COMBINED MECHANICAL AND PRO-INFLAMMATORY STRESS CONTRIBUTES TO WEAKENING OF THE ANULUS FIBROSUS IN A BOVINE AF ORGAN CULTURE APPROACH

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Introduction: Anulus fibrosus (AF) disruption can lead to intervertebral disc prolapse or disc herniation (1). The trans-lamellar bridging network (TLBN) is a proteoglycan and elastic fiber-rich structure that separates the collagen rich AF lamellae and forms transverse bridges which connect the concentric layers of the AF (2). Little is known about how mechanobiological factors influence the TLBN and anular wall integrity (2,3,4). We hypothesize that matrix components of the TLBN are altered by mechanical overloading in the presence of inflammatory factors, thereby contributing to tissue weakening. To study this hypothesis we established a bovine AF organ culture approach (AF-OC) to analyze the influence of defined cyclic strain in concurrence with a pro-inflammatory stimulus (IL-1β) on AF matrix composition and mechanical properties.

Methods: AF rings were cut and punched from bovine caudal discs. After 7 days of pre-incubation, AF-OCs were exposed to high physiological cyclic tensile strain (CTS) for 5 days (9% 1Hz, 3 hours/day) in a custom-made device (Fig.1A). A sub-group was cultured at presence of IL-1β (1ng/μL) to simulate a pro-inflammatory environment. Afterwards AF-OCs were assessed for PGE2 release (ELISA) and the expression pattern of COX-2, IL-6, and MMP3 in the tissue (immunohistochemistry, IHC). The mechanical strength of TLBN was evaluated in a peel-test. AF segments were dissected into a ‘Y’ configuration and pulled apart at 0.5mm/sec in a uniaxial material testing machine (Fig.1C). Delamination strength was calculated from the mean force in the plateau region of the force displacement curves as described (5). Statistics: ANOVA with Sidaks correction.

Results: The combination of cyclic strain and IL-1β (CTS+IL-1β) resulted in a significant 25-fold increase in PGE2 release compared to controls (p = 0.001, n=8). In contrast, CTS or IL-1β alone had no effect (Fig.1B). IHC showed that the CTS+IL-1β group was associated with a higher expression of IL-6 and MMP3 within the TLBN regions compared to adjacent lamellar matrix. Mechanical testing found a decrease in the adhesive peel force of the interlamellar matrix in the CTS+IL1β group compared to all other groups (Fig.1D).

Conclusions: The adhesion of adjacent lamella is an important factor in anular wall integrity. Our loaded bovine AF-OC model enables investigation of the AF and TLBN structure-function relationship. Our findings suggest that the combination of cyclic-strain and IL-1β act synergistically to increase pro-inflammatory and catabolic molecules within the AF, particularly the TLBN matrix, which consequently leads to a weakening of the tissue structure. This approach will contribute to a better understanding of the pathomechanism of disc herniation. References: 1. Adams et al. Spine

Disclosures:

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Background: Multimorbidity (co-occurrence of ≥2 comorbidities) is increasingly present in the elderly. The association between multimorbidity and treatment outcome in patients with lumbar spinal stenosis (LSS) is unknown. The aim of this study was to assess this association in LSS-patients undergoing non-surgical and surgical (decompression surgery with or without fusion) treatment.

Methods: We analyzed the association between comorbidities and the treatment outcome of patients included in the Lumbar Stenosis Outcome Study, a prospective multicenter cohort study including patients aged 50 and older undergoing treatment for LSS. Primary outcomes were quality of life (EQ-5D-3L sum-score, range 0 -100), pain (spinal stenosis measure (SSM)-symptoms (Sy), 1 -5) and function (SSM-F, 1 -4) after two years. We explored the association between the cumulative illness rating scale (CIRS-sum score, 0 -56) as well as the impact of ≥4 present illnesses (pulmonary, cardiac, vascular, endocrine, renal, neurological, musculoskeletal disease, and mental health problems), a cut-off commonly used in the literature. We fit linear models to the two-year outcomes based on the treatment group, the baseline value and comorbidity.

