

International Spinal Cord Injury

Spinal Interventions and Surgical Procedures Basic Data Set (Version 1.0)

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The treatment of acute traumatic spinal cord injury (SCI) involves performing therapeutic interventions with the goals of minimizing further neurological deterioration and promoting neurological recovery. The ultimate objective is to create a spinal column that is mechanically stable, not a source of pain, and resistant to further neurological injury or deformity over time.

In some cases, this can be achieved without open surgical procedures; that is, without general anesthesia and without a surgical incision that exposes the spinal elements.¹⁻³ In other situations, open surgical stabilization and decompression techniques may be the preferred approach to achieving the treatment goals described above.⁴⁻⁷ The authors recognize that there are unique clinical environments, variations in the injury pattern itself, the presence and absence of associated non-spinal injuries, as well as variability in not only surgeon training and local practice but also in the available resources that will impact and direct treatment decisions. It is not the purpose of this project to specify indications for treatment or even what may or may not be the preferred techniques of treatment. We acknowledge that the ultimate therapeutic objectives may be arrived at through the use of various techniques. This project attempts to standardize the nomenclature used to describe basic components of interventions and procedures that may influence the patients' outcome in a manner consistent with the principles of the International Spinal Cord Injury Data Set project.⁸

Spinal interventions may involve the application of skeletal traction by means of skull tongs or halo rings of varying design.^{9,10} Interventions may also involve manipulations and closed reduction maneuvers that reduce or realign fractures, dislocations, or subluxations.¹¹⁻¹³ These reductions and manipulations may occur over several minutes, hours, or even days and may require varying degrees of anesthesia from local, intravenous sedation to a full general anesthetic. Spinal interventions also include the application of external braces, casts, halo vests, and other forms of external immobilization.^{14,15} Prolonged bed-rest, which is prescribed as a specific therapy to enable fractures to heal, the spine to stabilize, or to facilitate natural neurological recovery, is also a specific spinal intervention which is applied over days or even weeks and months.^{3, 16, 17}

Surgical procedures in all cases require some form of anesthesia; most commonly a general anesthetic, but occasionally procedures may be performed under local anesthesia. Surgical procedures always involve an incision in the skin through which the spinal elements are accessed either with direct visualization or percutaneously. Surgical procedures also encompass the more recently described techniques of percutaneous insertion of screws and rods for stabilization.¹⁸ Generally, surgical procedures are performed through either anterior or posterior surgical approaches. Posterior approaches include midline incisions as well as minimally invasive, muscle splitting, or 'Wiltse' type paraspinous incisions.¹⁸ Posterior approaches always visualize or access the posterior elements (lamina, facets, transverse processes) although they may be used to access the anterior spinal elements (postero-lateral discectomy or corpectomy). Anterior surgical

approaches encompass all anterior and lateral approaches in the cervical, thoracic and lumbosacral spine. All anterior approaches will visualize the vertebral body and/or disk and do not enable visualization or direct manipulation of the lamina, facets, or other posterior spinal elements.¹⁹⁻²¹

Spinal interventions and surgical procedures will generally achieve their treatment goals by means of the following three steps:

1. Reduction and realignment of displaced vertebrae;
2. Direct or indirect decompression of neural elements;
3. Stabilization of vertebral elements.

It is not our goal to debate the relative merits and indications for the need for reduction, decompression, or stabilization; however, we simply propose that these are the relevant goals of most therapeutic interventions and procedures. There is considerable overlap between the above three steps and one or more of these steps may be achieved by means of a single open surgical procedure or alternately through one or various therapeutic interventions that do not require general anesthesia or an open surgical incision. At one specific date a patient may have a combination of interventions and procedures; for example, an open surgical procedure may also involve the intervention of the application of an external brace to be worn after surgery. An attempted closed reduction of vertebral elements (intervention) that is not successful may be followed on the same day by an open surgical procedure.²²

