EUROSPINE 2017 Scientific Programme quick fires

Wednesday, 19 September, 2018
14:00 – 15:20 Degenerative Spine, Non-Operative Techniques

QF31

PROSPECTIVE COMPARISON OF THE THERAPEUTIC VALUE OF PERIRADICULAR AND FACET JOINT INFILTRATIONS

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Introduction:
CT-based infiltrations of facet joints and nerve roots with local anaesthetics and steroids are an established part of the conservative treatment of lumbar degenerative diseases. The therapeutic value regarding the mid-term effectiveness of these two approaches is still unclear. The aim of the present study was to research the differences of the effectiveness of both treatment options.

Methods:
From 9/2016 to 01/2017 symptomatic patients with nucleus prolapse, neuroforaminal stenosis and/or facet joint arthrosis based on lumbar segment degeneration and eventually presence of a spondylolisthesis were consecutively included in the present prospective study. All patients received a CT-based infiltration with a local anaesthetic and in part (facet joint infiltrations - all) with a steroid. In patients with radiculopathy it was performed at the affected nerve root (PRT), in those with facet arthrosis at the joints (FJI). Pre- and postintervention (directly and after 6 weeks, 3 and 6 months) scores for pain (NRS back and leg) and disability (Oswestry Disability Index - ODI) were ascertained and the satisfaction level was queried. The influence of the underlying pathology and the type of intervention on the results were evaluated with 2-way ANOVA for repeated measures as well as chi squared test (SPSS V22.0) statistically considering the different baseline values of both groups for back and leg pain.

Results:
At 6 months follow-up 103 patients (65 women) were available for analysis. The mean age of the patients was 63 years. 51 patients received a FJI, 52 a PRT. Baseline value of ODI was comparable in both groups (46 %). The PRT group started with a higher NRS leg (7.4 vs. 4.3/10) and the FJI group with a higher NRS back (6.9 vs. 5.2/10). Patients receiving a PRT reported a higher improvement of back and leg pain as well as ODI compared to the FJI group. Improvement in the FJI group was even below the MCID (minimally clinically important difference) already at 6 weeks (Figure 1). Consecutively, patient satisfaction was significantly better in the PRT group. Regarding the pathologies included, spondylolistheses demonstrated the most inferior outcome.

Discussion:
Based on the results, no therapeutic value of FJI could be demonstrated already after 6 weeks. Therefore, we suggest performing FJI just for differential diagnostic reasons like for planning of a
denervation or fusion. In contrast and regardless the cause of compression (nucleus prolapse vs. neuroforaminal stenosis) nerve root infiltrations have a clinically significant mid-term effect.

Figure 1

Disclosures:
TOWARD A SURGICAL BABEL: A 4-NATION SURVEY ON VARIATIONS IN SURGICAL INDICATION FOR DEGENERATIVE SPINAL DISORDERS

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Background
Significant variations in treatment of many lumbar degenerative conditions exist among spine surgeons. This clinical uncertainty is to be related to the lack of established consensus in the literature.

The purpose of this study was to examine the extent of variation in treatment decisions among spine surgeons of 4 countries for 5 specific clinical scenarios involving degenerative lumbar conditions.

Methods
A total of 102 surgeons (57 orthopaedics, 45 neurosurgeons) of 4 countries (France=27, USA=26, Spain=24, Germany=25) answered online survey regarding the need for surgery and procedure for 5 vignette cases. Cases included: (1) monolevel stenosis in a young patient, (2) lytic spondylolisthesis, (3) isthmic lysis with foraminal stenosis, (4) degenerative scoliosis and (5) multilevel stenosis in an elderly patient. The variability of indications in each country was calculated according the Index of Qualitative Variation (important variability if IQV>0.8). Chi-square and non-parametric test were used to assess variability between countries indications. We used Fleiss' kappa (range: from -1, poor agreement, to 1: almost perfect agreement) for assessing the reliability of agreement between the participants concerning specialties, countries and age groups.

Results
Intranational variations: In each country, the 2 lytic cases received the most homogeneous proposals (IQV<0.70). The case of degenerative scoliosis provoked major variability (IQV > 0.80) in the 4 groups. Attitudes toward lumbar stenosis were also highly heterogeneous. France attitude was very variable on 3 cases on 5 (IQV>0.80), all others countries had 3 or more cases with low variability.

International variations: Concerning the lytic cases, all countries had IQV>0.80 without significant difference. Concerning the degenerative scoliosis, all attitude were highly heterogeneous with IQV>0.8 (n.s.). Concerning the 2 stenosis cases, USA surgeons were more likely to recommend pure decompression for elderly (p=0,02) and young patient (p=0,006), than the 3 European groups that were more heterogeneous.

Concerning the specialty, the overall interrater agreement was equally slight for neurosurgeons (Fleiss'Kappa =0,04) and orthopedics (Fleiss'Kappa=0,13). These findings were similar for the overall interrater agreement concerning countries (No Kappa > 0,13) and age groups (No Kappa > 0,1).

Conclusion
This study found substantial agreement for some spinal conditions but high variability in some others: intranational and international variations can be observed, reflecting the lack of literature
consensus and some surgeons-specific factors.