Results: Overall, 450 patients (41 conservative care, 58 infiltrations, 351 undergoing surgery) completed the two-year follow-up and were analyzed. The median age was 73, 76 and 74 years, respectively. The median CIRS score was 9; ≥4 comorbidities were present in 243 (54%) patients. Baseline characteristics were comparable. In the multiple model, CIRS was associated with a lower quality of life (for each additional CIRS-score point: -0.9 points, 95% confidence interval -1.3 to -0.6, p<0.001), more pain (0.03, 0.006 to 0.05, p=0.009), and more disability (0.4, 0.3 to 0.5, p<0.001) at two years. Patients with ≥4 comorbidities reported lower quality of life (-5.7, -2.7 to -8.7, p<0.001), more disability (0.4, 0.3 to 0.5, p<0.001), more pain (0.5, 0.4 to 0.6, p<0.001) at two years. Whereas CIRS scores ≤11 (Figure) seemed less to influence the improvement after treatment, CIRS scores >11 were exponentially associated with less improvement in all outcomes.

Conclusion: In patients undergoing treatment for LLS multimorbidity was associated with a lower quality of life, more symptoms and disability at two-year follow-up. A cut-off score of ≥4 comorbidities may not reflect the true impact of comorbidities depending on their severity.
Disclosures:
LONG TERM OUTCOME AFTER LUMBAR DISC HERNIATION SURGERY AT DIFFERENT AGES
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Background/introduction
Lumbar disc herniation is uncommon at youth and associated with a good treatment outcome. Prospective data on long term outcome is missing.

Purpose of the study
To investigate the risk of any additional surgery in the lumbar spine and patient reported outcome after surgery for lumbar disc herniation at different ages, including adolescents.

Materials and Methods
Data from a national spine register cohort of 10,615 patients were used. Age was used as a continuous variable or divided into age groups; 18 years or younger (n=151), 19-39 years (n=4,386), 40-59 years (4,844) and 60 years or older (n=1,234). Primary outcome was the risk of any additional surgery in the lumbar spine with a mean follow-up of 11.3 years (range 6.0 to 19.3 years). Secondary outcomes were patient reported outcome data, which were available for 6,777 of the 10,615 patients at a mean time of 7 years after surgery. These consisted of patient satisfaction, global assessment of leg and back pain, Visual Analog Scale (VAS) leg pain and back pain, Oswestry disability index (ODI), and EQ-5D. Statistical analyses were made with Chi-square test, Friedman Test, Welch-Satterthwaite t-test and logistic regression.

Results
15% of all operated patients underwent additional surgery in the lumbar spine. The odds ratio for the risk of any additional surgery with a 1 year increase in age was 0.99 (95% confidence interval 0.98-0.99) (Figure 1). All age groups improved their patient reported outcome data after surgery (all p<0.001). When looking at the age groups, from the youngest to the oldest, satisfaction was reported by 80%, 86%, 82% and 78%, and global assessment for significantly decreased leg pain by 81%, 84%, 77% and 69%, and for significantly decreased back pain by 81%, 81%, 77% and 73%, respectively (all p<0.001). VAS, ODI and EQ-5D-3L behaved similarly as the global assessments.

Conclusion
This study, with a large patient sample including adolescents and with prospective data, shows that the risk for subsequent surgery was lower with higher age. Lumbar disc herniation can be attributed to the progress of spinal degeneration, irrespective of age. Patient reported outcome data were poorest in the oldest age group.

Figure legend
Figure 1. Odds ratio for any additional surgery in the lumbar spine at different ages with the risk of surgery at the age of 40 years as reference.
Disclosures:
author 1: none; author 2: none; author 3: none
POSTOPERATIVE SICK LEAVE IS CORRELATED TO THE LENGTH OF PRE-OPERATIVE SICK LEAVE IN PATIENTS WITH HERNIATED LUMBAR DISC TREATED WITH DISCECTOMY.

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Background:

Lumbar disc herniation (LDH) is associated with great morbidity and significant socio-economic impact in many parts of the world, as the majority of the patients are of working age. The patients' ability to return to the workforce following an illness depends on the person's workload, strength of social relationships, level of education and length of sick leave.

Purpose:

The purpose of this study is to determine if the duration of pre-operative sick leave is predictive of return to work following discectomy

Methods:

A retrospective study of prospectively collected data from the Danish Spine database (DaneSpine) and the Danish Ministry of Employment's national register of public sickness benefits (DREAM database).