In accordance with the goal of the International Spinal Cord Injury Data Set project, the aim of the International SCI Spinal Interventions and Surgical Procedures Basic Data Set is to standardize the collection and reporting of a minimal amount of clinically relevant information about the interventions and procedures performed on individuals with spinal column and spinal cord injuries.^{8, 23-26} The International SCI Spinal Interventions and Surgical Procedures Basic Data Set is applicable to adult (skeletally mature) and pediatric (skeletally immature) individuals with traumatic supraconal or conal spinal cord injury or cauda equina injuries. It is intended to be used with the International SCI Spinal Column Injury Basic Data Set and the International SCI Core Data Set.^{24, 26} To ensure that data are collected in a uniform manner, each variable and the corresponding response categories have been defined.

The International SCI Spinal Interventions and Surgical Procedures Basic Data Set is intended to be used with the International SCI Spinal Column Injury Basic Data Set and the International SCI Core Data Set.^{24, 26} The Core Data Set documents whether or not a spinal intervention or surgical procedure (including laminectomy, neural canal restoration, reduction, spinal fusion or internal or external fixation of the spine) was performed during the inpatient hospitalization following a spinal cord injury. The International SCI Spinal Intervention and Surgical Procedures Basic Data Set standardizes the collection and reporting of a minimal amount of

clinically relevant information on spinal column related therapeutic interventions that are performed on patients with spinal cord injuries. The procedures recorded using this form are described in the glossary of terms at the end of this document.

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VARIABLE NAME: Intervention/procedure date and start time

DESCRIPTION: This variable documents the date and time on which an intervention or procedure was started.

CODES: YYYY/MM/DD; HH:MM

COMMENTS: This variable documents the date and time on which an intervention or procedure was started. When a surgical procedure is initiated on a specific day, that date is specified and then all subsequent aspects of that procedure are recorded for that date. The time that the surgical procedure begins; the time that the initial skin incision is made, is recorded as the Intervention/Procedure time. The time component of this variable documents the time of the surgical incision using a 24-hour clock. If part of the information is known (hour but not minute), then this can be entered. The data element "Unknown" is assigned when no information is available. For non-surgical interventions such as traction or closed manipulations or prescribed bedrest, the time data element may be left unknown as it may not be necessary.

If an intervention lasts for more than one day, such as traction or bed-rest, then the date that the interventions were initiated is recorded and the time need not be specified. Furthermore, when several interventions or procedures are all performed or initiated on one date, then a single date is entered and all other variables are completed for that specific date. When multiple procedures are performed on separate dates, then these separate interventions and procedures are recorded on individual forms using separate dates that serve as the procedure identifier.

VARIABLE NAME: Non-surgical - bed rest and external immobilization

DESCRIPTION: This variable documents whether there was any non-surgical intervention initiated.

CODES: No:
Patient was not prescribed bed-rest nor has any external immobilization been utilized.

Enforced bed-rest:
Specifically prescribed to either allow fractures to heal or neurologic impairment to improve over a time greater than 10 days.

External immobilizing device:
External immobilizing device has been applied and this includes body casts, external braces, or halo thoracic vests.

Both enforced bed-rest and external immobilizing device:
Patient was prescribed both bedrest and external immobilization.

Unknown:
No information regarding non-surgical interventions.

COMMENTS: This includes prescriptive bed-rest which usually involves more than 10 days of enforced bed-rest and does not include the normal recumbency which follows injury or surgery as a patient is slowly mobilized. The application of external spinal immobilization devices such as braces, casts, halo thoracic vests, etc. is also a specific spine intervention.

VARIABLE NAME: Spinal intervention - closed manipulation and/or reduction of spinal elements

DESCRIPTION: This variable documents whether closed manipulation and/or reduction of displaced spinal elements has been attempted regardless of whether or not it was successful.

CODES: No:
Indicates that no attempt was made to perform a closed manipulation or reduction of vertebral elements.

Yes:
Indicates that a closed reduction or manipulation was attempted or performed successfully.

Unknown:

The presence or absence of a manipulation or reduction attempts is not known.

