out of two (or more) different treatments. RCTs are the gold standard for clinical trials and are often used to test the efficacy of various types of interventions. Interventions are randomly assigned after subjects have been assessed for eligibility and recruited, but before beginning the studied intervention.

Multicenter trials are clinical trials conducted at more than one medical center. This is done for the ability to include a larger number of participants at different geographic locations. This will shorten the time spent for inclusion and increase the study's generalizability. Efficacy can vary between centers, due to a variety of treatment skills and different demographic factors.

1.9: Measurement of treatment effects

There are multiple ways of measuring effect after LSS treatment.[71] Imaging the postoperative spine can show the change in areal or morphological grading A–D.[45 72] Physical tests evaluated by the physicians, like treadmill walking distance[73], can, when compared to the preoperative state, measure the walking ability gained after the treatment. A common way to assess the results is by patient-reported outcome measures (PROMs). PROMs are multidimensional and provide insight into how the impact of diseases and treatments are perceived by the patients. Several questionnaires have been developed for patients to report about their present state of health, symptoms, or disability. One-dimensional scores can ask a question about a symptom or condition; examples are the visual analog scale (VAS) and numeric rating scale (NRS).[74] They can score the pain from 'no pain at all' to 'worst imaginable pain,' and the difference between preoperative and postoperative state is regarded as the treatment effect. Most diseases have implications in more than one dimension. LSS will usually give symptoms like pain in the leg, but a functional disability can also be measured. Likewise, the impact on social and psychological function can be assessed. There are multidimensional questionnaires for providing a profile of scores, where each scale can be scored and reported separately or as an overall score. Generic and preference-weighted measures of health-related quality of life (HRQoL) is usually expressed as an index and can provide clinical data for cost-effectiveness analyses across different diseases and treatments. There are also multidimensional, but more condition-specific questionnaires designed for a specific disease.

1.10: Cost-effectiveness analyses

Cost-effectiveness analyses (CEAs) are conducted to compare two different treatment options, usually a new treatment to an established or "standard" treatment. For the new treatment to be chosen, it must have a beneficial cost and effect profile compare to the standard treatment. The usual procedure is to find the mean cost and mean effect for each treatment alternative.

Cost

The cost calculated usually reflects the mean cost of each treatment. The cost can be seen from different perspectives, where the main alternative perspectives are the healthcare and societal perspectives. The healthcare perspective includes only costs incurred by the health service, while the societal perspective includes all costs regardless of who incurs them, for example costs to patients or employers in form of productivity losses in addition to health service costs. There is no consensus on which perspective to use, and the rationale can vary from study to study.

There are also different ways to calculate treatment cost for the hospital. In the top-down model the total expenses for each department is divided by the actual number of specific cost units this department yields. These cost units depend on the departments' role and what kind of health-related service they produce. For a surgery department the typical cost units would be surgical minutes. The total cost within a year will be divided by the number of actual operation minutes performed during that year. The cost will include the salary for a standard operation team, all equipment used, and all service expenses related to this department. A cost-weight analysis is done to allocate overall cost to each department. A bottom-up model, by contrast, will typically calculate costs by counting the equipment actually used, the actual use of employees, and the expenses for the specific service acquired.

Effect

When measuring effect in cost-effectiveness studies we would like to use the results as a basis for prioritizing resources across different disease conditions. By measuring HRQoL before and at several time points after treatment, the improvement (or lack of improvement) indicates the treatment's effect over time.

An HRQoL index can be calculated in different ways, and the values usually reflect the rank of health preferences from most preferred to least preferred by a normal population. Different instruments can measure these preferences. Time trade-off (TTO) tariff and standard gamble (SG) are two commonly used examples. In TTO, two alternatives are offered to the subject: either to live with a certain disease for a certain time (t) followed by death or to be healthy for time (x) where $x < t$. Time x is then varied until the subject is indifferent between the two alternatives.[75] In the SG approach, two alternatives are offered to the subject: either live with a certain chronic disease until death, or chose the other alternative to return to perfect health and live for additional years with a probability (p) or immediate death with a probability 1-p. Then p is varied until the subject is indifferent between the two alternatives.

QALY

When the HRQoL index is calculated prior to treatment and at several follow-ups after treatment within a definite time, it is possible to calculate quality-adjusted life-year (QALY). One QALY is defined as one year in perfect health.

QALY can be calculated as the area under the curve by using the trapezoidal method, plotting each measurement in a timeline. The area between treatment B and treatment A is considered as the difference in QALY gained (ΔE) between the two methods (Figure 2).

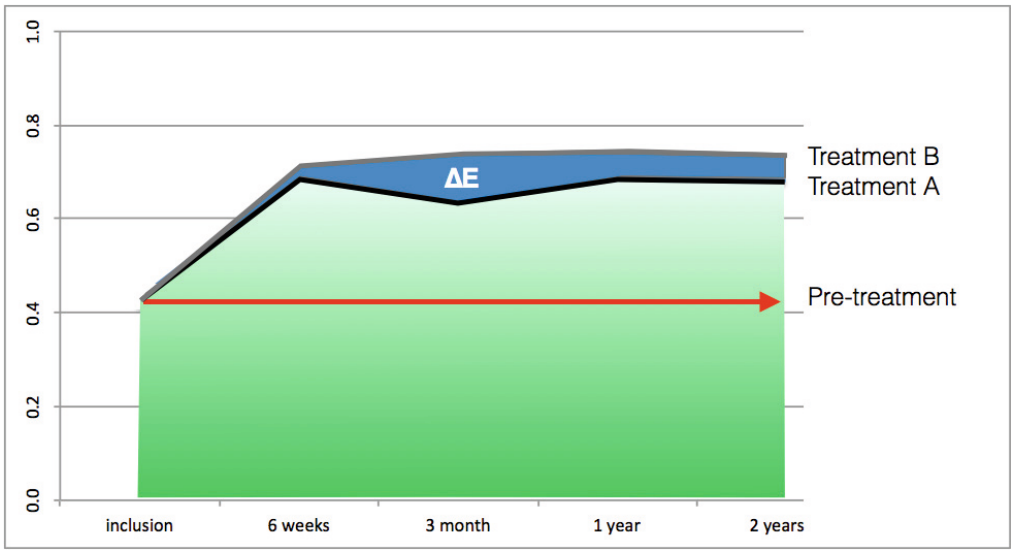

Figure 2: Calculating QALY as area under the curve and the difference in QALY (ΔE) as the difference in area between the two treatment options (A and B), 2 years period.

ICER

Each treatment method will now have a mean cost and a mean effect. Then the difference in cost (ΔC) and effect (ΔE) is presented as a ratio: incremental cost-effectiveness ratio (ICER), which reflects the cost per unit of health gained when switching from standard treatment A to new treatment B. A difference in treatment costs and treatment effect, the ICER, is expressed in the following formula:

$ICER = Cost_{new} - Cost_{std} / Effect_{new} - Effect_{std} = \Delta C/\Delta E$ = cost per unit of health gained.

Variation in incremental cost and the incremental effect can be presented in following cost-effectiveness (CE) plane (Figure 3):

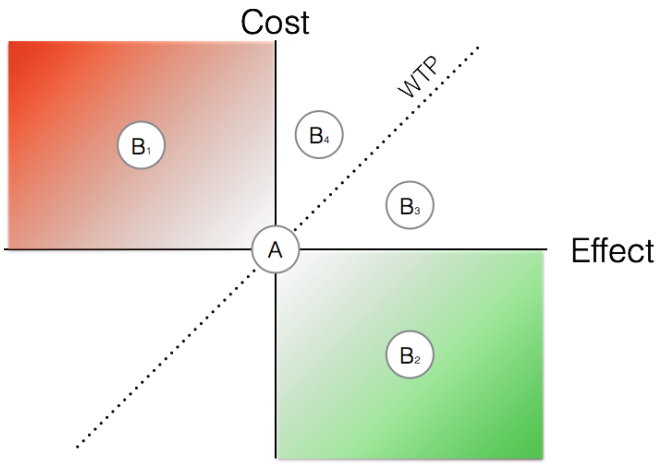

Figure 3: Cost-effectiveness plane

If treatment A is the standard treatment (or control group), the new treatment B can be more or less effective and more or less costly. If less effective and more expensive, the new treatment B_1 will be rejected (northwest quadrant, red); if more effective and less expensive (southeast quadrant, green), the new treatment B_2 will be preferred over the standard treatment A. If the new treatment B_3 is much more effective and with an acceptable additional cost, we may prefer the new one to the standard, depending on the willingness to pay (WTP). If the new treatment B_4 is slightly more effective and far more expensive, we would probably not be willing to pay this extra cost for this extra effect gained. Both will be in the northeast quadrant. The ICER represents the cost for one extra QALY at which there is a 50% chance that treatment B is cost-effective if you change from treatment A. If willing to pay more for a QALY, the chance that the

new treatment B will be cost-effective will increase. The accuracy of the sample means can be visualized in the CE plane by bootstrap technique and by showing a cost-effectiveness acceptability curve (CEAC).[76 77]

2: Aims of the study

The study aimed to compare a new operative technique, X-stop, to what is regarded as the gold standard, namely minimally invasive decompression. We wanted to assess the image evaluation done prior to the operative treatment, and to find out whether X-stop or minimally invasive decompression provides the best clinical outcome and health economic efficacy two years after treatment.

2.1: Specific aims

Paper I

Paper I assessed the inter- and intraobserver agreement of DSCA and morphological grading A–D on preoperative MRI of patients operated on for LSS. We also studied the correlation between the two methods in their ability to distinguish between no stenosis, relative stenosis, or significant stenosis.

Paper II

Paper II compared the effect of X-stop to minimally invasive decompression in patients with neurogenic intermittent claudication and one- or two-level LSS.

Paper III

Paper III compared the cost-effectiveness of X-stop to minimally invasive decompression in LSS.

3: Materials and methods

3.1: Research design

This is a prospective randomized controlled multicenter study, where patients were enrolled from six different Norwegian hospitals between June 2007 and September 2011. The study was designed to have an 80% power to detect a minimal clinically important difference (MCID) of 0.5 points in symptom severity and physical function in the primary outcome measurement, the Zürich Claudication Questionnaire (ZCQ). Based on a standard deviation of 0.9 and a significance level of 0.05, 52 patients were required in each intervention group. We then added up for the heterogeneity in multicenter studies (20%), the risk of dropouts (20%), and the health economics evaluation (20%) to n = 180 (90 in each study arm). A midway interim analysis was performed when 90 patients were treated. They were randomized to either minimally invasive decompression or X-stop and operated on within three months after randomization.

Patients were randomized with randomly selected block sizes by a computer-based web solution hosted by the medical faculty at the Norwegian University of Science and Technology (NTNU). Repeated measurements of the main response variables (preoperatively, six weeks, three months, and one- and two-year follow-ups) were collected. Details from all hospitals were available to a coordinating secretary not involved in the treatment. Independent observers entered data, and permission to store the data was granted by the Norwegian data inspectorate.

3.2: Study participants

Participants were recruited from patients submitted to the six hospitals for NIC due to LSS and included or excluded according to specific criteria. All four health regions in Norway were represented. Eligible patients were aged 50–85 years and exhibited symptoms of neurogenic intermittent claudication within 250 meters walking distance for at least six months. Inclusion criteria also entailed conservative treatment without sufficient effect prior to the inclusion, or such treatment was considered as inexpedient. Symptom relief through spinal flexion was an inclusion criterion, since this was a necessary indication for the use of X-stop. Patients were asked in detail about situations that provided relief, where flexion relief was considered if two of the following conditions were present: the patient was able to sit for more than 30 minutes without pain, could move for a longer distance with the use of a walking aid, bicycle a long distance without pain, and/or used to sleep in a flexed position to avoid pain. All participants had preoperative MRIs to confirm spinal stenosis and x-rays of the lower spine to rule out osteoporotic fractures, deformity, or signs of instability. An orthopedic surgeon or a neurosurgeon at one of the six participating hospitals evaluated the patient before inclusion in the study.

In the MRI study (Paper I) preoperative images from 84 patients were available and included. Three university hospitals, three district hospitals, and some private imaging institutions provided images to the study. In the randomized study (Paper II) and the cost-effectiveness study (Paper III) 96 patients were enrolled from six hospitals between June 2007 and September 2011 either to X-stop or minimally invasive decompression.

3.3: Imaging

The investigation was performed in different hospitals or MRI centers, using 1.5 T MRI systems. All the images were stored directly in DICOM format. All patients had sagittal T1 and T2 weighted images of the lumbar spine. All levels from L2 to L5 available in axial view (197 levels) were investigated regardless of whether the levels were operated later (104 levels) or not (93 levels). Most patient (n = 75) had axial T2-weighted images, but some (n = 9) had proton-weighted images. Based on a visual assessment of signal-to-noise, image contrast, and the presence of artifacts, the image quality was rated by radiologists as good in all patients. All MRI examinations were independently evaluated on a radiologic workstation by two experienced neuroradiologists (interpreter 1 and interpreter 2). The investigators were blind to the operated level. In the intraobserver agreement analysis, 20 images were re-evaluated after 12 months by both interpreters.

In addition, the lumbar spine in flexion and extension was x-rayed to rule out any instability, osteoporotic fractures, or greater scoliosis (Cobbs angle greater than 10°).

DSCA

The dural sac cross-sectional area (DSCA) is defined as the area occupied by the dural sac and its content on the narrowest part at the disc level.[20] The measurement was done on axial images by drawing the outer contour of the sac on a scrollable image set. The investigators were blind to the operated level. In the intraobserver agreement analysis, 20 images were re-evaluated after 12 months by both interpreters. Areal measurement of 100 mm^2 or more represents no stenosis, an area between 100 and 76 mm^2 is relative stenosis, and an area < 75 mm^2 is significant stenosis.[39]

The morphological grading A–D

The morphological grading A–D is based on the CSF/rootlet ratio as seen on axial T2-weighted images. The original publication defined four subgroups of grade A.[44] We did not use these subgroups since they all are defined as no or minor stenosis. In the morphological grading A–D, we defined grade A as no stenosis, grade B as relative stenosis, and grades C and D as significant stenosis.