**Index of qualitative variation (IQV) according the 5 lumbar degenerative conditions**

![IQV chart](chart.png)

N.B.: The IQV can range from 0 to 1, with 0 indicating no variability and 1 maximal variability. An IQV > 0.8 was considered to highlight a high variability.

Disclosures:
Gender- and Age-Specific Analgesia for Early Postoperative Pain Management After Lumbar Decompressive Surgery: A Randomized Clinical Trial

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Background: Adequate postoperative pain management has emerged as one of the best ways for earlier mobility and functional recovery, reduced hospital stay and re-admission, less medical complications, and greater patient satisfaction. Multimodal analgesia has shown effective postoperative pain control in spinal surgery, however, there is no consensus on the ideal multimodal analgesic regimen.

Purpose of the study: To compare the efficacy and safety of nonsteroidal anti-inflammatory drugs (NSAIDs) and opioids for acute pain management after lumbar decompressive surgery.

Materials and methods: This prospective randomized clinical trial recruited adult patients who underwent single-level lumbar decompressive surgery. Patients were randomized to receive our postoperative analgesic regimen including either a NSAID (celecoxib) or an opioid (extended-release oxycodone) from postoperative day 1 to 14. The visual analogue scale (VAS) and Oswestry Disability Index (ODI) were used to evaluate effectiveness preoperatively and on postoperative days 2, 3, 7, and 14, and at 6 months. Drug-related adverse effects were also recorded.

Results: One hundred patients were enrolled and 93 patients (46 patients with celecoxib versus 47 patients with oxycodone) were randomized. No differences were observed in patient demographics, and preoperative pain and functional status between the two groups. The VAS and ODI were no different at all postoperative time points. However, sub-analysis according to gender and age, revealed significant differences in efficacy between the two groups: Celecoxib was effective in females and oxycodone was effective in males on postoperative days 7 and 14; oxycodone was effective in patients aged above 65 years on postoperative days 7 and 14. Although nausea/vomiting and constipation were more common in the oxycodone group than in celecoxib group, other adverse effects were not different.

Conclusions: In patients who underwent single-level lumbar decompressive surgery, treatment with celecoxib and oxycodone for postoperative pain management showed no significant differences in efficacy. However, sub-analysis showed that each drug was effective in different ages and gender groups.

THE RELATIONSHIP BETWEEN COMPENSATORY MECHANISMS OF RESIDUAL KYPHOTIC
DEFORMITY AFTER OSTEOPOROTIC VERTEBRAL FRACTURES AND HEALTH-RELATED QUALITY
OF LIFE
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Introduction:
Thoracolumbar kyphotic deformity after osteoporotic vertebral fractures (OVFs) may cause
persistent back pain and adverse effects on health-related quality of life (HRQOL). However, the
influence of radiographic parameters after OVFs on HRQOL is still unknown. The aim of this study
is to assess the relationship between compensatory mechanisms of residual kyphotic deformity
after OVFs and HRQOL.

Material and methods:
A total of 95 patients with residual kyphotic deformity after osteoporotic vertebral fractures were
enrolled in this study. Patients with painful new (within three months) OVFs, nonunion, pathological
fracture, and a previous history of spine surgery were excluded from the study. The mean age was
78 years, and there were 8 males and 87 females. Radiographical parameters included thoracic
kyphosis (TK), lumbar lordosis (LL), lower lumbar lordosis (LLL), thoracolumbar kyphosis (TL),
sagittal vertical axis (SVA), T1 pelvic angle (TPA), pelvic tilt (PT), and pelvic incidence (PI).
Compensatory mechanisms were categorized based on pelvic inclination into three types: Group A,
no compensation (PT <20°); Group B, compensated by pelvic retroversion (PT >20°, SVA <50mm);
Group C, decompensation (PT >20°, SVA >50mm). Clinical outcomes including Oswestry Disability
Index (ODI), Japanese Orthopedic Association Back Pain Evaluation Questionnaire (JOABPEQ),
and visual analogue scale (VAS) of low back pain (LBP) were compared among the 3 groups.

Results
The median ODI (Group A: 20, Group B: 22, Group C: 44, P=0.002) and LBP VAS (Group A: 21,
Group B: 22, Group C: 50, P=0.006) were significantly worse in Group C than in Group A and
Group B. The pain-related disorders (Group A: 71, Group B: 71, Group C: 43, P=0.029) and gait
disturbance (Group A: 71, Group B: 64, Group C: 29, P<0.001) in JOABPEQ were significantly
worse in Group C than in Group A and Group B. There were no significant differences in social life
dysfunction (Group A: 62, Group B: 54, Group C: 49, P=0.055) and psychological disorders (57 vs
51 vs 50, P=0.262) among the 3 groups. The TL was significantly greater in Group C than in Group
A and Group B (Group A: 30°, Group B: 27°, Group C: 38°, P=0.028). The LLL was significantly
greater in Group A than in Group B and Group C (Group A: 41°, Group B: 34°, Group C: 33°,
P=0.002). The PT (Group A: 18°, Group B: 25°, Group C: 32°, P<0.001) and TPA (Group A: 16°,
Group B: 22°, Group C: 33°, P<0.001) were significantly different among three groups. ROC curve
analysis showed that the optimal cut-off value of the TPA was 26° (AUC=0.685, sensitivity=63%,
specificity=67%).

