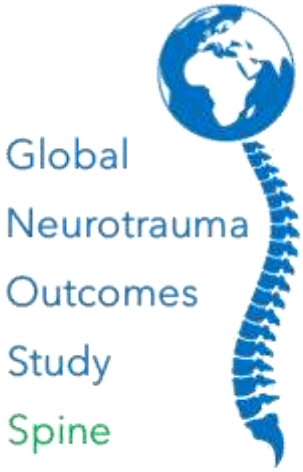
Global Neurotrauma Outcomes Study: Spine

GNOS Spine

An international, multi-centre, prospective, observational study on traumatic spine injury



Data Collection Glossary of Terms

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Contents

This glossary of term will clarify how to answer each question on the case report form, to aid whilst entering data for GNOS Spine.

If you have any further questions or queries regarding specific points of the case report form that are not answered in this glossary, please contact us at info@globalspinetrauma.com and we would be happy to provide clarification. We request that teams please do not submit data if the local study team is unsure of the accuracy. There is the option on the online platform to save a draft form, to allow time to clarify and confirm details that the local study team are not sure on, either through consulting senior colleagues or contacting the central study team.

Thank you and we hope this document is useful during your data collection!

1. Injury & Admission Data

1.1 Unique patient identifier

This is a unique ID that the local study team will generate for each patient and enter into the study. Note that this should not be the same as the patient's local medical record number, and the local study team will be required to keep a secure record (electronic or paper) at the institution linking the unique ID generated for each patient with the patient's local medical records number for the local study team to maintain as a reference to the data. The central study team will not have access to this information, so it is paramount that this is completed correctly and maintained locally.

1.2 Gender

Self-explanatory.

1.3 Age (in years at time of admission)

Please include the patient's age at the time of the admission in years.

1.4 Mechanism of injury

Self-explanatory.

1.5 Date and Time of injury

Self-explanatory. If there is uncertainty as to the time of the injury, try to provide an estimate to the nearest hour if possible.

1.6 Date of admission to the current institution

This is the date of admission to the institution at which data collection is taking place i.e. the date the patient first presents to the current institution.

1.7 Time of admission to the current institution

As above.

1.8 Was the patient directly transferred from the accident scene to your current institution?

The patient may have been taken to a different hospital first and subsequently transfer was arranged to your facility for further care – if this is the case, answer 'No' here. Similarly, the patient may have delayed seeking appropriate medical attention and not gone directly from the accident scene to your institution – again, in this case, answer 'No' here.

1.9 Method of transport to your institution

If the patient was transferred directly from the accident scene, enter the method of transport between the scene and your institution. If the patient presented to another hospital prior to yours and was transferred directly from there to your institution, enter the method of transport between their hospital and yours.

1.10 American Society of Anaesthesiologists (ASA) grade

ASA grading is defined as:

1. Normal healthy patient.
2. Patient with mild systemic disease
3. Patient with severe systemic disease
4. Patient with severe systemic disease that is a constant threat to life
5. Moribund patients are not expected to survive without the operation.

1.11 Glasgow Coma Score on admission

Please use the patient's Glasgow Coma Score (GCS) before any sedation or intubation has If the patient has been sedated or intubated and ventilated before arriving at your institution (for example, at a previous institution or by pre-hospital teams), please use the most recent GCS documented when they were not on sedation.

1.12 Kampala trauma score

The Kampala Trauma Score (KTS) is a physiological scoring system and was developed for use in resource-limited settings and has been shown to be a robust predictor of death. The data capture form requests you to enter the components of the Kampala Trauma Score, not the actual scores. The overall score will be calculated by the central study team using the individual components that you enter into the case report form.

Age (years) - self-explanatory

Number of serious injuries - The value for the number of serious injuries used in the KTS was derived from the Abbreviated Injury Scale (AIS) coding in the ISS, with any AIS of ≥ 2 considered a severe injury.

