Statistical Analysis Plan (SAP)

SunBurst Trial

Study title: The StUdy oN Burst Fractures (SunBurst) - a register-based, randomised controlled trial on thoracolumbar burst fractures

Protocol: The protocol is available on the Swedish Fracture Register webpage: https://registercentrum.blob.core.windows.net/sfr/r/Clinical-Study-Protocol-SunBurst-v2-0-O2brW5bAf.pdf. The protocol has also been published: https://actaorthop.org/actao/article/view/1614

SAP version: 1.0

SAP date: Feb 4, 2026

Trial registration: ClinicalTrials.gov: NCT05003180

Sponsor: Uppsala University

Principal investigator: Paul Gerdhem

Statistician: Henrik Renlund

Health economist: Gylfi Olafsson

1. Purpose of the SAP

This Statistical Analysis Plan prespecifies the analyses of the primary and secondary outcomes of the SunBurst trial. The SAP was finalised prior to completion of the last one-year follow-up and prior to database lock for the primary analysis.

2. Study design summary

SunBurst is a pragmatic, multicentre, register-based, parallel-group randomised controlled trial comparing surgical versus non-surgical treatment of thoracolumbar burst fractures in Sweden and Norway.

3. Analysis populations

3.1 Intention-to-treat (ITT) population

All randomised participants analysed according to allocated treatment group, regardless of treatment received, crossover, or protocol deviations.

3.2 Per-protocol (PP) population

A per-protocol sensitivity analysis will exclude participants with major protocol deviations related to crossover. Crossover from non-surgical to surgical treatment will be considered

protocol-permitted only if it meets the criteria in section 5.4.2 of the protocol on the Swedish Fracture Register webpage (https://registercentrum.blob.core.windows.net/sfr/r/Clinical-Study-Protocol-SunBurst-v2-0-02brW5bAf.pdf): neurological compromise after inclusion in the study, or inability to initiate mobilization due to intense pain despite adequate analgesics and possibly a brace. Surgery due to increasing kyphosis alone, or canal compromise in the absence of neurological symptoms, will be classified as non-permitted crossover and treated as a major protocol deviation. Failure to receive allocated surgical treatment following randomisation to the surgical group will be considered a major protocol deviation, irrespective of reason, and such participants will be excluded from the per-protocol analysis.

Deviations from protocol concerning treatment will be presented as total number and percentage of patients, and reason.

No as-treated analyses are planned, as such analyses would compromise the benefits of randomisation.

4. Withdrawal of Patients from the Trial

Participants are able to withdraw from the trial at any time. Collected data on patients who choose to withdraw their consent will be retained in the study database.

5. Estimands

Population: All randomised patients with thoracolumbar burst fractures (Th10-L3).
Treatment: Assignment to surgical versus non-surgical treatment.
Variable: Oswestry Disability Index (ODI) score at 1 year.
Intercurrent events: Treatment crossover, additional spine surgery (unplanned and planned), death, and loss to follow-up.
Handling strategy: Treatment-policy (intention-to-treat).
Summary measure: Mean difference in ODI at 1 year with 95% confidence interval.

6. Endpoints

6.1 Primary endpoint

The primary end-point is the patient-reported Oswestry Disability Index (ODI) at approximately 1 year after randomisation.

Scoring rules:
The Oswestry Disability Index will be calculated as a percentage score based on answered items (0–100; higher scores indicate greater disability). If one question is left blank or missed, the ODI score is calculated as the percentage of the answered questions. If more than one box is marked for a question, the highest value will be counted.

6.1.1 Secondary analysis of the primary outcome

Proportion with ODI 0-20 at 1 year.

6.1.2 Sensitivity analyses of the primary outcome

ODI at 1 year, adjusted for age, sex and fracture type (A3 vs A4).

The first item on ODI (pain intensity) at 1 year.

6.2 Secondary endpoints
ODI; EQ-5D-5L index; EQ-VAS; SMFA dysfunction index; SMFA bother index at about 3-4 months and EQ-5D-5L index; EQ-VAS; SMFA dysfunction index; SMFA bother index at 1 year. Change in ODI; EQ-5D-5L index; EQ-VAS; SMFA dysfunction index; SMFA bother index from preinjury to about 3-4 months and change from preinjury to about 1 year. Radiographic parameters at about 3-4 months and about 1 year, change in radiographic parameters from injury to about 3-4 months, and from 3-4 months to about 1 year. Additional spinal surgery; adverse events; sick leave; analgesic and antibiotic use; health economic outcomes during the follow-up.