Discussion:
Global sagittal alignment of Group A was compensated by hyperlordosis of the lower lumbar spine,
and Group B was compensated by thoracic hypokyphosis and pelvic retroversion. Clinical
outcomes were significantly worse in the decompensation group.
Disclosures:
DELAYED PERCUTANEOUS VERTEBROPLASTY IS OF CLINICAL BENEFIT IN THE MANAGEMENT OF OSTEOPOROTIC VERTEBRAL COMPRESSION FRACTURES

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Introduction:
Percutaneous vertebroplasty (PV) is recommended by NICE for the treatment of patients with ‘recent’ unhealed osteoporotic vertebral compression fractures (OVCF), unresponsive to adequate analgesic management. However, the definition of ‘recent’ is not stated, but three months is implied and consequently the timing of surgical intervention in those with persistent symptoms is still debated. Many units in Europe will not perform vertebroplasty if the fracture is older than six weeks.

Purpose of the study:
The aim of this prospective observational cohort study was to determine the outcome of patients undergoing PV more than three months following the onset of OVCF. There have been no previous prospective studies on the outcome of vertebroplasty in old fractures.

Methods:
A prospective study of consecutive patients presenting with OVCF, between October 2014 and October 2017, was undertaken. OVCF was confirmed by MRI scanning with positive STIR sequence. Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI) scores were collected. PV was performed via a bipedicular approach with fluoroscopic guidance under general or local anaesthesia. VAS and ODI scores were recorded at a six-week post-operative review clinic.

These prospectively collected scores were reviewed, along with baseline demographic data. For this study, the primary outcome was the change in VAS score on a scale of 0-100 relating to back pain. The change in ODI was a secondary outcome. Statistical analysis was performed, and descriptive statistics and paired t-test or Wilcoxon signed rank tests, depending on the normality of data, are reported with significance as p<0.05.

Results:
Forty-five patients had MRI STIR positive scans, with symptoms longer than three months and complete pre- and post-operative outcome measures. The mean age was 72 years, and 71% of patients were female. The median time from onset of OVCF symptoms to surgery was eight months (range 3 - 38 months). The median pre-operative VAS score was 75 which reduced to 27 following surgery (Z-score -5.5, p<0.0001). The mean reduction in ODI score was 21, from 57 pre-operatively to 36 post-operatively (95% CI 14.7 - 28.5, p<0.0001).

Conclusion:
Old osteoporotic fractures, with positive STIR sequence on MRI, and pain around the fracture site,
respond very well to vertebroplasty. The results are little different from acute fractures. Age of fracture should not be a factor on deciding whether vertebroplasty is indicated.

Disclosures:
author 1: grants/research support: Orthopaedic Research UK; author 2: none; author 3: none; author 4: none
THE PREVALENCE OF INCIDENTAL AND SYMPTOMATIC LUMBAR SYNOVIAL FACET CYSTS

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Background: The prevalence of symptomatic and asymptomatic synovial facet cysts in the lumbar spine has been incompletely established.

Questions/Purposes: Our study aims to assess the prevalence of incidental (i.e. asymptomatic) and symptomatic lumbar synovial facet cysts on MRI. Secondly, we will assess if the prevalence of lumbar synovial facet cysts increases with age and what other factors are associated with its prevalence. In addition, we will assess differences in patient and cysts characteristics between asymptomatic and symptomatic facet cysts.

Patients and Methods: This is a retrospective cohort study from two affiliated tertiary care referral centers for spine disease. We included 19,010 consecutive patients that underwent a dedicated lumbar spine MRI between 2004 and 2015. Our outcome measures were symptomatic and asymptomatic facet cysts. A symptomatic cyst was defined as a cyst with symptoms of radiculopathy on the same side as the cyst. The prevalence of incidental, symptomatic, and overall synovial facet cysts was reported as a percentage with 95% confidence interval (95%CI). Multivariable logistic regression analysis was used to assess if age, sex, race, and indication for MRI were associated with having a facet cyst. Generalized estimating equation analysis was used to assess differences between symptomatic versus asymptomatic synovial facet cyst: age, sex, race, side, level, cyst size, cyst location.

Results: The overall synovial facet cyst prevalence was 6.5% (95%CI: 6.1 to 6.8)[1,228/19,010]. These 1,228 patients had 1,553 synovial facet cysts of which 46% cysts (721/1,553) were incidental and 54% cysts (832/1,553) were symptomatic. The prevalence of having one or more incidental synovial facet cysts was 2.7% (95%CI: 2.5 to 3.0%) [518/19,010], the prevalence of having one or more symptomatic synovial facet cysts was 3.2% (95%CI: 3.0 to 3.5%) [617/19,010], and the prevalence of having both one or more incidental and one or more symptomatic synovial facet cysts was 0.49% (95%CI: 0.39 to 0.59%) [93/19,010]. Increased age was independently associated with a higher likelihood of having a synovial facet cyst (odds ratio [per 10 years increase in age]: 1.24, 95%CI: 1.20 to 1.29, p<0.001). Large cyst size (odds ratio: 1.64, 95%CI: 1.23 to 2.20, p = 0.001), and anterior location (odds ratio: 1.39, 95%CI: 1.08 to 1.79, p = 0.010) of the synovial facet cyst were the only factors independently associated with having radiculopathy.

