# Spine Trauma Outcome Measures for Patients and Clinicians

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# Spine Trauma Outcome Measures for Patients and Clinicians

**Uitkomstmaten bij Traumatische Wervelletsels voor Patiënten en Behandelaars**
(met een samenvatting in het Nederlands)

**Proefschrift**

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**Said Sadiqi**
geboren op 1 juli 1988
te Kabul, Afghanistan

**Promotoren** prof. dr. F.C. Oner
prof. dr. M.W.M. Post

**Copromotor** dr. J.J. Verlaan

*To my parents*

## Contents

# Chapter 1

## Introduction, Aims and Outline of this Thesis

# INTRODUCTION

## Quality of care

While treating their patients, healthcare professionals take the quality of care into account. They are keen on, as well as expected to, providing the highest possible quality of care. This concept of quality of care consists of three main components, i.e. 'structure', 'process' and 'outcome'.[1] More recently, the concept of value-based healthcare has emerged, in which the outcomes of interest are those that reflect 'value', i.e. the ratio between the patient-relevant benefits and costs of medical care.[2,3] Measurement of outcomes is relevant in clinical trials as well as in routine clinical practice. In this respect, it is imperative to realize that there is not a single 'objective' outcome, and that the outcome measurement instruments should reflect the different and potentially conflicting standpoints such as the perspectives of the patient, treating physician, care-payer and society. The so-called routine outcomes measurement could contribute to these perspectives in different ways:

- Patients would be able to follow their degree of recovery over time, as well as gain insight in their treatment results;
- Treating physicians could monitor the effectiveness of a specific intervention;
- From care-payer's perspective the (cost-)effectiveness of the provided care could be assessed;
- And finally, as example from the society, data could be provided between various institutions for quality improvement purposes.

The latter has been shown to have potential to improve health care's value.[4] While randomized controlled trials (RCTs) are not yet performed, not available, or even not applicable for many interventions, routine outcomes measurement should be used to increase our knowledge on the effectiveness and efficiency of the provided treatments. Unfortunately, in the field of spine trauma the assessment of the quality of care is not optimal, as is reflected by the longstanding controversies.

## Longstanding controversies

Spine trauma remains a global public health concern, in terms of both care and costs. The influence of spine injuries on individuals' social, functional, and financial situation is more significant than most other traumatic injuries. A subset of spine-injured patients is dealing with an associated neurologic injury, which can contribute to substantial disability with long-term consequences and considerable associated health-care-related costs.[5-8] Epidemiological studies have reported annual incidences of traumatic spine fractures between 19 and 88 per 100,000 population.[9,10] The estimated global incidence-rate of traumatic spinal cord injury (TSCI) is reported as 23 per million, with a worldwide variation of 3.6 per million (Canada) to 195.4 per million (Ireland).[11,12] The annual incidence of TSCI in the Netherlands is estimated as 14.0 per million.[13]

A number of longstanding controversies exist in the field of spine trauma care, both for patients with, without or resolving neurologic deficits.[14-21] The persistent controversies could be summarized in six areas:

- The role and timing of medical and surgical interventions for patients with associated neurologic injury;
- Type and timing of surgical stabilization for multiply injured patients;
- The role of nonsurgical versus surgical treatment;
- The role of different surgical approaches and techniques;
- Methods of nonoperative management;
- Care of elderly patients with concurrent complex disorders.

These areas are discussed in detail in a recent Focus Issue article on spine trauma.[22] In short, at this time there are no definitive guidelines regarding surgical or non-surgical management of spine injuries in the cervical and thoracolumbar spine where there is minimal risk of secondary neurologic deterioration or high propensity for progressive deformity (e.g., odontoid fractures of the elderly and type A burst fractures (AOSpine Thoracolumbar Spine Injury Classification System Subtype A3 and A4) without associated neurologic or posterior tension band injuries (type B)).[23] It is not clear yet in which of these patients a surgical intervention might be cost-effective. Even when the care provider has made a decision on either non-surgical or surgical treatment, there also remains controversy on which specific treatment should be performed.

One of the reasons for these persistent controversies is the lack of specifically designed and validated outcome measurement instruments for spine trauma patients. Measurement of outcomes regarding various treatment options using validated outcome instruments that are specifically designed for spine trauma patients may lead to improvements in the quality of provided care.

**Measurement of outcomes in general**

Historically the primary model for the concept of outcome measurement in medicine was mortality. Mortality is a simple, objective and noncontroversial binary (dead or alive) outcome measure. However, when mortality is not (or no longer) the main issue due to improvements in emergency care and life-sustaining techniques, what could serve as a meaningful outcome and how this outcome should be measured becomes a subject of dispute. In the case of trauma, the greater majority of patients do survive traumatic events, which makes different outcome measurements increasingly important, as well as difficult.

Various types of outcome measures exist. One distinction is that between generic versus disease-specific outcome instruments. Generic measurement tools can be used to measure general health outcomes, and provide normative data from general population that allow for demographically adjusted comparisons between populations. On the other hand, disease-specific tools are designed to measure certain parameters that are considered important for a specific condition.

The so-called 'single parameter' outcomes are often part of commonly used generic or disease-specific outcome instruments, but they are also applied independently to measure a single parameter as the outcome. This type of outcome measurement, such as measuring return to work (RTW), return to home, or independency in activities of daily living, has also been implemented as a way to expedite the outcome assessment process. RTW is a significant and interesting single-parameter item as it is both important from the patient's perspective as well as from the perspective of the society.[24,25]

Outcome measures could also be stratified as tools to measure the outcomes from either the patients' or clinicians' perspective. Patient-reported outcome measures (PROMs) have become very popular in health care, as they are meant to reflect purely the patient's perspective on the impact of disease and its treatment on health status and daily functioning.[26] These self-reported measures are useful in many ways, such as determining whether treatments are doing more good than harm, or for assessing whether health and quality of life are improving or worsening.

The concept of clinician-reported outcome measurement is already known in several medical areas, among others those in which patients are not able to report on their health status. Examples of such patient populations with diminished insights include central nervous system diseases (e.g. schizophrenia, Alzheimer, and depression), traumatic brain injury or stroke.[27] In spine trauma care, a clinician-reported outcome measure is also required because of the possible discrepant views when comparing patients' to clinicians' perspective. These evaluations by the clinician may differ substantially from the patient's perception, e.g. MRI findings compared to outcomes measured by PROMs.[28,29] Such discrepant views have also been shown for a variety of other disease, e.g. rheumatoid arthritis, multiple sclerosis, and prostate cancer.[30-32]

**Challenges in spine trauma**

Several challenges arise when instruments are intended to be used for the measurement of outcomes in spine trauma patients, and several distinguishing characteristics of spinal trauma patients need to be considered.

First, the absence of individualized pre-injury baseline data brings methodological obstacle specific to trauma outcome. In reflection to this dilemma, population-wide normative data, which is collected by surveys, could be used representing trauma patients as a random sample of their society. Nevertheless, as the pre-injury physical, psychological, and general health-related characteristics of spine-injured patients may very well deviate from those of the general population, there is an acknowledged lack of baseline or pre-injury measurement.[33,34] The relatively high amount of interpersonal variability in normative functioning and health-related quality of life (HRQoL) makes individualized baseline data preferable.

In contrast to many other subacute or chronic conditions, in this case the ideal outcome is recovery of previous level of function. In general, acute trauma patients typically