Systolic blood pressure (mmHg)

Please use the patient's systolic blood pressure in mmHg on arrival to your institution.

Respiratory rate (breaths/min)

Please use the patient's respiratory rate (breaths per minute) on arrival to your institution.

Neurologic status (AVPU system) - The AVPU system is a simplified version of the Glasgow Coma Score

1.13 Frankel Grade

Frankel Grade at initial assessment: the level of initial injury can be classified using Frankel grade. It has 5 grades (A-E) according to the neurological injury. Descriptions and examples for each Frankel Grade can be found below.

A: Complete motor and sensory loss – classified as complete sensory and motor loss below the level of injury. (For example, if there is a fracture with cord transection at T10 level, the patient will be paralysed and would have loss of sensation from the umbilicus down, with loss of conscious bowel and bladder function)

B: Complete motor loss, incomplete sensory loss - classified as complete paralysis and sensory disturbance below the level of injury. Some sensation can be preserved such as light touch, proprioception pain or temperature. (For example, if the patient has a lesion at T10 level, the patient

will have lower limb paralysis but will have preserved sensory function - crude touch, vibration, or joint position sense with preserved sensation of bladder filling)

C: Incomplete motor loss without practical use - classified as preserved sensation and a degree of paralysis but, weakness in the muscle groups is severe below the level of injury. For example, if a patient has an injury at L1 Level, to be classified as C he should have a weakness that is stopping him from mobilisation or <3 power.

D: Incomplete motor loss, able to ambulate with or without walking aids - classified as incomplete injury with mild paralysis of muscle groups.

E: Free of neurological symptoms - no neurological symptoms.

1.14 Major intracranial injury (defined as requiring hospital admission in its own)

Major intracranial injury requiring hospitalization is classified as any patient who would have been admitted for observation after traumatic brain injury. Examples include patients with GCS <15 on presentation (<13 moderate brain injury, <9 severe brain injury), head injury with concurrent use of anticoagulation, GCS 15 but signs of post-traumatic amnesia or a period of loss of consciousness, persisting nausea, and vomiting.

1.15 Site of PRIMARY spinal cord injury

Please use the primary level as the level of injury of spinal cord according to neurological symptoms. For example, if a patient has a cervical spinal cord injury at the level of C5/6, they will have weakness in both arms in the proximal muscle groups. The injury is classified as the primary site where there are symptoms. In this example, the level will be C5 as this is the highest level with normal function. If there is injury at L1, and patients present with lower limb paralysis and numbness at the level of the umbilicus the level will be T10 as this is the last level that has normal function. Primary cord injury sometimes extends beyond the borders of a single fracture.

1.16 Primary Vertebral Fracture Level

Please clarify the primary spinal vertebral fracture if multiple levels are involved. If there are multiple injuries, please select the primary injury according to the following hierarchy:

First, try to decide based on the **degree of intervention** (e.g. the level that has been chosen for surgical fixation).

If multiple levels received intervention, please then choose the primary level based on the **degree of clinical impact** (e.g. the fracture level that is most symptomatic - e.g. causing neurological deficit, or has the highest degree of deformity)

If this is also equivocal, please use the injury which has the highest **AO spine grade**.

1.17 Deformity

This is defined as the presence of any new deformity post-trauma such as kyphosis, lordosis, angulation, or translation between vertebral levels.

1.18 Any other injury

Please specify if the patient has sustained any other injuries, such as injuries to the chest, abdomen, pelvis, or long bones. Multiple items can be selected on the online case report form.

1.19 Admission location

Please select the location in which the patient was cared for in.

High dependent unit (HDU) is defined as an area with higher nursing to patient ratio and higher intensity of observation and care compared to a general ward, but intermediate in comparison to intensive care. In the UK, patients in HDU are those who have single organ failure (e.g. heart failure or respiratory failure or need of renal replacement therapy), while patients in ICU usually have two or more systems that need support (e.g. cardiac and respiratory failure).