Conclusions: Approximately 1 in 15 patients have at least one synovial facet cyst and about half of them is symptomatic and half is asymptomatic. Having a facet cyst -symptomatic and asymptomatic- is strongly associated with increased age supporting the theory that degenerative spine disease underlies development of facet cysts. Large cyst size and anterior location of the cysts are associated with an increased likelihood of having neurological symptoms.

Disclosures:
MICRO-DECOMPRESSION ALONE AS GOOD AS DECOMPRESSION PLUS INSTRUMENTED FUSION FOR LUMBAR DEGENERATIVE SPONDYLOLISTHESIS. A PRAGMATIC NON-INFERIORITY STUDY FROM THE NORWEGIAN REGISTRY FOR SPINE SURGERY

Ivar Magne Austevoll, Rolf Gjestad, Tore Solberg, Jens Ivar Brox, Kjersti Storheim, Frode Rekeland, Erland Hermansen, Kari Indrekvam, Christian Hellum
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Background: In many countries a majority of patients with degenerative spondylolisthesis are operated on with decompression plus instrumented fusion, but the scientific evidence for adding fusion is controversial.

Purpose: To evaluate whether micro-decompression alone is as good as (non-inferior to) decompression plus instrumented fusion in patients with degenerative spondylolisthesis.

Materials and Methods: In the period from September 2007 to December 2016, 1068 patients were recorded with a primary operation at index level. Of those patients, 476 (45%) were operated with a micro-decompression (midline-preserving decompression) alone and 318 (30%) with decompression and instrumented fusion (with or without an intervertebral cage). To reduce selection bias due to differences in baseline parameters, a propensity score matching of the treatment groups was performed. After matching, 285 patients in each group were compared. Primary outcome was the responder rate, i.e., the proportions of patients with an improvement of baseline Oswestry Disability Index (ODI) of 30 % or more at 12 month follow-up. We wanted to detect whether the responder rate for the micro-decompression group was less than 15 percentages lower than for the fusion group. Due to 23% missing data at 12 month follow-up a sensitivity analysis with multiple imputation (MI) was performed to reduce bias.

Results: For the unmatched cohort the responder rate was 71% for the micro-decompression group and 70% for the fusion group (p= 0.88). The matched groups had the same baseline ODI (41) and NRS leg pain (6.7), and NRS back pain was 6.7 and 6.8 (fusion). At 12 month follow-up it was a statistical insignificant difference in the responder rate (68% vs. 72% (fusion). The 95% confidence interval (-5 to 12%) for the 4% difference was below the predefined limit of 15% for non-inferiority of micro-decompression alone. The mean ODI at 12 month follow-up was not different between the groups (22 vs. 21 (fusion); p= 0.42). The micro-decompression group had statistically significantly more leg pain (NRS 3.5 vs. 2.7; p=0.017) and back pain (NRS 3.8 vs. 3.3; p=0.043) compared to the fusion group at 12 month follow-up. The operation time (89 vs 180 minutes; p≤0.001) as well as the length of hospital stay (2.5 vs 6.4 days; p≤0.001) was shorter for the micro-decompression group. Additional sensitivity analysis did not reveal any differences in responder rates between the groups (64% vs 67% (fusion); p=0.54).

Conclusion: The primary outcome indicates that decompression alone is as good as decompression plus instrumented fusion among patients with degenerative spondylolisthesis, and the operation time as well as the hospital stay were longer. A small statistically significant but uncertain clinical relevant better outcome in leg and back pain was found for instrumented fusion.

BACTERIA IN DISCS - PAIN CAUSING OR CONTAMINATION
Peter Fritzell, Hans Tropp, Bodil Jönsson, Olle Hägg, Paul Gerdhem, Per Ekman, Siv Andersson, Björn Knutsson, Anders Lundin, Christina Welinder-Olsson
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Background
Lumbar disc herniation (LDH) is a common world-wide disorder, and a frequent indication for surgery. Several studies have found, using culturing during surgery for LDH, the common skin bacteria Propionibacterium Acnes in removed disc material (1). It has been suggested that Modic changes on MRI are associated with an infection. Consequently, physicians might use antibiotics in LDH/LBP-patients when other options have failed, or before surgery. As there is a global concern about increasing antibiotic resistance, it is imperative to assess if bacteria actually are engaged in the pain producing mechanism in patients with LDH, or are a result of peroperative contamination. We conducted a multicenter consecutive study including 60 patients operated for either LDH or Scoliosis (control group).