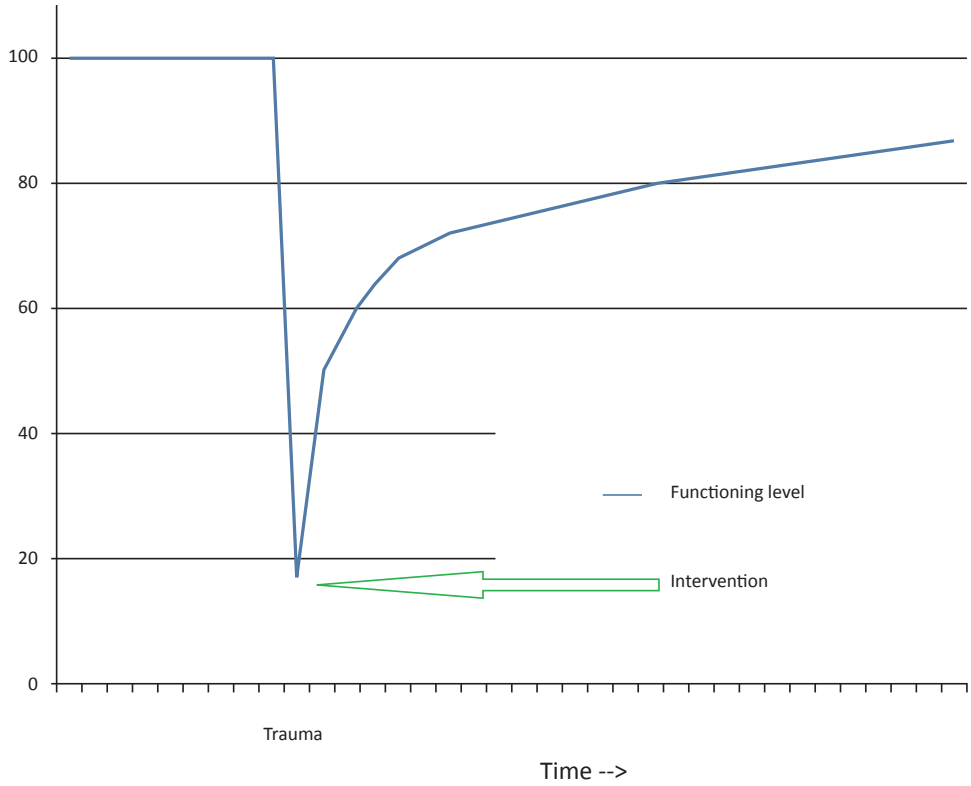


***Figure 1.*** Schematic drawing of a theoritical level of function of a spine trauma patient.

have a fairly high level of function in their pre-injury state, which suddenly falls to a low level due to the impact of trauma (Figure 1). The provided treatment aims to regain the pre-injury level of function. Patients with non-traumatic spine conditions typically have relatively low level of function at baseline, which is intended to be improved after intervention. Usually, when spine trauma patients return to their pre-injury environment upon discharge, they make an assessment of the amount and extent of restrictions they encounter in their daily living and professional activities. In this respect, a response scale that uniquely reflects the degree to which a spine trauma patient has returned to his or her pre-injury state of health and function is crucial. Currently, no such scale is available for this specific patient population.

Finally, it should be recognized that for traumatic spinal column injury patients without neurologic deficit somewhat different factors may be relevant when comparing to patients with severe neurologic deficit. This makes it very challenging, if not impossible, to use a single specific instrument to measure the outcomes of spine trauma patients with the complete spectrum of neurologic involvement patterns varying from no involvement to

subtle dysfunction to incomplete neurological injury to complete paralysis. Thus, in the field of spine trauma practically two different populations could be distinguished:

1. Patients with severe and persistent spinal cord or cauda equina injury who will have to deal with chronic conditions and require long-term rehabilitation,
2. Patients with no, mild, or transient neurological deficit who mainly deal with the acute and subacute phase after their injury while having the potential to recover completely.

**Present state of outcomes measurement in spine trauma**

Several initiatives have been established to collect, describe, and recommend instruments for outcome measurement in spine trauma. Nevertheless, most of them focus more specifically on SCI patients with severe or complete paralysis.

One of the initiatives was started in the first decade of this century by a group of international experts who reviewed measures based on a framework to describe and evaluate psychometric evidence. Various results were published in this effort, focusing on a variety of domains including participation and functional measures, and also neuroimaging.[35-38] Another initiative is the Common Data Element Project, which mainly focuses on standardization of data for clinical research purposes in neurological disorders and stroke. As a subset, a first set of Common Data Elements for use in SCI was developed by expert groups in 2012.[39] Because of the wide range of domains that are dealt with by SCI patients, many different measures were identified as relevant for individuals with SCI. Furthermore, the Canadian research collaboration Spinal Cord Injury Rehabilitation Evidence (SCIRE) project was initiated to cover a comprehensive set of topics relevant to SCI rehabilitation and community reintegration. As can be found at the online SCIRE outcome measurement page, an extensive amount of work was performed including descriptions of more than 100 measures which have been used in SCI studies.[40]

These initiatives show that an extensive amount of instruments are available or recommended in SCI. As a consequence, others have initiated the development of toolkits that aim to support clinicians and researchers with a selection of appropriate measures in a specific situation, e.g. the Participation and QoL (PAR-QoL) Toolkit.[41] The situation and selection of the measure(s) depends on the domain that is deemed most relevant:

- General function (examples of measures: Spinal Cord Independence Measure (SCIM) and Functional Independence Measure (FIM)) [36,42-44];
- HRQoL (e.g. Medical Outcome Study 36-item Short Form (SF-36))[45];
- Walking (e.g. Walking Index for Spinal Cord Injury (WISCI II))[46];
- Well-being and life satisfaction;
- Participation;
- Wheelchair mobility;
- Arm/hand function.

The aforementioned initiatives and projects show that the described or recommended outcome measures are mainly used in the rehabilitation setting and focus on the impact of severe neurologic function loss only, which makes them less suitable for use in patients with mild, resolving or no neurological deficits. A systematic literature review published in 2010 focused on the identification of outcome measures used in spinal column injuries with or without SCI.[44] The authors identified a total of 21 different outcomes measures used in spine trauma research, indicating that a wide range of patient- and clinician-reported instruments, which were not specifically designed and validated for this patient population, have been used to assess spine trauma outcomes.

The concept of clinician-reported outcome measurement is a very new concept in spine trauma care. Clinicians involved in the care of spine trauma patients already use similar concepts in their daily clinical practice without explicit and consistent definition. Suppose, a spine trauma patient is seen at the outpatient clinics several days or weeks after the initial treatment. The treating surgeon takes various clinical and radiological parameters into account to make a judgment on the progress of the treatment as well as to anticipate on any changes, which may require a change in the treatment plan. It is unknown which parameters are exactly taken into account by spine surgeons around the world. A simple and reliable clinician-reported outcome measure that formalizes the most relevant parameters to reflect the clinician's perspective adequately, and that is able to predict the course and clinical outcomes of spine trauma patients is lacking, Such a tool would facilitate a common language between clinicians across the world. It would also guide in treatment algorithms and provide a holistic view on patient's health status when used together with the disease-specific PROM. Furthermore, it would assist in documentation outcomes from the clinician's perspective. Finally, the tool would have the potential to enhance spine trauma research and provide data that could be used in comparative effectiveness analysis.

**Persistent issues**

Many outcome measures exist and there is no consensus on their use in spine trauma care. Although initiatives such as the SCIRE project and the PAR-QoL Toolkit may contribute to reduction of the ongoing confusion in spine trauma care and research, there is a real need for (further) standardization of outcomes measurement in this field. Currently, it is difficult, if not impossible, to adequately measure the effect size of various treatment options in a wide spectrum of spine injuries, which perpetuates the ongoing controversies related to the evaluation and optimal treatment of this patient population. Based on the abovementioned, several important issues persist in the concern of spine trauma:

- No specific outcome measurement instrument is specifically designed or validated for spinal column injury patients with only mild, transient or no neurological impairment, or one that can be applied to the total spectrum of neurological involvement (ranging from no neurological impairment to complete paralysis);

- No clinician-reported outcome measure is available for spine trauma patients, rather observer-reported outcomes, which only focus on severe spinal cord injured patient.

Thus, the measurement of the effectiveness of interventions on the outcomes of spine trauma patients should be addressed with one or more reliable instrument(s) that is sensitive to changes inherent in various treatment alternatives. In close collaboration with an international group of experts from the AOSpine, the AOSpine Knowledge Forum Trauma, it was decided to address this void by initiating a project to develop disease-specific outcome instruments for spine trauma patients. This Knowledge Forum consists of eight steering committee members who aim to improve the clinical practice by providing the best evidence for current practices, and formulate clinical studies in the domain of spine trauma.

## AIM OF THIS THESIS

With more individuals surviving serious trauma, the measurement of the effectiveness of interventions and the influence of spine injury on the health-related quality of life are becoming increasingly important. Outcome measures specifically designed and validated for spine trauma patients are imperative for these evaluations. However, the absence of such measures contributes to the present lack of consensus and ongoing controversies regarding the optimal treatment of many types of spine injuries. The aim of this Thesis is to describe the development of universal condition-specific outcome instruments for spine trauma. Because of the possible discrepancies when comparing outcomes from the patients' perspective to clinical and radiological assessments by the clinicians, two separate tools were developed: the Patient Reported Outcome Spine Trauma (AOSpine PROST), and the Clinician Reported Outcome Spine Trauma (AOSpine CROST).

## THESIS OUTLINE

This Thesis consists of two main sections. The first section (Chapters 3-7) describes the developmental process and initial validation of the AOSpine PROST. Chapter 2 introduces this section by a systematic literature review. The second section (Chapters 8-10) outlines the developmental process and validation of the AOSpine CROST. The aim of each chapter from both sections is described below.

