EUROSPINE 2021 scientific programme oral presentations

Wednesday, 6 October 2021, 08:30–10:00

Thoracolumbar degenerative disease

1

COMPREHENSIVE IN VITRO COMPARISON OF CELLULAR AND OSTEOGENIC RESPONSE TO ALTERNATIVE BIOMATERIALS FOR SPINAL IMPLANTS

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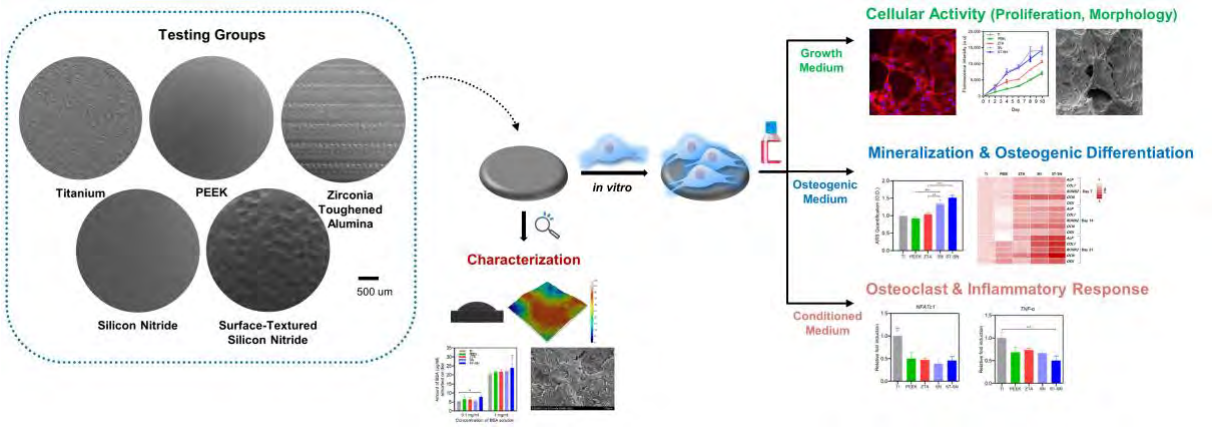
Backgrounds: To restore functional alignment and stability and to facilitate bone formation, the use of implants has become a standard solution for spinal fusion surgery. The choice of appropriate biomaterials became one of the key success paths for spinal fusion implants, resulting in a higher rate of fusion, less postoperative pain, a shorter hospital stays and fewer complications. Titanium alloy and polyether ether ketone (PEEK) are commonly used materials, while the ceramic silicon nitride (Si3N4) has recently emerged as a potential candidate. Silicon nitride can be further modified by surface texturing to potentially increase bone formation. To date, there is scarce data on the osteogenic/conductive potential of as-fired and surface-textured silicon nitride.

Purpose of the study: We aimed to evaluate and compare the in vitro biological response to standard discs of silicon nitride (SN) and surface-textured silicon nitride (ST-SN). For reference, the standard spinal implant materials titanium alloy Ti6Al4V (TI) and PEEK were included, and zirconia toughened alumina (ZTA), as an established ceramic widely used for joint replacement in hip and knee arthroplasty.

Materials and Methods: Material-specific characteristics of these biomaterials were evaluated, such as surface roughness, wettability, protein adsorption and apatite forming capacity in simulated body fluid. The activity of pre-osteoblasts seeded on the discs was characterized by measuring viability, proliferation, attachment and morphology. Then, the osteogenic differentiation of pre-osteoblasts was compared in vitro from early to late stage by Alizarin Red S staining and real-time PCR analysis. Finally, osteoclast activity and inflammatory response were assessed by real-time PCR analysis.