3.4: Primary outcome

Zürich Claudication Questionnaire

ZCQ is the primary outcome in this study and measures symptom severity, physical function, and patient satisfaction. ZCQ is a multi-dimensional condition-specific questionnaire for LSS. Patient satisfaction is measured only at follow-ups. In the symptom severity scale, seven questions address overall pain, pain frequency, pain in the back, pain in the leg, numbness, weakness, and balance disturbance. In the physical function scale, five questions address walking distance and the ability to walk for pleasure, for shopping, for getting around the house, and from bathroom to bedroom. In the patient satisfaction scale, six questions focus on overall treatment results, pain relief after treatment, walking ability, ability to do housework, and strength and balance in the legs. The answers for each question in the symptom severity scale range from 1 to 5 in severity, while the answers in the physical function and patient satisfaction scales range from 1 to 4. All scales have 1 as the best option, and in both symptom severity and physical function, a change of 0.5 is considered as MCID.[78 79] The scores are reported separately. The questionnaire has been validated into Norwegian (see appendix).[80]

A failure in our ZCQ resulted in omitting the question about leg pain, one out of seven questions in the symptom severity scale. Leg pain is an important feature in NIC. To solve this problem we had the possibility to look at results from another Norwegian trial where we had complete ZCQ data.[80] Here, we substituted the ZCQ question on leg pain with the result from the visual analogue scale score for leg pain. By doing this we were able to demonstrate a Pearson correlation coefficient of 0.98 between the ZCQ symptom severity scale with the original item and the substituted item. To display a realistic and comparable level of this scale, we therefore decided to substitute the omitted question in our ZCQ with the leg pain-specific item from NRS11. The value of NRS11 on leg pain was collected from the same patient at the same time, where 0–1 points in NRS11 equal 1 point in ZCQ, 2–3 equal 2, 4–6 equal 3, 7–8 equal 4, and 9–10 equal 5 points in the omitted question.

3.5: Secondary outcome

ODI

Oswestry Disability Index 2.0 (ODI) is the most commonly used condition-specific outcome measure for spinal disorders in general.[81] The score ranges from 0 to 100, with a lower score indicating less severe pain and disability. It has been validated into Norwegian and tested for psychometric properties (see appendix).[82]

EQ-5D

The EuroQol EQ-5D utility index is a generic score with five dimensions based on responses from a questionnaire: mobility, self-care, activities of daily life, pain, and anxiety/depression. Each dimension is described by three possible levels of problems (no, mild to moderate, and

severe). Hence, this descriptive system contains 243 combinations, or health states, revised into an HRQoL index with a range from −0.59 to 1.00, where 1.00 indicates full health. Syntax files were obtained from the EQ-5D society to calculate the index based on the UK TTO tariff.[83] We used the validated Norwegian version of the EQ-5D (see appendix).[84]

SF-36

Short Form 36 (SF-36) is a generic health-related quality of life questionnaire that measures along eight dimensions: physical function, role limitations due to physical problems, bodily pain, general health, vitality, social function, role limitations due to emotional problems, and mental health.[85] There are 4–6 items per dimension and score ranges from 0–100, where a higher score is related to better health. It is based on the standard gamble (SG) and we used the SF-36 version 2.0 and the index based the UK SG tariff that has been validated to Norwegian (see appendix).[86]

SF-6D

SF-6D is a six-dimensional health state classification system based on SF-36 .[87] The six dimensions are physical functioning, role limitations, social functioning, pain, mental health, and vitality, revised into an HRQoL index with a range from 0.29–1.00, where 1.00 indicates full health.

NRS11

NRS11 is a one-dimensional pain scale from 0 to 10 where the two extreme categories are labeled as ‘no pain at all’ and ‘worst imaginable pain’ (see appendix). NRS11 has proved to be applicable for one-dimensional assessments of pain in most settings, but here it has been used to assess lower-back pain and leg pain.[88]

3.6: Calculating cost-effectiveness

The cost-effectiveness study has a healthcare perspective. Unit costs were estimated in a non-center-specific (single-center) approach by calculating unit costs from a district hospital and applied to all other participating centers. The hospital unit costs were estimated from the hospital department's actual expenses by means of the top-down approach. These were based on a cost-weight analysis done in the revision of diagnosis-related group (DRG) payment system conducted by The Norwegian Directorate of Health.[89-91] The cost units were related to the treatment path of this particular patient group. Resource utilization data for all individuals in the trial were collected and then attach to a standard unit cost for each resource item in order to calculate a cost per patient.[92] All unit costs were calculated in Norwegian Krone (NOK) and adjusted for inflation, with 2010 as the reference year, and converted into Euro using the rate 1 $€_{2010}$ = 8.47 NOK_{2010}.

QALY is based on HRQoL from EuroQoL EQ-5D utility index, measured at baseline, six weeks, three month, one year, and two years after index treatment.[93] QALYs were estimated by combining the HRQoL index and time, calculating the area under the curve by using the trapezoidal method. In the sensitivity analysis, we used HRQoL calculated from SF-6D.

3.7: Statistics

Study 1

In this inter- and intrarater agreement study, the weighted Kappa was analyzed by comparing the two different radiologists' evaluations of DSCA and morphological grading A–D level to level. All levels available in axial view were evaluated, regardless of whether or not they were operated

on. Possible differences in the radiologists' interpretation of number of levels due to transitional vertebrae were not corrected for. The correlation between the radiological findings regarding the two methods was estimated by Spearman rank correlation coefficient.

The weighted Kappa was calculated via Internet freeware, available at http://vassarstats.net/kappa.html. SPSS (IBM SPSS Statistics 19) for Mac was used for other statistical analyses.

Study 2

In this study, which compared the clinical effect of X-stop to minimally invasive decompression, a linear mixed model was used to calculate the mean in the repeated measurements of the main response variables. We measured outcome, at six weeks, three months, one year, and two years postoperatively. In the main evaluation we used an intention to treat (ITT) method. We used a student t-test to compare the means in baseline data. The risk analysis for secondary surgery and complications were given as odds ratios (OR). SPSS (IBM SPSS Statistics 21) and Microsoft Excel 2011 for Mac was used for statistical analyses.

Study 3

In this health economic evaluation study, repeated measurements of the EQ-5D and the arithmetic means of effect were calculated with independent student t-test at each follow-up. Missing data in EQ-5D and SF-6D were handled by multiple imputations with 100 imputed data sets, where one set was randomly picked for the bootstrapping process. QALYs were calculated as the area under the curve, plotting each measurement in a timeline.[94 95] The costs were calculated as the product of the mean amount of units used multiplied by the cost per unit over the two-year period.

ICER was reported as a point estimate. A non-parametric bootstrap method with 1000 replications was used to account for the heterogeneity in costs and health outcomes, and reported in the cost-effectiveness (CE) plane and cost-effectiveness acceptability curves (CEAC). The CEAC reports the likelihood that X-stop is cost-effective according to different levels of WTP. Statistical analyses were performed via SPSS 21 and Microsoft Excel 2011 for Mac.

3.8: Procedures

The procedures used in this randomized trial are both well-defined and described thoroughly in various papers and strictly predefined in a protocol approved by all researchers.

Minimally invasive decompression

Minimally invasive decompression was performed with the patient in a knee-elbow or prone position. A fluoroscope was used to identify the correct level for a 3–5 cm midline skin incision. A microscope was used in combination with a retraction system. Decompression was performed by a partial excision of the lower part of the lamina and the medial aspects of the facet joint exposing the ligamentum flavum. The ligament was resected from the canal to expose the dural sac and the nerve roots. A similar procedure was used for decompression on the other side, or decompression was performed as a bilateral decompression with the ipsilateral approach.

X-stop

X-stop was inserted with the patient in a right lateral decubitus position. A fluoroscope was used to ensure correct level for an approximately 4–6 cm midline skin incision keeping the supraspinous ligament intact. A small, curved dilator was inserted across the interspinous space at the stenotic level as far anterior as possible, as verified by fluoroscopy and expanded by a

larger dilator. A distractor was used, and an assistant flexed the patient's lumbar spine until the supraspinous ligament tightened. The X-stop was then inserted through the interspinous ligament and locked by two wings located laterally on the implant. The X-stop's position was secured by the supraspinous ligament posteriorly and by the lamina anteriorly.

3.9: Study approval

The study was conducted in accordance with the Helsinki Declaration and approved by the Regional Committees for Medical and Health Research Ethics (REC) for central Norway. The data were collected and entered by independent observers, and permission to store the data was granted by the Norwegian data inspectorate. Each patient gave written, informed consent before inclusion. The trial is registered under ClinicalTrials.gov, number NCT00546949.

4: Results

The midway interim analysis showed a significant higher reoperation rate due to lack of improvement or recurring symptoms in the X-stop group. We therefore decided to end recruitment when 96 patients had been included.

4.1: Paper I

Title: "MRI evaluation of lumbar spinal stenosis: Is a rapid visual assessment as good as area measurement?"

Study population

In this paper, preoperative images from 84 patients were available for analyses. The two methods were not used to determine eligibility in the RCT—i.e. the radiological evaluation was performed after the inclusion was completed.

Inter- and intraobserver agreement

The interobserver agreement (95% CI) on DSCA was 0.69 (0.61 to 0.77). The interobserver agreement on the morphological grading A–D was 0.65 (0.56 to 0.74). Thus, the interobserver agreement (95% CI) was good for both methods.[96] The intraobserver agreements for DSCA for the two investigators were 0.77 (0.60 to 0.74) and 0.80 (0.66 to 0.93), and 0.78 (0.65 to 0.92) and 0.81 (0.68 to 0.94) for the morphological grading A–D.

Correlation between the methods

The Spearman rank correlation coefficient was 0.85 ($p < 0.001$). The box plot illustrates a strong, positive correlation between the two methods. Both radiologists graded morphological changes

as C and D if DSCA measurements were under the cut-off value for significant stenosis (75 mm^2).

4.2: Paper II

Title: "Minimally invasive decompression versus X-stop in lumbar spinal stenosis: A randomized controlled multicenter study."

Study population

Mean age was 67 years in both groups; 51% were female. All patients had one- (76%) or two- (24%) level stenosis. There were no significant differences in baseline data between the groups, except for significantly more smokers in the minimally invasive decompression group (P = 0.022). Follow-up data at two years were provided from 81 (84.4%) patients, 41 in the minimally invasive decompression group and 40 in the X-stop group.

Outcome analysis

In terms of primary outcome measures, all ZCQ sub-scales reported no significant differences between groups at any time at follow-up. Both groups had statistically and clinically significant improvements at six weeks and throughout the observation period in the intention-to-treat analyses ($p < 0.01$). The results were similar in the per protocol analysis. Between the groups, there were statistically but not clinically significant differences in symptom severity at three months and one year in favour of X-stop, but not at two years. Mean difference was 0.4 at three months and 0.41 at one year, which is less than MCID. All secondary outcome measures also showed significant improvement in both groups, from preoperative to all follow-ups, again without significant differences between groups.

Complications and reoperations

The risk of surgical complication was equal in both groups. Three patients in the minimally invasive decompression group had postoperative hematoma, and all had reoperation within one week. One of these patients had postoperative cauda equina syndrome and persistent symptoms two years after surgery. Two had dural lesions; one of them had postoperative symptoms (urine retention). In the X-stop group one patient had a perioperative fracture of the spinous process, one had a late fracture, and one had dislocation of the X-stop. All three had secondary surgery; the X-stop was removed and minimally invasive decompression was performed. No postoperative infections were registered.

Two patients (4.9%) in the minimally invasive decompression group and 10 (25%) in the X-stop group had a secondary operation due to persistent or recurrent symptoms. The OR (95% CI) for secondary surgery in X-stop group was 6.5 (1.3 to 31.9) compared to minimally invasive decompression. Symptom persistence was defined as no clinically significant improvement at six weeks. Combined OR (95% CI) for secondary surgery in the X-stop group, including surgery due to complications, was 3.5 (1.1 to 10.9). Two patients in the minimally invasive decompression group had surgery for new pathologies unrelated to former treatment.

4.3: Paper III

Title: “Comparing cost-effectiveness of X-stop to minimally invasive decompression in lumbar spinal stenosis: A randomized controlled trial.”

Study population

The mean age was 67 years in both groups; 51% were female. All patients had one- (76%) or two- (24%) level stenosis. See Paper II for further details.

Data

Hospital cost data from index treatment and follow-ups were provided from 81 (84%) of the patients. Data from patients' expenses were provided from 75 (78%) patients. Mean days of sick leave or rehabilitation (SD) after index treatment were 66 (150) for X-stop and 48 (134) for minimally invasive decompression. In the X-stop group 55% of the patients received age-related pension. The corresponding number in the minimally invasive decompression group was 51%. Some 3.4% of the questions were missing in the initial EQ-5D scores.

Difference in cost and effect

The incremental cost for X-stop compared to minimally invasive decompression was € 2,832 (95% CI: 1,886 to 3,778), while the incremental health gain was 0.11 QALY (95% CI: -0.01 to 0.23). Based on the incremental cost and effect, the ICER was € 25,700. The difference in effect was insignificant. The significantly higher cost of X-stop is mainly due to implant cost and the significantly higher reoperation rate.

Cost-effectiveness plane and cost-effectiveness acceptability curve

The cost-effectiveness plane reports the 1000 ICERs based on the bootstrap method. The main share of the replicates is located in the northeast quadrant (Figure 3), indicating a better health outcome for X-stop, but there are many replicates in the northwest quadrant, indicating that the difference is not significant. The CEAC shows the probability that X-stop is cost-effective given

different levels of WTP for a QALY. Given a WTP in Norway at € 60,200, the probability that X-stop is a cost-effective alternative is about 77%.

Sensitivity analysis

A sensitivity analysis was performed by applying various costs per hospital unit.[90], by using PP analysis instead of ITT, by using SF-6D as the base for QALY, by adding patient costs to total costs, and by excluding one patient with a severe complication. Except from the PP analysis, the conclusions were not altered by the sensitivity analysis.

5: Discussion

5.1: The main findings

We found the inter- and intraobserver agreement between DSCA and morphological grading A–D to be acceptable.

Enrollment was closed after the midway interim analysis showed a significantly higher reoperation rate in the X-stop group.

There were no significant differences in primary (ZCQ) or secondary outcomes between the groups at any follow-ups.

In the cost-effectiveness analysis based on the incremental cost and effect, the ICER was € 25,700.

The significantly higher cost of X-stop is mainly due to implant cost and the significantly higher reoperation rate.

5.2: Image assessment (Paper I)

In Paper I we compared a quantitative and a qualitative method for classifying LSS. Both area measurements and visual assessments are used in everyday clinical practice. We did not define a strict value in area measurement for inclusion in the study, but instead let the clinicians decide whether or not stenosis was present and whether or not the symptoms most likely derived from LSS. The uncertainties that characterize MRI findings[23 35 72 97] and the actual everyday practice[45] supports a pragmatic approach to this assessment. The distinction between no stenosis, relative

stenosis, or significant stenosis is therefore reasonable. Relative stenosis will represent a greater uncertainty regarding the cause of symptoms than significant stenosis.

We demonstrated that the inter- and intraobserver agreement of DSCA and morphological grading A–D were equal and acceptable, and that the correlation between the two methods was strong. This means that both methods are able to detect a relative or significant LSS. Both methods can thus be used in surgical decision-making.