7. General statistical principles

All tests will be two-sided with a significance level of 0.05 for the primary endpoint. Effect estimates will be reported with 95% confidence intervals.

No formal adjustment for multiple comparisons will be applied; secondary analyses are considered supportive.

Statistical software: R version 4.5.2 or later.

7.1 Missing data

To investigate the potential effect of missing values an additional data set will be created using the method of multiple imputation using chained equations, using 100 imputations. Variables included here will be age, sex, randomization group, fracture type, and the questionnaires (ODI, SMFA dysfunction and bother index, EQ-5D-5L, and EQ-VAS) collected at baseline and at the follow-ups (3-4 months and 1 year, respectively).

8. Baseline data

Baseline characteristics will be tabulated by randomised group without hypothesis testing. Baseline ODI, SMFA dysfunction and bother index, EQ-5D-5L and EQ-VAS reflect the preinjury state, and were assessed using a recall technique, referring to the week prior to the fracture.

9. Measurements

All patient reported outcomes will be answered by the patients themselves on paper questionnaires or digital questionnaires without assistance of care givers. However, if

patients do not reply on reminders, telephone calls will be made, questions asked over the phone which consist of at least the primary outcome questionnaire (ODI).

Radiographic analysis on baseline radiographs (computed tomography; CT and magnetic resonance imaging; MRI) will be performed on anonymized images independently by two trained physicians blinded for treatment allocation. Measurements will include classification (AO type A3/A4), the Load Sharing Classification (McCormack et al, Spine, 1994, pp1741-1744), the kyphosis angle (Keynan et al, Spine, 2006, pp E156-165), the wedge angle and the anterior/posterior vertebral height ratio (Isomi et al, J Spinal Dis, 2000, pp404-411). The MRI will be used to identify the presence or absence of an edema in the posterior ligament complex structure at the fracture level.

The mean value of continuous measurements from these two physicians will be used. In case of inconsistencies in categorical classifications, a third trained physician, also blinded for treatment allocation will make the final decision.

The same physicians will analyse the post-treatment radiographs (plain radiographs, CT and MRI) in a session separate from the analyses of the pretreatment radiographs. Blinding is not possible on the post-treatment radiographs since treatment allocation will be visible.

Data on adverse events will be collected from patients, patient files, radiographs and registries.

10. Analysis

10.1 Primary outcome analysis

The primary analysis will compare ODI at the 1-year follow-up between treatment groups according to the intention-to-treat principle using an unadjusted analysis. Results will be presented as mean difference (surgery – non-surgery) with 95% confidence interval. Statistical inference will be made with Student's t-test. Consistent with the protocol, the primary analysis will use complete-case data. We expect a small number of missing data of the primary outcome.

10.1.1 Secondary analyses of the primary outcome

ODI categories at the 1-year follow-up will be presented descriptively as number (%) in the groups. ODI category 0-20 will be compared with ODI categories 21-100 in the groups and presented descriptively as number (%). The risk ratio (RR) of achieving ODI 0–20 will be presented with 95% confidence intervals. Absolute risk differences (RD) will be presented with 95% confidence intervals calculated using the Newcombe–Wilson hybrid method.

10.2 Sensitivity analyses of the primary outcome

The analysis of the primary outcome will also be pooled over imputations.

The between-group difference in ODI at the 1-year follow-up will be compared using linear regression adjusting for age, sex, fracture type (A3 vs A4) and country (Sweden/Norway). Adjusted means (95%CI) will be presented, for complete case and pooled over imputations.

The first item on ODI (pain intensity) at the 1-year follow-up will be presented descriptively as mean (95%CI) and median (25^{th}, 75^{th} percentile) in the groups, for complete case and pooled over imputations.

11. Secondary outcome analyses

We expect a small number of missing data of EQ-5D-5L, EQ-VAS, SMFA dysfunction index, and SMFA bother index.