Methods
In seven clinics 40 patients were operated on for a MRI-confirmed LDH. In two clinics 20 young patients were operated on for scoliosis. Sampling procedures:
1. skin before incision,
2. subcutaneously,
3. over the laminae,
4. biopsy from the vertebrae below the disc, which was divided into four pieces and put into two separate sterile tubes, two opposite pieces in each tube, and frozen,
5. the same procedure as in 4 was used for removed disc material,
6. after removal of the herniated disc, sampling was performed deep in the wound,
7. skin after suturing.
In two independent laboratories, culturing and DNA-analysis (PCR) were performed on the vertebral pieces, and the disc material. All other culturing (except for the vertebra and the disc), were performed in each operating centre.
A pre-study video was used by each clinic to ensure equal sampling procedures. To further ensure this the same study nurse participated during the first procedure in each clinic.

Results
In 2/40 (5%) of LDH patients, bacteria were solely identified in the disc/vertebra, without bacteria being found in adjacent tissues. The corresponding figure for the control group was 1/20 (5%).
In 12/40 (30%) LDH patients with positive bacteria in the disc/vertebra, corresponding bacteria were also identified on the preoperatively washed skin and/or on two sites in the soft tissues.
Corresponding figure in the control group was 4/20 (20%).
Reminding 26/40 (65%) LDH patients were negative for the disc/vertebra and in other tissues. The corresponding figure in the control group was 15/20 (75%).
Bacteria found was mostly Propionibacterium Acnes, and in few cases also other common skin bacteria like Staph. epidermis and Staph. capitis.
In the LDH group, 57% had Modic changes at the herniation level. In the control group 1/20 (5%)
had Modic changes. There were no associations between Modic changes and bacterial findings.

Conclusion
Our results support that findings of bacteria in disc/vertebra during surgery for lumbar disc herniation is caused by contamination and that infection may not be associated with Modic changes.

1. Albert HB, et al, Eur Spine J. 2013 Apr;22

Bacterial findings;

Grey; positive findings only in Disc/Vertebra without findings on the way in/out
Blue; No findings in any samples
Red; Findings in Disc/Vertebra where bacteria was also found on skin or in the soft tissues on the way out/in.

Disclosures:
RE-OPERATION FOR RECURRENT LUMBAR DISC HERNIATION DOES NOT ADVERSELY AFFECT LONG TERM OUTCOME

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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. As surgery also comes with the risk of complications, and in this case, especially recurrent herniation, the impact of these complications on outcome is of great interest. Very few studies have investigated the long-term consequence of recurrent lumbar disc herniation and subsequent surgical outcome.

Purpose of the study:
The aim of this study is to evaluate if patients with recurrent lumbar disc herniation have poorer long-term surgical outcome measured using patient reported outcome measures.

Materials and Methods:
Consecutive series of patients in a single-center, multi-surgeon spine center who underwent surgery for first episode LDH were included for investigation. Data were prospectively collected in DaneSpine, the Danish National Spine Registry. Subjects were divided into two groups based on whether they had recurrent disc herniation within 12-month of their initial surgery. A subset of the cohort were then used to compared the two groups with regards to patient-reported outcomes (PROs) and data on perioperative complications. 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:
492 patients had undergone surgery more than five years ago and were included in the study. Complete five-year follow-up were available on 309 patients (63%) and an overall reoperation rate within 12 month of 7%. Incidence of surgical complications showed no difference between groups who underwent surgery for recurrent herniation and those who underwent primary surgery. At five-years follow-up, we found statistically significant improvement in both EQ-5D, ODI and VAS-leg and -back. All means reaching Minimal Clinically Important Difference. No significant difference were found between the two groups with regards to EQ-5D, ODI and VAS, five years after surgery.

Conclusion:
Patients with LDH who undergo surgery and subsequently experience recurrent disc herniation at the same level, will not have higher complication rates from re-operation. Furthermore their five-year outcome is equal to that of patients who undergo primary surgery for LDH.

Disclosures:
EFFECTIVENESS OF AN ANNULAR CLOSURE DEVICE IN PATIENTS THAT MEET RCT SCREENING CRITERIA VS. A REAL-WORLD POPULATION: RETROSPECTIVE ANALYSIS OF A PROSPECTIVE REGISTRY

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Introduction
Most randomized controlled trials (RCT) implement highly specific inclusion and exclusion criteria, which results in a study population that only represents a subset of the patients that will ultimately be treated with the device under its approved indications. Therefore, increased focus has been put on the use of ‘real-world’ data to support RCT evidence for clinical decision-making. The objective of this study was to assess the performance of an annular closure device (ACD) in a consecutive series of ‘real-world’ patients that have been retrospectively stratified according to the screening criteria of an on-going RCT.

Methods
This was a retrospective analysis of a single-center prospective registry including 164 subjects with a large annular defect (≥6 mm width) who underwent limited discectomy augmented by the ACD for symptomatic lumbar disc herniation. Patients were stratified into two unique groups using the selection criteria of the pivotal RCT on the same device: Trial (met inclusion criteria; n=44) or non-Trial (did not meet inclusion criteria; n=120). Key RCT inclusion criteria, beyond the large defect criterion, were: leg pain graded on the visual analog scale (VAS) higher than 40/100, dysfunction graded on the Oswestry Disability Index (ODI) greater than 40/100, no prior herniation at the index level, and a minimum posterior disc height of 5 mm. Patient reported outcomes included ODI scores and VAS for leg and back pain scores. Adverse events were collected from baseline to last follow-up (mean: Trial - 15.6 months; non-Trial - 14.6 months). Statistical analyses were performed with significance set at p<0.05.