COMMENTS: Performance of a closed reduction or manipulation may require application of pins, tongs, head halters, or various other forms of traction and then the subsequent manipulation. This may be performed over several hours or the patient may be left in traction for several days in an attempt to slowly effect a reduction.

VARIABLE NAME: Surgical procedure - approach

DESCRIPTION: This variable documents whether the open surgical procedure was performed by means of an anterior or posterior surgical approach or both.

CODES: No:
No open surgical procedure performed.

Anterior open surgical procedure:
Any anterior open surgical approach was utilized.

Posterior open surgical procedure:
A posterior approach was used for an open surgical procedure including percutaneous posterior fixation.

Both anterior and posterior open surgical procedures:
Both anterior and posterior approaches were used as a part of the same surgical procedure performed on the same date.

Unknown:
An open surgical procedure was performed, but the surgical approach is unknown.

COMMENTS: Anterior surgical approaches include all anterior and lateral cervical approaches as well as any thoracic or lumbar approach that visualizes the vertebral body or inter-vertebral disk such as thoracotomy, thoracoscopy, thoracoplasty, thoraco-abdominal, retro-peritoneal, trans-peritoneal, or variations of lateral lumbar approaches. A posterior approach includes midline posterior incisions, paraspinal and Wiltse type incisions that expose the lamina, facet joints, and/or the transverse processes. Also included in posterior approaches are percutaneous or minimally invasive surgical techniques that enable insertion of spinal implants through stab incisions.

VARIABLE NAME: Date and time of the intervention completion or surgical closure

DESCRIPTION: This variable documents the date and the time of the completion of the intervention or the date and time of the surgical closure and is recorded in a format similar to the “Date and Time of the surgical incision”.

CODES: YYYY/MM/DD; HH:MM

COMMENTS: We acknowledge that a surgical procedure may begin on one day and then be completed on the same or another day. The date is recorded in standard Year/Month/Day format and the time is recorded using the 24-clock and partial information can be entered. For non-surgical interventions such as traction or closed manipulations or prescribed bedrest, the time data element may be left unknown as it may not be necessary. The data variable “Unknown” is selected if there is no information available.

VARIABLE NAME: Surgical procedure - open reduction

DESCRIPTION: This variable is used to document whether or not, during the performance of an open surgical procedure, the spinal elements were manipulated to effect a reduction of a displaced fracture, a subluxation, or a dislocation.

CODES: No:
No open reduction was performed.

Yes:
An open reduction was performed to reduce a mal-alignment, subluxation or dislocation.

Unknown:
An open surgical procedure was performed, but it is not known whether or not an open reduction was performed.

COMMENTS: Most commonly, open reduction is performed through a posterior surgical approach, but may, on occasion such as the anterior cervical discectomy which is followed by a reduction of a facet dislocation, be performed through an anterior approach.

VARIABLE NAME: Surgical procedure - direct decompression of neural elements

DESCRIPTION: This variable documents whether there has been direct surgical

decompression of neural elements by removing bone, disk, ligaments, soft tissue, haematoma, or foreign bodies (bullet fragments, blades, or other foreign matter) from adjacent to or within the dura mater.

CODES:

No:
No direct decompression of neural elements (spinal cord, cauda equina, or individual nerve roots) has been performed.

Yes:
Direct surgical decompression of neural elements (spinal cord, cauda equina, or individual nerve roots) has been performed through either an anterior or posterior approach or a combination of both.

Unknown:
A surgical procedure was done but whether or not a direct surgical decompression of neural elements has been performed is not known.

COMMENTS: This includes removing bone or disk that may be compressing one or more nerve roots. Direct surgical decompression does NOT include the indirect reduction that occurs with an open or closed reduction of neural elements, which may restore the spinal canal dimensions or restore the anatomy of neural foraminae. This may be performed through either an anterior or posterior surgical approach but requires direct visualization of the neural elements (dura). As such, it cannot be performed percutaneously.

VARIABLE NAME: Surgical procedure - stabilization and fusion – segment number

DESCRIPTION: This variable documents whether or not there was an open stabilization and or fusion procedure.