Results: We confirmed that ZTA, SN and ST-SN presented higher cell proliferation rates than TI and PEEK. Selected osteoclast-specific genes (NFATc1, RANKL) were down-regulated on all surfaces, compared to TI ($p<0.01$). For inflammatory response, TNF-alpha was down-regulated for ST-SN, compared to TI ($p<0.005$), and IL-6 was down-regulated for PEEK ($p<0.01$) and ST-SN ($p<0.005$) compared to TI. Osteogenic differentiation was enhanced on ZTA, SN and ST-SN, compared to TI after 7 days ($p<0.001$ for ALP, COL1, RUNX2). A further enhancement of osteogenic differentiation was observed at day 14 and 21 (ALP, COL1, RUNX2, OCN, OSX) for SN and ST-SN, compared to ZTA, which itself exhibited a more pronounced and persistent osteogenic differentiation compared to TI. For osteoclastic and inflammatory response, all other materials generally showed downregulation compared to TI.

Conclusion: Overall, we could show that SN and ST-SN showed a higher osteogenic effect than the other reference groups, an inhibitive effect against bone resorption and low inflammation, and the results indicate that silicon nitride has a promising potential to be developed further for fusion implants that require enhanced osseointegration.



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THE EFFECT OF VARIOUS OPTIONS FOR DECOMPRESSION OF DEGENERATED LUMBAR SPINE MOTION SEGMENTS ON THE RANGE OF MOTION: A BIOMECHANICAL IN VITRO STUDY

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Background: Lumbar spinal stenosis (LSS) is a common disease in the aging population. Treatment options range from conservative management to surgical treatment of the spinal stenosis. Surgical decompression surgery of LSS currently represents the gold standard, however a risk of segmental destabilization depending on the selected approach and the extent of decompression is discussed. So far, biomechanical studies on decompression techniques were mainly conducted on non-degenerated specimens. This biomechanical in vitro study aimed to investigate the increase in segmental range of motion (ROM) depending on the extent of a decompression in degenerated segments.

Methods: On the basis of preinterventionally CT scans 12 degenerated fresh frozen lumbar specimens, which would receive surgical decompression were selected for the study. Specimen were embedded in polymethylmethacrylate (PMMA) and loaded in a spine tester with pure moments of ±7.5 Nm in lateral bending (LB), flexion/extension (FE), and axial rotation (AR). Following testing the native state of the specimens four different extents of decompression were consecutively performed in all specimens: unilateral interlaminar decompression (DC1), unilateral approach with "over the top" decompression (DC2), bilateral interlaminar decompression (DC3) and laminectomy (DC4). To emphasize the changes in ROM relative to the native segment, the ROM for all surgical decompressions of the index segment is reported as percentage of the native.

Results: Specimen were measured in intact state prior to decompression and the ROM was defined as 100% (LB: 5.4±2.8°; FE: 6.3±2.3°; AR: 3.0±1.6°) Decompressive interventions showed a continuous ROM increase in LB (after DC1: 103.7%±6.0; after DC2: 104.9%±7.3; after DC3: 107.8%±8.3; after DC4: 110.8%±9.9), as well as in FE (DC1: 104.3%±4.5; DC2: 108.1%±8.3; DC3: 108.1%±8.3; DC4: 120.0%±15.9) and in AR (DC1: 106.7%±6.0; DC2: 109.2%±7.9; DC3: 115.1%±11.5; DC4: 118.6%±10.5). Compared to the native, a significant increase in ROM was measured after DC4 for all motion directions. The highest individual ROM difference compared to the intact state was observed in AR.

Conclusion: This is the first biomechanical in vitro study investigating the effect of decompression surgery in degenerated lumbar spine segments. Unilateral and/or bilateral decompressive surgery resulted in a small and negligible ROM increase in the majority of the tested levels. Two degenerated specimens showed a noticeable ROM increase after decompression, especially AR. Therefore, there might be a potential for a device to intraoperatively measure the flexibility in axial rotation before and after decompression to identify patients who might benefit from an additional treatment.