The study population comprised of a consecutive cohort of patients aged between 17 and 62 years at the time of operation, treated at a single spine specialty center due to LDH during the period from 1 June 2010 to 31 May 2013. All patients had Magnetic Resonance Imaging demonstrating lumbar disc herniation at the level and side corresponding with the patient's symptoms.

Data available from the DREAM database included weekly public transfer payments to the patients two years prior to the date of operation and two years postoperative. As work force attachment is a cyclically sensitive parameter, a control cohort was also made available. The control cohort was matched to the LDH cases based on date of birth, sex and municipality of residence on the week of surgery. After linking data from DaneSpine and the DREAM register the surgical and vocational record for each person was established. We examined the weekly status of any type of transfer income in each of the weeks two years prior and after the date of surgery to describe the socio-economic history for each person before and after the surgery.

Results:

A total of 1,134 consecutive patients operated due to herniated lumbar disc and 3,402 age and sex matched controls were included in the study. The mean age in both cohorts was 48.16 ± 14.75. One year post-operative the employment rate for cases was fairly constant, at 15 % below the controls.

There was a strong association between the duration of pre-operative sick-leave and post-operative sick-leave, with a correlation coefficient of 0.832 (p<0.000). The majority of the patients who returned to the work force within a year had less than 20 week’s pre-operative sick-leave.

Conclusions:

Denmark has a public and free health care system, which minimizes socio-economic differences in
the access to health care, thus reducing the risk of bias in the present study. Due to free health care socio-economic factors should not affect the duration of pre-operative sick leave. The study indicated a need to address the patients with sick leave exceeding 3 months due to LDH to avoid long-term sick leave, risk of developing chronic pain syndromes and risk of early retirement.

Disclosures:
Background/introduction:
Lumbar disc herniation (LDH) is associated with great morbidity and significant socioeconomic impact in many parts of the world. Studies have shown that most LDH can be treated effectively with non-operative management. However, for some patients where pain and disability is unacceptable, surgical intervention provides effective clinical relief. Currently there is little consensus in the medical community on the timing of surgery for patients suffering from radicular pain due to LDH. Multiple studies suggest that prolonged symptom duration adversely affects clinical outcome.

Purpose of the study:
The aim of this study is to investigate if prolonged preoperative symptom duration will result in a less favorable outcome following surgery for LDH.

Materials and Methods:
Consecutive series of patients scheduled for first time surgery for LDH in a single-center, multi-surgeon spine center. Data were prospectively collected in DaneSpine, the Danish National Spine Registry. Subjects were divided into three groups based on their self-reported duration of leg pain prior to enrollment into the registry: <3-months, 3-12 months and >12-months. Associations between patient-reported outcomes (PROs), perioperative complications and duration of symptoms were evaluated. Outcome measures were Oswestry Disability Index (ODI), EuroQol-5D (EQ-5D) and Visual Analog Scale (VAS) for back and leg pain (0 to 100).

Results:
1,834 patients were included in the study, with complete one-year follow-up on 1,448 patients (79%) and an overall reoperation rate of 8.4%. Prolonged preoperative symptoms adversely influenced all PROs (EQ-5D, ODI, VAS) one year after surgery (p=0.001). Changes in PROs are shown in figure 1. Furthermore, reoperation rates increased with longer duration of preoperative symptoms. A statistically significant trend (p=0.009) of increasing incidence of reoperation was found with increasing length of symptom duration. Incidence of surgical complications, specifically dural tears, was higher with increasing duration of leg pain, however, this did not reach statistical significance (p=0.028).

Conclusion:
We found that longer duration of preoperative leg pain results in inferior patient reported outcomes and increased reoperation rates. Patients who underwent surgery within the first 3 months of onset of leg pain, achieved the best outcome one year after surgery.
Disclosures:
INTERSPINOUS PROCESS DISTRACTION COMPARED TO NONOPERATIVE CARE FOR MODERATE LUMBAR DEGENERATIVE DISC DISEASE

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Background. Interspinous process distraction devices (IPD) aim to alleviate back and leg pain by limiting extension and offloading the disc at the affected lumbar level. IPDs may offer a treatment option for symptomatic degenerative disc disease (DDD) when disc replacement or fusion is not yet indicated.

Purpose. To report the results of a randomized, controlled clinical trial at 23 US centers, comparing the safety and effectiveness of IPD and nonoperative care after 2 years for the treatment of moderate low back pain secondary to DDD.