Results
Patient reported outcomes were not significantly different between groups at last follow-up (p≥0.15) and clinical success (≥15-point improvement in ODI score; ≥20-point improvement in VAS scores) was achieved in both groups at similar frequencies (Table 1). Three non-Trial (2.5%) and three Trial (6.8%) patients experienced symptomatic reherniation (p=0.34). The rates of reoperation, ACD mesh dislocation/separation, and other radiographic findings were also similar between groups (p=1.00).

Conclusion
Outcomes with the ACD were advantageous in both groups, particularly in comparison to historical reherniation rates reported in the same high-risk, large annular defect population. Stratification of this ‘real-world’ series on the basis of RCT screening criteria did not result in significant between-group differences in this Level II study. This observation supports the efficacy of annular closure in large defect patients beyond the stringent criteria of this RCT. Reducing the reherniation rate following lumbar discectomy in this high-risk population has positive clinical and economic
implications. The methods used in this study can be leveraged by other investigators to determine if stratification of their patient series produces similar results.

<table>
<thead>
<tr>
<th>Trial Group (n=44)</th>
<th>non-Trial Group (n=120)</th>
<th>p-value</th>
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<tbody>
<tr>
<td>ODI</td>
<td>84% (37/44)</td>
<td>71% (85/120)</td>
</tr>
<tr>
<td>VAS Leg</td>
<td>84% (37/44)</td>
<td>79% (94/119)</td>
</tr>
<tr>
<td>VAS Back</td>
<td>68% (30/44)</td>
<td>62% (74/119)</td>
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</tbody>
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* Defined as 15-point improvement in ODI score and 20-point improvement in VAS scores

ODI = Oswestry Disability Index, VAS = Visual Analog Scale for pain

“Trial” patients met RCT inclusion criteria while “non-Trial” patients did not

Disclosures:
author 1: grants/research support: Intrinsic Therapeutics, consultant: Intrinsic Therapeutics; author 2: grants/research support: intrinsic therapeutics
ABDOMINAL TRUNK MUSCLE WEAKNESS IS ASSOCIATED WITH CHRONIC LOW BACK PAIN AND LOCOMOTIVE SYNDROME

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BACKGROUND: Trunk muscle weakness has been reported as a risk factor for chronic low back pain (LBP). Strengthening exercises are considered the most effective intervention to improve functional outcomes in LBP patients. We developed an innovative exercise device for the abdominal trunk muscles, which has a built-in system to measure muscle strength. Our validation study demonstrated that strength training using the device increased the abdominal trunk muscle strength measured by the device and activated the abdominal trunk muscles, including the diaphragm, abdominal rectus, external and internal oblique, transverse abdominal muscles, and pelvic floor muscles.

PURPOSE: The present study aimed to measure abdominal trunk muscle strength using our device in middle-aged or elderly women, and investigate the correlations between the muscle weakness and the presence of chronic LBP, and the decreased physical ability associated with the locomotive syndrome, which is a condition of reduced mobility due to impairment of locomotive organs.

METHODS: This study included 160 women with a mean age of 65 years, who were scheduled for joint surgery in the lower extremities at our institution. We took their anthropometric measurements (body height, body weight, body mass index) and the 25-Geriatric Locomotive Function Scale (GLFS-25), which is a screening tool for the early detection of locomotive syndrome. We measured their grip power using a dynamometer and abdominal trunk muscle strength using our device. The correlations between the abdominal trunk muscle strength and the other measurements were evaluated by Pearson correlation coefficient analysis. The subjects were divided into LBP group (60 subjects with chronic LBP) and non-LBP group (100 subjects without chronic LBP) based on the scores of LBP in GLFS-25. All measurements including abdominal trunk muscle strength were compared between the two groups using Mann-Whitney U test.

RESULTS: Abdominal trunk muscle strength showed a significant positive correlation with grip power and a significant negative correlation with GLFS-25 scores. The mean abdominal trunk muscle strength in the LBP group was significantly lower than that in the non-LBP group (4.3 ± 2.6 kPa versus 5.8 ± 3.3 kPa, p < 0.05). The mean score of GLFS-25 in the LBP group was significantly higher than that in the non-LBP group (52.7 ± 19.9 versus 34.5 ± 19.6, p < 0.05). There were no significant differences in the other measurements between the groups.

CONCLUSION: We measured abdominal trunk muscle strength in middle-aged or elderly women using our innovative device, and found that the muscle weakness was associated with chronic LBP and the locomotive syndrome. The abdominal core created by the abdominal trunk muscles including the diaphragm and pelvic floor muscles has an important role in stabilization of the lumbar spine, and the muscle weakness can produce LBP and reduce physical functions in the elderly.

Disclosures:
PARASPINAL MUSCLE, FACET JOINT, AND DISC PROBLEMS: RISK FACTORS FOR ADJACENT SEGMENT DEGENERATION AFTER LUMBAR FUSION

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BACKGROUND CONTEXT: Adjacent segment degeneration (ASD) is one of the major complications after lumbar fusion. Several studies have evaluated the risk factors of ASD. Although the paraspinal muscles play an important role in spine stability, no study has assessed the relationship between paraspinal muscle atrophy and the incidence of ASD after lumbar fusion.