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CHONDROITINASE VERSUS PAPAIN DIGESTION LEADS TO DIFFERENT OUTCOME FOR IN VITRO SIMULATION OF DEGENERATED DISCS

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Introduction

Freshly isolated intervertebral discs (IVDs) from bovine tails are often used as an alternative to limited available native human tissue for biomechanical and biological studies. However, they correspond to young human IVDs rather than degenerated ones. Chondroitinase ABC (ChABC) and papain have been used to induce matrix degradation in bovine IVDs to simulate disc degeneration in vitro. But biomechanical changes resulting from enzyme degradation, such as range of motion (ROM), have not been evaluated yet. Hence, the aim of this study was to treat bovine IVD organ cultures with ChABC or papain to simulate degeneration in vitro and to evaluate ROM, disc height, macroscopic morphology and glycosaminoglycan (GAG) content.

Methods

In total, 18 single motion segments (CY3/4) from 18 fresh bovine tails were embedded in PMMA. ChABC (0.25 U/ml), papain (65 U/ml), or PBS as control (n=6 per group) were injected into the nucleus pulposus (NP). Subsequently, specimens were cultured for 7 days (free-swelling, 6% O2, 37°C). Then, complex loading using lateral bending, flexion-extension (both ± 10°), and axial compression (150 N) was applied for 1 hour to mitigate IVD swelling during incubation. The ROM and IVD height were determined before and after enzyme treatment and after complex loading. IVDs were processed for histology and for GAG quantification (DMMB). Statistics: Shapiro-Wilk, Mann-Whitney-U, and Friedman test ($p \leq 0.05$).

Results

At day 7, all specimens digested with papain developed a cavity in the IVD space, while ChABC specimens macroscopically stayed intact (Fig. 1A). During incubation with papain, the disc height decreased, whereas it increased for ChABC and control ($p \leq 0.009$). Complex loading led to a decrease of the disc height in all groups ($p \leq 0.004$). After incubation, the ROM decreased for ChABC and control but not for papain (shown in flexion/extension graph, $p=0.002$, Fig. 1B). Complex loading increased significantly the ROM in all groups ($p \leq 0.028$). According to the histological staining and GAG quantification, both enzymes induced GAG loss, but papain showed a more pronounced effect in the NP (Fig. 1C).

Discussion

Cavities and resulting significant biomechanical changes highlight a stronger digestion of the tissue for papain treatment than for ChABC, supported by the GAG content. For papain, the increase in ROM and height loss indicates a similar behavior as described for human discs with cavities resulting from disc herniation or nucleotomy [1]. The specific digestion of GAG by ChABC led to milder structural defects and biomechanical changes; thus, it mimics more closely real disc degeneration occurring without cavities. These results have enhanced our knowledge of the biomechanical impact of IVD digestion with ChABC and papain, and will enable future targeted simulation of different IVD pathologies in fresh young bovine tail discs for testing purposes.