Materials and Methods. 278 patients with moderate low back pain for less than 1 year plus radiographic evidence of 1-level DDD (L2-L5) who failed at least 6 weeks but less than 6 months of conservative care were randomized and treated as follows: Investigational treatment (n=181) consisted of implantation of a non-rigid IPD and nonoperative treatment, as necessary; Control treatment (n=97) included patient education on low back pain, medication, physical therapy, and epidural and/or facet joint steroidal injections.

The primary endpoint was Overall Success, a composite variable that included: 1) Oswestry Disability Index (ODI) score improvement of ≥15 points; and 2) no serious adverse event (AE) related to the treatment; and 3) no secondary surgery (investigational) or treatment surgery (control) at the involved level. Treatment effectiveness endpoints included ODI, back and leg pain, SF-36; adverse events (AEs) and secondary surgeries were also analyzed.

Statistical analyses used Bayesian methods with non-informative priors. Last observations were carried forward for patients lost to follow-up, and patients receiving surgery (control crossovers) or additional surgery (investigational) at the involved level.

Results. Baseline characteristics and outcomes scores were not statistically different between the 2 groups. The investigational rate of Overall Success at 24 months was statistically superior to control (observed rate of 63.0% vs. 13.4%, respectively; posterior probability of superiority (pps) >99.9%). The improvement in outcomes for IPD was statistically superior to control (pps >99.9%) for ODI (26.4 vs. 1.0), back pain (8.4 vs. 1.2), leg pain (4.9 vs. +1.1 pain increase in control group), PCS (12.6 vs. 1.3), and MCS (4.4 vs. -0.9 decrease in control group). Spinous process bony erosion increased slowly to 33.7% (61/181) of IPD patients but was not related to clinical outcomes. Control treatment-related serious AEs were associated with increasing low back pain. Fifteen (8.3%) IPD patients and 34 (35.1%) control patients experienced a treatment-related serious AE. Twenty (11.0%) IPD patients had secondary surgery at the index level. After 6 months of non-op treatment, control patients had the option to cross over to IPD or other surgery: 69.1% (67) of controls (58.8% (57) to IPD) had crossed over by 24 months.

Conclusions. Analyses support the superiority this IPD over conservative care for moderate back pain.

Disclosures:
RESULTS OF A PROSPECTIVE, RANDOMIZED MULTI-CENTER STUDY WITH 2-YEAR FOLLOW-UP TO COMPARE THE PERFORMANCE OF DECOMPRESSION WITH AND WITHOUT INTERLAMINAR STABILIZATION

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Surgical decompression is extremely effective at relieving pain symptoms due to lumbar spinal stenosis. Decompression with interlaminar stabilization (D+ILS) is as effective as decompression with posterolateral fusion for stenosis, as shown in a US FDA pivotal trial. This study reports a multi-center, randomized controlled trial comparing D+ILS to decompression alone (DA) for treatment of moderate to severe lumbar spinal stenosis.

Under approved institutional ethics review, six sites in Germany treated 230 patients (1:1 ratio) randomized to either DA or D+ILS (coflex, Paradigm Spine, New York, NY). Patients had moderate to severe lumbar spinal stenosis at one or two adjacent segments from L3 to L5. Outcomes were evaluated up to two years postoperatively, including Oswestry disability index (ODI), presence of secondary surgery or lumbar injections, neurologic status, and the presence of device or procedure-related severe adverse events. Composite clinical success (CCS) was defined as combining all four of these outcomes, a success-definition validated in a US FDA pivotal trial. Additional secondary endpoints included visual analog scales, Zurich claudication questionnaire, narcotic usage, walking distance, and radiographs.

The follow-up rate was 91% at 2 years. There were no significant differences in patient-reported outcomes (PROs) at 24 months (p > 0.05). The CCS was superior for D+ILS (p = 0.017). The risk of secondary intervention was 1.75 times higher among DA patients compared to D+ILS patients (p = 0.055). The DA arm had 228% more lumbar injections (P=0.0065) compared to D+ILS. DA patients had a numerically higher rate of narcotic use at every time point post-surgically (16.7% D+ILS vs. 23% DA at 24 month). The walking distance test results were statistically significantly different from baseline where D+ILS had greater than 5 times improvement compared to only a 2 times improvement for DA from baseline. Foraminal height and disc height was largely maintained in D+ILS patients, while DA patients showed a significant decrease at 24 months postoperative (p<0.001).