The EQ-5D-5L index value will be presented as mean (95% confidence interval; CI) and median (25th, 75th percentile) in the groups, for complete case and pooled over imputations. We will use the latest available country specific societal value sets for the EQ-5D-5L index (Sun et al, Health Qual Life Outcomes, 2022, 20, 167, Garratt et al, Qual Life Res 2025, pp417-427). Country-specific data will be presented descriptively, and the primary between-group comparison will be performed in pooled analyses with adjustment for country.

EQ-VAS will be presented as mean (95% confidence interval; CI) and median (25^{th}, 75^{th} percentile) in the groups, for complete case and pooled over imputations.

SMFA dysfunction index will be presented as as mean (95% confidence interval; CI) and median (25^{th}, 75^{th} percentile) in the groups, for complete case and pooled over imputations.

SMFA bother index will be presented as mean (95% confidence interval; CI) and median (25^{th}, 75^{th} percentile) in the groups, for complete case and pooled over imputations.

Changes of the PROMs (ODI, EQ-5D-5L index, EQ-VAS, SMFA dysfunction index, SMFA bother index) between preinjury, the follow-up at about 3-4 months and the 1-year follow-up will be presented descriptively as mean (95%CI) as supplementary data; no formal hypothesis testing is planned, for complete case and pooled over imputations.

The published protocol mentions dichotomisation of PROMs other than ODI "based on ongoing studies". At present prespecified cut points or dichotomisation rules for these PROMs are not available. Any further exploratory predictor analyses involving dichotomised PROMs will not be undertaken unless fully specified prior to database lock and will be clearly labelled exploratory.

Secondary outcomes will include unplanned surgical events and mortality, and will be presented descriptively as number of events occurring between baseline and 1 year (365 days) after randomization. Some institutions regularly plan for spine implant removal. This is not considered an adverse event and will be presented descriptively as number of events occurring between baseline and 1 year (365 days) after randomisation. Complete case data will be used.

Sick leave/return to work up to 1 year (365 days) after randomisation will be obtained from official registries (Sweden), or the hospital files (Sweden and Norway).

Radiographic data include the kyphosis angle (Keynan et al, Spine, 2006, pp E156-165), the wedge angle and the anterior/posterior vertebral height ratio (Isomi et al, J Spinal Dis, 2000, pp404-411) measured on computed tomography, or if not available on conventional radiographs, and will be presented descriptively as mean (95%CI). Changes in radiographic parameters from baseline to the follow-ups at about 3-4 months and the 1-year follow-up will be presented descriptively as mean (95%CI) as supplementary data. Complete case data will be used.

Continuous outcomes will be analysed using Student's t-test, or the Mann-Whitney test if distributional assumptions are not met.

Binary outcomes, such as adverse events, will be compared between treatment groups using chi-square or Fisher's exact tests, as specified in the protocol. Effect estimates will additionally be obtained using log-binomial regression, or if the model fails to converge with Poisson regression with robust standard errors, and presented as risk ratios with 95% confidence intervals in a Supplementary Table. For outcomes with ≤5 total events or zero events in one group, risk ratio estimates will be omitted.

Time-to-event for adverse events and sick leave/return to work will be analysed using Kaplan–Meier methods and Cox proportional hazards models, adjusted for age and sex, between baseline and 1 year (365 days). Patients without event or other censoring will be censored on day 365.

Sick leave/return to work will as additional analysis be stratified by pre-fracture working status.

12. Subgroup analyses

Exploratory subgroup analyses will be performed based on fracture type (A3 vs A4). Other protocol-mentioned subgroup analyses will not be performed (or will be reported only descriptively) and will be labelled exploratory if later added.

13. Interim analyses

No interim analyses are planned, or have been performed.

14. Data outside this statistical analysis plan

Multivariate regression to identify predictors of ODI at 1 year will not be performed in the primary outcome manuscript.

Imaging: Additional analyses of baseline CT for spinous process, facet and other injuries for prediction of outcome is outside this statistical analysis plan. Additional analysis of baseline MRI for soft tissue injuries are outside this statistical analysis plan. Analysis of the standing

sagittal and coronal radiographs and MRI data at 1 year are outside this statistical analysis plan.

The influence of minimal invasive and open surgery on outcome are outside this statistical analysis plan.

Five- and 10-year outcomes are outside this statistical analysis plan.