References 1. Wilke et al, 2013

Acknowledgements EU grant iPSpine No. 825925

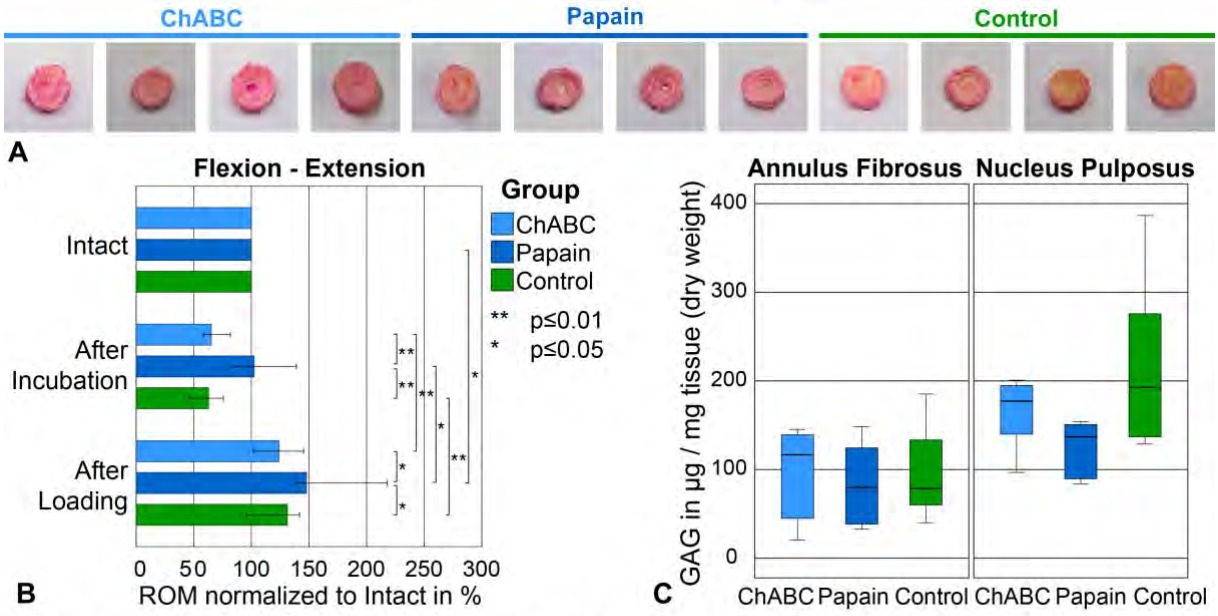

Fig. 1 A) Exemplary macroscopic views of 4 IVDs per group. B) ROM after incubation and subsequent complex loading. C) GAG content after testing at day 7

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ADDITION OF KETOROLAC TO LOCAL ANESTHESIA FOR WOUND INFILTRATION BEFORE CLOSURE IN MULTILEVEL POSTERIOR LUMBAR SPINAL FUSION: A RANDOMIZED CONTROLLED TRIAL

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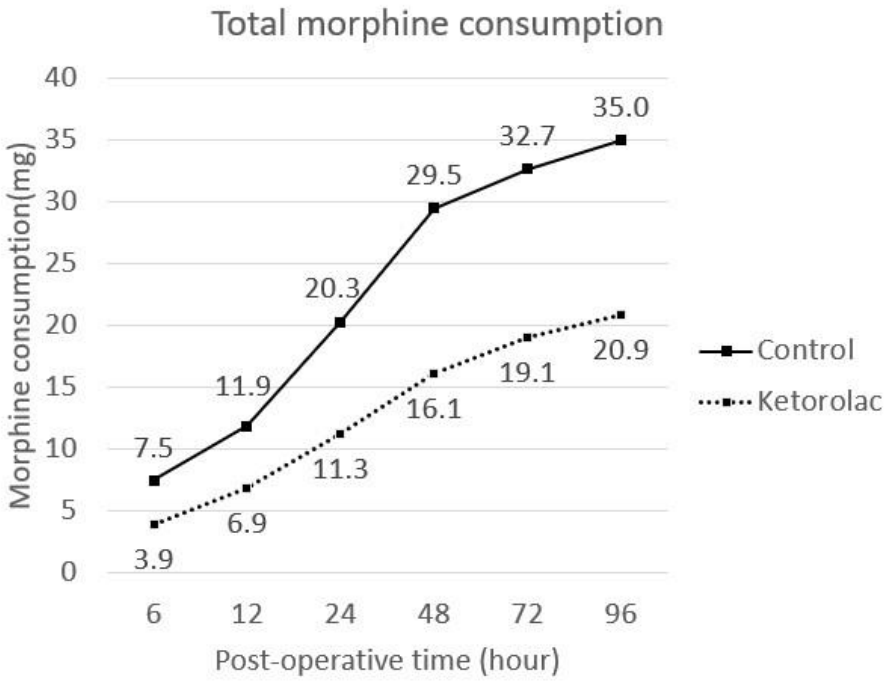
Background: Postoperative pain control is an important factor to reduce morbidity, enhance recovery, and improve patient satisfaction after lumbar spine surgery. Multimodal analgesia injection at the surgical site is being used in many surgical procedures but data on a combination of NSAIDs and local anesthesia for wound infiltration in spinal surgery is still limited.

Purpose: The purpose of this study is to determine the effect of adding ketorolac to local anesthesia for wound infiltration after lumbar spine fusion.