CODES:

1 – Most cephalic spinal column injury:
Assigned if only one segment of the spine has undergone instrumentation and fusion or to indicate the most cephalic of two or more spinal regions that have undergone fusion and/or instrumentation.

2 – Second most cephalic spinal column injury if there are two or more discrete spinal column injuries:
Assigned to the second most cephalic fused or instrumented segments.

3, 4, etc. – Third, fourth, etc. most cephalic spinal column injury if there are three or more discrete spinal column injuries:
Assigned values for three or four etc. discrete segments of the spinal column which have been fused and/or instrumented with each number assigned in a progressive cephalic to caudal direction.

Unknown:

Assigned when the order and assignment of instrumented and fused spinal segments is unknown.

COMMENTS: When a surgical procedure is performed it may or may not include the insertion of instrumentation to stabilize vertebral levels and may or may not involve a formal fusion procedure with or without insertion of local or distantly harvested structural or non-structural bone graft or substitutes. This variable encompasses any and all of the above in one single data point. This variable orders and assigns numbers to each region of the spine which has undergone a spinal instrumentation or fusion procedure beginning with the most cephalic region that has been instrumented and fused and progressing to the most caudal fused region regardless of which level of spinal column injury is the most severe or significant injury or which injury may or may not contribute to the patient's neurological injury. If a patient has had a vC5-6 anterior fusion and also a vT12 to vL2 posterior instrumentation, then each of these non-contiguous instrumented and fused regions would receive a numerical score beginning with 1 for the vC5-6 fusion and 2 for the vT12-vL2 instrumentation.

VARIABLE NAME: Surgical procedure - stabilization and fusion – segment level

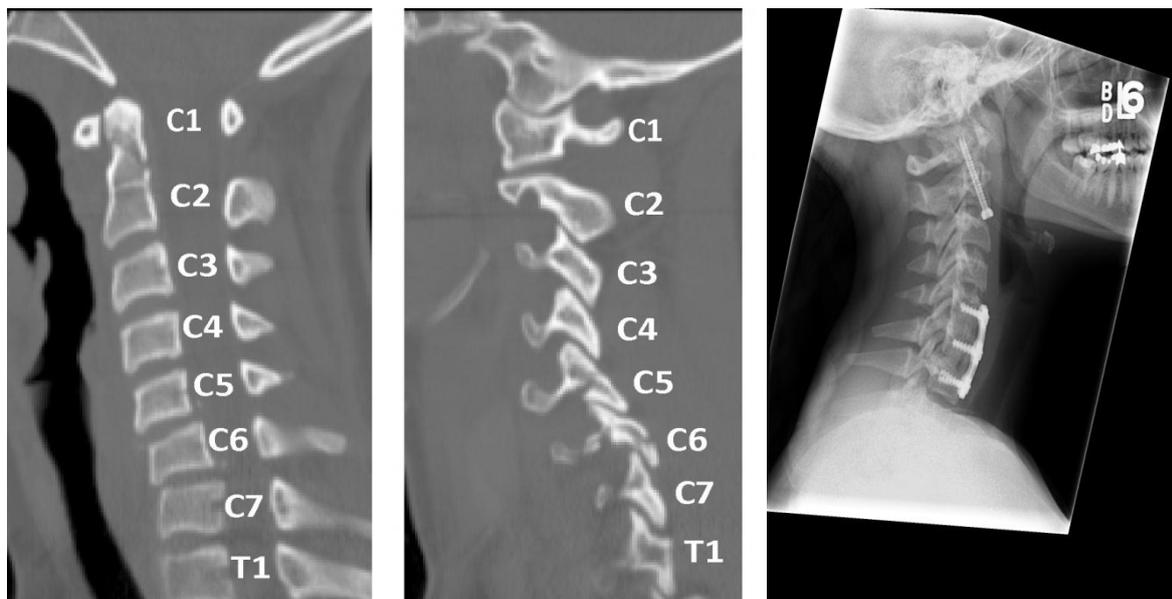
DESCRIPTION: This variable documents whether or not there was an open stabilization and or fusion procedure.