As the basis for the development of the AOSpine PROST, we decided to use the systematic approach and methodology of the International Classification of Functioning, Disability, and Health (ICF) of the World Health Organization (WHO).[47-51] The bio-psycho-social perspective of the ICF relies on a globally accepted framework to describe and classify functioning, disability, and health in people with a variety of diseases, conditions, or health states. The ICF recognizes that problems in functioning can be understood and

described using different components: *body functions (b), body structures (s), activities and participation (d),* and *environmental factors (e)*. Personal factors such as age, gender, or habits are not yet categorized in the ICF. With 1454 categories hierarchically organized into different level of details, the ICF is comprehensive of all aspects of life and can be seen as a catalogue from which appropriate items can be chosen. ICF also proposes certain procedures to make the appropriate choices toward the development of a Core Set for a specific condition. In the developmental process, the initial focus was on patients sustaining injuries to their spinal column and excluding completely paralyzed and polytrauma patients.

Four different studies were conducted in the preparatory phase of the AOSpine PROST development. Three studies aimed to identify ICF categories relevant to measure the outcomes of traumatic spinal column injuries from different perspectives.

In **Chapter 2**, the research perspective is investigated by a systematic literature review in which the patient-reported and clinician-based outcome measures most frequently used to evaluate the function and health of spine trauma patients are evaluated. The contents of the identified measures are linked to the ICF using established linking rules.[52,53]

In **Chapter 3**, the expert perspective is explored through an international cross-sectional web-based survey among 150 experienced spine trauma surgeons from all world regions.

In **Chapter 4**, the patient perspective is investigated in an international cross-sectional empirical study, including 187 traumatic spinal column injury patients from 9 trauma centers in 7 countries.

In **Chapter 5**, in a preliminary validation study we investigate various question and response formats not only for their validity and reliability but also the degree to which they are understandable for spine trauma patients, thus enabling them to accurately compare their current level of function and health with their pre-injury state.

The results of these four studies create the necessary background for an international consensus conference during which a selection of core ICF categories and response scale could be decided on for universal outcome measurement in this specific patient population. The outcome of the consensus process is described in **Chapter 6**.

The transition of somewhat abstract ICF categories to specific items of the AOSpine PROST, and the integration of those items into the selected response scale, as well as the results of a pilot study of the first draft of the Dutch version among a representative sample of 25 patients with spinal column injury are presented in **Chapter 7**.

**Chapter 8** is the start of the second section, which focuses on the development and validation of the AOSpine CROST. In this chapter, an international expert survey explores the perspective of a worldwide sample of spine surgeons on relevant clinical and radiological parameters when evaluating clinical and functional outcomes of subaxial cervical spine trauma patients.

In **Chapter 9**, we report on the identification of the parameters that spine surgeons consider to be relevant when evaluating clinical and functional outcomes of patients sustaining a traumatic injury to the thoracic and lumbar spine.

In **Chapter 10**, it is investigated whether wide variations are seen in the measurement techniques preferred by spine surgeons around the world to assess traumatic fracture kyphosis and vertebral body height loss in both the thoracolumbar spine and the cervical spine. This is important for the nomenclature of the parameters of the AOSpine CROST tool.

This Thesis concludes with the third section (**Chapters 11 and 12**), which includes a general discussion and future perspectives, as well as a final general summary.

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# Chapter 2

## Toward the development of a universal outcome instrument for spine trauma: a systematic review and content comparison of outcome measures used in spine trauma research using the ICF as reference

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## ABSTRACT

*Study Design.* Systematic literature review

*Objective. 1*) To identify patient reported and clinician based outcome measures most frequently used to evaluate the function and health of spine trauma patients, 2) to identify and quantify the concepts of these measures using the ICF as reference, and 3) to describe their clinimetric properties.

*Summary of Background Data.* There is a real need for a disease specific outcome instrument to measure the effect size of various treatment options in a variety of traumatic spinal column injuries.

*Methods.* A systematic literature search was conducted in several databases. From the included studies, outcome measures were extracted. The items and underlying concepts of the identified outcome measures were specified and linked to the ICF categories. Finally, as far as available in literature, the clinimetric properties of the obtained measures were analyzed.

*Results.* Out of 5117 screened references, 245 were included, and 17 different frequently used outcome measures were identified. Meaningful concepts of the items and response options of the retrieved outcome measures were linked to a total of 105 different ICF categories, aggregated to 57 first- or second-level categories. The categories were linked to the components *activities and participation* (n=31), *body functions* (n=17), *environmental factors* (n=8), and *body structures* (n=1). Overall, there is only limited evidence on the measurement properties, except for some disease specific questionnaires, such as ODI, RMDQ, NDI, and CSOQ.

*Conclusions.* The current systematic literature review revealed great diversity in the use and content of outcome measures to evaluate the functioning and health of spine trauma patients, with 17 different outcome measures linked to 57 unique ICF categories. This study creates an evidence base for a consensus meeting during which a core set of ICF categories for outcome measurement in spine trauma will be decided.

## INTRODUCTION

Traumatic spinal column injuries represent only a minority of all fractures, with a reported incidence of 4.6% to 23.2% in different epidemiological studies.[1-3] However, their influence on individuals' social, functional and financial situation is more significant than other injuries as they may contribute to disability with long-term consequences and associated health related costs.[4,5] As more individuals survive serious trauma, the measurement of the effectiveness of interventions on their outcome with a reliable instrument that is sensitive to changes inherent in various treatment alternatives is becoming increasingly important.[1,6,7] However, in the absence of a validated disease specific outcome instrument, a wide range of tools have been extensively used, including generic outcome measures and instruments designed for the assessment of spine patient populations that bear little resemblance to the spine trauma population (e.g. chronic degenerative back-pain and poly-trauma patients).[8,9] Therefore, there is a real need for a disease specific outcome instrument to measure the effect size of various treatment options in a variety of traumatic spinal column injuries.

The AOSpine Knowledge Forum Trauma decided to address this void by initiating a project to develop and validate disease specific outcome instruments for spine trauma patients, that include both the patients' and health professionals' perspective.[10] In the developmental phase and initial validation of the patient reported part of this outcome instrument, completely paralyzed and poly-trauma patients were not included in order to focus on a well-defined patient population with spinal column trauma as the primary diagnosis. We chose to use the systematic approach of the International Classification of Functioning, Disability, and Health (ICF) of the World Health Organization (WHO)[11-13] as the basis for the development of this patient reported outcome.[14] With its 1454 categories, the ICF is a comprehensive and universally accepted framework to describe and classify individuals' functioning, disability and health. The classification is organized into the components *body functions (b), body structures (s), activities and participation (d)* and *environmental factors (e).* Personal factors as age, gender or habits are not yet categorized in the ICF. As a classification system, the ICF provides alphanumeric codes for each of the ICF categories or functioning domains, arranged in a hierarchical fashion in different levels (see Figure 1).

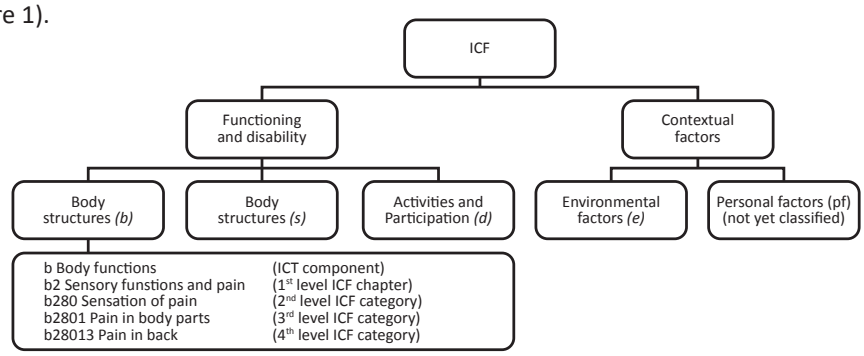


***Figure 1.*** The bio-psycho-social structure of the International Classification of Functioning, Disability and Health (ICF), along with an example of the hierarchical fashion in different levels.

The preparatory phase of this project focuses on identifying the most relevant ICF categories for spine trauma patients from three different perspectives. Beside the patient and expert perspective,[15,16] it is crucial to include the research perspective by identifying the outcome measures most frequently used in spine trauma research and the concepts covered by these measures. Therefore, the main objective of this systematic review was to evaluate the outcome measures used in spine trauma research. Specifically we sought (1) to identify patient reported and clinician based outcome measures most frequently used to evaluate the function and health of spine trauma patients, (2) to identify and quantify the concepts of these measures using the ICF as reference, and (3) to describe their clinimetric properties.

## MATERIALS AND METHODS

### Study design

This study was performed in four steps.[17] First, a systematic literature search was conducted in several databases. Second, outcome measures were extracted from the included studies. Third, the items and underlying concepts of outcome measures cited in at least five articles were specified and linked to the ICF categories. Finally, as far as available in literature, the clinimetric properties of the obtained measures were analyzed.

### Search strategy and inclusion criteria

An electronic search was conducted in MEDLINE, EMBASE, Web of Science and Cochrane Central for literature published between January 2000 and June 2013, limited to human studies. The areas of search along with the associated search terms are listed in Table 1. The exact search strategies varied across databases and can be retrieved from the corresponding author. References were managed with Reference Manager Version 11.