DSCA

In their study, Ogikubo et al. demonstrate a linear correlation between area and symptoms[5], although MRI findings in other studies show significant stenosis but without any NIC symptoms.[13 24] Furthermore, some studies have found a limited correlation between patient symptoms and MRI findings among patients with LSS.[14 37 97-99] Corresponding positive MRI findings are important for the diagnosis, but it is unclear if the threshold values used in DSCA reflect the degree of symptoms.[98] Accurate area measurement alone cannot give the information needed for decision-making prior to surgery.

Morphological grading A–D

Morphological grading A–D is a qualitative method and can be decided by a rapid visual assessment, but is more subjective than DSCA.[44] The fact that both grades C and D were under the cut-off value (75 mm^2) for significant stenosis when using the DSCA indicates that our definition of significant stenosis in morphological grading was reasonable. The method has not been tested on asymptomatic individuals, nor has it been proved as a predictor for outcome after treatment. Surgeons in an outpatient clinic may have access to the images but usually not the tools for DSCA measurement. They are used to performing direct visual assessments of the

stenosis. Therefore, the morphological grading A–D represents an option to document the degree of stenosis that is close to daily clinical practice.

The value of classification is mainly to support the decision-making process in a systematic and reproducible way. Schizas et al. demonstrated recently that clinicians prefer to classify LSS according to their visual assessment rather than DSCA.[45]

Various MRI centers have different protocols for imaging the lumbosacral part of the vertebral column. Some angulate the slices parallel to each lumbar disc; others have one fixed angulation through all investigated discs. The discs are usually not parallel. How the axial MRI images are angulated relative to each disc will often vary, and this will have an impact on the DSCA measurements.[100] Hence, the area measurement will differ depending on the chosen method. Morphological grading A–D seems to be less affected by image angulation on the disc level since the ratio between the CSF and the nerve rootlets will be the same.[100]

Morphological grading A–D depends on the visualization of the rootlets in the dural sac. In the original publication by Schizas from 2010[44] the patients were investigated using a 3T MRI system. High signal-to-noise and high resolution as in 3T MRI will provide better-defined rootlets and better contrast between rootlets and CSF in T2-wighted axial images compared to more commonly available 1.5T MRI. Since the latter was the one available for our study, this may have an influence on our results. The distinction between grades B and C can be particularly challenging, since this distinction depends on the visualization of a thin brim of fluid. A few axial images in our material (9 out of 84) were proton-weighted and not T2-weighted. This can make it even more difficult to differentiate between the rootlets and CSF. Using 3T MRI from a

single center would probably give more standardized images, but the images we used are more representative for daily practice at the hospitals.

DSCA is more time-consuming for the radiologists, since they often have to use a separate digital program for the measurement. An alternative method to DSCA must be simple to use and give the same possibility to classify the stenosis as relative or significant. The morphological grading A–D has this potential. Further agreement studies should be done between a clinician and a radiologist as well as between clinicians to assess the method.

5.3: Comparison of treatment effects (Paper II)

In the second paper, no significant differences in primary or secondary outcomes were seen between the groups. Both groups showed significant improvement at all follow-up time points from six weeks to two years. Our results are similar to a recent study comparing X-stop to laminectomy and suggest that both operation methods are effective treatments for neurogenic intermittent claudication due to spinal stenosis.[70]

As published in the protocol, we performed a midway interim analysis and found that the reoperation rate due to lack of improvement or symptom recurrence was significantly higher for X-stop than for minimally invasive decompression. Reoperation rate is considered to be an important outcome variable in clinical studies, and the causal relationship between the surgical methods and this outcome is strong. Since the ITT analysis shows that X-stop is non-significantly superior to minimally invasive decompression, some may claim that the study should be continued. We did not at that time know the final results of the two-year outcome. Ethical considerations also favored the study's termination at this point, since there is extra risk

related to an additional operation, extra resources are unnecessarily used, and it was not in accordance with the information given to the patients prior to inclusion. Moreover, reoperation after X-stop is not as straightforward as primary operations with decompression, due to scar tissue formation and hypertrophic bone changes, according to personal reports from colleagues.

In addition, at the point of stopping the study some new cohort studies reported a high reoperation rate in X-stop[67 101], in contrast to the earlier studies by Zucherman et al..[102] This growing uncertainty was not known when planning the study, and the reason why interim analyses were planned was to see if there were obvious differences between the two methods. A secondary operation is a great disadvantage to the patient and something surgeons try to avoid. We thought that continuing the study with the knowledge of this high reoperation rate in the X-stop group would introduce a bias in patient selection among the participating surgeons.

The first published study comparing X-stop to non-operative treatment revealed a significant improvement compared to non-operative treatment[3 66], and only 6.5% were reported to have secondary surgery at two-year follow-up.[102] Some recently published studies report similar frequency of secondary surgery to our study,[70 101] while others do not.[103 104] This discrepancy is difficult to explain. The initial studies were part of an ongoing FDA-approved investigational protocol and conducted by surgeons who also "received benefits for personal or professional use from a commercial party related directly or indirectly to the device".[102] This may lead to undefined differences in the patient selection, operation techniques, and/or reoperation criteria, and the study results could be biased.

Barbagallo suggests that there are anatomic features of the spine that could potentially be the underlying causes of complications.[67] He proposed an anatomic scoring system, where the shape

of the spinal process was assessed. Hypertrophic facet joints or short dysmorphic processes could more easily lead to dislocation. Difficulties with placing the device as far anterior as possible could also be a reason for failure. Although this has been an issue in several studies, a single anatomical cause for reoperation has not been revealed.

Minimally invasive decompression is performed by a partial excision of the lower part of the lamina and the medial aspects of the facet joint exposing the ligamentum flavum. The ligament is resected from the canal to expose the dural sac and the nerve roots. This may lead to scar tissue formation in the spinal canal and increase the risk of complications during reoperation. We are aware of the possibility of introducing a selection bias due to the possibility that the threshold for reoperation after X-stop could be lower compared to minimally invasive decompression. A weakness of the study is that we did not register outcome data directly prior to the secondary surgery on symptoms that led to the reoperation. We did a PP analysis showing a statistically significant, but not clinically relevant difference between the methods at three-month and one-year follow-up. No significant difference was found at two years. This could indicate that the median effect in patients undergoing secondary surgery in the X-stop group was lower than the rest of the group.

Pain relief from lumbar spinal flexion is required for X-stop effectiveness.[105] Not all of the patients suffering from LSS experience this.[106] We ensured that all patients had substantial pain relief from lumbar spinal flexion and used the same indication as described by Lauryssen for X-stop.[105] Hence, all patients were suitable for both treatments. However, this results in selection bias and weaker external validity in our study.

The perioperative complication rate was small in both groups, but higher in the minimally invasive decompression group. Three patients in the minimally invasive decompression group had postoperative epidural hematoma and were reoperated shortly after the index treatment. One of them had cauda equina syndrome with persistent symptoms two years after surgery. The risk of such complication is very low according to previous studies.[107 108] Unfortunately it appeared in this study, thus indicating that entering the spinal canal has the potential danger for nerve damage. The complications in the X-stop group were one dislocation of the device and two with a fracture of the posterior spine process. The risk of major complication is thus potentially higher with minimally invasive decompression. Since the outcomes as measured by the PROMs for both groups were comparable, secondary surgery, which is another important outcome, must be taken into account.

5.4: Comparing cost-effectiveness (Paper III)

In the cost-effectiveness study, X-stop had significantly higher costs than minimally invasive decompression. With an ICER at € 25,700, there is a 50% chance that the X-stop is cost-effective compared to minimally invasive decompression if we are willing to pay extra for a QALY.

The suggested WTP for a QALY in Norway is € 60,200.[109] With a non-significant superior effect, it is 77% likely that X-stop is cost-effective at that price. In the cost-effectiveness plane, reporting the 1000 ICERs based on the bootstrap method, shows that the main share of the replicates is located in the northeast quadrant (Figure 3), indicating better health outcomes for X-stop, but at a higher cost. On the other hand, a significant amount of the replications are in the northwest quadrant, indicating uncertainty about the effect gained. This also reflects the insignificant difference in effect gained in the primary and secondary outcome in Paper II. Still,

the cost difference is significant since none of the replicates are in the southeast quadrant. This difference could mainly be explained by implant cost and the significantly higher reoperation rate in the X-stop group. A high reoperation rate is a disadvantage that undoubtedly has an influence on the assessment of X-stop.

Health economic evaluations are based on estimates from a complex patient pathway. Multiple considerations have to be taken into account when describing the cost of these treatments. We used a health service perspective, since the main difference in the methods is covered by the index treatment. The follow-ups are in principle the same in both groups.

A sensitivity analysis was performed to assess the results towards other variables. We used different unit costs based on calculations from one of the participating university hospitals.[90] SF-6D based on transmission from SF-36 was used as the quality of life index, instead of EQ-5D, to calculate QALY. Patients' personal costs were added to hospital costs and included visits to GP, physiotherapist, and other health providers, in addition to the cost of medication used and other out-of-pocket costs. And we performed a PP analysis, where patients with reoperations and complications are excluded, instead of an ITT analysis. Except from the PP analysis, the conclusions were not altered by the sensitivity analysis. PP analysis excluded reoperated patients and revealed an increase in QALYs gained in the X-stop group compared to ITT. This indicates that individuals undergoing reoperation report lower QALYs than the average in the X-stop group. Given the real-world setting, economic questions relate to treatment decisions, and trial-based cost-effectiveness analyses should adopt an ITT design.[94]

This economic evaluation was from a health service perspective, although one may argue for using a societal perspective by adding indirect costs from patient expenses and loss of

production. Indeed, patient expenses are accounted for in the sensitivity analysis, but they do not alter the conclusion. Loss of production can be calculated from days of sick leave or rehabilitation, and the results convey significantly more days of sick leave in the X-stop group. Since more than half of the patients received age-related pensions, the number of patients still at work is low and the result uncertain. Hence, these indirect costs are not accounted for. There is no consensus on whether to use a societal or health service perspective.[76] The rationale for the latter is to maximize value for money from the national health system budget.

One patient in the minimally invasive decompression group had a permanent nerve injury, which had a certain negative impact on the cost-effectiveness analysis, but not the conclusion. Yet the risk for this type of injury is low.[16 107 110]

Earlier studies comparing cost-effectiveness show that operative treatment of LSS seems to be more cost-effective than non-operative treatment, independent of operation method.[111 112] But the way of estimating cost-effectiveness in spine surgery can vary.[113] Hence, the conclusions may be influenced by the estimation method.

Research has found that minimally invasive decompression is more cost saving and probably has better outcomes than laminectomy.[114] X-stop is more cost-effective than non-operative treatment, but the difference is uncertain compared to decompression alone..[115 116]

Based on a structured literature review of 108 publications, Burnett et al. employ a cost-effectiveness model to compare different LSS treatments.[115] They report that laminectomy is the most effective treatment strategy, followed by X-stop, and then by conservative treatment at a two-year time horizon. Data were pooled from several sources and categorized into X-stop or laminectomy, regardless of decompression method and number of levels treated. All X-stop

procedures were classified as “outpatient and local anesthesia” cases, and all laminectomy procedures as “inpatient and general anesthesia” cases. In our RCT study, the groups were compared directly. Both groups could be operated in the lower-cost outpatient setting. This would lower the cost of the index treatment, although the implant cost and secondary surgery rate for X-stop would probably be the same. Hence, the fact that we operated on both groups as inpatients would probably not have an impact on the final conclusions.

Skidmore et al. (25) compared the cost-effectiveness of X-stop to conservative care. Patients who failed conservative care were recruited to laminectomy. They observed that X-stop was more cost-effective than conservative care and dominant to laminectomy. However, selecting laminectomy patients from those who failed in conservative treatment introduces a possible selection bias.

From a health provider’s view the higher cost and reoperation rate will have a negative impact on X-stop’s feasibility. From the clinician’s point of view the cost-effectiveness aspect is interesting but may not reflect the major disadvantages represented by the high risk of secondary surgery. The deviance between the clinical decision and the indication from the cost-effectiveness analysis could be explained by the fact that the health outcome does not capture the effect that reoperation has on HRQoL.

5.5: Strength and limitations

We planned to recruit 180 patients, but enrollment was terminated after inclusion of 96 patients, due to higher reoperation rate in X-stop group. Hence, the study’s power to detect a minimal clinically important difference is low (type II error). The study’s power was estimated for the

purpose of finding a difference of 0.5 points between the two groups in ZCQ. However, the initial power analysis before we added up for different aspects suggested 104 patients. This is not far away from the 96 we finally recruited. All the researchers discussed the prospects of ending the study after the midway interim analysis, and continuing the study was regarded as unacceptable due to the significantly higher reoperation rate.

In Paper I the comparison between the two methods for assessing and grading LSS is based on central LSS. With the new morphological grading A–D, the study should preferably also be evaluated in a more general population with neurogenic claudication, not only those eligible for this study. All patients in our study were candidates for surgery and highly selected for a RCT. The results of the present study might therefore have low external validity beyond specialist care.

Furthermore, patients with lateral or foraminal LSS were not included in this study. The absence of a standardized classification system and the difference in biomechanical conditions are the main reasons for this. Lateral stenosis can, however, be an important reason for neurogenic intermittent claudication, and it does not rule out any of these two operation methods as treatment options.[117] A small study also shows that X-stop implants may be effective treatment for lumbar radiculopathy secondary to foraminal stenosis.[118]

In Paper II, the failure in our ZCQ questionnaire that resulted in omitting one out of seven questions in the symptom severity scale was not detected until late in the study, and was somewhat difficult to compensate for. The question omitted concerned leg pain, an important part of the symptomatology of NIC. Therefore, not modifying this item could have important consequences when measuring clinical outcome. Since EQ-5D, ODI, and NRS11 back pain and NRS11 leg pain all gave similar results, and both groups were equally affected, we decided that

this was the best way to report the primary outcome. Thus, using the NSR11 on leg pain as a proxy for the missing ZCQ item would be the most correct value method. Comparing our results with other studies should, however, be done with caution.

In Paper II the result on EQ-5D were reported without imputation and slightly different from those used for calculating QALY in Paper III. The reason is that EQ-5D in Paper III is used after a multiple imputation was performed. In addition to gender and age, the imputation considered values like operation time, hospital stay, and smoking. These are values that favor X-stop and might have had an impact on the results of the imputation, although they do not necessarily have an impact on later quality of life. The difference was still not statistically significant, so the conclusion remains the same.

Committed surgeons agreed about the inclusion and exclusion criteria and evaluated all recruited patients. Nonetheless, the indication for surgery in this population is not always definite. Patients with spondylolisthesis grade 1 were not excluded.[66 119] The indication for fixation and fusion in this patient group is not clear and depends partly on the surgeon's preferences; thus, some surgeons may have excluded patients who would be included by others.