1.20 Admitting Team

Please enter which team the patient was admitted under from the options of orthopaedics, neurosurgery, general surgery, or medicine (which includes all medical specialties). If the patient was not admitted but presented to the emergency department from where they were discharged directly, please select “Emergency Department”.

2 Imaging

2.1 Date/Time of first imaging

Please inset the date and time of the first imaging received by the patient (of any modality including X-rays).

2.2 Most advanced type of imaging performed

Please include the most advanced type of imaging performed imaging performed for the patient during their admission. For example, if a patient admitted had and X-ray, CT scan and an MRI, please select MRI. If a patient presents and has only plain radiographs, please choose this option.

2.3 Anatomical area of spine included on imaging

Multiple options can be selected – please select all of the areas of the spine that have been imaged via any imaging modality.

2.4 Level of fracture

Please clarify the primary spinal vertebral fracture identified on imaging. If there are multiple fractures, please select the primary injury according to the following hierarchy:

First, try to decide based on the **degree of intervention** (e.g. the level that has been chosen for surgical fixation).

If multiple levels received intervention, please then choose the primary level based on the **degree of clinical impact** (e.g. the fracture level that is most symptomatic - e.g. causing neurological deficit, or has the highest degree of deformity)

If this is also equivocal, please use the injury which has the highest **AO spine grade**.

2.5 AO Classification of Injury

AO Spine classification classifies fracture type according to their level and presence of specific additional characteristics to aid decision making, treatment and stability.

To aid entry of the AO Spine Classification of Injury for the patient’s injury type, you will be prompted to open an infographic specific to the area of injury that you have selected. By clicking this

link, you will be able to see the relevant section of the AO Spine classification, with images, to help you select the most appropriate AO Spine classification of the injury.

2.6 Subluxation/Translation

From the AO spine classification. More information can be found at: https://aospine.aofoundation.org/clinical-library-and-tools/aospine-classification-systems.

2.7 Traumatic herniated nucleus pulposus [not required if only a plain radiograph is available]

This refers to traumatic disc herniation towards the thecal sac. This is visualised more easily on an MRI scan; however, it can also be seen on a CT scan. It may be helpful to request a radiologist to review the CT scan if there is a radiologist available to help.

2.8 Haematoma [not required if only a plain radiograph is available]

This refers to an epidural haematoma. Please state yes if present.

3 Injury Management

3.1 What was the intended injury management?

In this question, we aim to identify what the team selected the ideal management of this patient's injury to be. There may be a number of reasons as to why the patient does not end up receiving the intended management filled into this data field, such as funding, theatre availability, clinical deterioration or patient choice.

Please select the **intended** management for the patient from the options listed. For example, if it was intended that the patient should receive operative management, please select this, regardless of if the patient ultimately received surgery or not.

3.2 Was there immobilisation during transfer

Self-explanatory.

3.3 Did the patient have a surgical bedrest?

Defined by the type of therapeutic recommendation given regarding mobility management. Surgical bedrest is defined as direction given to the patient to confide to a bed and a specific set of instructions regarding assisted mobility in bed (log-roll) or independent mobility in bed. This is to reduce the risk of translation, rotation or subluxation and displacement of unstable vertebral body fractures with risk of neurological compromise. The option "bed-rest" includes all patients who have been recommended to remain on a flatbed rest or a specific degree of head elevation (e.g. 30 degrees). Log-roll is defined as a specific manoeuvre that ideally requires at least 5 personnel to rotate the patient while maintaining vertebral column alignment.

3.4 Traction?

Please specify if a type of traction device been applied e.g. head clamp and weights according to the fractured spinal level. Traction devices are used to achieve gentle in-line traction of the cervical spine to achieve alignment. Traditionally, this is used for upper cervical spine injuries. The weight used is guided by the spinal level that needs to be addressed.

3.5 Did the patient receive any specialist therapy as an inpatient?

Self-explanatory.

If yes, please select all of the types of additional therapy that the patient received whilst in hospital.