The retrieved references were screened and assessed for eligibility by two reviewers (ML and WJ) independently, according to the selection criteria described in Table 2. Full text articles were obtained if eligibility could not be determined from the title and abstract. If no full-text article was available, the corresponding author was contacted. Any disagreement on the inclusion or exclusion of a full-text article was resolved by discussion. If no consensus could be reached between the two reviewers, a third reviewer (FCO) was consulted.

### Data extraction

Information concerning the included studies, patients, treatments and outcome measures was gathered using a pre-developed electronic form. Data extraction was performed by one reviewer (ML) and checked by a second reviewer (WJ); data extraction of Chinese papers was performed by a Chinese reviewer from another author's (MF) institution. Disagreements were again resolved by consensus.

**Table 1.** The areas of search and the associated search terms

| Area | Search terms |
|---|---|
| Spinal trauma | ("Fractures, Bone"[Mesh] OR "Fractures, Compression"[Mesh] OR "Spinal Fractures"[Mesh] OR trauma[tiab] OR fracture[tiab] OR fractures[tiab]) AND ("Spine"[Mesh] OR vertebral[tiab] OR Spine[tiab] OR spinal[tiab]) |
| Outcome assessment | (questionnaire[tiab] OR rating[tiab] OR score[tiab] OR scale[tiab] OR "Outcome Assessment (Health Care)"[Mesh] OR outcome[tiab] OR "functioning"[tiab] OR "Disability Evaluation"[Mesh] OR "disability"[tiab] OR "functional assessment"[-tiab] OR "quality of life"[tiab] OR "Quality of Life"[Mesh]) |
| Human | NOT (Animal NOT human) |
| Study types | ("Clinical Trials as Topic"[Mesh] OR "Controlled Clinical Trial"[Publication Type] OR "Clinical Trial, Phase IV"[Publication Type] OR "Clinical Trial, Phase III"[Publication Type] OR "Clinical Trial, Phase II"[Publication Type] OR "Clinical Trial, Phase I"[Publication Type] OR "Randomized Controlled Trial"[Publication Type] OR "Clinical Trial"[Publication Type] OR "Clinical Trials, Phase I as Topic"[Mesh] OR "Cross-Over Studies"[Mesh] OR "Cohort Studies"[Mesh] OR cohort[tiab] OR "Cross-Sectional Studies"[Mesh] OR "case series"[tiab] OR "follow-up"[tiab] OR "Epidemiologic Studies"[Mesh] OR "Case-Control Studies"[Mesh] OR "case control"[tiab] OR "case-control"[tiab]) |

**Linking to the ICF**

In the next step, the patient reported and clinician based outcome measures cited in at least five articles were further analyzed. Questionnaires as well as single items on functioning and health were included. Outcome measures already linked for other core set projects were obtained from the ICF Research Branch[18]. In addition, if necessary, outcome measures were obtained by reference checking or Internet searches.

The content of the measures was translated to the universal classification framework of the ICF, according to established and updated linking rules.[19,20] Within each item and response option of the included outcome measures, meaningful concepts were identified and linked to the most precise ICF category. The so-called "other specified" and "unspecified" ICF categories were not used, but a lower level category was assigned instead. Meaningful concepts that could not be linked to the ICF were classified as follows: "not definable" (nd) if the information provided by the concept was not sufficient to make a decision about the most precise ICF category, "health condition" (hc) if the concept referred to a diagnosis or health condition, "personal factor" (pf) if the concept was clearly a personal factor, and "not covered" (nc) if the aforementioned criteria did not apply and the concept was not contained in the ICF.

Linking was performed independently by two researchers trained in the principles of the ICF and linking rules (ML and SS). Any inconsistencies in the linked categories were resolved by discussion, otherwise a third reviewer (FCO or MP) was consulted to reach consensus.

**Table 2.** Eligibility criteria

| |
|---|
| Inclusion criteria:<br>Full text article published in a peer reviewed journal<br>1 describing a primary study (randomized clinical trial, controlled clinical trial, observational study, qualitative study or multiple case-reports/series)<br>2 included at least 10 patients aged 18 years or over<br>3 suffering from acute traumatic injury to the spinal column as main diagnosis, and<br>4 used at least one patient reported or clinician based outcome measure focusing on functioning, disability or health as defined by the ICF |
| Exclusion criteria:<br>1 Studies with more than 50% of the spinal trauma patients suffering from:<br>• complete paralysis (ASIA impairment grade A or B) postoperatively,<br>• poly-trauma (ISS >15),<br>• traumatic spinal cord injury without vertebral fractures, or<br>• non-traumatic injuries like pathological or osteoporotic fractures<br>2 Studies unclear about the target population or studies with exclusively clinical, laboratory or radiographic measures were excluded as well. |

ASIA= American Spinal Injury Association
ISS= Injury Severity Score

**Data analysis**

Characteristics of the included articles were analyzed using descriptive statistics. Absolute frequencies of the included outcome measures and linked ICF categories were calculated, along with their frequencies relative to the total number of articles. ICF categories assigned repeatedly within a single outcome measure were counted only once to avoid bias. In line with similar studies published in the literature, concepts linked to third- or fourth-level ICF categories were aggregated to the second level.

**Clinimetric properties**

Clinimetric properties of the outcome measures were defined as validity properties (content, criterion and construct validity, and internal consistency), reproducibility, and usability (responsiveness, floor and ceiling effects, and interpretability).[21] These were identified in an additional structured literature search in multiple databases (Medline and Web of Science), reference lists, and citation tracking of included articles. Also primary publications and available websites were searched for any included measures. The predefined search and selection criteria can be retrieved from the corresponding author. The clinimetric properties of the included measures were evaluated with the ''quality criteria for measurement properties of health status questionnaires" by Terwee et al.[21]

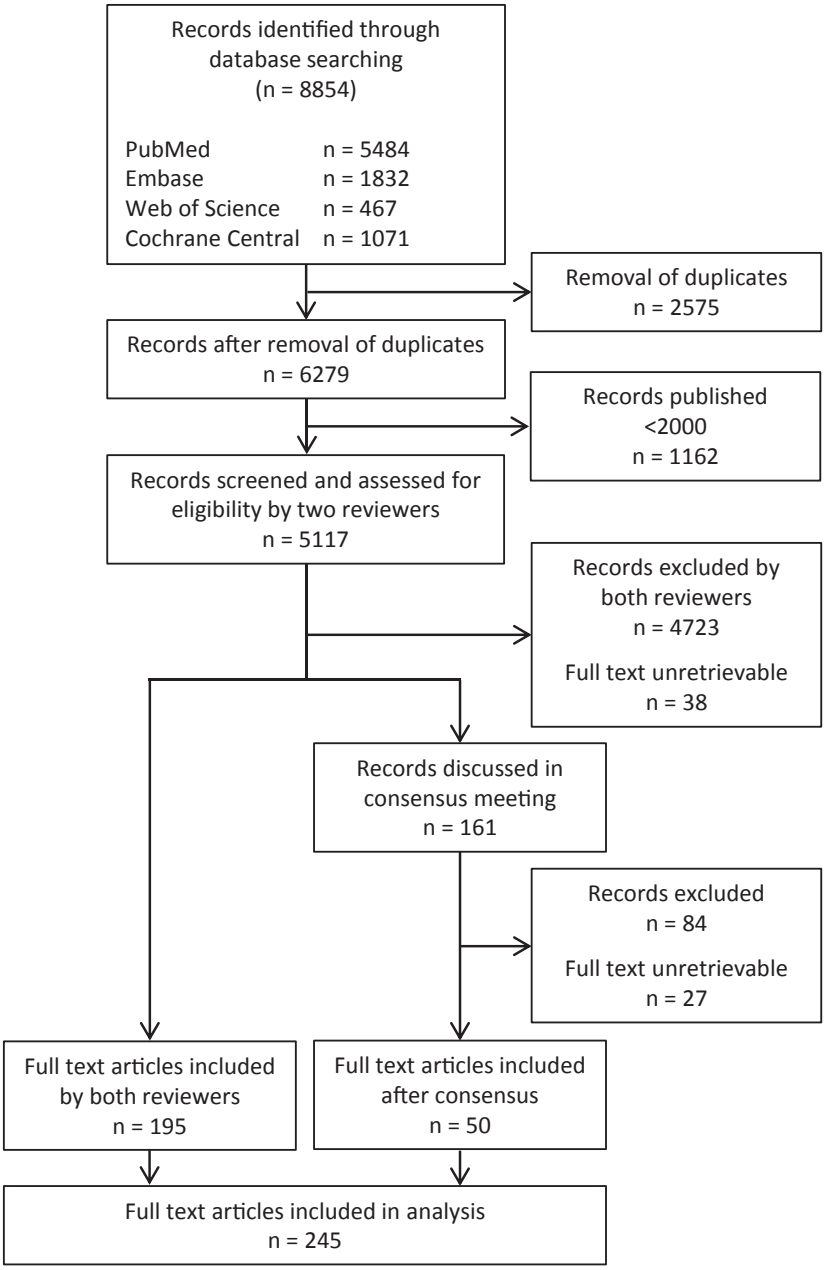


***Figure 2.*** The search and selection process.

## RESULTS

### Literature search and study characteristics

The results of the search and selection process are outlined in Figure 2. The search strategy identified 5117 unique references, of which 245 (4.8%) met the eligibility criteria, including 27 non-English articles. As shown by Table 3, most of these articles were published by authors from Europe (50.6%) and Asia Pacific (31.8%). Over 80% of the studies had an observational design, whereas the total number of retrospective and prospective studies was comparable. Furthermore, the majority of the studies focused on thoracic and lumbar fractures (78.0%) and outcomes after surgical treatment (71.4%).