Our study showed no significant difference in the individual PROs between the treatments when viewed in isolation. The CCS is statistically superior for interlaminar stabilization. D+ILS increases walking distance, decreases compensatory pain management, and maintains foraminal height extending the durability and sustainability of a decompression procedure.

Disclosures:
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INTERTRANSVERSE FUSION RATES FOLLOWING NON-INSTRUMENTED LUMBAR FUSION. RESULTS FROM A RANDOMIZED DOUBLE BLIND CLINICAL TRIAL OF ABM/P-15 VERSUS ALLOGRAFT.

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Background/ introduction:
Due to poor bone stock in the elderly, a non-instrumented fusion is commonly performed in Scandinavia when instability is present. Allograft bone is often used as graft extender with consequent low fusion rates. The use of ABM/P-15 has shown superior fusion rates in dental and cervical spinal surgery, but no clinical studies have been conducted in non-instrumented lumbar fusion surgery.

Purpose of the study:
To evaluate the intertransverse fusion rate in patients with degenerative spondylolisthesis (DS) undergoing decompression and non-instrumented posterolateral fusion with either 15 amino acid residue (ABM/P-15) or allograft.

Materials and Methods:
101 patients who underwent decompression and non-instrumented fusion were enrolled in the study and randomized 1:1 to either ABM/P-15 (mixed 50/50) or allograft bone (30g/level), both mixed with local bone graft. The patients underwent one-year postoperative fine slice CT-scans (0.9 mm) with reconstructions, independently evaluated by 3 reviewers. Fusion status was concluded by consensus of 2 of the 3 as „fusion“ or „no fusion“.

Results:
There were 50 patients in the ABM/P-15 group and 51 patients in the allograft group. The two groups were similar in terms of sex distribution, age and number of levels fused. Radiographic fusion was seen in 63 of 126 segments (50%) in the ABM/P-15 group and 23 of 114 segments (20%) in the allograft group (p<0.001). In single-level fusions, the fusion rates were better in the ABM/P-15 group (29 of 72, 40%) compared to allograft (17 of 80, 21%, p=0.011). This was also true in patients with two-level surgeries (ABM/P-15: 34 of 54, 63%; allograft 6 of 34, 18%, p<0.001).

Conclusions:
Patients undergoing non-instrumented posterolateral fusion augmented with ABM/P-15 had a statistically significantly higher intertransverse fusion rate compared to allograft when evaluated using CT.

Disclosures:
ADJACENT DISC DEGENERATION AFTER LUMBAR TOTAL DISC REPLACEMENT OR NON-OPERATIVE TREATMENT: A RANDOMISED STUDY WITH EIGHT-YEAR FOLLOW-UP

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Background
Total disc replacement (TDR) was introduced as a motion-preserving alternative to spinal fusion, which has been reported to increase the risk of adjacent disc degeneration (ADD). However, ADD may develop naturally regardless of any surgery, and no randomised study has assessed the long-term development of ADD after TDR versus non-operative treatment.

Purpose of the study
We aimed to assess the long-term development of ADD after lumbar total disc replacement (TDR) or non-operative treatment, and to analyse the association between ADD development and clinical outcome.

Materials and methods
The study included 126 of the 173 patients with chronic low back pain originally included in a randomised study comparing TDR with multidisciplinary rehabilitation. Magnetic resonance imaging of the lumbar spine was performed before treatment and at eight-year follow-up. ADD was categorised as increased or not increased based on an evaluation of Modic changes, disc height reduction, disc contour, herniation size, nucleus pulposus signal and posterior high intensity zones. We used a χ² test or a Fisher’s exact test to compare crude proportions, and multiple linear regressions to analyse the association between increased ADD (yes/no) and change in Oswestry Disability Index (ODI) from pre-treatment to follow-up.

Results
ADD increased (for at least one ADD variable) in 23 of 57 patients (40%) treated non-operatively, and 29 of 69 patients (42%) treated with TDR (p=0.86). We found no significant associations between ADD increase and the change in ODI.

Conclusion
Increased ADD occurred with similar frequency after TDR and after non-operative treatment, and was not related to the clinical outcome at eight-year follow-up.