3.6 Was spinal surgery performed?

Self-explanatory.

4 Operative Data

4.1 Grade of the most senior surgeon present in the operating theatre

Please choose the highest grade of operating surgeon present during the patient's surgery.

4.2 Type of anaesthesia used

If general and local anaesthesia were both received, please select general.

4.3 Grade of most senior anaesthetist present

Please select the highest grade of anaesthetist present during the patient's surgery

4.4 Date of operation

Self-explanatory.

4.5 Were prophylactic antibiotics given pre-incision?

Please state yes if the patient has received any antibiotics at the start or during the operation whist in the operating theatre.

4.6 Class of surgical wound

Surgical wounds can be classified as clean, clean-contaminated, contaminated, and dirty – infected wounds. For example, if there is no penetrating injury, the spinal surgical wound would typically be classified as clean.

4.7 Location of surgery

This question refers to the anatomical location of the surgical intervention. If multiple. please select all of the levels that apply.

4.8 What was the main procedure undertaken?

For the procedure type, you will be guided through a flowchart that will expand as you select different options as below.

● Open (surgical procedure)

a. Approach: Anterior (surgical access to the front of the spine) /Posterior (surgical access from the back of the spine)/360 (combined anterior and posterior approach, i.e. jumped cervical spine facets – with anterior cage fixation followed by posterior fixation)

b. Minimally invasive surgery? Sparing approach to the spine with small incision

c. Open Reduction? Open reduction is a term used to define fracture reduction during the operation.

d. Direct decompression? (This is to state weather a laminectomy/ discectomy was performed)

e. In situ fusion? Fusion in situ means that the vertebrae will be fused at level of the fracture with little or no correction of the spine.

f. Fusion? This refers to joining two separate joints into one to provide stability. Fusion is achieved by allograft or autograft after decortication of the bone.

▪ Type of instrumentation

● None

● OC – Occipito-cervical - Fusion between the occipital bone and the upper cervical spine. There are different methods and implants for this to be done. The most common is the use of occipital plates and transpedicular screws (shown below). There are other types of implants and techniques that can be used; however, **Figure 1** shows a general representation.

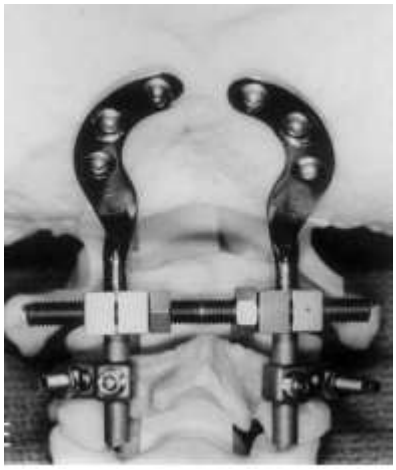

Figure 1. An example of an occipito-atlanto-axial fixation.[1]

● C1/2 - instrumentation between the C1 and C2 spinal vertebrae, as shown in **Figure 2**.