The strength of this study is the use of minimally invasive decompression as the gold standard. Some studies have demonstrated better outcomes with this technique compared to traditional open laminectomy.[120 121] They report less lower-back pain and instability problems after minimally invasive decompression, which also has shorter hospital stays and rehabilitation times. Since X-stop also is categorized as a minimally invasive technique, factors such as soft tissue damage and rehabilitation time are probably more comparable to minimally invasive decompression.

6: Conclusions

We found that the inter- and intraobserver agreements of DSCA and morphological grading A–D were acceptable and that the intercorrelation between the methods was strong. This means that both methods may be used in the MRI evaluation of LSS.

Both minimally invasive decompression and X-stop led to significant symptom improvements. There were no significant clinical differences in effect between the methods at any of the follow-up time points. X-stop had a significantly higher risk of secondary surgery. Complications were more severe for minimally invasive decompression.

Comparing cost-effectiveness of X-stop to minimally invasive decompression, the majority of the bootstrap samples fell within the northeast corner of the CE plane, giving a 50% likelihood that X-stop is cost-effective at the price of € 25,300 (ICER) for a QALY. The difference in effect was insignificant. The higher cost of X-stop is mainly due to implant cost and the significantly higher reoperation rate.

7: Future challenges

The growing number of elderly, paired with greater demands on quality of life, will probably increase the number of operations in the future. Most studies comparing surgery to non-operative treatment for LSS show that surgery is better, regardless of surgical technique. Improvement in quality of life is good and treatment effect is comparable to total hip and knee replacement.[122 123] Guidelines for which surgical treatment to choose are vague, and the level of evidence and recommendations in UpToDate are weak (grade 2c).[18] Many meta-studies are conducted to reveal if there are differences between the methods. Several national spine registries are established to monitor the effect of different techniques. But differences in treatment traditions, patient selection, and methods make this difficult to compare in a larger scale. International cooperation in defining inclusion criteria and outcome measurements will have a greater potential to look at different methods.

Minimally invasive decompression is at present the gold standard for treating central lumbar spinal stenosis. By entering the spinal canal there are some challenges that one should try to solve, like the risk of major complications. X-stop does not seem to be the solution to these challenges, because of high risk of reoperation. The principle of the IPD systems seems to be effective, however. Decompression with an interspinous spacer may be a valid alternative for treating NIC in the future. However, the risk of secondary surgery seems to be high at present. The treatment strategy for LSS appears to differ, the role of IPD is not well defined, and the reason for differences in outcome for X-stop is not well understood. Assessing the differences in patients selected for surgery, based on imaging and clinical evaluation, type of surgical procedure, and related outcome measurements, could give valuable information to this important

patient group. Perhaps technical adjustments on the devices will address the problem of high reoperation rates.

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Paper I

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Paper II

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Paper III

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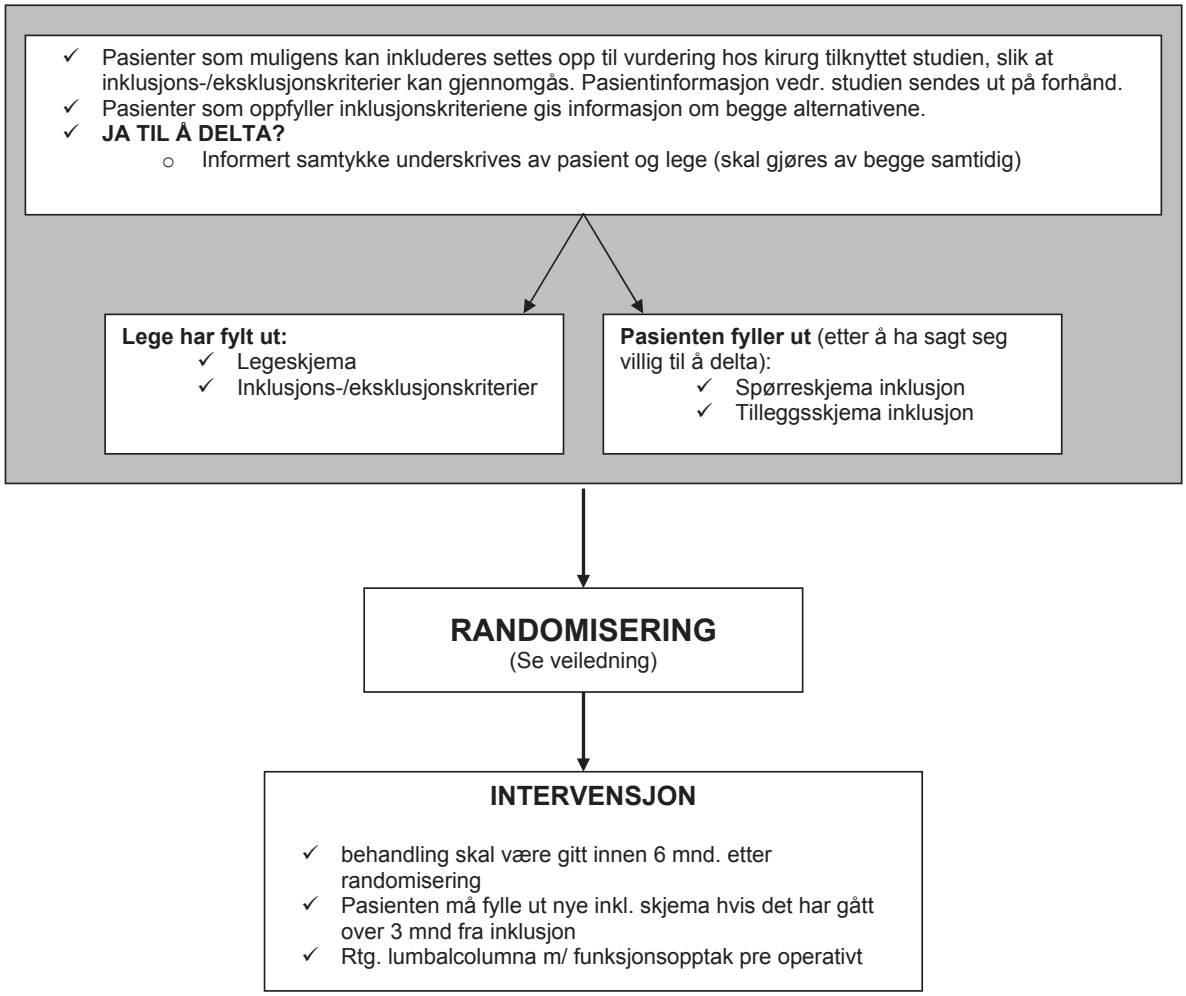
Appendix

FLYTSKJEMA ”SENTRAL LUMBAL SPINAL STENOSE STUDIEN”

INKLUSJON:



KONTROLLER:

	Skjemaer *	MR	rtg.m/funksj.	Helseøkonomi	Møte/kontroll hos
6 uker	✓				Kirurg
3 mnd	✓	✓		✓	Koordinator
1 år	✓	✓	✓	✓	Kirurg
2 år	✓	✓	✓	✓	Kirurg
5 år	✓	✓			

* Skjemaer: Kontroll(pasient og lege)+ Tilleggsskjema

www.spinalstenose.no

Oversikt sjemaer til Spinal stenose studien							
Skjemaer	**Inklusjon**	**Beh. start**	**6 uker**	**3 mnd**	**1 år**	**2 år**	**5 år**
Brev til fastlege	X						
Brev til trygdekontor					X	X	
Helseøkonomisk dagbok		X		X	X		
Informasjon til pasienter	X						
Kirurgisk registreringsskjema		X					
Lege/spl. opplysninger	X		X	X	X	X	X
Personalia	X						
Registrering sykehusressurser				X	X	X	
Registreringsskjema helseøkonomi		X					
Samtykke hovedstudie	X						
Sjekkliste inkl./ekskl. kriterier	X						
Spørreskjema til pasienter.....	X		X	X	X	X	X
Tilleggsskjema pasient	X		X	X	X	X	X

SPØRRESKJEMA FOR PASIENTER SOM DELTAR I STUDIE SOM SAMMENLIKNER TO ULIKE OPERASJONSMETODER FOR LUMBAL SPINAL STENOSE

LUMBAL SPINAL STENOSE STUDIEN
En nasjonal multisenterstudie

INKLUSJON

Pasientdata

Navn

Fødselsnr. (11 siffer)

Adresse

Alder (år) ☐☐

Kjønn ☐ Mann ☐ Kvinne

Formålet med dette spørreskjemaet er å gi leger, sykepleiere og fysioterapeuter bedre forståelse av ryggpasienters plager og å vuredre effekter av behandling. Din utfylling av skjemaet vil være til stor nytte for å kunne gi et best mulig behandlingstilbud til ryggpasienter i fremtiden.

Spørreskjemaet har fire deler. Første del omhandler ulike sider ved din utdanning og familie samt dine smerter og plager. De neste delene består av tre ulike sett spørsmål for måling av din nåværende helse. Det første av disse (kalt Oswestry) måler hvordan ryggplagene påvirker dagligdagse gjøremål. Det andre (kalt EQ-5D) måler din helserelaterte livskvalitet. Den siste delen er en skala der du skal merke av hvor god eller dårlig din helsetilstand er.

Dato for utfylling ☐☐ ☐☐ ☐☐
Dag Måned År

Røyker du? ☐ Ja ☐ Nei

Utdanning og yrke

1. Hva er din høyeste fulførte utdanning (Sett ett kryss)

☐ Grunnskole 7-10 år, framhaldsskole eller folkehøyskole

☐ Yrksfaglig videregående skole, yrkesskole eller realskole

☐ Allmennfaglig videregående skole eller gymnas

☐ Høyskole eller universitet (mindre enn 4 år)

☐ Høyskole eller universitet (4 år eller mer)

2. Hvilket yrke har du, eller hadde du tidligere (før du eventuelt ble arbeidsledig, permittert, trygdet eller pensjonert)

_____

_____

Familie og barn

1. Sivilstatus (sett ett kryss)

☐ Gift/ Reg.partner

☐ Samboende

☐ Enslig

2. Hvor mange barn har du? ☐☐

Morsmål

☐ Norsk

☐ Samisk

☐ Annet, angi hvilket

_____

Hvor sterke smerter har hatt siste uke?

Hvordan vil du gradere smertene du har hatt i **rygg/hofte** i løpet av den siste uken? Sett ring rundt ett tall

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Så vondt som det går an å ha

Hvordan vil du gradere de smertene du har hatt i **benet (ett eller begge)** i løpet av den siste uken? Sett ring rundt ett tall

0 1 2 3 4 5 6 7 8 9 10

Ingen smerter — Så vondt som det går an å ha

Funksjonsscore (Oswestry)

Disse spørsmålene er utarbeidet for å gi oss informasjon om hvordan dine smerter har påvirket dine muligheter til å klare dagliglivet ditt. Vær snill å besvare spørsmålene ved å sette kryss (kun **ett** kryss for hvert avsnitt) i de rutene som passer best for deg.

1. Smerte

- ☐ Jeg har ingen smerter for øyeblikket
- ☐ Smertene er veldig svake for øyeblikket
- ☐ Smertene er moderate for øyeblikket
- ☐ Smertene er temmelig sterke for øyeblikket
- ☐ Smertene er er veldig sterke for øyeblikket
- ☐ Smertene er de verste jeg kan tenke meg for øyeblikket

2. Personlig stell

- ☐ Jeg kan stelle meg selv på vanlig måte uten at det forårsaker ekstra smerte
- ☐ Jeg kan stelle meg selv på vanlig måte, men det er veldig smertefullt
- ☐ Det er smertefullt å stelle seg selv, og jeg gjør det langsomt og forsiktig
- ☐ Jeg trenger noe hjelp, men klarer det meste av mitt personlige stell
- ☐ Jeg trenger hjelp hver dag til det meste av mitt eget stell
- ☐ Jeg kler ikke på meg, har vanskeligheter med å vaske meg og holder sengen

3. Å løfte

- ☐ Jeg kan løfte tunge ting uten å få smerter
- ☐ Jeg kan løfte tunge ting, men får smerter
- ☐ Smertene hindrer meg i å løfte tunge ting opp fra gulvet, men jeg greier det hvis det som skal løftes er gunstig plassert, for eksempel på et bord
- ☐ Smertene hindrer meg i å løfte tunge ting, men jeg klarer det lett hvis det er gunstig plassert
- ☐ Jeg kan bare løfte noe som er veldig lett
- ☐ Jeg kan ikke løfte eller bære noe i det hele tatt

4. Å gå

- ☐ Smerter hindrer meg ikke i å gå idet hele tatt
- ☐ Smerter hindrer meg i å gå mer enn 1 ½ km
- ☐ Smerter hindrer meg i å gå mer enn ¾ km
- ☐ Smerter hindrer meg i å gå mer enn 100 m
- ☐ Jeg kan bare gå med stokk eller krykker
- ☐ Jeg ligger for det meste i sengen, og jeg må krabbe til toalettet

5. Å sitte

- ☐ Jeg kan sitte så lenge jeg vil i hvilken som helst stol.
- ☐ Jeg kan sitte så lenge jeg vil i min favorittstol.
- ☐ Smerter hindrer meg i å sitte i mer enn en time.
- ☐ Smerter hindrer meg i å sitte i mer enn en halv time.
- ☐ Smerter hindrer meg i å sitte i mer enn ti minutter.
- ☐ Smerter hindrer meg i å sitte i det hele tatt.