CODES: vC00 - vC07 - Cervical (C0-C7)
vT01 - vT12 - Thoracic (T1-T12)
vL01 - vL05 - Lumbar (L1-L5)
vS01 – vS05 - Sacrum (S1-S5)
vC99 – Unknown cervical (C0-C7)
vT99 – Unknown thoracic (T1-T12)
vL99 – Unknown lumbar (L1-L5)
vS99 – Unknown sacral (S1-S5)
vX99 - Unknown level

COMMENTS: This variable is used to document each of the level(s) of spinal fusion or instrumentation. For a single fused motion segment injury, such as a C5-6 anterior fusion and plating, both the cephalic and caudal of the two adjacent vertebrae are identified and separated by a dash (-). The prefix “v” references the fact that we are referring to a spinal column level (vertebral level) and helps distinguish the spinal column injury level from the neurological level. The cervical region is represented by vC00-vC07. The occiput is considered to be the most cephalic vertebral level and is designated by vC00. The thoracic region is represented by vT01-vT12.

The lumbar region is represented by vL01-vL05. The sacrum is considered to be the most caudal vertebral level and is designated by vS01-vS05. When the specific spinal column level is not known, however the spinal region (cervical, thoracic, lumbar, and sacral) is known then the regions may be represented by vC99, vT99, vL99, and vS99 for cervical, thoracic, lumbar and sacral respectively. When both the spinal column level and the region of the spine are not known, then these levels are documented as vX99. Where there are multiple spinal column injuries, separate entries will be completed for each level of spinal column injury.

Figure 1: This patient has sustained multiple closed injuries of the cervical spine. In addition to the Type II odontoid fracture, there are fractures of the C5 and C6 facet joints with a subluxation at both the C5-6 and C6-7 levels.



Through a single anterior incision (started February 6, 2010 at 16:30 hrs and finished at 22:45 hrs) this patient underwent anterior stabilization of the C2 fracture with screw fixation and anterior discectomies; direct decompression by means of the resection of the posterior longitudinal ligament and posterior annulus; and stabilization from vC5 to vC7. The patient afterwards wore an external orthosis for 6 weeks. This would be coded as follows:

Intervention/procedure date and start time:

2010/02/06; 16:30 hrs Unknown

Non-surgical bed rest and external immobilization:

- No
- Enforced bed-rest
- External immobilizing device
- Both enforced bed-rest and external immobilizing device
- Unknown

Spinal intervention - closed manipulation and/or reduction of spinal elements:

- No
- Yes
- Unknown

Surgical procedure - approach:

- No
- Anterior open surgical procedure
- Posterior open surgical procedure
- Both anterior and posterior open surgical procedures
- Unknown

Date and time of the intervention completion or surgical closure:

2010/02/06; 22:45 hrs Unknown

If an open surgical approach was performed (anterior, posterior, or both anterior and posterior), fill in the data elements below.

Surgical procedure – open reduction:

- No
- Yes
- Unknown

Surgical procedure – direct decompression of neural elements:

- No
- Yes
- Unknown

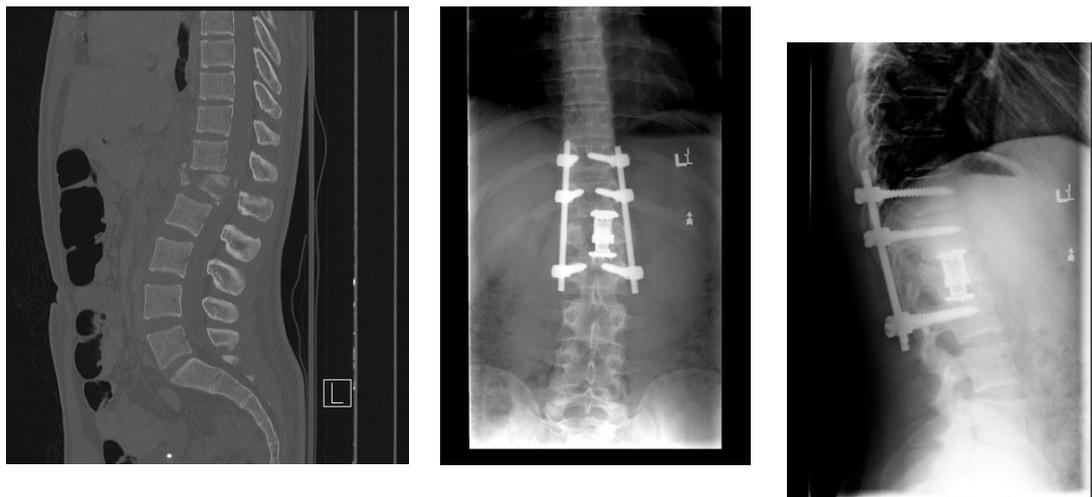
Surgical procedure – stabilization and fusion: (one to be filled in for each level of injury, starting with the most cephalic injury):