Methods: This study was a randomized double-blind controlled trial that included patients undergoing 2 to 4 levels posterior lumbar decompression and instrumented posterolateral fusion. The patients were randomized into two groups. A control group received 0.5% bupivacaine hydrochloride 20 ml combined with normal saline 20 ml injected into paraspinal muscles before wound closure, and a ketorolac group received 0.5% bupivacaine hydrochloride 20 ml, normal saline 19 ml, and ketorolac 30mg (1ml). The patients, surgeons, and clinical assessors were blinded to group assignment. Post-operative numerical rating scale (NRS) for back pain, leg pain, morphine consumption, and adverse events were recorded.

Results: A total of 30 patients were randomized into two groups (15 in each group). The mean age was 60.8 years old. Mean NRS for back pain at 6 hours after surgery was 5.7±2.8 points for the control group and 2.9±2.2 points in the ketorolac group with a mean difference of 2.7±0.9 points ($p = 0.005$). Mean NRS for back pain were not significantly different at the other time points. Mean NRS for leg pain was not different at all time points. Total morphine consumption at 6, 12, 24, 48, 72, and 96 hours after surgery were 7.5±5.5, 11.9±6.0, 20.3±10.0, 29.5±12.7, 32.7±13.5, and 35.0±14.9 mg respectively in the control group. and were 3.9±3.0, 6.9±5.9, 11.3±9.2, 16.1±13.7, 19.1±14.6, and 20.9±15.1 mg in the ketorolac group. The ketorolac group consumed less morphine than the control group for 9.0±3.5 mg in the first 24 hours after the operation, 13.4±4.8 mg after 48 hours, 13.6±5.1 mg after 72 hours, and 14.1±5.5 mg after 96 hours ($p<0.05$). Postoperative drainage, nausea, vomiting, wound complication, and the need for rescue analgesia was not different between the two groups.

Conclusions: The addition of ketorolac to bupivacaine for wound infiltration after posterior lumbar spine decompression and fusion reduces early postoperative pain and total morphine consumption compared to bupivacaine alone.



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author 1: none; author 2: none; author 3: none

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DEVELOPMENT OF A MACHINE-LEARNING BASED MODEL FOR PREDICTING MULTIDIMENSIONAL OUTCOME AFTER SURGERY FOR DEGENERATIVE DISORDERS OF THE SPINE

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Background: Recent years have seen the emergence and increasing use of patient-reported outcomes in clinical studies of treatment effectiveness, and it has become clear that individual outcomes can be quite heterogeneous. When consenting a patient for surgery, it is important to be able to offer an evidence-based, individualised prediction regarding the likely outcome. This study used a comprehensive set of data collected over 12 years in an in-house registry to develop a parsimonious model to predict the multidimensional outcome of patients undergoing surgery for degenerative spinal pathology.

Methods: Data from 8374 patients (mean age 63.9 (14.9-96.3) yrs, 53.4% female) were used for model development, predicting the 12-month scores for the Core Outcome Measures Index (COMI) and its subdomain scores. The data were split 80:20 into a training and test set. The top predictors were selected by applying recursive feature elimination based on a Lasso cross validation model retaining the top 15 predictors (out of 172) per outcome, allowing the retention of a practical number of 20 (out of 39) input variables to be used as a clinical decision-support system (CDSS). Based on the 111 top predictors (of the 20 variables), Ridge cross validation models were trained, validated, and tested for each outcome dimension.

Results: Preoperative back and leg pain, nationality, the number of previous spine surgeries, age, type of intervention, preoperative quality-of-life, body-mass index, number of affected levels, Charlson comorbidity, and ASA score, were among the strongest outcome predictors in most models. The R2 of the models on the validation/test sets averaged 0.16/0.13. Models based on all 39 input variables performed only slightly better in terms of R2 (0.17/0.14) underlining the good performance of the CDSS based on 20 input variables. A preliminary online tool was programmed to present the predicted outcomes for individual patients, based on their presenting characteristics.