6. Å stå

- ☐ Jeg kan stå så lenge jeg vil uten å få mer smerter
- ☐ Jeg kan stå så lenge jeg vil, men får mer smerter
- ☐ Smerter hindrer meg i å stå i mer enn en time
- ☐ Smerter hindrer meg i å stå i mer enn en halv time
- ☐ Smerter hindrer meg i å stå i mer enn ti minutter
- ☐ Smerter hindrer meg i å stå i det hele tatt

7. Å sove

- [ ] Søvnen min forstyrres aldre av smerter
- [ ] Søvnen min forstyrres av og til av smerter
- [ ] På grunn av smerter får jeg mindre enn 6 timers søvn
- [ ] På grunn av smerter får jeg mindre enn 4 timers søvn
- [ ] På grunn av smerter får jeg mindre enn 2 timers søvn
- [ ] Smerter hindrer all søvn

8. Seksualliv

- [ ] Seksuallivet mitt er normalt og forårsaker ikke mer smerter
- [ ] Seksuallivet mitt er normalt, men forårsaker noe smerte
- [ ] Seksuallivet mitt er normalt, men svært smertefullt
- [ ] Seksuallivet mitt er svært begrenset av smerter
- [ ] Seksuallivet mitt er nesten borte på grunn av smerter
- [ ] Smerter forhindrer alt seksualliv

9. Sosialt liv (omgang med venner og kjente)

- [ ] Det sosiale livet mitt er normalt og forårsaker ikke mer smerter
- [ ] Det sosiale livet mitt er normalt, men øker graden av smerter
- [ ] Smerter har ingen betydelig innvirkning på mitt sosiale liv, bortsett fra at de begrenser mine mer fysisk aktive sider, som sport osv.
- [ ] Smerter har begrenset mitt sosiale liv, og jeg går ikke så ofte ut
- [ ] Smerter har begrenset mitt sosiale liv til hjemmet
- [ ] På grunn av smerter har jeg ikke noe sosialt liv

10. Å reise

- [ ] Jeg kan reise hvor som helst uten smerter
- [ ] Jeg kan reise hvor som helst, men det gir smerter
- [ ] Smertene er ille, men jeg klarer reiser på to timer
- [ ] Smerter begrenser meg til korte reiser på under en time
- [ ] Smerter begrenser meg til korte, nødvendige reiser på under 30 minutter
- [ ] Smerter forhindrer meg fra å reise, unntatt for å få behandling

Beskrivelse av helsetilstand (EQ-5D)

Vis hvilke utsagn som passer best på din helsetilstand i dag ved å sette kryss i en av rutene utenfor hver av dimensjonene nedenfor

1. Gange

- [ ] Jeg har ingen problemer med å gå omkring
- [ ] Jeg har litt problemer med å gå omkring
- [ ] Jeg er sengeliggende

2. Personlig stell

- [ ] Jeg har ingen problemer med personlig stell
- [ ] Jeg har litt problemer med å vaske meg eller kle meg
- [ ] Jeg er ute av stand til å vaske meg eller kle meg

3. Vanlige gjøremål (f.eks. arbeid, studier, husarbeid, familie eller fritidsaktiviteter)

- [ ] Jeg har ingen problemer med å utføre mine vanlige gjøremål
- [ ] Jeg har litt problemer med å utføre mine vanlige gjøremål
- [ ] Jeg er ute av stand til å utføre mine vanlige gjøremål

4. Smerte og ubehag

- [ ] Jeg har verken smerter eller ubehag
- [ ] Jeg har moderat smerte eller ubehag
- [ ] Jeg har sterk smerte eller ubehag

5. Angst og depresjon

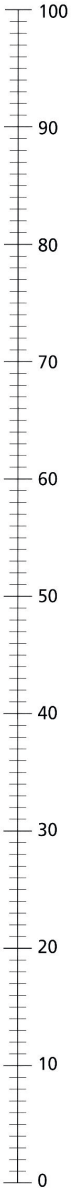
- [ ] Jeg er verken engstelig eller deprimert
- [ ] Jeg er noe engstelig eller deprimert
- [ ] Jeg er svært engstelig eller deprimert

Helsetilstand

For at du skal kunne vise oss hvor god eller dårlig din helsetilstand er, har vi laget en skala (nesten som et termometer), hvor den beste helsetilstanden du kan tenke deg er markert med 100 og den dårligste med 0.

Vi ber om at du viser din helsetilstand ved å trekke ei linje fra boksen nedenfor til det punkt på skalaen som passer best med din helsetilstand.

Best tenkelige helsetilstand



Verst tenkelige helsetilstand

Nåværende helsetilstand

Smertestillende medisiner

Bruker du smertestillende medisiner på grunn av dine rygg- og/eller beinsmerter?

- ☐ Ja
- ☐ Nei

Har du svart ja: Hvor ofte bruker du smertestillende medisiner? (Sett ett kryss)

- ☐ Sjeldnere enn hver måned
- ☐ Hver måned
- ☐ Hver uke
- ☐ Daglig
- ☐ Flere ganger daglig

Har du søkt om uføretrygd?

(Sett ett kryss)

- ☐ Ja
- ☐ Nei
- ☐ Planlegger å søke
- ☐ Er allerede innvilget

Har du søkt om erstatning fra forsikringsselskap eller folketrygden (evt. yrkesskadeerstatning)?

(Sett ett kryss)

- ☐ Ja
- ☐ Nei
- ☐ Planlegger å søke
- ☐ Er allerede innvilget

Pasientens navn:.....

Dato:.....

TILLEGGSSKJEMA

LUMBAL SPINAL STENOSE STUDIEN
En nasjonal multisenterstudie

INKLUSJON

Denne studien er en nasjonal multisenterstudie der forskere fra flere sykehus er involvert. Resultatene fra studien vil bli rapportert både nasjonalt og internasjonalt. Dette stiller store krav til hvilke spørsmål som inngår og resulterer i at neon spørsmål overlapper hevrandre. Vi ber om forståelse for overlappingen og håper dette ikke vil virke distraherende.

Zürich Claudicatio questionnaire. Disse spørsmålene omhandler dine symptomer og din funksjon. Sett ett kryss i en av rutene for hvert punkt

I løpet av siste måneden, hvordan vil du beskrive:

1. Smertene du har hatt i gjennomsnitt i korsrygg, setet samt smerter som går ned i bena?

- ☐ Ingen
- ☐ Svake
- ☐ Moderate
- ☐ Sterke
- ☐ Meget sterke

2. Hvor ofte har du hatt smerter i rygg, sete eller bena?

- ☐ Mindre enn en gang i uken
- ☐ Minst en gang i uken
- ☐ Hver dag, minst noen minutter
- ☐ Hver dag, det meste av dagen
- ☐ Hvert eneste minutt av dagen

3. Smertene i rygg eller sete?

- ☐ Ingen
- ☐ Milde
- ☐ Moderate
- ☐ Sterke
- ☐ Meget sterke

4. Nummenhet eller prikking i bena eller føttene?

- ☐ Ingen
- ☐ Milde
- ☐ Moderate
- ☐ Sterke
- ☐ Meget sterke

5. Svakhet i bena eller føttene?

- ☐ Ingen
- ☐ Milde
- ☐ Moderate
- ☐ Sterke
- ☐ Meget sterke

6. Problemer med balansen?

- ☐ Nei, jeg har ikke hatt problemer med balansen
- ☐ Ja, noen ganger føler jeg at balansen er dårlig, eller at jeg ikke har en trygg fot.
- ☐ Ja, ofte føler jeg balanse er dårlig, eller at jeg ikke har en trygg fot.

I løpet av den siste måneden på en typisk dag:

1. Hvor langt har du greid å gå?

- ☐ Lengre enn 3 km
- ☐ Under 3 km, men lengre enn 500 m
- ☐ Under 500 m, men lengre enn 20 m
- ☐ Kortere enn 20 m

2. Har du gått turer utendørs eller på kjøpesentra for fornøyelsens skyld?

- ☐ Ja, uten ubehag
- ☐ Ja, men noen ganger med smerter
- ☐ Ja, men alltid med smerter
- ☐ Nei

3. Har du handlet dagligvarer eller andre ting?

- ☐ Ja, uten ubehag
- ☐ Ja, men noen ganger med smerter
- ☐ Ja, men alltid med smerter
- ☐ Nei

4. Har du gått omkring i rommene i leiligheten eller huset ditt?

- ☐ Ja, uten ubehag
- ☐ Ja, men noen ganger med smerter
- ☐ Ja, men alltid med smerter
- ☐ Nei

5. Har du gått mellom soverommet ditt og badet?

- ☐ Ja, uten ubehag
- ☐ Ja, men noen ganger med smerter
- ☐ Ja, men alltid med smerter
- ☐ Nei

Nedenfor finner du en liste over vanlige sykdommer / lidelser. Vennligst sett ring rundt ja eller nei i Kolonne 1 om noe av dette, nå for tiden, gjelder deg.

Svarer du "ja" i Kolonne 1 besvarer du også spørsmålene i Kolonne 2 og Kolonne 3.

Nederst angir du om du lider av noe som ikke står på listen.

	Kolonne 1		**Kolonne 2**		**Kolonne3**	
Sykdom/lidelse:	Har du denne sykdommen / lidelsen?		Får du behandling for det?		Begrenser det dine aktiviteter / virkelyst?	
Hjertesykdom	Nei	Ja →	Nei	Ja	Nei	Ja
Høyt blodtrykk	Nei	Ja →	Nei	Ja	Nei	Ja
Lungesykdom	Nei	Ja →	Nei	Ja	Nei	Ja
Sukkersyke	Nei	Ja →	Nei	Ja	Nei	Ja
Magesår eller magesykdom	Nei	Ja →	Nei	Ja	Nei	Ja
Nyresykdom	Nei	Ja →	Nei	Ja	Nei	Ja
Leversykdom	Nei	Ja →	Nei	Ja	Nei	Ja
Blodmangel eller annen blodsykdom	Nei	Ja →	Nei	Ja	Nei	Ja
Kreft	Nei	Ja →	Nei	Ja	Nei	Ja
Depresjon	Nei	Ja →	Nei	Ja	Nei	Ja
Artrose, slitasjegikt	Nei	Ja →	Nei	Ja	Nei	Ja
Ryggsmerter	Nei	Ja →	Nei	Ja	Nei	Ja
Reumatoid artritt, leddgikt	Nei	Ja →	Nei	Ja	Nei	Ja
Andre medisinske problemer:						
.....	Nei	Ja →	Nei	Ja	Nei	Ja
.....	Nei	Ja →	Nei	Ja	Nei	Ja
.....	Nei	Ja →	Nei	Ja	Nei	Ja

SF-36 Spørreskjema om helse

Dette spørreskjemaet handler om hvordan du ser på din egen helse. Disse opplysningene vil hjelpe oss til å få vite hvordan du har det og hvordan du er i stand til å utføre dine gjøremål

Hvert spørsmål besvares ved å sette et kryss i den boksen som passer best for deg. Hvis du er usikker på hva du skal svare, vennligs svar så godt du kan.

1. Stort sett, hvordan vil du si din helse er?

☐ Utmerket ☐ Meget god ☐ God ☐ Nokså god ☐ Dårlig

2. Sammenlignet med for for ett år siden, hvordan vil du si din helse er nå?

☐ Mye bedre nå enn for ett år siden
☐ Litt bedre nå enn for ett år siden
☐ Omtrent det samme som for ett år siden
☐ Litt dårligere enn for ett år siden
☐ Mye dårligere enn for ett år siden

3. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er din helse slik at den begrenser deg i utførelsen av disse aktivitetene nå? Hvis ja, hvor mye)

	Sett kryss	**Ja, begrenser meg mye**	**Ja, begrenser meg litt**	**Nei, begrenser meg ikke i det hele tatt**
a	Anstrengende aktiviteter som å løpe, løfte tunge gjenstander, delta i anstrengende idrett			
b	Moderate aktiviteter som å flytte etbord, støvsuge, gå en tur eller drive med hagearbeid			
c	Løfte eller bære en handlekurv			
d	Gå opp trappen flere etasjer			
e	Gå trappen opp en etasje			
f	Bøye deg eller sitte på huk			
g	Gå mer enn to kilometer			
h	Gå noen hundre meter			
i	Gå hundre meter			
j	Vaske eller kle på deg			

4. I løpet av de siste 4 ukene, har du hatt noen av følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av din fysiske helse?

	Sett kryss	**Hele tiden**	**Mye av tiden**	**En del av tiden**	**Litt av tiden**	**Ikke i det hele tatt**
a	Du har måttet **redusere tiden** du har brukt på arbeid eller på andre pågjøremål					
b	Du har **utrettet mindre** enn du hadde ønsket					
c	Du har vært hindret i å utføre **visse typer** arbeid eller gjøremål					
d	Du har hatt **problemer** med å gjennomføre arbeidet eller andre gjøremål (for eksempel fordi det krevde ekstra anstrengelser)					

5. I løpet av de siste 4 ukene, har du hatt noen av følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av følelsesmessige problemer (som for eksempel å bære deprimert eller engstelig)?

Sett kryss	Hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
Du har måtte **redusere tiden** du har brukt på arbeid eller andre gjøremål					
Du har **utrettet mindre** enn du hadde ønsket					
Du har utført arbeidet eller andre gjøremål mindre **grundig** enn vanlig					

6. I løpet av de siste 4 ukene, i hvilken grad har din fysiske helse eller følelsesmessige problemer hatt innvirkning på din vanlige sosiale omgang med familie, venner, naboer eller foreninger?

☐ Ikke i det hele tatt ☐ Litt ☐ En del ☐ Mye ☐ Svært mye

7. Hvor sterke kroppslige smerter har du hatt i løpet av de siste 4 ukene?

☐ Ingen ☐ Meget Svake ☐ Svake ☐ Moderate ☐ Sterke ☐ Meget sterke

8. I løpet av de siste 4 ukene, hvor mye har smerter påvirket ditt vanlige arbeid (gjelder både arbeid utenfor hjemmet og husarbeid

☐ Ikke i det hele tatt ☐ Litt ☐ En del ☐ Mye ☐ Svært mye

9. De neste spørsmålene handler om hvordan du har følt deg og hvordan du har hatt det de siste 4 ukene. For hvert spørsmål vennligst velg det svaralternativet som best beskriver hvordan du har hatt det. Hvor ofte i løpet av de siste 4 uken har du:

		Hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
a	Følt deg full av liv?					
b	Følt deg veldig nervøs?					
c	Vært så langt nede at ingenting har kunnet muntre deg opp?					
d	Følt deg rolig og harmonisk?					
e	Hatt mye overskudd?					
f	Følt deg nedfor og trist?					
g	Følt deg sliten?					
h	Følt deg glad?					
i	Følt deg trett?					

10. I løpet av de siste 4 ukene, hvor mye av tiden har din fysiske helse eller følelsemessige problemer påvirket din sosiale omgang (som det å besøke venner, slektninger, osv.)

☐ Hele tiden ☐ Mye av tiden ☐ En del av tiden ☐ Litt av tiden ☐ Ikke i et hele tatt

11. Hvor RIKTIG eller GAL er hver av de følgende påstandene for deg?

	Sett kryss	Helt riktig	Delvis riktig	Vet ikke	Delvis gal	Helt gal
a	Det virker som om jeg blir syk lettere enn andre					
b	Jeg er like frisk som de fleste jeg kjenner					
c	Jeg tror helsen min vil forverres					
d	Jeg har utmerket helse					

Vennligst kontroller at du har besvart alle spørsmålene.

Tusen takk for hjelpen!

REGISTRERINGSSKJEMA FOR PASIENTER SOM DELTAR I STUDIE SOM SAMMENLIKNER TO ULIKE OPERASJONSMETODER FOR LUMBAL SPINAL STENOSE

LUMBAL SPINAL STENOSE STUDIEN
En nasjonal multisenterstudie

(Skjemaet fylles ut av lege/sykepleier)

INKLUSJON

Dato for utfylling ☐☐ Dag ☐☐ Måned ☐☐ År

Pasientdata

Navn

Fødselsnr. (11 siffer) ☐☐☐☐☐☐☐☐☐☐☐

Alder ☐☐ Kjønn ☐ Mann ☐ Kvinne

Høyde og vekt

Høyde ☐☐☐ (cm) Vekt ☐☐☐ (kg)

Sykehistorie

Tidligere operert?