Stabilization and Fusion – Segment Number: 1
Stabilization and Fusion – Segment Level: vC02
Stabilization and Fusion – Segment Number: 2
Stabilization and Fusion – Segment Level: vC05 – vC07

vC00-vC07-Cervical (C0-C07)
vT01-vT12-Thoracic (T1-T12)
vL01-vL05-Lumbar (L1-L5)
vS01-vS05-Sacral (S1-S5)

vC99-Unknown Cervical (C0-C07)
vT99-Unknown Thoracic (T1-T12)
vL99-Unknown Lumbar (L1-L5)
vS99-Unknown Sacral (S1-S5)
vX99-Unknown Level

Figure 2: This patient has sustained an L1 burst fracture without ligament injury.



The fracture was stabilized (started June 26, 2011 at 23:00 hrs and ended the following day at 04:30 hrs) through a posterior approach with fixation between vT11 and vL2 and then a subsequent anterior vertebral body resection (corpectomy) with direct decompression of the neural elements. Anterior stabilization with a cage was performed. No bed-rest or external immobilization was prescribed.

Intervention/procedure date and start time:

2011/06/26; 23:00 hrs Unknown

Non-surgical bed rest and external immobilization:

- No
- Enforced bed-rest
- External immobilizing device
- Both enforced bed-rest and external immobilizing device
- Unknown

Spinal intervention - closed manipulation and/or reduction of spinal elements:

- No
- Yes
- Unknown

Surgical procedure - approach:

- No
- Anterior open surgical procedure
- Posterior open surgical procedure
- Both anterior and posterior open surgical procedures
- Unknown

Date and time of the intervention completion or surgical closure:

2011/06/27; 04:30 hrs Unknown

If an open surgical approach was performed (anterior, posterior, or both anterior and posterior), fill in the data elements below.

Surgical procedure – open reduction:

- No
- Yes
- Unknown

Surgical procedure – direct decompression of neural elements:

- No
- Yes
- Unknown

Surgical procedure – stabilization and fusion: (one to be filled in for each level of injury, starting with the most cephalic injury):

Stabilization and Fusion – Segment Number: 1

Stabilization and Fusion – Segment Level: vT11 – vL2

vC00-vC07-Cervical (C0-C07)

vT01-vT12-Thoracic (T1-T12)

vL01-vL05-Lumbar (L1-L5)

vS01-vS05-Sacral (S1-S5)

vC99-Unknown Cervical (C0-C07)