### Overview of measures

In total, 17 different outcome measures were cited in at least five articles to assess functioning and health outcomes after spine trauma and retrieved for content analysis.

These 17 measures are listed in Table 4, along with a brief description and the overall absolute and relative frequencies. Results are also stratified by fracture level and treatment type. A variety of disease specific questionnaires were identified, including five questionnaires developed for the thoracic and lumbar spine (Oswestry Disability Index (ODI),[22] Visual Analogue Scale Spine Score (VASSS),[23] Roland Morris Disability Questionnaire (RMDQ),[24] Low Back Outcome Scale (LBOS),[25] Prolo Scale (PS)[26] and two measuring neck specific disability (Cervical Spine Outcome Questionnaire (CSOQ),[27] and Neck Disability Index (NDI)[28]. Six dimension specific outcomes were included: the Denis Pain Scale (DPS),[29] Denis Work Scale (DWS)[29] and various single item scales to assess pain (Pain), satisfaction (Satisfaction), ability to participate in recreational activities (Recreation), and return to work (RTW). In addition, three clinician based outcome measures were identified: two neurological classifications represented by the Frankel Scale (FS),[30] and ASIA Impairment Scale (AIS)[31] and the back disability specific Hannover Spine Score (HSS)[32]. Finally, only one generic questionnaire (SF-36)[33] was identified.

Overall, pain was the most frequently used outcome parameter (34.5%), followed by the neurological classifications FS (28.7%) and AIS (24.1%), and a disease specific questionnaire. Of the disease specific outcome questionnaires, the NDI and ODI were most frequently applied to assess outcomes of cervical, and thoracic and lumbar spine trauma respectively.

### ICF categories

Meaningful concepts of the items and response options of the retrieved outcome measures were linked to a total of 105 different ICF categories, aggregated to 57 first- or second-level categories. The frequency of these categories relative to the total number of articles is illustrated by Table 5. Note that the content of the single item 'Satisfaction Scale' was not covered by the ICF and coded as "nc". The 57 categories were linked to the components

**Table 3.** Study characteristics (n=245)

| | |
|---|---|
| AOSpine world region, n (%): | |
| Asia Pacific | 78 (31.8) |
| Europe | 124 (50.6) |
| Latin America | 7 (2.9) |
| Middle East | 4 (1.6) |
| North America | 32 (13.1) |
| Study type, n (%): | |
| Retrospective | 109 (44.5) |
| Retrospective and prospective follow-up | 23 (9.4) |
| Prospective observational | 84 (34.3) |
| Prospective RCT/CCT | 29 (11.8) |
| Spinal level, n (%): | |
| C | 47 (19.2) |
| CTL | 7 (2.9) |
| TL | 191 (78.0) |
| Treatment type, n (%): | |
| Conservative | 28 (11.4) |
| Surgical | 175 (71.4) |
| Both | 42 (17.1) |

RCT=Randomized Controlled Trial; CCT= Controlled Clinical Trial
C= cervical spine; TL=thoracic and lumbar spine; CTL=cervical, thoracic, and lumbar spine

*activities and participation* (n=31), *body functions* (n=17), *environmental factors* (n=8), and *body structures* (n=1). With 11 categories, the chapter *mobility (d4)* contained the most linked ICF categories.

The linking results of each outcome measure are included as Appendix 1 in this Chapter. The CSOQ contained the highest number of unique second-level ICF categories (n=25), whereas the DWS and DPS only assessed the categories *remunerative employment (d850)* and *sensation of pain (b280),* respectively. These categories were also most frequently measured in the overall analysis, with *sensation of pain (b280)* being measured by 11 outcome measures, and *remunerative employment (d850)* by 9 measures. On the other hand, 26 (45.6%) ICF categories were only covered by a single outcome measure, most of them related to the component *activities and participation* (n=14), followed by *body functions* (n=9), and *environmental factors* (n=3). None of the ICF categories were contained in all outcomes measures, neither was one specific ICF component represented by all outcome measures.

**Clinimetric properties**

The quality of the evidence on the measurement properties for the included outcome measures are given in Appendix 2 in this Chapter. Overall, there is only limited evidence on the measurement properties, except for some disease specific questionnaires, such as ODI, RMDQ, NDI, and CSOQ. All measures had a near absence of evidence for content validity, criterion validity, floor and ceiling effects, reliability, and interpretability.

**Table 4.** Identified outcome measures, along with a brief description and number of items of each measure, as well as the overall absolute and relative frequency, and frequencies stratified to fracture level and treatment type.

| Outcome measure* | Brief description | Items | Frequency, n (%)[1] | | | | |
|---|---|---|---|---|---|---|---|
| | | | Overall (n=237) | C[b] n=(47) | TL[b] (n=191) | Cons[b] (n=28) | Surg[b] (n=175) |
| FS | Neurological classification of spinal cord injury | 5 | 68 (28.7) | 8 (17.0) | 58 (30.4) | 4 (14.3) | 64 (36.6) |
| AIS | Neurological classification of spinal cord injury | 5 | 57 (24.1) | 19 (40.4) | 35 (18.3) | 4 (14.3) | 41 (23.4) |
| HSS | Back specific disability | 14 | 7 (3.0) | 0 | 7 (3.7) | 0 | 6 (3.4) |
| Pain[a] | Perceived pain intensity | 1 | 82 (34.6) | 14 (29.8) | 68 (35.6) | 10 (35.7) | 64 (36.6) |
| ODI | Back specific disability | 10 | 49 (20.7) | 0 | 49 (25.7) | 6 (21.4) | 40 (22.9) |
| SF-36 | Generic health status | 36 | 40 (16.9) | 8 (17.0) | 32 (16.8) | 6 (21.4) | 25 (14.3) |
| DPS | Perceived pain intensity and disability | 5 | 37 (15.6) | 0 | 37 (19.4) | 9 (32.1) | 23 (13.1) |
| DWS | Work disability | 5 | 31 (13.1) | 1 (2.1) | 30 (15.7) | 9 (32.1) | 19 (10.9) |
| RTW | Work disability | 1 | 27 (11.4) | 2 (4.3) | 25 (13.1) | 6 (21.4) | 14 (8.0) |
| VASSS | Thoracolumbar fracture specific disability | 19 | 24 (10.1) | 0 | 24 (12.6) | 4 (14.3) | 13 (7.4) |
| Satisfaction[a] | Satisfaction with treatment or outcomes | 1 | 24 (10.1) | 6 (12.8) | 18 (9.4) | 5 (17.9) | 15 (8.6) |
| RMDQ | Low back specific disability | 24 | 18 (7.6) | 0 | 17 (8.9) | 4 (14.3) | 8 (4.6) |
| LBOS | Low back specific disability | 13 | 9 (3.8) | 0 | 9 (4.7) | 2 (7.1) | 6 (3.4) |
| Recreation | Ability to participate in recreational activities | 1 | 9 (3.8) | 1 (2.1) | 8 (4.2) | 1 (3.6) | 5 (2.9) |
| NDI | Neck specific disability | 10 | 8 (3.4) | 8 (17.0) | 0 | 2 (7.1) | 3 (1.7) |
| PS | Low back specific disability | 10 | 6 (2.5) | 0 | 6 (3.1) | 1 (3.6) | 5 (2.9) |
| CSOQ | Neck specific disability | 35 | 5 (2.1) | 5 (10.6) | 0 | 1 (3.6) | 1 (0.6) |

* FS=Frankel Scale; AIS=ASIA Impairment Scale; HSS=Hannover Spine Score; Pain=Pain Scale; ODI=Oswestry Disability Index; SF-36=Short-Form 36; DPS=Denis Pain Scale; DWS=Denis Work Scale; RTW=Return to Work; VASSS=Visual Analog Scale Spine Score; RMDQ=Roland-Morris Disability Questionnaire; LBOS=Low Back Outcome Score; Recreation=Recreational Activities; NDI=Neck Disability Index; PS=Prolo Scale; CSOQ=Cervical Spine Outcomes Questionnaire.

a Visual Analogue Scale (VAS), Verbal Rating Scale (VRS) or Numeric Rating Scale (NRS)
b C=Cervical spine; TL=Thoracic and Lumbar spine; Cons=Conservative treatment; Surg=Surgical treatment

1 Articles unclear about the use of the AIS or FS are excluded from the overall frequency analysis (n=8). Relative frequencies of the fracture levels and treatment types were calculated according to the number of articles evaluating specifically this certain type of fracture level or treatment type. The sum of relative frequencies exceeds 100%, as multiple measures could be addressed by a single article.