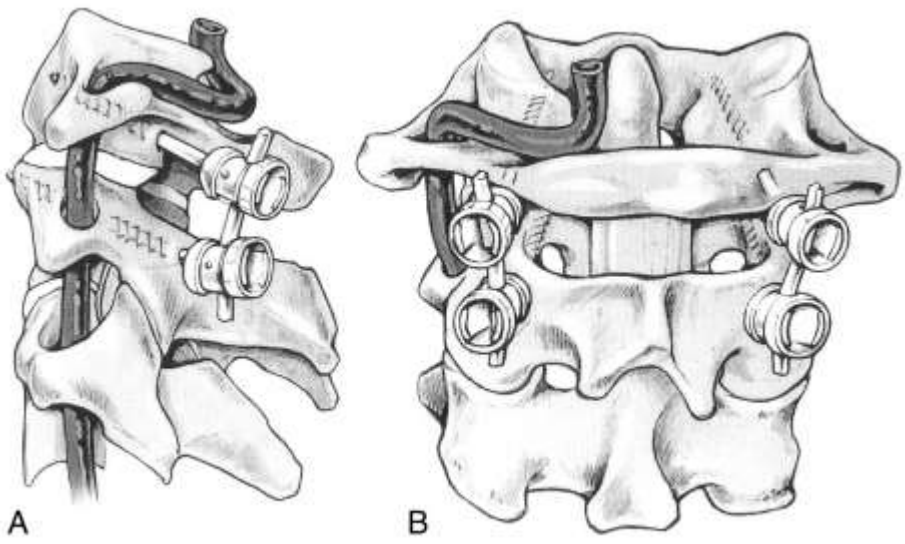

Figure 2. "Upper cervical spine after C1–C2 fixation by the polyaxial screw and rod fixation technique. A Lateral view. B, Posterior view;"[2]

● Lateral mass - fixation going through the lateral mass of the vertebrae (see **Figure 3A**).

● Pedicle - fixation going through the pedicle of the vertebrae (see **Figure 3B**)

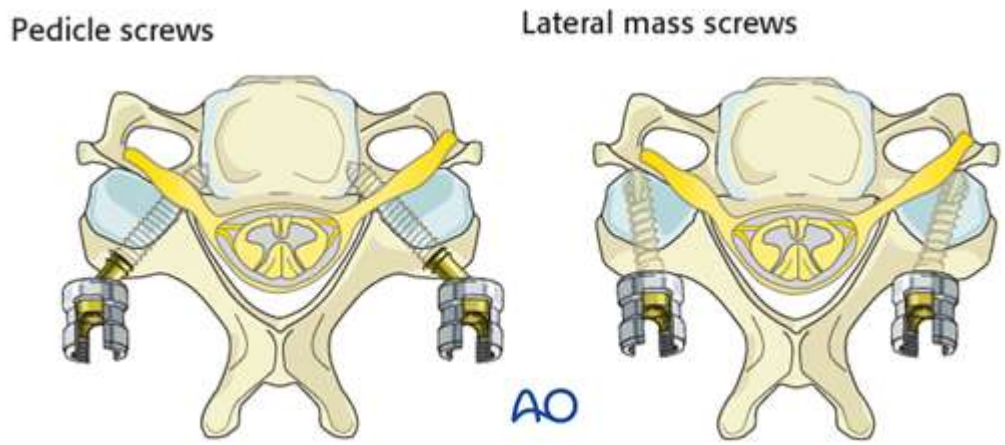

Figure 3. Examples of fixation using either **A:** pedicle screws or **B:** lateral mass screws.[3]

● Anterior plating (for anterior approaches) as shown in **Figure 4**.

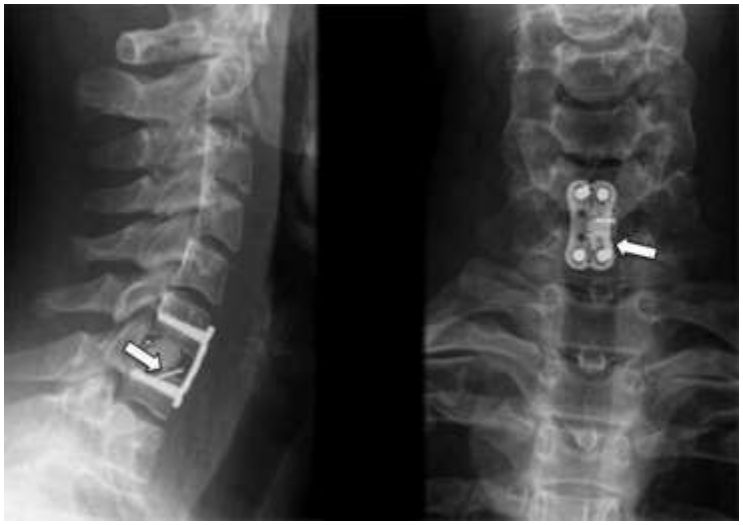

Figure 4. "Lateral (a) and anterior (b) X-rays showing anterior cervical fusion by a PEEK cage filled with synthetic bone graft combined with an anchoring clip (arrows) and an anterior locking plate"[4]

● Bone graft - bone grafting can be used to replace a disc with anterior approaches. This bone is usually taken from the iliac crest. Bone grafts are used to: (i) fuse joints to prevent movement, (ii) repair broken bones (fractures) that have bone loss or (iii) repair injured bone that has not healed. An example of a bone graft is shown in **Figure 5**.