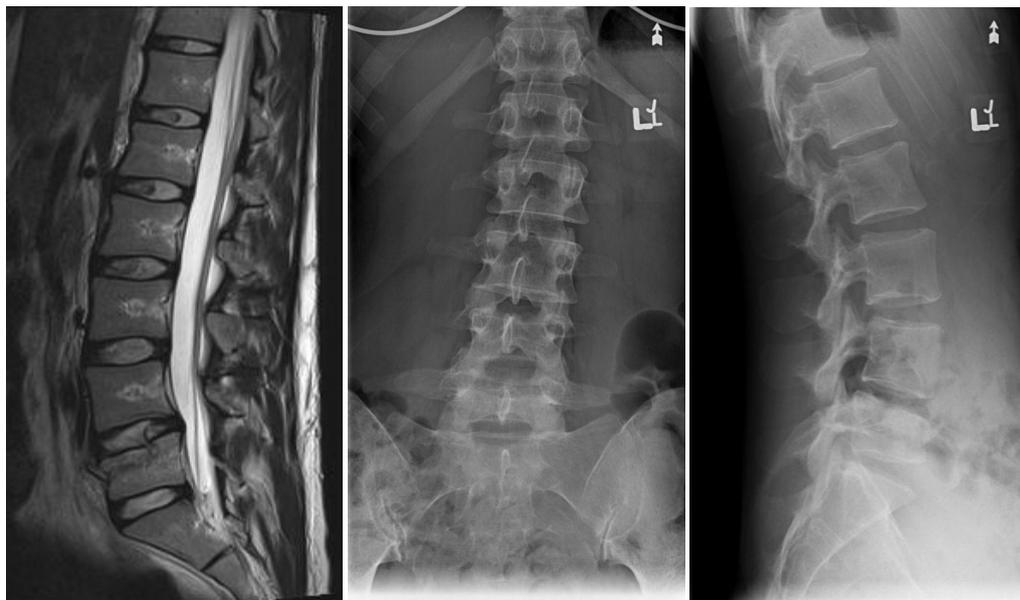
vT99-Unknown Thoracic (T1-T12)

vL99-Unknown Lumbar (L1-L5)

vS99-Unknown Sacral (S1-S5)

vX99-Unknown Level

Figure 3: This female fell August 15, 2012 off a balcony landing on her buttocks. She sustained an L5 burst fracture and was the same day treated with bedrest until September 5, 2012, and then gradual mobilization without a brace or orthosis. She did not have surgery.



Intervention/procedure date and start time:
 2012/08/15; time unknown Unknown

Non-surgical bed rest and external immobilization:
 No
 Enforced bed-rest
 External immobilizing device
 Both enforced bed-rest and external immobilizing device
 Unknown

Spinal intervention - closed manipulation and/or reduction of spinal elements:
 No
 Yes
 Unknown

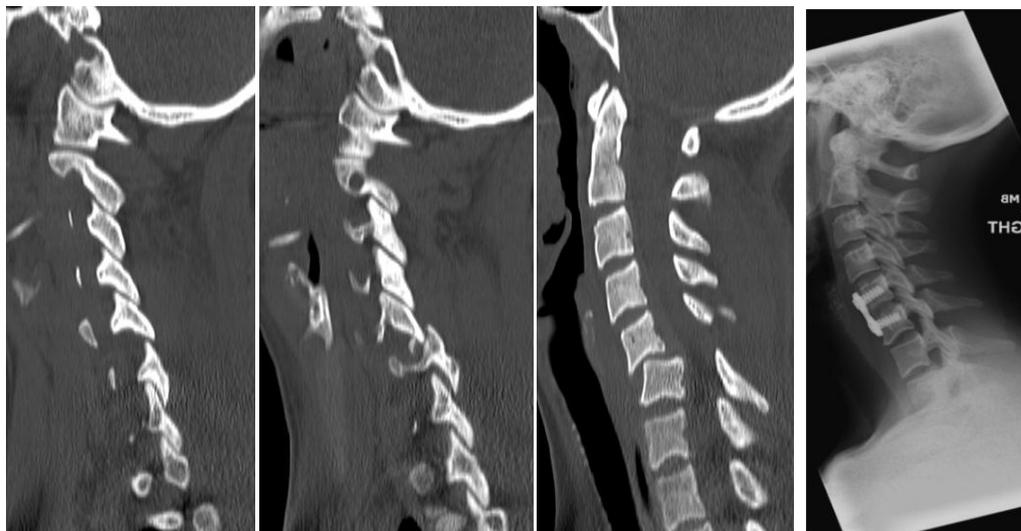
Surgical procedure - approach:
 No
 Anterior open surgical procedure
 Posterior open surgical procedure
 Both anterior and posterior open surgical procedures
 Unknown

Date and time of the intervention completion or surgical closure:
 2012/09/05; time unknown Unknown

If an open surgical approach was performed (anterior, posterior, or both anterior and posterior), fill in the data elements below.