Disclosures:
LUMBAR ARTIFICIAL DISC REPLACEMENT WITH A NOVEL CONTROLLED MOBILE CORE DEVICE: FIVE YEAR RESULTS FROM A RANDOMIZED CONTROLLED FDA TRIAL
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PURPOSE: To report on the comparative long-term safety and efficacy outcomes of first generation lumbar artificial disc replacements with the latest generation controlled mobile core device (MCD) in the treatment of patients with symptomatic, single-level degenerative disc disease (DDD).

STUDY DESIGN: Prospective, multicenter, randomized, controlled, investigational device exemption study with five year follow-up.

PATIENT SAMPLE: Patients with symptomatic single-level lumbar DDD who failed at least six months of nonsurgical treatment.

OUTCOME MEASURES: Oswestry Disability Index (ODI) success, radiographic range of motion (ROM), serious adverse events (SAE), visual analogue scale (VAS), and correlation of ROM to clinical outcome.

METHODS: Patients were randomly allocated (2:1) to treatment with the MCD (Investigational) (n = 218) or one of two previously FDA approved disc replacement systems (n = 106). At five years follow-up, 185 Investigational patients and 90 Control patients provided five year follow-up data.

RESULTS: Between the MCD and Control devices effectiveness outcomes were comparable at five years and the improvement from baseline was sustained. Improvement in back pain (VAS) greater than 20mm was seen in 81.7% of MCD patients and 74.5% of Control patients (p=0.17). Oswestry Disability Index (ODI) improvements of greater than 15 points were seen in 80.3% and 74.5% of the MCD and Control patients respectfully (p=0.63). Average ROM at baseline in the MCD and Control groups were similar (6.6 and 6.2 degrees). At five year follow-up average ROM was 6.1 degrees in the MCD group and 4.2 degrees in the Control group. The 31% drop-off of average ROM in the Control group was statistically significant (p=0.02). Additionally, a statistically significant inverse correlation between ROM, VAS and ODI was seen at five years. In terms of safety, at five years a total of only nine patients from the full study group reported that they had developed the need to undergo revision, reoperation, removal or supplemental fixation of their disc prosthesis (2.8%). Freedom from a SAE through 5 years was in favor of the MCD (p<0.01).

CONCLUSIONS: The immediate post-operative safety and efficacy benefits of total disc replacement are sustained through five years. Across devices, when ROM was preserved pain and functionality were improved. Further, the MCD is safer (p<0.01) and similarly efficacious versus Control devices over the long-term.

Disclosures:
DOES A WEB-BASED SPINE PLATFORM FEATURING SOCIAL INTERACTION AND ANIMATED INFORMATION AFFECT PATIENT REPORTED OUTCOMES IN PATIENTS UNDERTAKING LUMBAR SPINE FUSION SURGERY? A RANDOMIZED CLINICAL TRIAL

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Aim. To examine the effect of a web-based Spine Platform featuring Interaction and Information by Animation (w-SPIINA) on symptoms of anxiety and depression, disability, health related quality of life and pain in patients undergoing lumbar spine fusion (LSF) surgery.

Background. Approximately one third of patients going through spine surgery are found to have symptoms of anxiety and depression and these symptoms are found to correlate with surgical outcomes as greater pain, functional disability and lower health related quality of life. The use of web-based informative strategies before surgery and principles from cognitive behavioural therapy has been applied in other patient groups, facilitating mobility and encouraging beneficial pain coping behaviour regarding pain. However, these didactic techniques have not been targeted patients going through spine surgery. Thus, aiming to reduce anxiety and depression and thus, potentially improve mobility, pain and health related quality of life, there is a need to explore the effect of alternative cognitive and educative methods in patients undergoing LSF.

Methods. A randomized clinical trial in which patients going through 1-3 level instrumented LSF were randomized into two groups; usual care i.e., a standard regimen, containing a joint two-hour patient information meeting (control group) or to the intervention group, receiving access to w-SPIINA in addition to the standard joint two-hour information meeting. Primary outcome was the change in Hospital Anxiety and Depression Scale (HADS) from baseline, mean 18 days (range 6-36) before surgery to 3 months after. Secondary outcomes were change in HADS 6 months after surgery, disability using Oswestery Disability Index (ODI), health related quality of life using EQ-5D-5L and back and leg pain using Low Back Pain Rating Scale (LBPRS) 3 and 6 months after surgery.