## DISCUSSION

To the best of our knowledge, this is the first systematic literature review investigating the most frequently used outcome measures to evaluate the function and health status of spine trauma patients without complete spinal cord injury, including a description of clinimetric properties, as well as a quantification and comparison the contents using the ICF as reference. In total, 17 different frequently used outcome measures were identified from 245 articles, and linked to 57 unique first- or second-level ICF categories.

Based on the identification of 21 different outcome instruments, the review by Stadhouder *et al*. (2010)[9] concluded that there remains disagreement regarding the preferred outcome measurement tools for spine trauma patients. In line with the results of the current systematic review, they showed a wide range of outcome instruments used, including generic instruments such as the SF-36, and disease specific instruments such as the ODI, RMDQ and LBOS. Interestingly, there are some differences in the identified measures. The major differences are the mental/psychological measures identified by Stadhouder et al., i.e. Hamilton Depression Rating Scale(HDRS),[34] Beck Depression Inventory(BDI),[35] and Hospital Anxiety and Depression Scale(HADS),[36] as well as 2 spinal cord injury measures, i.e. the Spinal Cord Independence Measure (SCIM)[37] and Walking Index for Spinal Cord Injury (WISCI).[38] These differences may be explained by the use of different selection criteria, as Stadhouder et al. also reviewed studies that included severe spinal cord injury patients and poly-trauma patients with spinal injury. On the other hand, they did not describe the use of the neurological classifications AIS and FS.

The ICF was used as a reference as it has proven to be a common language of functioning and disability, as well as a useful tool for examination and comparison of outcome measures. This is emphasized by the development of ICF-based instruments such as the WHODAS-II,[39] IMPACT-S,[40] and ASAS Health Index.[41] Moreover, ICF Core Sets[42] have been defined for several neurological and musculoskeletal diseases,[43-46] including individuals with severe spinal cord injury in the early post-acute context[47] and long-term context,[48] but also the examination and comparison of outcome measures in various patient populations, e.g. traumatic brain injury,[49] Crohn's disease,[50] inflammatory bowel-disease,[51] lower limb amputation,[52] stroke,[53] stroke rehabilitation,[54] and vocational rehabilitation.[55]

The measures identified in the current systematic review focus on different and broad aspects of functioning and health, as most of the identified ICF categories related to almost all chapters of the components *body functions (b)* and *activities and participation (d)*. The strongest emphases are put on pain and neurological status. The component *body structures* was only represented by the category *spinal cord and related structures (s120)*. However, because of the extensive use of the neurological classification systems AIS and FS, this category showed a very high relative frequency. These findings indicate that pain and neurological status are the most frequently used measures in the literature to assess

**Table 5.** The relative frequency of linked ICF categories.

| ICF code | Description | Frequency, %[1] |
|---|---|---|
| *Body functions (n=17)* | | |
| b130 | Energy and drive functions | 21.9 |
| b134 | Sleep functions | 37.6 |
| b140 | Attention functions | 3.4 |
| b152 | Emotional functions | 18.1 |
| b2 | Sensory functions and pain | 52.7 |
| b260 | Proprioceptive function | 2.1 |
| b265 | Touch function | 25.7 |
| b270 | Sensory functions related to temperature and other stimuli | 24.1 |
| b280 | Sensation of pain | 76.4 |
| b510 | Ingestion functions | 2.1 |
| b525 | Defecation functions | 28.7 |
| b620 | Urination functions | 28.7 |
| b640 | Sexual functions | 20.7 |
| b7 | Neuromusculoskeletal and movement-related functions | 52.7 |
| b730 | Muscle power functions | 54.4 |
| b735 | Muscle tone functions | 28.7 |
| b840 | Sensation related to the skin | 2.1 |
| *Body structures (n=1)* | | |
| s120 | Spinal cord and related structures | 52.7 |
| *Activities and participation (n=31)* | | |
| d166 | Reading | 3.4 |
| d230 | Carrying out daily routine | 16.9 |
| d4 | Mobility | 16.9 |
| d410 | Changing basic body position | 26.2 |
| d415 | Maintaining a body position | 35.9 |
| d430 | Lifting and carrying objects | 43.0 |
| d440 | Fine hand use | 2.1 |
| d445 | Hand and arm use | 16.9 |
| d450 | Walking | 64.6 |
| d455 | Moving around | 40.5 |
| d465 | Moving around using equipment | 23.6 |
| d470 | Using transportation | 10.1 |
| d475 | Driving | 13.5 |
| d5 | Self-care | 25.3 |
| d510 | Washing oneself | 40.5 |
| d540 | Dressing | 43.5 |
| d550 | Eating | 12.2 |
| d570 | Looking after one's health | 7.6 |
| d6 | Domestic life | 3.8 |
| d640 | Doing housework | 30.8 |
| d650 | Caring for household objects | 13.1 |
| d720 | Complex interpersonal interactions | 7.6 |
| d750 | Informal social relationships | 16.9 |
| d760 | Family relationships | 16.9 |

| | | |
|---|---|---|
| d770 | Intimate relationships | 33.8 |
| d850 | Remunerative employment | 49.8 |
| d855 | Non-remunerative employment | 11.4 |
| d9 | Community, social and civic life | 34.2 |
| d910 | Community life | 2.1 |
| d920 | Recreation and leisure | 43.5 |
| d930 | Religion and spirituality | 2.1 |
| *Environmental factors (n=8)* | | |
| e110 | Products or substances for personal consumption | 33.3 |
| e115 | Products or substances for personal use in daily living | 25.3 |
| e120 | Products and technology for personal indoor and outdoor mobility and transportation | 45.1 |
| e150 | Design, construction and building products and technology of buildings for public use | 7.6 |
| e155 | Design, construction and building products and technology of buildings for private use | 7.6 |
| e3 | Support and relationships | 28.7 |
| e355 | Health professionals | 2.1 |
| e580 | Health services, systems and policies | 25.3 |

[1]Articles unclear about the use of the AIS or FS are excluded from the frequency analysis (n=8). The sum of relative frequencies exceeds 100%, as multiple measures could be addressed by a single article.

functional outcomes after spine trauma. This is reflected by many studies from all over the world reporting neurological status as a strong determinant of outcome in spine trauma,[56-60] and the experienced pain as an outcome measure.[56-59,61,62] Furthermore, most measures contained concepts linked to ICF categories related to the chapter *mobility (d4)*. This is an important finding for the development of a disease specific outcome instrument for spine trauma, as optimization of mobility has been described as an important tool for improving the quality of life after spine trauma.[63]

The evidence on the clinimetric properties of the included outcome measures is very limited, and only available for four disability specific measures, i.e. two back specific (ODI, RMDQ) and two neck specific (CSOQ, NDI). Although a wide array of ICF categories are covered by these measures, further consensus efforts are needed to establish the required set of IFC categories for spine trauma patients.

We do recognize that this study has several limitations. First, studies with less than 50% of spinal trauma patients with complete paralysis or poly-trauma were also included. This may have biased our finding of the extensive use of neurological classifications. Second, we did not perform the ICF linking for the combination of measures used in each study. Third, our study was limited to patient reported outcome measures. These measures should be used with objective measurements such as medications, work status, schooling, or volunteer work. When objective physical measures are predictive of subjective outcomes, interventions can be better targeted to improve patient outcomes. Finally, the selection of most frequently used outcome measures was based on the arbitrary cut-off point of citation in at least five articles.

In conclusion, the current systematic literature review revealed great diversity in the use and content of outcome measures to evaluate the function and health of spine trauma patients, with 17 different outcome measures linked to 57 unique ICF categories. These results support the hypothesis that there is no consensus on outcome assessment in spine trauma research, and that there is no outcome instrument designed or validated for this specific patient population. Together with the findings of the other preparatory studies, this study creates an evidence base for a consensus meeting during which a core set of ICF categories for outcome measurement in spine trauma will be decided.