- ☐ Ja, samme nivå
- ☐ Ja, annet nivå
- ☐ Nei

- Pasienten har vært operert.....ganger tidligere i LS-columna
(fylles kun ut ved reoperasjon)

Arbeidsstatus

- ☐ I arbeid
- ☐ Hjemmeværende (ulønnet)
- ☐ Pensjonist
- ☐ Arbeidsledig
- ☐ Sykemeldt
- ☐ Aktivt sykemeldt
- ☐ Delvis sykemeldt .....% sykemeldt
- ☐ Attføring/rehabilitering
- ☐ Uføretrygdet evt. .....% uføretrygdet

Andre relevante sykdommer eller plager

- ☐ Nei
- ☐ Ja, spesifiser

.....

.....

Symptomvarighet

Varighet av nåværende rygg-/hoftesmerter:

- ☐ Pasienten har ingen rygg-/hoftesmerter
- ☐ Mindre enn 3 måneder
- ☐ 3 til 12 måneder
- ☐ 1 til 2 år
- ☐ Mer enn 2 år

Varighet av nåværende utstrålende smerter:

- ☐ Pasienten har ingen utstrålende smerter
- ☐ Mindre enn 3 måneder
- ☐ 3 til 12 måneder
- ☐ 1 til 2 år
- ☐ Mer enn 2 år

Varighet sykemelding/attføring/rehabilitering pga. aktuelle plager ☐☐☐ (uker)

Radiologisk vurdering (sett evt. flere kryss)

1. Undersøkelse

- ☐ CT
- ☐ MR
- ☐ Radikulografi
- ☐ Diskografi
- ☐ Diagnostisk blokade
- ☐ Røntgen LS-columna
- ☐ Med fleksjon/ekstensjon

2. Funn

- ☐ Skiveprolaps
- ☐ Sentral spinal stenose
- ☐ Recesstenose
- ☐ Degenerativ rygg
- ☐ Spondylolistese
  - ☐ Istmisk spondylolistese
  - ☐ Degenerativ spondylolistese
- ☐ Degenartiv skoliose
- ☐ Annet, spesifiser

Operasjonsindikasjon (sett evt. flere kryss)

- ☐ Smerter
  - ☐ Rygg-/hoftesmerter
  - ☐ Bensmerter
  - ☐ Begge deler
- ☐ Parese, grad 0-5:..... Se evt. rettledning
- ☐ Cauda equina ayndrom
- ☐ Annet, spesifiser.....

Operasjonsdato ☐☐ ☐☐ ☐☐
Dag Måned År

Operasjonskategori

☐ Elektiv ☐ Øyeblikkelig hjelp ☐ 1/2 øyeblikkelig hjelp

Dagkirugi

☐ Ja ☐ Nei

ASA-klassifisering

- ☐ I Ingen organisk, fysiologisk, biokjemisk eller psykisk forstyrrelse. Den aktuelle lidelsen er lokalisert og gir ikke generelle systemforstyrrelser
- ☐ II Moderat sykdom eller forstyrrelse som ikke forårsaker funksjonelle begrensninger
- ☐ III Alvorlig sykdom eller forstyrrelse som gir definerte funksjonelle begrensninger
- ☐ IV Livstruende organisk sykdom som ikke behøver å være knyttet til den aktuelle kirurgiske lidelse eller som ikke bedres ved det planlagte kirurgiske inngrepet
- ☐ V Døende pasient som ikke forventes å overleve 24 timer uten kirurgi

Operasjonsmetode (Sett evt. flere kryss)

Har operatøren brukt mikroskop eller lupebrille?

☐ Ja ☐ Nei

Prolapsekstirpasjon?

- ☐ Nei
- ☐ Ja, med tømming av skive (diskektomi)
- ☐ Ja, uten tømming av skive

Kirurgisk dekompresjon

- ☐ Dekompresjon uten laminektomi
  - ☐ Unilateral
  - ☐ Bilateral
- ☐ Laminektomi
- ☐ Fasettektomi i ett eller flere nivå
  - ☐ Unilateral
  - ☐ Bilateral

Andre operasjonemstoder

- ☐ Endoskopi
- ☐ Ekspanderende interspinøst implantat
- ☐ Skiveprotese
- ☐ Fusjonskirurgi (se nedenfor)

Annet, spesifiser:.....

Type fusjonskirurgi (Sett evt. flere kryss)

- ☐ Bakre
  - ☐ Instrumentell
  - ☐ ikke instrumentell
- ☐ Fremre
  - ☐ Instrumentell
  - ☐ ikke instrumentel

Annet, spesifiser:.....

Operert(e) nivå(er) og side(r) (Sett evt- flere kryss)

☐ L2/L3	☐ Hø.	☐ Ve.
☐ L3/L4	☐ Hø.	☐ Ve.
☐ L4/L5	☐ Hø.	☐ Ve.
☐ L5/S1	☐ Hø.	☐ Ve.

Annet, spesifiser:.....

Tidsforbruk

1. Tidsforbruk i forbindelse med inngrepet

Medgått tid fra pasienten forlot sengeposten til han/hun kom tilbake ☐☐ ☐☐ timer/min

Knivtid (hud-hud) ☐☐ ☐☐ timer/min

2. Antall liggedøgn i forbindelse med inngrepet

☐☐☐ Dager

Antibiotikaprofylakse

☐ Ja ☐ Nei

LUMBAL SPINAL STENOSE STUDIEN
En nasjonal multisenterstudie

KIRURGISK REGISTRERINGSSKJEMA

Pasientens navn: _____ F.dato: _____

Dato operert:_____ Random.nummer:_____

Operasjonstid (hud – hud) _____ minutter Anestesitid _____ minutter

Peroperativ blødning _____ ml

Peroperative komplikasjoner: _____

☐ Narkose ☐ Lokal anestesi ☐ Spinal **Opr. nivå**:_____

Type kirurgi: ☐ Bilat. dekompresjon ☐ Unilat. dekompresjon
☐ X-stop ☐ Laminektomi

AB-profylakse? ☐ Ja ☐ Nei Type og varighet:_____

POSTOPERATIV REGISTRERING

Liggetid recovery/p.o: _____minutter Total blødning: _____ml

Mobilisert dato:_____ Liggedager sengepost _____dager

Liggedager pasienthotell _____dager

Status ved hjemreise

	Ja	**Nei**	
Hematom:	☐	☐	
Infeksjon, overfladisk	☐	☐	
Infeksjon, dypt	☐	☐	
Annet	☐	☐	Type:_____

Smertestillende ved utreise:_____

Skjema er fylt ut av: ……(navn på postsykepleier)

(Skjemaet fylles ut av lege/sykepleier)

LUMBAL SPINAL STENOSE STUDIEN
En nasjonal multisenterstudie

REGISTRERINGSSKJEMA FOR PASIENTER SOM DELTAR I STUDIE SOM SAMMENLIKNER TO ULIKE OPERASJONSMETODER FOR LUMBAL SPINAL STENOSE

Kontroll: ☐ 6 UKER ☐ 3 MND ☐ 1 ÅR ☐ 2 ÅR

Dato etterundersøkelse ☐☐ Dag ☐☐ Måned ☐☐ År

Pasientdata

Navn

Fødselsnr. (11 siffer) ☐☐☐☐☐☐☐☐☐☐☐

Alder ☐☐ Kjønn ☐ Mann ☐ Kvinne

Har pasienten møtt til personlig etterkontroll?

☐ Ja

☐ Nei

Hvis nei, er skjema besvart pr.brev?

☐ Ja

☐ Nei

Arbeidsstatus

☐ I arbeid

☐ Hjemmeværende

☐ Pensjonist

☐ Arbeidsledig

☐ Sykemeldt

☐ Aktivt sykemeldt

☐ Delvis sykemeldt

.....% sykemeldt

☐ Attføring/rehabilitering

☐ Uføretrygdet

evt. .....% uføretrygdet

Frismeldt?

Hvis ja, angi dato ☐☐ Dag ☐☐ Måned ☐☐ År

Varighet av sykemelding etter operasjonen ☐☐☐

Komplikasjoner til inngrepet?

☐ Nerveskade, spesifider

.....

☐ Blødning

☐ Infeksjon

☐ Overflatisk sårinfeksjon

☐ Dyp sårinfeksjon/diskitt/ spondylitt

☐ Liquorlekkasje

☐ Annet, spesifiser

.....

☐ Reoperet innen 3 måneder etter operasjonen

Har pasienten fortsatt?

☐ Parese, grad 0-5: ☐

☐ Cauda equina ayndrom

☐ Annet, spesifiser

.....

Andre relavante sykdommer, skader eller plager?

☐ Nei

☐ Ja, spesifiser

.....

SPØRRESKJEMA FOR PASIENTER SOM DELTAR I STUDIE SOM SAMMENLIKNER TO ULIKE OPERASJONSMETODER FOR LUMBAL SPINAL STENOSE

LUMBAL SPINAL STENOSE STUDIEN
En nasjonal multisenterstudie

3 MÅNEDER

Pasientdata

Navn	
Fødselsnr. (11 siffer)	
Adresse	
Alder (år)	☐☐
Kjønn	☐ Mann ☐ Kvinne

Formålet med dette spørreskjemaet er å gi leger, sykepleiere og fysioterapeuter bedre forståelse av ryggpasienters plager og å vuredre effekter av behandling. Din utfylling av skjemaet vil være til stor nytte for å kunne gi et best mulig behandlingstilbud til ryggpasienter i fremtiden.

Spørreskjemaet har fire deler. Første del omhandler ulike sider ved din utdanning og familie samt dine smerter og plager. De neste delene består av tre ulike sett spørsmål for måling av din nåværende helse. Det første av disse (kalt Oswestry) måler hvordan ryggplagene påvirker dagligdagse gjøremål. Det andre (kalt EQ-5D) måler din helserelaterte livskvalitet. Den siste delen er en skala der du skal merke av hvor god eller dårlig din helsetilstand er.

Dato for utfylling ☐☐ Dag ☐☐ Måned ☐☐ År

Hvilken nytte mener du at du har hatt av operasjonen?

(Sett ett kryss)

- ☐ Jeg er helt bra
- ☐ Jeg er mye bedre
- ☐ Jeg er litt bedre
- ☐ Ingen forandring
- ☐ Jeg er litt verre
- ☐ Jeg er mye verre
- ☐ Jeg er verre enn noen gang før

Hvor fornøyd er du med behandlingen du har fått på sykehuset?

(Sett ett kryss)

- ☐ Fornøyd
- ☐ Litt fornøyd
- ☐ Verken fornøyd eller misfornøyd
- ☐ Litt misfornøyd
- ☐ Misfornøyd

Hvor sterke smerter har hatt siste uke?

Hvordan vil du gradere smertene du har hatt i **rygg/hofte** i løpet av den siste uken? Sett ring rundt ett tall

0	1	2	3	4	5	6	7	8	9	10
Ingen smerter										Så vondt som det går an å ha

Hvordan vil du gradere de smertene du har hatt i **benet (ett eller begge)** i løpet av den siste uken? Sett ring rundt ett tall

0	1	2	3	4	5	6	7	8	9	10
Ingen smerter										Så vondt som det går an å ha

Funksjonsscore (Oswestry)

Disse spørsmålene er utarbeidet for å gi oss informasjon om hvordan dine smerter har påvirket dine muligheter til å klare dagliglivet ditt. Vær snill å besvare spørsmålene ved å sette kryss (kun **ett** kryss for hvert avsnitt) i de rutene som passer best for deg.

1. Smerte

- ☐ Jeg har ingen smerter for øyeblikket
- ☐ Smertene er veldig svake for øyeblikket
- ☐ Smertene er moderate for øyeblikket
- ☐ Smertene er temmelig sterke for øyeblikket
- ☐ Smertene er er veldig sterke for øyeblikket
- ☐ Smertene er de verste jeg kan tenke meg for øyeblikket

2. Personlig stell

- ☐ Jeg kan stelle meg selv på vanlig måte uten at det forårsaker ekstra smerte
- ☐ Jeg kan stelle meg selv på vanlig måte, men det er veldig smertefullt
- ☐ Det er smertefullt å stelle seg selv, og jeg gjør det langsomt og forsiktig
- ☐ Jeg trenger noe hjelp, men klarer det meste av mitt personlige stell
- ☐ Jeg trenger hjelp hver dag til det meste av mitt eget stell
- ☐ Jeg kler ikke på meg, har vanskeligheter med å vaske meg og holder sengen

3. Å løfte

- ☐ Jeg kan løfte tunge ting uten å få smerter
- ☐ Jeg kan løfte tunge ting, men får smerter
- ☐ Smertene hindrer meg i å løfte tunge ting opp fra gulvet, men jeg greier det hvis det som skal løftes er gunstig plassert, for eksempel på et bord
- ☐ Smertene hindrer meg i å løfte tunge ting, men jeg klarer det lett hvis det er gunstig plassert
- ☐ Jeg kan bare løfte noe som er veldig lett
- ☐ Jeg kan ikke løfte eller bære noe i det hele tatt

4. Å gå

- ☐ Smerter hindrer meg ikke i å gå idet hele tatt
- ☐ Smerter hindrer meg i å gå mer enn 1 ½ km
- ☐ Smerter hindrer meg i å gå mer enn ¾ km
- ☐ Smerter hindrer meg i å gå mer enn 100 m
- ☐ Jeg kan bare gå med stokk eller krykker
- ☐ Jeg ligger for det meste i sengen, og jeg må krabbe til toalettet

5. Å sitte

- ☐ Jeg kan sitte så lenge jeg vil i hvilken som helst stol
- ☐ Jeg kan sitte så lenge jeg vil i min favoritt stol
- ☐ Smerter hindrer meg i å sitte i mer enn en time
- ☐ Smerter hindrer meg i å sitte i mer enn en halv time
- ☐ Smerter hindrer meg i å sitte i mer enn ti minutter
- ☐ Smerter hindrer meg i å sitte i det hele tatt

6. Å stå

- ☐ Jeg kan stå så lenge jeg vil uten å få mer smerter
- ☐ Jeg kan stå så lenge jeg vil, men får mer smerter
- ☐ Smerter hindrer meg i å stå i mer enn en time
- ☐ Smerter hindrer meg i å stå i mer enn en halv time
- ☐ Smerter hindrer meg i å stå i mer enn ti minutter
- ☐ Smerter hindrer meg i å stå i det hele tatt

7. Å sove

- [ ] Søvnen min forstyrres aldre av smerter
- [ ] Søvnen min forstyrres av og til av smerter
- [ ] På grunn av smerter får jeg mindre enn 6 timers søvn
- [ ] På grunn av smerter får jeg mindre enn 4 timers søvn
- [ ] På grunn av smerter får jeg mindre enn 2 timers søvn
- [ ] Smerter hindrer all søvn