A health economic analysis is outside this statistical analysis plan and will be performed as a separate analysis at a later stage. The health economic analysis is dependent on data from official health registers that are not available at present. These registers include information on medical adverse events such as deep venous thrombosis, pulmonary emboli, and non-surgical adverse events, inpatient hospital stays also at other clinics than the initially treating clinic, outpatient visits, sick leave/working status data, and drug prescription data, and other surgical events.

Cost-utility analyses will be conducted from healthcare and societal perspectives. Quality-adjusted life years (QALYs) will be derived from EQ-5D-5L. Incremental cost-effectiveness ratios will be calculated and uncertainty assessed using non-parametric bootstrapping.

15. Database lock

The database for the primary analysis will be locked after completion of the last 1-year follow-up and resolution of primary outcome queries.

Complete radiographic and surgical data will be available later than the completion of the 1-year follow-PROM data and will be analysed after a subsequent lock.

Data from the National Board of Health and Welfare National Patient Register (NPR), the Swedish Social Insurance Agency ('Försäkringskassan') and data from the 'Longitudinal integrated database for health insurance and labour market studies' available at Statistics Sweden will be ready later than the completion of the 1-year follow-and will be analysed after subsequent locks.

16. Statistical analysis

An independent statistician will perform the statistical analysis. All statistical analyses will be performed with treatment groups coded until the primary analysis are completed.

17. Amendments

All amendments are listed in the protocol, which is available on the Swedish Fracture Register webpage: https://registercentrum.blob.core.windows.net/sfr/r/Clinical-Study-Protocol-SunBurst-v2-0-O2brW5bAf.pdf. They are also listed here. Compared to the original protocol the following amendments have been made:

2023-Jan-19

The protocol has been updated 2023-01-19 with added study sites in Sweden, including Halmstad, Jönköping, Kalmar and Västerås, and Norway, including Akershus, Bergen, Oslo, and Stavanger. Sentences describing how the study design and data collection are modified for Norwegian patients have been added to Synopsis, 1.1, 3.1, 3.2, 3.3, 4.3, 4.5, 5.4, 6.1, 6.2, 7.2, 8.1, 10.1 and 10.3.

2023-July-16
The protocol has been updated 2023-07-16 with added study site St Olavs Hospital in Norway. The wording of section 5.1. about surgical treatment has been adjusted to clarify that posterior fixation is the recommended treatment, but other surgical methods are allowed within the study to the surgeon's discretion.

Information clarifying when treatment cross-over is acceptable within the study has been added to 5.4.2 with the heading "Treatment cross-over control group".

The dnr from The Swedish Ethical Review Authority has been corrected from 2020-00011 to 2021-00011 in section 10.

2024-May-21
The protocol has been updated 2024-05-21. The update includes change of Research Body from Karolinska Hospital to Uppsala University, added ethical amendment in section 10. and updated contact details.

Information about the authorship guidelines that will be followed for the final manuscript have been added to section 12.1.

18. Deviations from the SAP

Any deviations from this SAP will be documented, justified, and reported transparently.

19. Signatures

Principal investigator: _Paul Gerdhem_____ Date: (digitally signed)_____

Statistician: _Henrik Renlund_____ Date: (digitally signed)_____

Attachments

Shell tables

Attachment

Shell Tables.

Table 1. Patient demographics at baseline presented as mean (range), mean (95%CI), median (25th, 75th percentile) or n(%).

Characteristic at baseline	**Surgical group** **n =** (posterior surgery only n= , anterior surgery only n= , anterior+ posterior surgery n=)	**Non-surgical group** **n =** (brace n= , no brace n=)	**Both groups** **n =**
Age (yrs), mean (range)			
Sex; female n (%)/male n (%)			
Comorbidity, any, n(%)			
Heart disease, n(%)			
Diabetes, n(%)			
Pulmonary disease, n(%)			
Other, n(%)			
Fracture characteristics			
Fractured vertebra: T10, n= , T11, n= , T12, n= , L1, n= , L2, n= , L3, n=			
Fracture classification: A3, n(%)/A4, n(%)			
Load sharing classification, median (25th, 75th percentile)			
No posterior tension band injury, n(%) / Indeterminate tension band injury, n(%)			
Number of patients with any additional spine fracture (not requiring any treatment), n(%)			
Number of patients with any additional extremity fracture, n(%)			
Neurology			
Neurology intact, n(%)			
Radicular symptoms, n(%)			
Table 1 continues on the next page			