## ACKNOWLEDGMENT

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# APPENDIX

**Appendix 1.** Content comparison of outcome measures based on the ICF linking.

| ICF categories | | Outcome measures | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ICF code | Description | AIS | CSOQ | DPS | DWS | FS | HSS | LBOS | NDI | ODI | Pain | PS | Recreation | RMDQ | RTW | SF-36 | VASSS |
| *Body functions* | | | | | | | | | | | | | | | | | |
| b130 | Energy and drive functions | | X | | | | | | | | | | | X | | X | |
| b134 | Sleep functions | | X | | | | | X | X | X | | | | X | | | X |
| b140 | Attention functions | | | | | | | | X | | | | | | | | |
| b152 | Emotional functions | | X | | | | | | | | | | | | | X | |
| b2 | Sensory functions and pain | X | | | | X | | | | | | | | | | | |
| b260 | Proprioceptive function | | X | | | | | | | | | | | | | | |
| b265 | Touch function | X | X | | | | | | | | | | | | | | |
| b270 | Sensory functions related to temperature and other stimuli | X | | | | | | | | | | | | | | | |
| b280 | Sensation of pain | | X | X | | | X | X | X | X | X | X | | X | | X | X |
| b510 | Ingestion functions | | X | | | | | | | | | | | | | | |
| b525 | Defecation functions | | | | | X | | | | | | | | | | | |
| b620 | Urination functions | | | | | X | | | | | | | | | | | |
| b640 | Sexual functions | | | | | | | | | X | | | | | | | |
| b7 | Neuromusculoskeletal and movement-related functions | X | | | | X | | | | | | | | | | | |
| b730 | Muscle power functions | X | X | | | X | | | | | | | | | | | |
| b735 | Muscle tone functions | | | | | X | | | | | | | | | | | |
| b840 | Sensation related to the skin | | X | | | | | | | | | | | | | | |
| *Body structures* | | | | | | | | | | | | | | | | | |
| s120 | Spinal cord and related structures | X | | | | X | | | | | | | | | | | |
| *Activities and participation* | | | | | | | | | | | | | | | | | |
| d166 | Reading | | | | | | | | X | | | | | | | | |
| d230 | Carrying out daily routine | | | | | | | | | | | | | | | X | |
| d4 | Mobility | | | | | | | | | | | | | | | X | |
| d410 | Changing basic body position | | | | | | X | | | | | | | X | | X | X |

| ICF code | Description | AIS | CSOQ | DPS | DWS | FS | HSS | LBOS | NDI | ODI | Pain | PS | Recreation | RMDQ | RTW | SF-36 | VASSS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| d415 | Maintaining a body position | | | | | | x | X | | x | | | | x | | | x |
| d430 | Lifting and carrying objects | | X | | | | x | | x | x | | | | | | x | x |
| d440 | Fine hand use | | x | | | | | | | | | | | | | | |
| d445 | Hand and arm use | | | | | | | | | | | | | | | X | |
| d450 | Walking | | | | | X | X | X | | x | | | | x | | x | X |
| d455 | Moving around | | | | | | X | | | X | | | | X | | x | x |
| d465 | Moving around using equipment | | | | | | X | | | X | | | | | | | |
| d470 | Using transportation | | | | | | | | | | | | | | | | x |
| d475 | Driving | | | | | | | | x | | | | | | | | X |
| d5 | Self-care | | X | | | | | | X | x | | | | | | | |
| d510 | Washing oneself | | X | | | | | | x | x | | | | | | X | X |
| d540 | Dressing | | X | | | | X | X | x | x | | | | x | | X | |
| d550 | Eating | | X | | | | | | | | | | | | | | X |
| d570 | Looking after one's health | | | | | | | | | | | | | X | | | |
| d6 | Domestic life | | | | | | | X | | | | | | | | | |
| d640 | Doing housework | | x | | | | | X | | | | X | | x | | X | x |
| d650 | Caring for household objects | | x | | | | | X | | | | | | X | | | |
| d720 | Complex interpersonal interactions | | | | | | | | | | | | | X | | | |
| d750 | Informal social relationships | | | | | | | | | | | | | | | X | |
| d760 | Family relationships | | | | | | | | | | | | | | | X | |
| d770 | Intimate relationships | | X | | | | | X | | x | | | | | | | X |
| d850 | Remunerative employment | | X | X | x | | | X | X | | | x | | | X | x | X |
| d855 | Non-remunerative employment | | | | | | | | | | | | | | X | | |
| d9 | Community, social and civic life | | | | | | | X | | x | | | | | | X | |
| d910 | Community life | | X | | | | | | | | | | | | | | |
| d920 | Recreation and leisure | | X | | | | | X | x | x | | x | X | | | x | |
| d930 | Religion and spirituality | | X | | | | | | | | | | | | | | |

| ICF code | Description | AIS | CSOQ | DPS | DWS | FS | HSS | LBOS | NDI | ODI | Pain | PS | Recreation | RMDQ | RTW | SF-36 | VASSS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *Environmental factors* | | | | | | | | | | | | | | | | | |
| e110 | Products or substances for personal consumption | | x | x | | | x | x | | | | | | | | | x |
| e115 | Products or substances for personal use in daily living | | | | | | | | | x | | | | x | | | |
| e120 | Products and technology for personal indoor and outdoor mobility and transportation | | | | | x | | | | x | | | | | | | |
| e150 | Design, construction and building products and technology of buildings for public use | | | | | | | | | | | | | x | | | |
| e155 | Design, construction and building products and technology of buildings for private use | | | | | | | | | | | | | x | | | |
| e3 | Support and relationships | | | | | | | | x | x | | | | x | | | |
| e355 | Health professionals | | x | | | | | | | | | | | | | | |
| e580 | Health services, systems and policies | | x | | | | | x | | x | | | | | | | |

Categories included in more than one item of an outcome measure are indicated with ‘x’.

**Appendix 2.** Clinimetric properties of the outcome measures.

| Outcome meaure*† | Quality of measurement properties of health status questionnaires (according to Terwee et al)‡ | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Content Validity | Internal consis-tency | Criterion validity | Construct validity | Reproducibility | | Responsive-ness | Floor or ceiling effects | Interpret-ability |
| | | | | | - Agreement | - Reliability | | | |
| ODI § | ? | ++ | 0 | ++ | ++ | 0 | +++ | 0 | 0 |
| DPS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| DWS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| VASSS | 0 | + | 0 | ?? | + | 0 | 0 | 0 | 0 |
| RMDQ § | ? | ++ | 0 | ++ | ++ | 0 | +++ | 0 | 0 |
| LBOS | 0 | + | 0 | 0 | - | ? | ++ | 0 | 0 |
| NDI ¶ | ?+ | ++ | 0 | ?+? | ?++?+ | 0 | ++?+ | + | 0 |
| HSS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| PS | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| CSOQ | 0 | +? | 0 | +++ | + | + | ?+ | + | 0 |

* ODI=Oswestry Disability Index; DPS= Denis Pain Scale ; DWS= Denis Work Scale; VASSS=Visual Analog Scale Spine Score; RMDQ = Roland-Morris Disability Questionnaire; LBOS = Low Back Outcome Score; NDI = Neck Disability Index; HSS = Hannover Spine Score; CSOQ = Cervical Spine Outcomes Questionnaire; PS=Prolo Scale.

† Frankel Scale and Asia Impairment Scale were not included as these are not evaluable. Visual Analog Scale, Numeric Rating Scale, Visual Rating Scale for pain and satis faction, Short Form 36, and Return to Work are general outcome tools beyond the scope of this clinimetric overview.

‡ Each +,?,- represents a clinimetric study: + = positive; ? = doubtful ; - = poor; 0 = no information available / no studies found.

§ Based on 2 reviews

¶ Including 2 reviews

# PART I

## The development of a universal disease-specific patient reported outcome instrument

# Chapter 3

## Towards the development of an outcome instrument for spinal trauma: an international survey of spinal surgeons

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## ABSTRACT

*Study Design.* International web-based survey.
*Objective.* To identify the most relevant aspects of human function and health status from the perspective of health care professionals involved in the treatment of spinal trauma patients.
*Summary of Background Data.* There is no universally accepted outcome instrument available that is specifically designed or validated for spinal trauma patients, contributing to controversies related to the optimal treatment and evaluation of many types of spinal injuries. Therefore, the AOSpine International aims to develop such an instrument using the International Classification of Functioning, Disability and Health as its basis.
*Methods.* Experts from the five AOSpine International world regions were asked to give their opinion on the relevance of a compilation of 143 ICF categories for spinal trauma patients on a three-point scale: 'not relevant', 'probably relevant', or 'definitely relevant'. The responses were analyzed using frequency analysis. Possible differences in responses between the five world regions were analyzed with the Fisher's exact test and descriptive statistics.
*Results.* Out of 895 invited AOSpine International members, 150 (16.8%) participated in this study. A total of 13 (9.1%) ICF categories were identified as 'definitely relevant' by more than 80% of the participants. Most of these categories were related to the ICF component *activities and participation* (n=8), followed by *body functions* (n=4) and *body structures* (n=1). Only some minor regional differences were observed in the pattern of answers.
*Conclusions.* More than 80% of an international group of health care professionals experienced in the clinical care of adult spinal trauma patients, indicated 13 out of 143 ICF categories as 'definitely relevant' to measure outcomes after spinal trauma. This study creates an evidence base to define a core set of ICF categories for outcome measurement in adult spinal trauma patients.