Results. A total of 114 patients fulfilled the inclusion criteria and randomized from September 2015 to May 2017. Minimal clinically Important differences (MCID) in HADS was not reached in either of the two groups at 3 or 6 months follow-up. In each of the two groups MCID was reached in LBPRS, ODI and EQ-5D-5L at 3 and at 6 months after surgery (table 1). Comparing the two groups, no statistically significant differences were found in the overall change of anxiety, depression, disability, health related quality of life or pain neither at 3 nor 6 months after surgery.

Conclusions. Providing patients with access to w-SPIINA in addition to a standard two-hour joint patient information meeting has no additional effect on HADS and patient reported outcome 3 or 6 months after surgery. Thus, our findings support the need for further research in order to accommodate symptoms of anxiety and depression in patients going through LSF.
Table 1. Effect of w-SPIINA on symptoms of anxiety and depression, disability, pain and health related quality of life 3 and 6 months after surgery

<table>
<thead>
<tr>
<th></th>
<th>Intervention group Change from baseline Median (IQR)</th>
<th>N</th>
<th>Control group Change from baseline Median (IQR)</th>
<th>N</th>
<th>Between-group differences P</th>
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<tr>
<td>HADS-A 3 months</td>
<td>-1 (1 to -3)</td>
<td>45</td>
<td>-1.5 (0 to -3)</td>
<td>46</td>
<td>0.37</td>
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<tr>
<td>6 months</td>
<td>-1 (1 to -3)</td>
<td>43</td>
<td>-1 (1 to -3)</td>
<td>45</td>
<td>0.78</td>
</tr>
<tr>
<td>HADS-D 3 months</td>
<td>-1 (2 to -3)</td>
<td>45</td>
<td>-1 (0 to -3)</td>
<td>46</td>
<td>0.78</td>
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<tr>
<td>6 months</td>
<td>0 (1 to 2)</td>
<td>43</td>
<td>0 (2 to -2)</td>
<td>45</td>
<td>0.97</td>
</tr>
<tr>
<td>ODI 3 months</td>
<td>-10 (0 to -23)</td>
<td>45</td>
<td>-15.5 (0 to -27.5)</td>
<td>48</td>
<td>0.42</td>
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<tr>
<td>6 months</td>
<td>-11(0 to -30)</td>
<td>43</td>
<td>-9(5 to -29)</td>
<td>47</td>
<td>0.78</td>
</tr>
<tr>
<td>Back pain – the mean back pain within the last 14 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>-2(-0.5 to -3.5)</td>
<td>44</td>
<td>-3 (-1 to -4)</td>
<td>48</td>
<td>0.26</td>
</tr>
<tr>
<td>6 months</td>
<td>-2 (-1to -4)</td>
<td>42</td>
<td>-2 (-1 to -4)</td>
<td>47</td>
<td>0.98</td>
</tr>
<tr>
<td>Leg pain – median leg pain within the last 14 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>-3 (-5 to -1)</td>
<td>45</td>
<td>-3(-5 to -1)</td>
<td>49</td>
<td>0.55</td>
</tr>
<tr>
<td>6 months</td>
<td>-2 (-5 to -1)</td>
<td>43</td>
<td>-3 (-5 to 0)</td>
<td>47</td>
<td>0.51</td>
</tr>
<tr>
<td>EQ-5D-5L 3 months</td>
<td>0.12 (0.20 to 0.022)</td>
<td>44</td>
<td>0.13(-0.056 to 0.23)</td>
<td>48</td>
<td>0.49</td>
</tr>
<tr>
<td>6 months</td>
<td>0.076 (0.24 to 0.009)</td>
<td>41</td>
<td>0.16 (0.24 to 0.06)</td>
<td>45</td>
<td>0.25</td>
</tr>
</tbody>
</table>

IQR indicates interquartile ranges (25th and 75th percentile); HADS-A, Anxiety subscale in Hospital anxiety and Depression Scale; HADS-D, Depression subscale in Hospital anxiety and Depression Scale; ODI, Oswestry Disability Index; Back pain and Leg pain from Low Back Pain Rating Scale; EQ-5D-5L index-values for health related quality of life.

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