Characteristic at baseline	Surgical group n = (posterior surgery only n= , anterior surgery only n= , anterior+ posterior surgery n=)	Non-surgical group n = (brace n= , no brace n=)	Both groups n =
Mechanism of injury			
Fall from height, n(%)			
Road traffic accident, n(%)			
Horse riding accident, n(%)			
Other, n(%)			
Treatment information			
Days from fracture to surgery; median (range)		NA	
Days from fracture to brace initiation (if braced) (median, range)	NA		
Patient reported outcome, preinjury			
ODI percentage score, mean (SD), median (25th, 75th percentile)			
ODI category, ODI 0-20 (n;%) vs ODI 21-100 (n;%)			
ODI first item (pain) (0-5), mean (SD), median (25th, 75th percentile)			
EQ-5D-5L, index, mean (SD), median (25th, 75th percentile)			
EQ-VAS mean (SD), median (25th, 75th percentile)			
SMFA Dysfunction index, mean (SD), median (25th, 75th percentile)			
SMFA Bother index, mean (SD), median (25th, 75th percentile)			

ODI = Oswestry Disability Index; SMFA= Short Musculoskeletal Function Assessment, EQ-5D-5L= EQ-5D five level, EQ-VAS= EQ-Visual Analog Scale. NA=not available / not applicable

Table 2. Intention to treat data. Secondary endpoints. Patient reported outcome at follow-up at about 3-4 months. Data presented as mean (95% confidence interval), median (25th, 75th percentile), or n(%). Effect estimate with 95% confidence interval is presented.

Patient reported outcome	Surgical group	Non-surgical group	Between group comparison (effect estimate, 95%CI)*
ODI percentage score, mean (95%CI), median (25th, 75th percentile)			
ODI category, ODI 0-20 (n;%) vs ODI 21-100 (n;%)			
ODI first item (pain) (0-5), mean (95%CI), median (25th, 75th percentile)			
EQ-5D-5L, index, mean (95%CI), median (25th, 75th percentile) (given for each country and pooled**)			
EQ-VAS, mean (95%CI), median (25th, 75th percentile)			
SMFA Dysfunction index, mean (95%CI), median (25th, 75th percentile)			
SMFA Bother index, mean (95%CI), median (25th, 75th percentile)			

ODI = Oswestry Disability Index; SMFA= Short Musculoskeletal Function Assessment, EQ-5D-5L= EQ-5D five level, EQ-VAS= EQ-Visual Analog Scale.

*Mean differences are reported for continuous outcomes and risk differences for categorical outcomes.

**Pooled between-group comparison is adjusted for country (Sweden/Norway). Country-specific summaries are descriptive.

Table 3. Intention to treat data. ODI at the 1-year follow-up. Data presented as mean (95% confidence interval), median (25^{th}, 75^{th} percentile), or n (%). Effect estimate with 95% confidence interval is presented.

	Surgical group	**Non-surgical group**	**Between group comparison (effect estimate, 95%CI)***
Primary outcome			
ODI percentage score, mean (95%CI), median (25^{th}, 75^{th} percentile), unadjusted			
Secondary analysis of the primary outcome			
ODI category, ODI 0-20 (n;%) vs ODI 21-100 (n;%), unadjusted			
Sensitivity analyses			
ODI percentage score, mean (95%CI), adjusted for age (continuous), sex (male/female), fracture type (A3/A4) (based on linear regression, see Supplementary Table 1)			
ODI first item (pain) (0-5), mean (95%CI), median (25^{th}, 75^{th} percentile), unadjusted			

ODI = Oswestry Disability Index

*Mean differences are reported for continuous outcomes and risk differences for categorical outcomes.

Table 4. Intention to treat data. Secondary endpoints. Patient reported outcomes other than ODI at follow-up at 1 year, presented as mean (95% confidence interval), or median (25^{th}, 75^{th} percentile).