8. Seksualliv

- [ ] Seksuallivet mitt er normalt og forårsaker ikke mer smerter
- [ ] Seksuallivet mitt er normalt, men forårsaker noe smerte
- [ ] Seksuallivet mitt er normalt, men svært smertefullt
- [ ] Seksuallivet mitt er svært begrenset av smerter
- [ ] Seksuallivet mitt er nesten borte på grunn av smerter
- [ ] Smerter forhindrer alt seksualliv

9. Sosialt liv (omgang med venner og kjente)

- [ ] Det sosiale livet mitt er normalt og forårsaker ikke mer smerter
- [ ] Det sosiale livet mitt er normalt, men øker graden av smerter
- [ ] Smerter har ingen betydelig innvirkning på mitt sosiale liv, bortsett fra at de begrenser mine mer fysisk aktive sider, som sport osv.
- [ ] Smerter har begrenset mitt sosiale liv, og jeg går ikke så ofte ut
- [ ] Smerter har begrenset mitt sosiale liv til hjemmet
- [ ] På grunn av smerter har jeg ikke noe sosialt liv

10. Å reise

- [ ] Jeg kan reise hvor som helst uten smerter
- [ ] Jeg kan reise hvor som helst, men det gir smerter
- [ ] Smertene er ille, men jeg klarer reiser på to timer
- [ ] Smerter begrenser meg til korte reiser på under en time
- [ ] Smerter begrenser meg til korte, nødvendige reiser på under 30 minutter
- [ ] Smerter forhindrer meg fra å reise, unntatt for å få behandling

Beskrivelse av helsetilstand (EQ-5D)

Vis hvilke utsagn som passer best på din helsetilstand i dag ved å sette kryss i en av rutene utenfor hver av dimensjonene nedenfor

1. Gange

- [ ] Jeg har ingen problemer med å gå omkring
- [ ] Jeg har litt problemer med å gå omkring
- [ ] Jeg er sengeliggende

2. Personlig stell

- [ ] Jeg har ingen problemer med personlig stell
- [ ] Jeg har litt problemer med å vaske meg eller kle meg
- [ ] Jeg er ute av stand til å vaske meg eller kle meg

3. Vanlige gjøremål (f.eks. arbeid, studier, husarbeid, familie eller fritidsaktiviteter)

- [ ] Jeg har ingen problemer med å utføre mine vanlige gjøremål
- [ ] Jeg har litt problemer med å utføre mine vanlige gjøremål
- [ ] Jeg er ute av stand til å utføre mine vanlige gjøremål

4. Smerte og ubehag

- [ ] Jeg har verken smerter eller ubehag
- [ ] Jeg har moderat smerte eller ubehag
- [ ] Jeg har sterk smerte eller ubehag

5. Angst og depresjon

- [ ] Jeg er verken engstelig eller deprimert
- [ ] Jeg er noe engstelig eller deprimert
- [ ] Jeg er svært engstelig eller deprimert

Smertestillende medisiner

Bruker du smertestillende medisiner på grunn av dine rygg- og/eller beinsmerter?

- [ ] Ja
- [ ] Nei

Har du svart ja: Hvor ofte bruker du smertestillende medisiner? (Sett ett kryss)

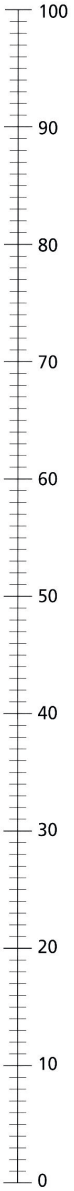
- [ ] Sjeldnere enn hver måned
- [ ] Hver måned
- [ ] Hver uke
- [ ] Daglig
- [ ] Flere ganger daglig

Helsetilstand

For at du skal kunne vise oss hvor god eller dårlig din helsetilstand er, har vi laget en skala (nesten som et termometer), hvor den beste helsetilstanden du kan tenke deg er markert med 100 og den dårligste med 0.

Vi ber om at du viser din helsetilstand ved å trekke ei linje fra boksen nedenfor til det punkt på skalaen som passer best med din helsetilstand.

Best tenkelige helsetilstand



Verst tenkelige helsetilstand

Nåværende helsetilstand

Arbeidsstatus

- ☐ I arbeid
- ☐ Hjemmeværende
- ☐ Pensjonist
- ☐ Arbeidsledig
- ☐ Sykemeldt
- ☐ Aktivt sykemeldt
- ☐ Delvis sykemeldt
  .....% sykemeldt
- ☐ Attføring/rehabilitering
- ☐ Uføretrygdet

evt. .....% uføretrygdet

Frismeldt?

Hvis ja, angi dato ☐☐ ☐☐ ☐☐

Dag Måned År

Varighet av sykemelding etter operasjonen ☐☐☐

Komplikasjoner til inngrepet?

- ☐ Uventet skade
- ☐ Blødning
- ☐ Infeksjon i operasjonssåret
- ☐ Allergisk reaksjon
- ☐ Annet (spesifiser)

.....

Har du søkt om uføretrygd?

(Sett ett kryss)

- ☐ Ja
- ☐ Nei
- ☐ Planlegger å søke
- ☐ Er allerede innvilget

Har du søkt om erstatning fra forsikringsselskap eller folketrygden (evt. yrkesskadeerstatning)?

(Sett ett kryss)

- ☐ Ja
- ☐ Nei
- ☐ Planlegger å søke
- ☐ Er allerede innvilget

Pasientens navn:.....

Dato:.....

LUMBAL SPINAL STENOSE STUDIEN
En nasjonal multisenterstudie

TILLEGGSSKJEMA

3 MÅNEDER

Denne studien er en nasjonal multisenterstudie der forskere fra flere sykehus er involvert. Resultatene fra studien vil bli rapportert både nasjonalt og internasjonalt. Dette stiller store krav til hvilke spørsmål som inngår og resulterer i at neon spørsmål overlapper hevrandre. Vi ber om forståelse for overlappingen og håper dette ikke vil virke distraherende.

Zürich Claudicatio questionnaire. Disse spørsmålene omhandler dine symptomer, din funksjon og hvor fornøyd du er.
Sett ett kryss i en av rutene for hvert punkt

I løpet av siste måneden, hvordan vil du beskrive:

1. Smertene du har hatt i gjennomsnitt i korsrygg, setet samt smerter som går ned i bena?

- ☐ Ingen
- ☐ Svake
- ☐ Moderate
- ☐ Sterke
- ☐ Meget sterke

2. Hvor ofte har du hatt smerter i rygg, sete eller bena?

- ☐ Mindre enn en gang i uken
- ☐ Minst en gang i uken
- ☐ Hver dag, minst noen minutter
- ☐ Hver dag, det meste av dagen
- ☐ Hvert eneste minutt av dagen

3. Smertene i rygg eller sete?

- ☐ Ingen
- ☐ Milde
- ☐ Moderate
- ☐ Sterke
- ☐ Meget sterke

4. Nummenhet eller prikking i bena eller føttene?

- ☐ Ingen
- ☐ Milde
- ☐ Moderate
- ☐ Sterke
- ☐ Meget sterke

5. Svakhet i bena eller føttene?

- ☐ Ingen
- ☐ Milde
- ☐ Moderate
- ☐ Sterke
- ☐ Meget sterke

6. Problemer med balansen?

- ☐ Nei, jeg har ikke hatt problemer med balansen
- ☐ Ja, noen ganger føler jeg at balansen er dårlig, eller at jeg ikke har en trygg fot.
- ☐ Ja, ofte føler jeg balanse er dårlig, eller at jeg ikke har en trygg fot.

I løpet av den siste måneden på en typisk dag:

1. Hvor langt har du greid å gå?

- ☐ Lengre enn 3 km
- ☐ Under 3 km, men lengre enn 500 m
- ☐ Under 500 m, men lengre enn 20 m
- ☐ Kortere enn 20 m

2. Har du gått turer utendørs eller på kjøpesentra for fornøyelsens skyld?

- ☐ Ja, uten ubehag
- ☐ Ja, men noen ganger med smerter
- ☐ Ja, men alltid med smerter
- ☐ Nei

3. Har du handlet dagligvarer eller andre ting?

- ☐ Ja, uten ubehag
- ☐ Ja, men noen ganger med smerter
- ☐ Ja, men alltid med smerter
- ☐ Nei

4. Har du gått omkring i rommene i leiligheten eller huset ditt?

- ☐ Ja, uten ubehag
- ☐ Ja, men noen ganger med smerter
- ☐ Ja, men alltid med smerter
- ☐ Nei

5. Har du gått mellom soverommet ditt og badet?

- ☐ Ja, uten ubehag
- ☐ Ja, men noen ganger med smerter
- ☐ Ja, men alltid med smerter
- ☐ Nei

Hvor fornøyd er du med:

1. Det generelle resultatet av ryggoperasjonen?

- ☐ Veldig fornøyd
- ☐ Noe fornøyd
- ☐ Noe misfornøyd
- ☐ Veldig misfornøyd

2. Reduksjonen i smertene etter operasjonen?

- ☐ Veldig fornøyd
- ☐ Noe fornøyd
- ☐ Noe misfornøyd
- ☐ Veldig misfornøyd

3. Dine evner til å gå etter operasjonen?

- ☐ Veldig fornøyd
- ☐ Noe fornøyd
- ☐ Noe misfornøyd
- ☐ Veldig misfornøyd

4. Dine evner til å gjøre husarbeid, hagearbeid, eller annet arbeid etter operasjonen?

- ☐ Veldig fornøyd
- ☐ Noe fornøyd
- ☐ Noe misfornøyd
- ☐ Veldig misfornøyd

5. Styrke i lår, ben og føttene?

- ☐ Veldig fornøyd
- ☐ Noe fornøyd
- ☐ Noe misfornøyd
- ☐ Veldig misfornøyd

6. Din balanse, eller stødighet på føttene?

- ☐ Veldig fornøyd
- ☐ Noe fornøyd
- ☐ Noe misfornøyd
- ☐ Veldig misfornøyd

SF-36 Spørreskjema om helse

Dette spørreskjemaet handler om hvordan du ser på din egen helse. Disse opplysningene vil hjelpe oss til å få vite hvordan du har det og hvordan du er i stand til å utføre dine gjøremål

Hvert spørsmål besvares ved å sette et kryss i den boksen som passer best for deg. Hvis du er usikker på hva du skal svare, vennligs svar så godt du kan.

1. Stort sett, hvordan vil du si din helse er?

☐ Utmerket ☐ Meget god ☐ God ☐ Nokså god ☐ Dårlig

2. Sammenlignet med for for ett år siden, hvordan vil du si din helse er nå?

☐ Mye bedre nå enn for ett år siden
☐ Litt bedre nå enn for ett år siden
☐ Omtrent det samme som for ett år siden
☐ Litt dårligere enn for ett år siden
☐ Mye dårligere enn for ett år siden

3. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er din helse slik at den begrenser deg i utførelsen av disse aktivitetene nå? Hvis ja, hvor mye)

	Sett kryss	**Ja, begrenser meg mye**	**Ja, begrenser meg litt**	**Nei, begrenser meg ikke i det hele tatt**
a	Anstrengende aktiviteter som å løpe, løfte tunge gjenstander, delta i anstrengende idrett			
b	Moderate aktiviteter som å flytte etbord, støvsuge, gå en tur eller drive med hagearbeid			
c	Løfte eller bære en handlekurv			
d	Gå opp trappen flere etasjer			
e	Gå trappen opp en etasje			
f	Bøye deg eller sitte på huk			
g	Gå mer enn to kilometer			
h	Gå noen hundre meter			
i	Gå hundre meter			
j	Vaske eller kle på deg			

4. I løpet av de siste 4 ukene, har du hatt noen av følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av din fysiske helse?

	Sett kryss	**Hele tiden**	**Mye av tiden**	**En del av tiden**	**Litt av tiden**	**Ikke i det hele tatt**
a	Du har måttet **redusere tiden** du har brukt på arbeid eller på andre pågjøremål					
b	Du har **utrettet mindre** enn du hadde ønsket					
c	Du har vært hindret i å utføre **visse typer** arbeid eller gjøremål					
d	Du har hatt **problemer** med å gjennomføre arbeidet eller andre gjøremål (for eksempel fordi det krevde ekstra anstrengelser)					

5. I løpet av de siste 4 ukene, har du hatt noen av følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av følelsesmessige problemer (som for eksempel å bære deprimert eller engstelig)?

Sett kryss	Hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
Du har måtte **redusere tiden** du har brukt på arbeid eller andre gjøremål					
Du har **utrettet mindre** enn du hadde ønsket					
Du har utført arbeidet eller andre gjøremål mindre **grundig** enn vanlig					

6. I løpet av de siste 4 ukene, i hvilken grad har din fysiske helse eller følelsesmessige problemer hatt innvirkning på din vanlige sosiale omgang med familie, venner, naboer eller foreninger?

☐ Ikke i det hele tatt ☐ Litt ☐ En del ☐ Mye ☐ Svært mye

7. Hvor sterke kroppslige smerter har du hatt i løpet av de siste 4 ukene?

☐ Ingen ☐ Meget Svake ☐ Svake ☐ Moderate ☐ Sterke ☐ Meget sterke

8. I løpet av de siste 4 ukene, hvor mye har smerter påvirket ditt vanlige arbeid (gjelder både arbeid utenfor hjemmet og husarbeid

☐ Ikke i det hele tatt ☐ Litt ☐ En del ☐ Mye ☐ Svært mye

9. De neste spørsmålene handler om hvordan du har følt deg og hvordan du har hatt det de siste 4 ukene. For hvert spørsmål vennligst velg det svaralternativet som best beskriver hvordan du har hatt det. Hvor ofte i løpet av de siste 4 uken har du:

		Hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
a	Følt deg full av liv?					
b	Følt deg veldig nervøs?					
c	Vært så langt nede at ingenting har kunnet muntre deg opp?					
d	Følt deg rolig og harmonisk?					
e	Hatt mye overskudd?					
f	Følt deg nedfor og trist?					
g	Følt deg sliten?					
h	Følt deg glad?					
i	Følt deg trett?					

10. I løpet av de siste 4 ukene, hvor mye av tiden har din fysiske helse eller følelsemessige problemer påvirket din sosiale omgang (som det å besøke venner, slektninger, osv.)

☐ Hele tiden ☐ Mye av tiden ☐ En del av tiden ☐ Litt av tiden ☐ Ikke i et hele tatt

11. Hvor RIKTIG eller GAL er hver av de følgende påstandene for deg?

	Sett kryss	Helt riktig	Delvis riktig	Vet ikke	Delvis gal	Helt gal
a	Det virker som om jeg blir syk lettere enn andre					
b	Jeg er like frisk som de fleste jeg kjenner					
c	Jeg tror helsen min vil forverres					
d	Jeg har utmerket helse					

Vennligst kontroller at du har besvart alle spørsmålene.

Tusen takk for hjelpen!