PURPOSE: In the present study, we aimed to verify the known risk factors of ASD, such as body mass index (BMI), preoperative adjacent facet joint degeneration, and disc degeneration, and to assess the relationship between paraspinal muscle atrophy and ASD.

STUDY DESIGN: This is a retrospective 1:1 pair analysis matched by age, sex, fusion level, and follow-up period.

PATIENT SAMPLE: To calculate the appropriate sample size for the study, we performed a prestudy analysis of the paraspinal muscle cross-sectional area (CSA), and estimated that at least 35 cases would be needed for each group. Among the 510 patients who underwent posterior lumbar fusion for degenerative lumbar disease between January 2009 and October 2009, a total of 50 patients with ASD after surgery were selected. Another group of 50 matched patients with degenerative lumbar disease without ASD after spinal fusion were selected as the control group. Each patient in the ASD group was matched with a control patient according to age, sex, fusion level, and follow-up period.

METHODS: The risk factors considered were higher BMI, preoperative adjacent segment disc and facet degeneration, and preoperative paraspinal muscle atrophy and fatty degeneration. The radiographic data were compared between the ASD and control groups to determine the predictive factors of ASD after posterior lumbar fusion by using logistic regression analysis. The study was not externally funded. The authors have no conflict of interest to declare.

RESULTS: Multivariate logistic regression analysis indicated that higher BMI (odds ratio [OR]: 1.353, p=.008), preoperative facet degeneration on computed tomography examination (OR: 3.075, p=.011), disc degeneration on magnetic resonance imaging (MRI) (OR: 2.783, p=.003), fatty degeneration (OR: 1.080, p=.044), and a smaller relative CSA of the paraspinal muscle preoperatively (OR: 0.083, p=.003) were significant factors for predicting the development of ASD.

CONCLUSIONS: The occurrence of radiological ASD is most likely multifactorial, and is associated with a higher BMI, preexisting facet and disc degeneration on preoperative examination, and a smaller preoperative relative CSA of the paraspinal muscle on MRI.

Disclosures:
author 1: none; author 2: none; author 3: none
ADJACENT SEGMENT DISC DEGENERATION IS ASSOCIATED WITH THE INDIVIDUALIZED SAGITTAL SHAPE AND ALIGNMENT

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Summary
In the long-term follow-up (mean 12.5 years) of a subgroup of 68 patients who had participated in a randomized controlled trial (RCT) of lumbar fusion versus nonoperative care for chronic low-back pain (LBP), disc space height at the adjacent segment was significantly associated with the individualized sagittal shape and alignment of the lumbar spine (i.e., expressed relative to the individual's PI), in both treatment groups.

Hypothesis
Individualized sagittal shape and alignment is associated with adjacent segment disc degeneration (ASDD).

Design
Long-term follow-up of RCT in patients with chronic LBP for ≥1 year.

Introduction
Concerns continue over the potential for ASDD in the long-term subsequent to fusion. It would appear to result from the increased mechanical load due to the fusion, age, and genetic factors. The effect of the sagittal plane on ASDD has not been well investigated. We evaluated the association between the individualized sagittal shape and alignment of the lumbar spine (i.e., expressed relative to the individual's PI) and ASDD in the long-term after fusion or nonoperative care.

Methods
Inclusion criteria: aged 25-55 yrs, fusion candidate with LBP of ≥1 yr and availability of standing lateral radiographs including femoral heads at long-term follow-up. Disc space height was measured for each lumbar segment using a validated computer-assisted distortion compensated roentgen analysis technique (Mannion et.al. Spine,2014). Relative Pelvic Version and Relative Lumbar Lordosis (expressed as a function of the patient's PI) and the Lordosis Distribution Index (L4-S1 lordosis as a proportion of L1-S1) were used to calculate the Lumbar-GAP (Global Alignment and Proportion, Yilgor et.al. JBJS Am,2017) Score, indicating sagittal shape and alignment. Differences between groups categorized as Proportioned, Moderately Disproportioned and Severely Disproportioned were analyzed using ANOVA.

Results
68 pts (33F, 35M; 42.9 (SD7.8) yrs) with a follow-up of 12.5 (SD 1.7) years were included. Severely disproportioned patients showed significantly lower adjacent segment disc height than did moderately disproportioned or proportioned patients (Fig. 1). The effect appeared to be more marked in fusion than non-operative patients (formal subanalysis limited by sample size).

Conclusion
Qualitatively similar findings were observed for the two levels above the adjacent level.
The individualized shape and alignment of the lumbar spine in patients with a degenerative disc may be an important determinant of the magnitude of disc height loss in the adjacent segment, especially in patients undergoing fusion.