	Surgical group	**Non-surgical group**	**Between group comparison (mean difference, 95%CI)**
EQ-5D-5L, index, mean (95%CI), median (25^{th}, 75^{th} percentile) (given for each country, and pooled*)			
EQ-VAS, mean (95%CI), median (25^{th}, 75^{th} percentile)			
SMFA Dysfunction index, mean (95%CI), median (25^{th}, 75^{th} percentile)			
SMFA Bother index, mean (95%CI), median (25^{th}, 75^{th} percentile)			

EQ-5D-5L= EQ-5D five level, EQ-VAS= EQ-Visual Analog Scale, SMFA= Short Musculoskeletal Function Assessment.

*Pooled between-group comparison is adjusted for country (Sweden/Norway). Country-specific summaries are descriptive.

Table 5. Intention to treat data. Secondary endpoints. Additional spine surgery and mortality up until 1 year of follow-up.

	Surgical group	**Non-surgical group**	**p-value (Chi-square or Fisher exact test)**
*Additional spine surgery, unplanned, n(%)**			
Mortality, n(%)			
Planned implant removal (not considered adverse event): n;%			NA

*Reasons for additional spine surgery, unplanned, listed here:

Table 6. Intention to treat data. Secondary endpoints. Radiographic characteristics at baseline (pretreatment), immediate postoperative if surgery, the 3-4 month follow-up and at the 1 year follow-up. Descriptive data.

	Kyphosis angle (degrees), mean (95%CI)	**Wedge angle (degrees), mean (95%CI)**	**Anterior/posterior vertebral height ratio, mean (95%CI)**
Surgical group			
Baseline (pre-treatment)			
Immediate postoperative			
3-4 months			
1 year			
Non-surgical group			
Baseline (pre-treatment)			
3-4 months			
1 year			

Supplementary Tables

Supplementary Table 1. Sensitivity analysis of the primary outcome, adjusted for age and sex. Intention to treat data. ODI at 1 year follow-up, adjusted for age (continuous), sex (male/female), and fracture type (A3/A4). Estimates represent coefficients from a linear regression model.

Variable	Estimate (unimputed data)	95% confidence interval (unimputed data)	Estimate (imputed data)	95% confidence interval (imputed data)
Treatment (surgical vs non-surgical)				
Age				
Sex				
A3/A4 fracture type				

Supplementary Table 2a. Intention to treat data. Secondary endpoints. Unimputed data. Change in patient reported outcomes from preinjury to follow-ups, presented as mean (95%CI).

	ODI	EQ-5D-5L, index (given for each country, and pooled*)	EQ-VAS	SMFA Dysfunction index	SMFA Bother index
Surgical group, n=					
Change from preinjury to 3-4 months, mean (95%CI)					
Change from preinjury to the 1 year follow-up, mean (95%CI)					
Non-surgical group, n=					
Change from preinjury to 3-4 months, mean (95%CI)					
Change from preinjury to the 1 year follow-up, mean (95%CI)					

*The pooled comparison is adjusted for country (Sweden/Norway). Country-specific summaries are descriptive.

Supplementary Table 2b. Intention to treat data. Secondary endpoints. Imputed data. Change in patient reported outcomes from preinjury to follow-ups, presented as mean (95%CI).

	ODI	**EQ-5D-5L, index (given for each country, and pooled*)**	**EQ-VAS**	**SMFA Dysfunction index**	**SMFA Bother index**
Surgical group, n=					
Change from preinjury to 3-4 months, mean (95%CI)					
Change from preinjury to the 1 year follow-up, mean (95%CI)					
Non-surgical group, n=					
Change from preinjury to 3-4 months, mean (95%CI)					
Change from preinjury to the 1-year follow-up, mean (95%CI)					

*Pooled between-group comparison is adjusted for country (Sweden/Norway). Country-specific summaries are descriptive.

Supplementary Table 3. Intention to treat data. Secondary endpoints. Change in radiographic characteristics from pretreatment to follow-ups, presented as mean (95%CI). Descriptive data.