Conclusion:

The prediction models provide reliable estimates to enable a bespoke prediction of the outcome of surgery for individual patients with varying degenerative pathologies and baseline features. The models form the basis of a simple, freely-available online prognostic tool developed to improve access to and usability of prognostic information in clinical practice. This should serve to facilitate decision-making and assist in managing patient expectations.

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DRAIN USAGE IN LUMBAR FUSION FOR DEGENERATIVE DISEASE: A RANDOMIZED, PROSPECTIVE, MULTICENTER STUDY

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Introduction: Drain usage in lumbar fusion is believed to prevent epidural hematomas, reduce wound tension, promote healing and diminish the risk of infection. However, there is no conclusive evidence to support the use of drainage to prevent complications.

Study design: Prospective, randomized, multicenter study.

Objective: To evaluate clinical, laboratory and complication rates in patients with and without subfascial (deep) drain undergoing posterior lumbar fusion for degenerative pathology.

Materials and Methods: In 9 centers patients were randomized (RedCap, Vanderbilt University) in two groups: with (Group A) and without (Group B) deep drainage. Inclusion criteria: between 40 and 80 years old, lumbar and radicular pain, posterior only lumbar decompression and fusion up to 3 levels with or without transforaminal or posterior lumbar interbody fusion (TLIF/PLIF), primary degenerative disease, elective surgery. Exclusion Criteria: Tumor, trauma, congenital or infectious disease, revision surgery, associated vascular pathology and/or coagulopathies, intraoperative bleeding over 2500cc, dural tear, use of bone morphogenetic protein, severe psychosis.
Quality of life and pain were evaluated using pre and 1 month post op lumbar and radicular visual analog scale (VAS), SF-36, and Oswestry Disability Index (ODI). Surgical parameters included: surgical time, estimated blood loss (EBL), post-operative temperature, pre-operative and discharge hematocrite (Ht), dressing and length of stay (LOS), postoperative rate infection and complications were also assessed.
Machine learning with principal component analysis (PCA) was performed to examine interrelationships among clinical variables between both groups.

Results: 88 patients were enrolled with 83 patients at the final follow up. 40 patients in group A and 43 patients in Group B. Both groups were comparable demographically.
Surgical time (p=0.780) EBL (p=0.143), pre - operative Ht (p=0.499) where not statistically significant between both groups.
Postoperative temperature was 36,76 ± 0.05°C for group A and 36.78 ±0.05°C for group B (p= 0,782).
Ht at discharge was 34.4±1.1 for group A and 36.6 ± 0.8 for group B (p=0.119), the difference between pre - operative and discharge Ht was not statistically significant between both groups (7.46; 6.4 days; p=0.275).
LOS was 3.9 ±0.2 days in group A and 2.8 ±0.1 days in group B (p=0.0004).
The dressing drainage was not statistically significant between groups (p=0.333).
Machine learning with PCA identified postoperative lumbar and radicular VAS, postoperative ODI and SF-36 score as major loading factors (>|0.25|) showing better clinical outcomes in the non-drainage group.
4 complications were registered (4,7%), 3 in group A and 1 in group B (p=0.333).

Conclusion: Non-drainage patients present shorter LOS, better clinical outcomes and low complication rate. We do not recommend the use of drainage in primary lumbar fusion for degenerative pathology.