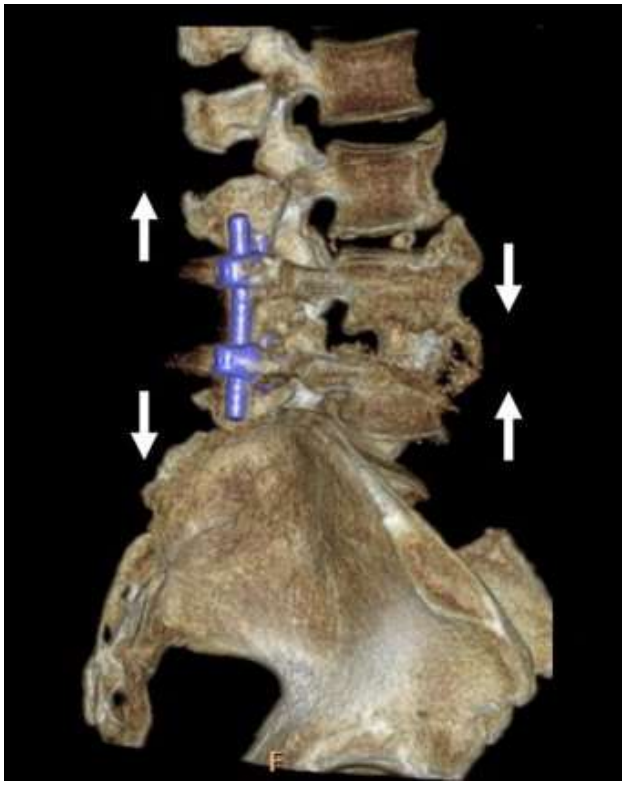

Figure 5. A 3D CT scan showing a bone graft and fixation at L5/S1 (interbody tricortical autograft, and posterior pedicular screw instrumentation).[5]

● Interbody fusion - this is a procedure in which the disc is removed and is replaced with different types of implants, such as a cage, or bone grafts or allograft. There are different techniques and materials used. In general, fusion is usually followed by a posterior fixation.

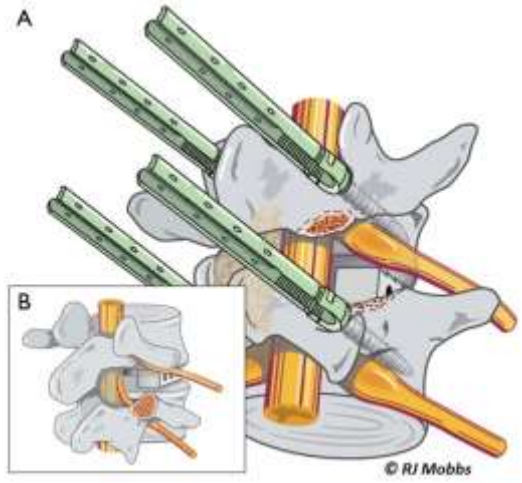

Figure 6. Illustration of a transforaminal lumbar interbody fusion (TLIF). (A) TLIF with percutaneous screws offers a minimally invasive option for interbody fusion (ES-2, Stryker, USA); (B) facetectomy followed by insertion of an interbody device performed via either a midline or paramedian approach.[6]

● Lateral plating - this is another type of fusion. There are different types of implants used, but this refers to any plating where it is positioned on the lateral side of the spine. The approach is lateral to the midline.