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Akershus Universitetssykehus HF
Universitetssykehuset Nord-Norge HF
Sykehuset Innlandet HF, Lillehammer
Sykehuset Innlandet HF, Elverum
Martina Hansens Hospital
Ålesund Sjukehus

Initialer:

Randnr:

For perioden fra **3 måneder** til etterkontroll **1 år** etter behandling

Helseøkonomisk sammenligning mellom to ulike operasjonsmetoder for lumbal spinal stenose

Dette er en ”kostnadsdagbok” der du fortløpende registrerer dine egne og dine pårørendes utgifter som eventuelt påløper p.g.a. plager i ben/ korsryggen eller smerter/problemer forbundet med ryggoperasjonen.

Vi registrerer dette fordi vi ønsker å bli bedre til å behandle våre pasienter! Flere spørsmål kan virke like, men vær vennlig å svare likevel.

På forhånd takk for dine svar!

Dine svar er strengt konfidensielle og kommer ikke til å kunne brukes av noen myndighet!

Ansvarlig for den helseøkonomiske utredningen:
Dr. Greger Lønne, Sykehuset Innlandet, Lillehammer

Dette spørreskjema tar du med på 1 års kontroll. Du vil bli oppringt med jevne mellomrom av en lokal representant for studien, som kan hjelpe deg å fylle i visse deler av spørreskjemaet.

Vil du snakke med forskningsansvarlig, kontakter du:

Når du fyller i opplysninger videre, tenk da på gjennomgående å skrive antall DAGER når vi ber deg om å angi forskjellige tider!

SYKEHUS

2. Har du i den aktuelle perioden oppsøkt sykehus akutt pga fortsatte plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen du har hatt?

☐ (1) Nei

☐ (2) Ja, På hvilket **sykehus** – hvor mange **ganger**?

Sykehus, år og måned	Antall dager innlagt (hvis du ble innlagt)
……	……..
……	……..
……	……..

3. Har du i den aktuelle perioden blitt behandlet på sykehus p.g.a. fortsatte plager i plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen du har hatt?

☐ (1) Nei

☐ (2) Ja, forsøk å angi ***antall besøk*** hos de yrkesgrupper du har besøkt

A Lege	B Sykepleier	C Fysioterapeut	D Ergoterapeut	E Psykolog	F Sosionom	G Annet*
.....	.....	.....	.....	.....	.....	.....

*Annet=.....

4. Har du i den aktuelle perioden blitt operert p.g.a. fortsatt plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen du har hatt?

☐ (1) Nei

☐ (2) Ja, På hvilket **SYKEHUS** – og hvor mange **LIGGEDØGN**?

Sykehus, klinikk år og måned	Antall liggedøgn
.....	…….
.....	…….
.....	…….

PRIMÆRHELSETJENESTEN

5. Har du i den aktuelle perioden besøkt primærhelsetjenesten pga fortsatte plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen du har hatt?

☐ (1) **Nei**

☐ (2) Ja Forsøk å angi ***antall besøk*** hos de forskjellige yrkesgruppene

A Lege	B Sykepleier	C Fysioterapeut	D Ergoterapeut	E Psykolog	F Sosionom	G Annet*
.....	.....	.....	.....	.....	.....	.....

*Annet=.....

6. Har du i den aktuelle perioden prøvd noen annen behandling pga fortsatte plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen du har hatt?

☐ (1) **Nei**

☐ (2) Ja, forsøk å angi ***antall besøk*** hos de yrkesgrupper du besøkt

A Lege Privat- eller bedriftslege	B Fysioterapeut (privat)	C Kiropraktor	D Naprapat	E Psykolog	F Sosionom	G Annet*
.....	.....	.....	.....	.....	.....	.....

*Annet=…….....

MEDISINER

7. Har du på grunn av fortsatte plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen du har hatt, brukt medisiner i den aktuelle perioden?

☐ (1) Nei
☐ (2) I begynnelsen, men ikke nå lengre. Forsøk å angi når du sluttet etter preparatnavnet.
☐ (3) Ja fremdeles. Forsøk å angi hvilke medisiner, samt hvor ofte du har brukt disse.

Preparat	Hver måned (a)	Hver uke (b)	Hver dag (c)	Flere ggr/ dag (d)
A …..…….……	☐	☐	☐	☐
B ……	☐	☐	☐	☐
C ……	☐	☐	☐	☐
D ……	☐	☐	☐	☐

ANNEN STØTTE

8. Har du på grunn av fortsatte plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen du har hatt, fått støtte fra trygdekontoret i den aktuelle perioden?

☐ (1) Nei

☐ (2) Ja, forsøk å angi ***antall dager*** og ***hvilken type av støtte***

Om Ja, angi navnet på ditt Trygdekontor og hvilken type støtte……

Hvilken type støtte		100 %	75 %	50 %	25 %	Annen %
A Medisinsk rehabilitering	Nei ☐ Ja ☐					
Om Ja, i hvilken periode (%-sats)		.....	.....	.....	.....	.....
B Uføretrygd	Nei ☐ Ja ☐					
Om Ja, siden når (%-sats)		.....	.....	.....	.....	.....
C Er du Sykemeldt?	Nei ☐ Ja ☐					
Om Ja, siden når (%sats)?		.....	.....	.....	.....	.....
D Spesielle bidrag	Nei ☐ Ja ☐					
Om Ja, siden når (%-sats)		.....	.....	.....	.....	.....
E Yrkesrettet attføring fra A-etat	Nei ☐ Ja ☐					
Om Ja, siden når (%-sats)		.....	.....	.....	.....	.....

9. Har du pga fortsatte plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen du har hatt, fått støtte fra andre instanser enn trygdekontoret i den aktuelle perioden?

☐ (1) Nei

☐ (2) Ja Om ja, forsøk å angi hvilken type av støtte i tabellen under:

Hvilken type støtte	**Nei**	**Ja**	**Omtrent hvor mange dager**
Kommunen			
A Hjemmehjelp	☐	☐	.....
B Kjøregodtgjørelse	☐	☐	.....
C Støttepersoner	☐	☐	.....
Arbeidskontoret			
D Utdanning/div. kurs	☐	☐	.....
E Annen rehabilitering	☐	☐	.....

10. Har du pga fortsatte plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen du har hatt i den aktuelle perioden fått økonomiske bidrag fra andre instanser enn de som er nevnt ovenfor?

☐ (1) Nei
☐ (2) Ja, forsøk å angi hvilken type av støtte og **antall dager**

	Hvilken type støtte	Dager
A Sosialbidrag	.....	.....
B Utviklingsbidrag	.....	.....
C Utdannelsesbidrag	.....	.....
F Arbeidsledighetstrygd	.....	.....
G Annet		.....

EGNE UTLEGG - PÅRØRENDE

11. Har du på grunn av fortsatte plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen du har hatt, fått annen hjelp i den aktuelle perioden som du har betalt helt selv og som ikke er oppført tidligere?
(for eksempel all privat pleie for ryggplager)

☐ (1) Nei
☐ (2) Ja, angi hvilken type pleie, og omtrent kostnader:

Hvilken type pleie ……..	Kostnad i aktuell periode .....

12. Har du på grunn av fortsatte plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen du har hatt iverksatt tiltak som kostet deg penger i den aktuelle perioden, og som ikke er nevnt tidligere?

☐ (1) Nei
☐ (2) Ja, angi hva, og omtrent hva det har kostet **deg**.

Hva ……	Kostnad i aktuell periode .....

13. Har du fått ekstra hjelp av pårørende i den aktuelle perioden som resultat av at du har hatt fortsatte plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen du har hatt?

☐ (1) Nei
☐ (2) Ja Om ja, forsøk å beskrive støtten og omfanget av det!

Hvilket yrke har den som du syns har gitt deg best hjelp?

Hvilken type støtte	Dager
A Skyss/reiser – OBS: en hel dag = 8 timer	…….
B Ærend utenfor hjemmet (handle, bank etc.)	…….
C Husarbeid	…….
D Personlig hjelp (kle på/av, medisinering etc.)	…….
E Har pårørende tatt ferie/avspasering for å hjelpe deg? Nei ☐ Ja ☐	
Om Ja, antall dager omtrent	…….

ANNET

14. Har din arbeidsgiver gjort noen aktiv innsats for at du lettere skal kunne arbeide på grunn av dine plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen du har hatt i den aktuelle perioden?

☐ (1) Ikke aktuelt – pensjonist
☐ (2) Nei
☐ (3) Jeg har vært borte fra arbeidet under hele den aktuelle perioden
☐ (4) Ja, hva har din arbeidsgiver gjort, og Når?

…….

…….

15. Ønsket du noen gang i den aktuelle perioden å ha tilgang til annen behandling for dine plager i ben/ korsryggen enn den du har fått?

☐ (1) Nei
☐ (2) Ja

Hva skulle du ønske du hadde tilgang til?

16. Hvordan syns du at helsevesenet *stort* sett har fungert i den aktuelle perioden? Sett kryss i passende alternativ!

	Ikke besøkt (0)	Veldig dårlig (1)	Ganske dårlig (2)	Verken eller (3)	Ganske bra (4)	Veldig bra (5)
A Ventetider til lege	☐	☐	☐	☐	☐	☐
B Ventetider på mottak	☐	☐	☐	☐	☐	☐
C Åpningstider	☐	☐	☐	☐	☐	☐
D Telefontider	☐	☐	☐	☐	☐	☐
E Sosial støtte	☐	☐	☐	☐	☐	☐
F Følelsesmessig støtte	☐	☐	☐	☐	☐	☐
G Personalet - imøtekommenhet	☐	☐	☐	☐	☐	☐
H Kontinuerlig kontakt med personal	☐	☐	☐	☐	☐	☐
I Avsatt tid for besøk	☐	☐	☐	☐	☐	☐
K Tilgodesett behov - ønsker	☐	☐	☐	☐	☐	☐
L Mulighet til å påvirke din behandling	☐	☐	☐	☐	☐	☐
M Informasjonen om behandling	☐	☐	☐	☐	☐	☐
O Samarbeid med andre behandlere	☐	☐	☐	☐	☐	☐
P Helhetlig inntrykk av behandlingen	☐	☐	☐	☐	☐	☐

17. Hvordan bedømmer du i dag din helse sammenlignet med andre på din alder?

Mye dårligere (1)	Dårligere (2)	Omtrent lik (3)	Bedre (4)	Mye bedre (5)
☐	☐	☐	☐	☐

18. Dersom du har egne synspunkter eller tanker så skriv dem gjerne ned her og /eller på baksiden.

Takk for hjelpen!

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Martina Hansens Hospital
Ålesund Sjukehus

Fylles ut av lokal koordinator / forskningssykepleier / studiesekretær som er ansvarlig for oppfølgingen.

Initialer: ……..Rand.nummer:……

Sjekkliste for bruk av SYKEHUSRESSURSER i perioden fra 3 måneder til etterkontroll 1 år etter avsluttet behandling.

1. Har pasienten i løpet av den aktuelle perioden søkt hjelp på sykehus p.g.a. plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen?

☐ (1) Nei
☐ (2) Ja,

Sykehus, HF, divisjon / avdeling, år og måned, antall ganger	Antall dager innlagt (dersom innlagt)
……	……..
……	……..
……	……..
……	……..

2. Har pasienten i løpet av den aktuelle perioden blitt operert (inkludert diagnostiske tester) p.g.a. plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen?

☐ (1) Nei
☐ (2) Ja,

Sykehus, HF, divisjon / avdeling, år og måned, hvilket inngrep ble utført?	Antall dager innlagt
……	……..
……	……..
……	……..
……	……..

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3. Har pasienten i løpet av den aktuelle perioden blitt <u>behandlet på en poliklinikk ved sykehuset</u> p.g.a plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen?

☐ (1) Nei

☐ (2) Ja, angi ***antall besøk*** hos de fagspesialiteter pasienten har møtt?

A Lege	B Sykepleier	C Fysioterapeut	D Ergoterapeut	E Psykolog	F Sosionom	G Annet*
.....	.....	.....	.....	.....	.....	.....

* Annet personell =

4. Har pasienten i løpet av den aktuelle perioden blitt <u>undersøkt med Rtg, CT eller MR</u> p.g.a. plager i ben/ korsryggen eller smerter forbundet med ryggoperasjonen?

☐ (1) Nei

☐ (2) Ja,

Sykehus, HF, divisjon/avdeling, år og måned, hvilken undersøkelse?	Antall undersøkelser
……	……..
……	……..
……	……..
……	……..

5. Har pasienten i løpet av den aktuelle perioden behandlet for frakturer eller smerter på annet/andre anatomiske områder en i ryggen?

☐ (1) Nei

☐ (2) Ja,

Sykehus, HF, divisjon / avdeling, år og måned, diagnose?	Tiltak
……	……..
……	……..
……	……..

Send opplysningene til Hege Andresen

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Martina Hansens Hospital
Ålesund Sjukehus

Pasientens navn:

Personnummer:

Oppfølgingsperiode: -

Dagsats for full kompensasjon:

1. Har pasienten hatt/fått:

Heltidspensjon (uføretrygd etc) i løpet av perioden? Nei ☐ Ja ☐

om ja, fra når

Deltidspensjon i løpet av perioden Nei ☐ Ja ☐

om ja, fra når og hvor stor prosent %

2. Sykemeldingsperioder, hel eller deltid, i løpet av perioden:

Periode 1	-	Hel ☐	Del ☐ %
Periode 2	-	Hel ☐	Del ☐ %
Periode 3	-	Hel ☐	Del ☐ %
Periode 4	-	Hel ☐	Del ☐ %

Ved flere perioder skal man gi opplysninger på eget ark.

3. Medisinsk attføring, hel eller deltid, i løpet av perioden:

Periode 1	-	Hel ☐	Del ☐ %
Periode 2	-	Hel ☐	Del ☐ %
Periode 3	-	Hel ☐	Del ☐ %
Periode 4	-	Hel ☐	Del ☐ %

Ved flere perioder skal man gi opplysninger på eget ark

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Ålesund Sjukehus

4. Yrkesrettet attføring, hel eller deltid, i løpet av perioden:

Periode 1	-	Hel ☐	Del ☐ %
Periode 2	-	Hel ☐	Del ☐ %
Periode 3	-	Hel ☐	Del ☐ %
Periode 4	-	Hel ☐	Del ☐ %

Ved flere perioder skal man gi opplysninger på eget ark

5. Rehabiliteringstiltak eller andre tiltak (eksempelvis IA) som trygdekontoret har betalt, hvilke og i hvilken periode, og til hvilken kostnad? Skriv gjerne nederst på arket hvis det ikke blir plass!

Tiltak:	Mellom hvilke dato	Kostned
1.	-	NOK
2	-	NOK
3.	-	NOK

6. Andre kostnader trygdekontoret har betalt for, eksempelvis dekning av reiseutgifter etc:

På forhånd takk!

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