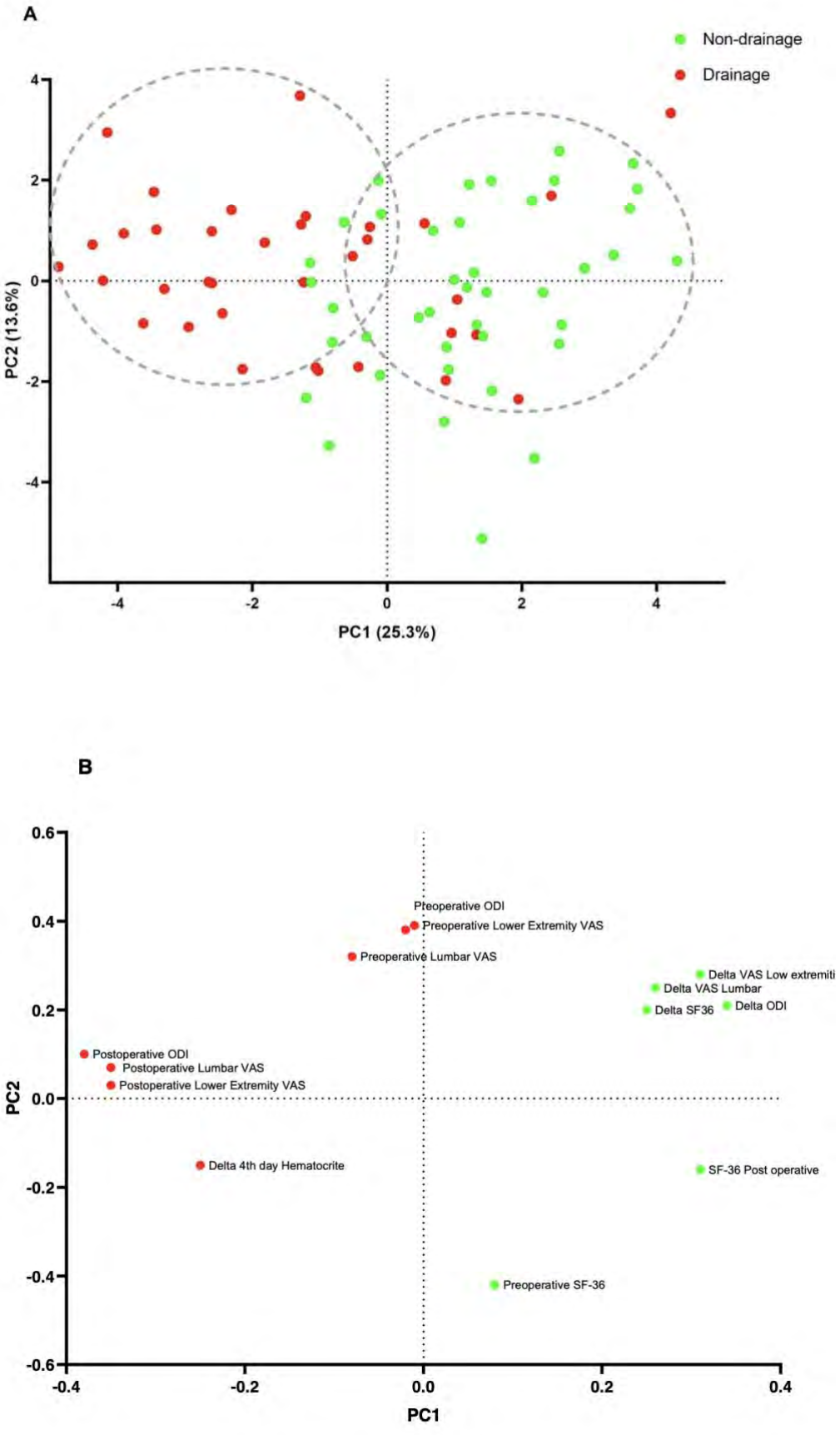

Figure. Machine learning analyses based on PCA

Scores plots in A show the spontaneous distribution and cluster formations of patients projected in the new dimensions described by PC1 and PC2, green dots correspond to non-drainage group, red dots correspond to drainage group. In parenthesis is expressed variance percentage for each PC. B show the loading plots of PC1 vs. PC2 projected in the new dimensions, variables with the highest value >|0.25| are shown.

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COMPARATIVE EFFECTIVENESS OF ANTERIOR (ALIF) VERSUS TRANSFORAMINAL (TLIF) LUMBAR INTERBODY FUSION OF L5-S1

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Background:
Fusion at the L5-S level can be performed through anterior or posterior surgical accesses. Possible advantages of Anterior Lumbar Interbody Fusion (ALIF) are sparing of the spinal muscles, lower risk of nerve root damage, broader access to the disc space and endplates allowing for large and lordotic cages. Possible advantages of Transforaminal Lumbar Interbody Fusion (TLIF) are usually higher surgeon experience and ability to directly decompress neural structures.
In this observational study, we aimed to compare the clinical effectiveness of lumbo-sacral ALIF vs. TLIF at 3 and 12 months after surgery.