Surgical procedure – open reduction:
 No

Figure 4: This patient sustained January 10, 2013 a cervical dislocation at C5-6 as a result of a high-speed motor vehicle accident. Initial treatment involved a closed reduction using tong traction in emergency (22:30 hrs -23:30 hrs). Subsequent surgery was performed the next day (08:00 hrs – 12:00 hrs), with no bed-rest or external immobilization prescribed.



Intervention/procedure date and start time:

2013/01/10; 22:30 hrs Unknown

Non-surgical bed rest and external immobilization:

- No
- Enforced bed-rest
- External immobilizing device
- Both enforced bed-rest and external immobilizing device
- Unknown

Spinal intervention - closed manipulation and/or reduction of spinal elements:

- No
- Yes
- Unknown

Surgical procedure - approach:

- No
- Anterior open surgical procedure
- Posterior open surgical procedure
- Both anterior and posterior open surgical procedures
- Unknown

Date and time of the intervention completion or surgical closure:

2013/01/10; 23:30 hrs Unknown

If an open surgical approach was performed (anterior, posterior, or both anterior and posterior), fill in the data elements below.

Surgical procedure – open reduction:

- No
- Yes

Surgical procedure – direct decompression of neural elements:

- No
- Yes
- Unknown

Surgical procedure – stabilization and fusion: (one to be filled in for each level of injury, starting with the most cephalic injury):

Stabilization and Fusion – Segment Number: 1

Stabilization and Fusion – Segment Level: vC05 – vC06

vC00-vC07-Cervical (C0-C07)

vT01-vT12-Thoracic (T1-T12)

vL01-vL05-Lumbar (L1-L5)

vS01-vS05-Sacral (S1-S5)

vC99-Unknown Cervical (C0-C07)

vT99-Unknown Thoracic (T1-T12)

vL99-Unknown Lumbar (L1-L5)

vS99-Unknown Sacral (S1-S5)

vX99-Unknown Level

Glossary of Terms

Open Surgical Procedure: A surgical procedure that requires an incision made in the skin through which the spinal elements are visualized. Includes percutaneous stabilization techniques where screws and rods are inserted through the incisions.

Spinal Intervention: A therapy applied specifically to the acutely injured spinal column that may involve one or several of the following; manipulation; realignment; application of skeletal fixation devices (tongs, pins, halo rings, etc.); and/or the application of traction to the spinal column. Includes periods of bed-rest over ten days when prescribed specifically to allow injuries to 'stabilize'.

Closed Manipulation or Reduction: The application of a longitudinal force to the spine (traction) usually applied by means of a halter (straps under the occiput and chin) or through skeletal pins, halo rings, or tongs. Traction may be direct by means of application of weights or direct forces or may be gravity dependent when the patient's body weight is used on a tilting table or bed to apply the traction. Some controlled movement of the neck may be performed in a cognitively intact patient with the attempt to manipulate dislocated or mal-aligned vertebrae back into a more normal anatomical alignment.

Laminectomy: The removal of bone fragments dorsal to the spinal cord, lamina, or other foreign body at the site of spinal cord damage through a dorsal (or posterior) approach.

Corpectomy/Discectomy: The removal of vertebral body bone and/or disk fragments, blood clots, or foreign bodies (such as bullet fragments) that are located ventral (or anterior) to the spinal cord. May be performed from either a posterior (dorsal) or an anterior (ventral) surgical approach or both.

Spinal Stabilization: The attachment of rods, plates, wires, screws etc. to the spine (individually or in combination) to provide internal surgical stabilization of the spinal column. This may be performed through either an anterior or a posterior approach or both. The addition of a bone graft to the vertebrae for the purpose of achieving intervertebral fusion or stability is sometimes performed and is included but not specified in this variable.