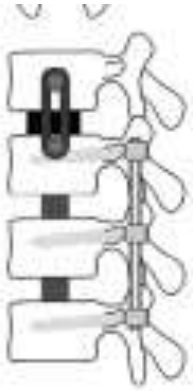

Figure 7. Example of a lateral plate and transforaminal lumbar interbody fusion (TLIF).[7]

o Fluoroscopy used: This is X-ray guidance used intraoperatively to aid visualisation during fixation.

● Closed (Non-operative)

- Gardener Wells/Halo: Gardner wells is used for in line cervical traction. Indications for use of Gardener Wells Traction:

- Sub axial cervical fractures that are maligned
- Sub axial cervical facet dislocations
- Selected odontoid fractures, hangman's fractures, and C1-C2 rotatory subluxation

- A halo vest (shown in **Figure 8**): The indications for halo-vest immobilization include unstable but neurologically intact cervical fractures and incomplete cord injuries with sensation preserved.

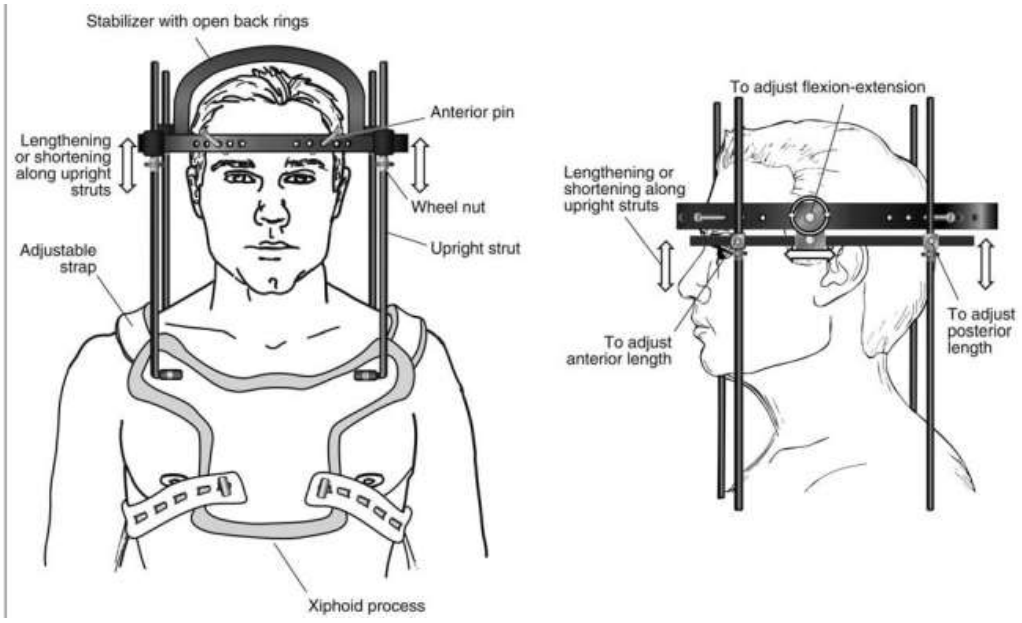

Figure 8. Frontal view of a halo device in place and side view of the upper components of a Halo device in place"[8.]

o Mechanism of Maintenance: Collar vs Halo vs Bedrest

If more than one procedure has been done. Please refer to the main procedure that the patient underwent. For example, if a patient had a surgical fixation followed by a period in a collar post-operatively, please refer to the surgical fixation.

4.9 Funding

Please specify all parties who contributed financially to the patient's procedure.

4.10 Did the patient experience a hypotensive episode during the surgical procedure (SBP < 90mmhg for > 5 minutes)

Self-explanatory.

4.11 Did the patient experience a hypoxic episode during the surgical procedure (SpO2 < 90% for > 5 minutes)

Self-explanatory.

