ClinicalTrials.gov Study Protocol

Controlled Reduction of Thoracolumbar AO Spine B3 Fractures in Ankylosing Spinal Disorders Using an Inflatable Positioning Device

Retrospective single-centre observational case series with an embedded technical note

Spine Center, Diakonie Klinikum Stuttgart, Stuttgart, Germany

Study registration information

ClinicalTrials.gov field	Protocol entry
Unique protocol identification number	IRB_003_2026
Secondary identifier	IRB_005_2026
Brief title	Outcomes After Surgery for B3 Spinal Fractures in Ankylosing Disorders
Official title	Controlled Reduction of Thoracolumbar AO Spine B3 Fractures in Ankylosing Spinal Disorders Using an Inflatable Positioning Device: A Retrospective Single-Centre Observational Case Series With an Embedded Technical Note
Study type	Observational
Observational model	Case-Only
Time perspective	Retrospective
Study period	January 2022 to December 2025
Sponsor	Diakonie Klinikum Stuttgart
Study location	Spine Center, Diakonie Klinikum Stuttgart, Stuttgart, Baden-Württemberg, Germany
Biospecimen retention	None retained

Brief summary

Ankylosing spinal disorders can make the spine rigid and susceptible to unstable hyperextension fractures after low-energy trauma. This retrospective observational study reviews adults treated surgically for AO Spine B3 fractures at a single German spine centre. It describes baseline characteristics, operative treatment, postoperative complications, and implant-related mechanical complications. Two illustrative cases describe a positioning technique in which an inflatable cushion is gradually inflated under fluoroscopy to reduce the fracture before final posterior rod fixation. No treatment was assigned by the study, and the study does not evaluate the comparative efficacy of the positioning technique.

Detailed description

AO Spine B3 fractures in ankylosing spinal disorders are unstable hyperextension injuries. Reduction can be difficult after induction of general anaesthesia because muscular support is lost, while osteoporosis and long lever arms can increase the mechanical demand on posterior instrumentation. This study retrospectively reviews all eligible surgically treated patients during the prespecified study period. The data set includes demographics, fracture region, neurological status, comorbidities, operative approach, navigation, cement augmentation, posterior construct length, postoperative complications, and implant-related mechanical events.

The technical note describes an inflatable positioning cushion placed beneath the prone patient immediately caudal to the fracture. The cushion is gradually inflated under lateral fluoroscopy until satisfactory alignment is obtained, deflated for pedicle-screw placement, and reinflated to reproduce the verified alignment before final rod locking. The technique is a surgical positioning adjunct documented in two illustrative cases.

Conditions and keywords

ClinicalTrials.gov field	Protocol entry
Conditions	Ankylosing spondylitis; spinal fractures; thoracolumbar fractures; hyperextension injury
Keywords	ankylosing spinal disorders; AO Spine B3; hyperextension fracture; posterior instrumentation; fracture reduction; inflatable positioning cushion; mechanical failure

Study population and eligibility

ClinicalTrials.gov field	Protocol entry
Study population	Adults treated at the Spine Center, Diakonie Klinikum Stuttgart, with an imaging-confirmed AO Spine B3 fracture in the setting of ankylosing spondylitis who underwent posterior instrumented stabilization between January 2022 and December 2025.
Sampling method	Consecutive retrospective review of eligible records in the institutional database.
Sex	All
Age	18 years and older
Healthy volunteers	No

Inclusion criteria

- Age 18 years or older.
- Documented diagnosis of ankylosing spondylitis.
- Imaging-confirmed AO Spine B3 fracture.

- Posterior instrumented surgical stabilization at the study centre during the study period.

Exclusion criteria

- Non-operative management.
- Spondylodiscitis, primary or metastatic neoplasia, or congenital spinal anomaly affecting the index injury.
- Insufficient source-record data for prespecified variables.
- No available follow-up to the 12-month outcome assessment.

Cohort and exposure

ClinicalTrials.gov field	Protocol entry
Cohort label	Surgically treated AO Spine B3 fractures in ankylosing spinal disorders
Cohort description	Single cohort of adults undergoing posterior instrumented stabilization. The positioning-cushion technique was documented in two illustrative cases.
Exposure of interest	Routine surgical management characteristics, including posterior construct length, navigation, cement augmentation, surgical approach, laminectomy, and documented use of the inflatable positioning cushion.

Outcome measures

ClinicalTrials.gov field	Protocol entry
Primary outcome	Major postoperative complication, defined as a Clavien-Dindo grade III, IV, or V complication, assessed from index surgery through 12 months after surgery.
Secondary outcome	Mechanical hardware-related complication, including screw pull-out, rod bending or breakage, implant migration, or another documented construct-related event, assessed from index surgery through 12 months after surgery.
Secondary outcome	Reoperation due to mechanical hardware failure, assessed from index surgery through 12 months after surgery.
Technical observation	Fluoroscopic documentation of positioning-assisted reduction before final rod locking in the two illustrative cases.

Data management and statistical analysis

Investigators extracted information from institutional electronic medical records into a de-identified study database using a unique study identifier. Direct identifiers were not included in the analysis data set. Data were stored and accessed according to institutional data-protection procedures. Continuous variables were summarized as median (IQR) and categorical variables as n (%). Exploratory comparisons used Wilcoxon rank-sum tests for continuous variables and Fisher exact tests for categorical variables. Analyses were performed in R. The small sample size and low event frequency precluded reliable multivariable modelling.

Ethics and data protection

The Internal Review Board for Study Projects at Diakonie Klinikum Stuttgart reviewed the projects under reference numbers IRB_005_2026 and IRB_003_2026. In both determinations, the Board concluded that no consultation with an external ethics committee was required under Section 15 of the MBO LAKBW. The determinations state that the projects did not involve interventions affecting physical or psychological integrity, use of human biological material, or use of data attributable to an identifiable person. All study data were processed in de-identified form with data-minimization measures.

Study officials and contacts

ClinicalTrials.gov field	Protocol entry
Study principal investigator	Fernando A. Núñez-Moreno, MD, MSc
Institutional affiliation	Spine Center, Diakonie Klinikum Stuttgart
Study site status	Completed

Dissemination

Results are intended for publication in a peer-reviewed journal. The study report will present aggregate results only. No individually identifiable participant data will be shared.