	Kyphosis angle (degrees)	**Wedge angle (degrees)**	**Anterior/posterior vertebral height ratio**
Surgical group, n=			
Change from baseline (pre-treatment) to immediate postoperative, mean (95%CI)			
Change from baseline (pre-treatment) to 3-4 months, mean (95%CI)			
Change from baseline (pre-treatment) to the 1-year follow-up, mean (95%CI)			
Non-surgical group, n=			
Change from baseline (pre-treatment) to 3-4 months, mean (95%CI)			
Change from baseline (pre-treatment) to the 1-year follow-up, mean (95%CI)			

Supplementary Table 4. Intention to treat data. Secondary endpoints. Additional spine surgery, unplanned, and mortality up until the 1-year follow-up. Risk ratios (RR) with 95% confidence intervals from log-binomial regression, or Poisson regression. For outcomes with ≤5 total events or 0 events in one group, RR estimates will be omitted.

	Surgical group	**Non-surgical group**	**RR (95%CI)**
*Additional spine surgery, unplanned, n(%)**			
Mortality, n(%)			

Supplementary Table 5. Per protocol data. Patient reported outcome at follow-up at about 3-4 months presented as mean (95% confidence interval), median (25^{th}, 75^{th} percentile), or n(%).

Patient reported outcome	**Surgical group, n=**	**Non-surgical group, n=**	**Between group comparison (mean difference, 95%CI)***
ODI percentage score, mean (95%CI), median (25^{th}, 75^{th} percentile)			
ODI category, ODI 0-20 (n;%) vs ODI 21-100 (n;%)			
ODI first item (pain) (0-5), mean (95%CI), median (25^{th}, 75^{th} percentile)			
EQ-5D-5L, index, mean (95%CI), median (25^{th}, 75^{th} percentile) (given for each country, and pooled**)			
EQ-VAS, mean (95%CI), median (25^{th}, 75^{th} percentile)			
SMFA Dysfunction index, mean (95%CI), median (25^{th}, 75^{th} percentile)			
SMFA Bother index, mean (95%CI), median (25^{th}, 75^{th} percentile)			

ODI = Oswestry Disability Index; SMFA= Short Musculoskeletal Function Assessment, EQ-5D-5L= EQ-5D five level, EQ-VAS= EQ-Visual Analog Scale

*Mean differences are reported for continuous outcomes and risk differences for categorical outcomes.

**Pooled between-group comparison is adjusted for country (Sweden/Norway). Country-specific summaries are descriptive.

Supplementary Table 6. Per protocol data. Patient reported outcome at the 1 year follow-up presented as mean (95% confidence interval), median (25th, 75th percentile), or n(%).

Patient reported outcome	Surgical group, n=	Non-surgical group, n=	Between group comparison (mean difference, 95%CI)*
ODI percentage score, mean (95%CI), median (25th, 75th percentile)			
ODI category, ODI 0-20 (n;%) vs ODI 21-100 (n;%)			
ODI first item (pain) (0-5), mean (95%CI), median (25th, 75th percentile)			
EQ-5D-5L, index, mean (95%CI), median (25th, 75th percentile) (given for each country, and pooled**)			
EQ-VAS, mean (95%CI), median (25th, 75th percentile)			
SMFA Dysfunction index, mean (95%CI), median (25th, 75th percentile)			
SMFA Bother index, mean (95%CI), median (25th, 75th percentile)			

ODI = Oswestry Disability Index; SMFA= Short Musculoskeletal Function Assessment, EQ-5D-5L= EQ-5D five level, EQ-VAS= EQ-Visual Analog Scale

*Mean differences are reported for continuous outcomes and risk differences for categorical outcomes.

**Pooled between-group comparison is adjusted for country (Sweden/Norway). Country-specific summaries are descriptive.

Supplementary Table 7. Per protocol data. Additional spine surgery and mortality up until the 1 year follow-up presented as n(%).

	Surgical group, n=	**Non-surgical group, n=**	**p-value (Chi-square test)**
*Additional spine surgery, unplanned, n(%)**			
Mortality, n(%)			
Planned implant removal (not considered adverse event): n;%			

Signature page

This document has been electronically signed using eduSign.

eduSign

Electronically signed by
Paul Gerdhem

Date and time of signature
2026-02-04 12:22 GMT

Authenticated by
Uppsala universitet

eduSign

Electronically signed by
Henrik Renlund

Date and time of signature
2026-02-05 10:50 GMT

Authenticated by
Uppsala University

Validate signed documents at: https://validator.edusign.sunet.se

SUNET