5 Outcome Data

All of the outcome data should be collected at 6-weeks if the patient is still an inpatient. If they have been discharged or have died, please include the outcome data at the time of discharge or death.

5.1 Death within the 6-week follow up period

Self-explanatory.

If you have responded yes to this question, please include the data of death.

Please specify if the patient was in ICU at the time of death.

5.2 Discharged within the 6-week follow up period

If you have responded yes and the patient was discharged within 6 weeks of admission, please input the date of discharge and the discharge destination as per the options provided.

5.3 Was the patient admitted to intensive care at any point during the 6-week follow up period

If yes please clarify the admission and discharge dates from the intensive care unit.

5.4 Was the patient intubated during admission?

Please state whether the patient has had a period of ventilation with respiratory wean.

If the patient was only intubated for their surgical procedure, this would not count, so please select "no", unless the patient continued to be sedated and intubated afterwards for a more prolonged period of time.

5.5 Did the patient require a tracheostomy?

Self-explanatory.

5.6 Was the patient requiring ventilatory support at time of death/the end of the 6-week follow up period (whichever comes first)?

This is to clarify if the patient was requiring ventilatory support at the time of death or at the end of the 6-week follow-up period.

5.7 Did any adverse events of special interest occur in the 6-week follow-up period?

Select all of the adverse events that occurred whilst the patient was in the hospital.

5.8 Did any surgical site infections occur within the 6-week follow up period?

A surgical site infection (SSI) is any infection that occurs at the site of surgery. This could be superficial (wound erythema or oedema) or deep (abscess or an infected collection), or any case with wound dehiscence.

If you answered yes to this question, please clarify the treatment that was required for the SSI.

5.9 Did the patient return to theatre for spinal surgery during the current admission?

Yes, planned - for example, a two-stage fixation operation.

Yes, unplanned - emergency return to theatre for an unforeseen reason. Please specify which level the further operation was performed at (if it was at the same level, e.g. two stage fixation anterior and posterior, or a different level)

5.10 Did the patient survive to the end of the follow-up period (6-weeks post-admission or until they were discharged or death, whichever comes first)?

If yes, was the patient still an inpatient at 6 weeks post-admission?

5.11 Frankel Grade at 6-weeks post-admission, or at discharge or death (whichever occurs first).

Descriptions and examples for each Frankel Grade can be found below.

A: Complete motor and sensory loss – classified as complete sensory and motor loss below the level of injury. (For example, if there is a fracture with cord transection at T10 level, the patient will be paralysed and would have loss of sensation from the umbilicus down, with loss of conscious bowel and bladder function)

B: Complete motor loss, incomplete sensory loss - classified as complete paralysis and sensory disturbance below the level of injury. Some sensation can be preserved such as light touch, proprioception pain or temperature. (For example, if the patient has a lesion at T10 level, the patient will have lower limb paralysis but will have preserved sensory function - crude touch, vibration, or joint position sense with preserved sensation of bladder filling)

C: Incomplete motor loss without practical use - classified as preserved sensation and a degree of paralysis but, weakness in the muscle groups is severe below the level of injury. For example, if a patient has an injury at L1 Level, to be classified as C he should have a weakness that is stopping him from mobilisation or <3 power.

D: Incomplete motor loss, able to ambulate with or without walking aids - classified as incomplete injury with mild paralysis of muscle groups.

E: Free of neurological symptoms - no neurological symptoms.

5.12 How independent is the patient in the following activities of daily living at the end of the follow up period or at time of discharge?

Please clarify whether the patient can perform each activity unaided, with assistance (with aid), or if they are completely dependent.

5.13 What is the patient using to mobilise at the end of the follow up period or at time of discharge or death (whichever event comes first)?

Please select which of the below is required for the patient to mobilise safely:

- Mobilises independently
- Use of one walking stick/ or other mobility sticks such as a crutch
- Use of two walking sticks/ or other mobility sticks such as a crutches
- Use of a frame
- Wheelchair bound
- Bed-bound

Figure References

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