Disclosures:
COMPARISON OF A LUMBAR GAP SCORE TO PI-LL MISMATCH TO PREDICT ADJACENT SEGMENT DISEASE IN THE DEGENERATIVE LUMBAR SPINE

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Introduction
A cut-off value of the difference between pelvic incidence and lumbar lordosis (PI-LL) of 10º has been suggested to increase the risk of revision surgery for adjacent segment disease (ASD) after short lumbar fusions. The concept of PI-LL as a measure of lumbo-sacral malalignment has come under scrutiny for sagittal deformities. The Global Alignment and Proportion (GAP) score has been shown to predict mechanical failure for long instrumentations more accurately than PI-LL combined with pelvic tilt (PT) and the C7 sagittal vertical axis (SVA). In the present study, we want to test whether a lumbar GAP score is accurate in predicting revision surgery and compare it to PI-LL.

Methods: Spinopelvic parameters (SPP) were measured and analysed in 84 patients: 45 with revision surgery for ASD and 39 controls with 5 year follow up. SPPs and GAP score without relative spinopelvic alignment (RSA) (L-GAP) were analysed using logistic regression. Tests of equality of ROC area under curve (AUC) were performed with adjusted significance levels for multiple tests via Sidak’s correction using Stata 13 for Mac.

Results:
The L-GAP score behaves similarly to PI-LL (ROC AUC 0.66 vs. 0.72, p=0.25). The relative lumbar lordosis (RLL) as a pelvic incidence-adjusted single parameter performs the same as L-GAP (RLL ROC AUC 0.67, p=0.53). Adjusting for pelvic incidence, L-GAP, PI-LL and RLL perform better in patients with low pelvic incidence, i.e. <1 standard deviation below the mean (<51º, AUC 0.74, 0.80, 0.80 respectively). L-GAP provides a predictive model at a cut-off value of >=3 (sens 0.44, spec 0.74) and RLL with a cut-off of -20.5º above which there is a higher risk (sens 0.44, spec 0.82 vs. PI-LL sens 0.71 spec. 0.81).

Conclusion:
Both L-GAP and RLL accurately predict the risk for revision surgery for ASD similar to PI-LL.
although their sensitivity is lower in the given patient population.
SEGMENTAL RECRUITMENT DURING FLEXION-EXTENSION MOTION AFTER CERVICAL DISC ARTHROPLASTY USING A MOBILE CORE PROSTHESIS

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Introduction: Individual motion segments of a healthy cervical spine move synchronously when the spine flexes forward or backward, with all segments moving continuously throughout the arc of motion. In the presence of focal segmental instability with substantial reduction in stiffness, motion occurs preferentially at the unstable segment, until the segment approaches its motion limit and the remaining motion segments begin to move. Segmental instability can thus be assessed by evaluating recruitment patterns, both in vivo and ex vivo. While this topic has been explored in native spines, the sequence of motion segment recruitment has not been studied after cervical disc arthroplasty. Mobile core prostheses by their design can impart segmental instability altering the normal recruitment pattern seen in healthy spines.

Methods: Eight cadaveric specimens (C3-T1, 42±6yr) were tested under physiologic loads; intact, then after implantation of a mobile core prosthesis (Mobi-C) at C5-C6 and C6-C7. Here we report our observations on segmental recruitment in flexion-extension before and after C5-C6 TDA.

Results: Intact segments of the C3-T1 specimen tended to move synchronously, with all segments moving continuously throughout the extension to flexion arc of motion (Fig. 1a). The percent contribution of individual intact segments to total motion remained nearly constant from extension to flexion. For example, in the intact specimen response shown in Fig. 1a the C5-C6 segment contributed 26% of the C3-T1 motion on average over the flexion-extension arc of motion. The deviation from this average contribution for this specimen was 4% while the peak deviation was 13%.

After disc arthroplasty, 5/8 specimens showed abnormal patterns of segmental recruitment, with the implanted levels showing limited motion over a portion of the arc of motion followed by sudden large angular changes (Fig. 1b). The contribution of the C5-C6 segment to the C3-T1 motion after C5-C6 disc arthroplasty averaged 30% from extension to flexion. The deviation from this average contribution for this specimen was 29% while the peak deviation was 64% (Fig. 1c).

Conclusions: Response of segments after disc arthroplasty with mobile-core prosthesis showed non-uniform motion recruitment. This was associated with delayed motion followed by sudden large segmental motion of the implanted level while the remaining segments were relatively motionless. This uncontrolled motion can occur when the prosthesis core translates during extension to flexion motion and was observed when the prosthesis endplates transitioned from a lordotic to kyphotic angulation. This motion delay followed by sudden motion is amplified by compressive load and is less evident without compressive preload. Potential consequences of this motion profile include soft tissue pain from increased muscle activity to control motion, excessive prosthesis wear, and reduced motion of adjacent native discs over time due to motion shielding.
**Figure 1.** Segmental motions of intact specimen and after disc arthroplasty at C5-C6 using a mobile core prosthesis. (A) Intact segments show continuous motion of all segments throughout the extension-to-fexion arc of motion. (B) Single level mobile core TDA at C5-C6. Motion response shows lack of motion at C5-C6 from extension to 10 degrees of flexion, at which time the prosthesis begins to move and all other segments stop motion. (C) Motion contributed by the C5-C6 segment before and after disc arthroplasty. The percent contribution of individual intact segments to total motion remained nearly constant from extension to flexion. C5-C6 disc arthroplasty with mobile-core prosthesis showed non-uniform motion recruitment.