Methods:
Prospectively collected data from the Norwegian Registry for Spine Surgery (NORspine) reported by patients treated with ALIF compared to those treated with TLIF in the L5-S1 level; performed during 2007-2017. We assessed baseline patient characteristics and operative data, the clinical outcomes were assessed by patient reported outcome measurements (i.e., ODI and the NRS back pain). The primary effectiveness outcome was defined as at least 15 points of improvement in ODI from baseline to 12 months after surgery. Secondary endpoints included the absolute follow-up scores on ODI and NRS back pain, duration of surgery and hospital stay and prevalence of perioperative complications

Results:
We identified 945 patients; 279 (29%) were treated with ALIF and 666 (70%) with TLIF. The follow-up rate was 672 (71%) at 12 months. At baseline, we found no relevant differences between the two groups, although the ALIF group had lower preoperative ODI compared to the TLIF group (39 (SD 14) vs. 42 (SD 14), mean difference (MD) = 3.4 points; p=0.001). More ALIF than TLIF patients were working before surgery, 25% vs 18%, relative risk (RR) = 0.91; p=0.002.
We did not find any significant difference in the proportion of patients who met the primary outcome (50% vs. 52%, RR (95% CI) = 1.04(0.88-1.11); p=0.679). Also, ALIF were no better than TLIF assessed by absolute values of ODI or NRS back pain at 3 and 12 months after surgery [ODI at 12 months: 22 (SD 19) vs 25 (SD 19) points, MD = 3,0; p=0.070].
The duration of surgery and length of hospital stay were shorter for ALIF vs. TLIF (MD = 46 min; p<0,001; and 1 day; p<0,001). There were no differences between the groups in prevalence of perioperative complications.

Conclusions:
In this register study of 945 patients operated with interbody fusion at the level of L5-S, the clinical effectiveness was not associated with the access of the surgery, but ALIF was associated with somewhat shorter operation time and hospital stay.

Disclosures:
author 1: none; author 2: none; author 3: none; author 4: none; author 5: none

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SURGICAL MICRODISCECTOMY VS STEROID NERVE ROOT INJECTION FOR SCIATICA UP TO 1YR; THE NERVES TRIAL

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Background:
Optimal treatment for sciatica secondary to a prolapsed lumbar disc remains controversial with lack of evidence for non-surgical treatments such as transforaminal epidural steroid injection (TFESI) compared to surgical microdiscectomy.

Methods:
163 patients with non-emergency sciatica (secondary to a prolapsed intervertebral disc) were randomised to surgical microdiscectomy or TFESI. Adults 16 to 65 years with symptom duration of less than 12 months, who failed simple conservative care were recruited from 11 UK specialist spinal units. Primary outcome was the Oswestry Disability Questionnaire (ODQ; at 18 weeks post-randomisation. Secondary outcomes included visual analogue scores for leg and back pain, modified Roland-Morris and Core Outcome Measures Index. Cost-effectiveness was estimated from EQ-5D-5L, Hospital Episode Statistics data, medication usage and self-report resource-use data. Adverse event (AE) data were collected.

Results:
No significant differences were found in ODQ at 18 weeks (mean improvement for surgery 26.7 points, TFESI 24.5 points; estimated treatment difference -4.25 (95% CI -11.09, 2.59). No significant differences were found for secondary outcomes up to 54 weeks. There were 4 (3.8%) serious adverse events in the surgery group, none in the TFESI group. Surgery had an incremental cost-effectiveness ratio of £38,737 per QALY gained, and a probability of 0.17 of being cost-effective at a willingness to pay threshold of £20,000 per QALY.

Conclusions:
No statistically significant difference was found between surgery and TFESI; surgery is unlikely to be a cost-effective alternative to TFESI.

Trial Registration Number: ISRCTN04820368, EudraCT: 2014-002751-25.
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