## INTRODUCTION

Traumatic spinal injuries remain a critical global public health concern, both in terms of care and costs. The incidence of spinal injuries ranges from 4.6% to 24.0%. Of these patients, 4.9% to 52.0% also suffer a concomitant neurologic injury.[1-5] These injuries are major contributors to disability with long-term consequences and associated considerable direct and indirect health care related costs. As the survival rate and life expectancy of major trauma victims have increased over the years, measuring functional and health outcomes after traumatic spinal injuries is becoming more urgent.[2-6] However, there is no universally accepted outcome instrument available that is specifically designed or validated for this patient population, especially for the patients who primarily sustain an injury to the spinal column, without an associated severe spinal cord injury or poly-trauma. In the absence of a validated injury specific outcome measure for spine trauma, combinations of available tools have usually been used in the literature including generic, spine-specific and neurological outcome measures. The lack of an appropriately responsive outcome instrument perpetuates the ongoing controversies related to the optimal treatment and evaluation of many types of spinal injuries.[7,8]

Therefore, AOSpine International started a project to develop a simple and globally applicable disease specific outcome instrument for spinal trauma patients. Such an instrument would be helpful in guiding efforts to improve the quality of care for spine trauma patients, assess the efficacy of interventions more uniformly, and guide future management and health policy decisions. As most spinal trauma patients are typically healthy and well-functioning individuals before the trauma, and with the stated goals of any intervention to return the individual as closely as possible to their pre-injury state, the ideal outcome instrument should be able to longitudinally compare the current level of functioning and health with the pre-injury state.

We have decided to use the systematic and comprehensive approach of the International Classification of Functioning, Disability and Health (ICF) of the World Health Organization (WHO) as the basis for the development of this future disease specific outcome instrument.[9,10] The ICF serves as a conceptual framework for a uniform definition and classification of all aspects of human functioning, disability and health (see Figure 1). It is composed of 1454 categories, hierarchically organized into chapters together with the four components: *body functions (b), body structures (s), activities and participation (d),* and *environmental factors (e)*.[9,11]

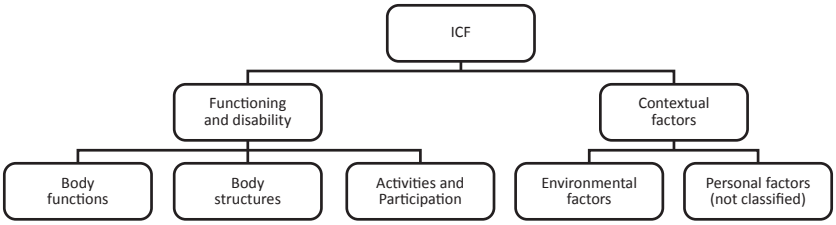


***Figure 1.*** Hierarchical structure of the International Classification of Functioning, Disability and Health (ICF), based on a bio psycho social model of functioning[11]

The preparatory phase of this outcome project aims to select those ICF categories that are relevant for spinal trauma patients from 3 different perspectives: the patient, researcher and health professional perspective. The results of these studies create the necessary background for a consensus meeting during which a core set of ICF categories for outcome measurement will be decided on. The present study aims to identify the most typical and relevant aspects of function and health status from the perspective of health care professionals directly involved in the treatment of spinal trauma patients.

## MATERIALS AND METHODS

### Study design

The study was conducted as a cross-sectional online survey and included spine surgeons from five AO world regions (North America, Latin America, Europe, Middle East and Asia Pacific). The survey questions were based on the categories of the ICF.

### Recruitment of participants

Experts were recruited through AOSpine International; a leading global community of spine-care professionals. A personal email invitation with an electronic link to the survey was sent to all AOSpine International members who stated spine trauma as one of their areas of expertise (n=895). To ensure the quality of the study, the eligibility criteria for participation were defined as follows: 1) orthopaedic surgeon, trauma surgeon or neurosurgeon, 2) at least five years of experience in the treatment of adult spinal trauma patients, 3) fluency in English, the language used for the survey. These criteria were confirmed at the start of the survey. Subsequently, a brief introduction to the study and the ICF, together with instructions to complete the questionnaire, were provided.

### Survey questionnaire

The survey questionnaire consisted of two parts. The expected completion time was 15 minutes.

In the first part, basic information about the participant was asked to obtain a clearer picture of the study population. This information included age, gender, region of practice,

professional background, main working field (>50% of time) and years of experience in the treatment of spinal trauma patients.

The second part of the questionnaire consisted of a compilation of ICF categories, based on the ICF checklist (version 2.1a), the brief ICF Core Sets for musculoskeletal conditions in the acute and post-acute care setting, and the brief Core Sets for spinal cord injury in the early post-acute and chronic situation.[12-16] The ICF Checklist is a user-friendly display of the most relevant ICF categories for clinical purposes. This Checklist was included in the survey to enable a comparison with the results of the ongoing empirical (patient reported) study whose aim is to identify relevant ICF categories from the patients' perspective. The brief Core Sets for musculoskeletal conditions and spinal cord injury are scientifically developed for partly overlapping, but dissimilar, patient populations. In total, 38 categories of the component *body functions* were included, 16 categories of *body structures*, 57 categories related to *activities and participation*, and 32 related to *environmental factors*. As illustrated by Figure 1, each second-level category is coded with a prefix (b, s, d and e respectively), followed by a three-digit code.



Participants of the survey were asked to rate the relevance of each of these compiled ICF categories for spinal trauma patients on a three-point scale: 'not relevant', 'probably relevant', or 'definitely relevant'. In this context, relevance was further defined as the importance of a category for patients' functioning, disability and health, and the meaningfulness of including a category in the measurement of clinical and functional outcome for spinal trauma patients. The target population was defined as patients ≥ 18 years of age who have suffered acute traumatic injury to the spinal column (C1-L5), excluding patients with complete paralysis (ASIA A or B) or poly-trauma (ISS > 15). The questionnaire included free text fields for any thoughts or comments the participants might have while completing the survey.

**Data collection**

The survey was conducted between 29 October and 8 December 2013. All invited AOSpine International members received a reminder after one week. To assure the representativeness of each world region, members of the world regions with lower response rates received a third email from the AOSpine Regional Director to encourage their participation. Responses were saved and analyzed anonymously by assigning a study identification number to each participant.

**Analysis**

The response rates and personal characteristics of the participants were analyzed using descriptive statistics. The responses to the ICF categories were analyzed using frequency analysis. Absolute and relative frequencies along with their bootstrapped 95% confidence intervals were calculated. Possible differences in responses between the five world regions were analyzed with the Fisher's exact test and descriptive statistics.

**Table 1.** Characteristics of surveyed experts (n=150)

| | |
|---|---|
| Gender (male), n (%) | 145 (96.7%) |
| Age, mean (range) in years | 44.0 (29-67) |
| AOSpine world region, n (%) | |
| Asia Pacific | 32 (21.3%) |
| Europe | 44 (29.3%) |
| Latin America | 44 (29.3%) |
| Middle East | 15 (10.0%) |
| North America | 15 (10.0%) |
| Profession, n (%) | |
| Neurosurgeon | 56 (37.3%) |
| Orthopaedic surgeon | 82 (54.7%) |
| Trauma surgeon | 4 (2.7%) |
| Spine surgeon, unspecified | 8 (5.3%) |
| Main working field, n (%) | |
| Clinic | 137 (91.3%) |
| Management | 8 (5.3%) |
| Education | 5 (3.3%) |
| Research | 0 (0.0%) |
| Years of experience, median (range) in years | 11.0 (5-42) |

## RESULTS

### Response rate

Of the 895 AOSpine International members who received the survey 179 responded. However, 29 surveys could not be included in the data analyses as the experts did not meet the eligibility criteria (n=14) or had only completed the first part of the survey (n=15). In total, 150 experts participated in this study.

### Characteristics of participants

The socio-demographic characteristics of the participants are presented in Table 1. Most of the participants were male (96.7%), as is consistent with the demographic of spine surgeons, and their mean age was 44 years (range 29-67 years). All AOSpine International world regions were represented, but the number of participants ranged from 10 (the Middle East and North America) to 44 (Europe and Latin America), with 32 participants from Asia Pacific. More than half of the participants were orthopaedic surgeons (54.7%), followed by neurosurgeons (37.3%) and trauma surgeons (2.7%); 5.3% of the participants did not specify their surgical background. The majority of the participants (91.3%) indicated the clinical practice as their main area of work. The number of years of experience in the treatment of spinal trauma patients ranged from 5 to 42 years with a median of 11.0 years.

**Table 2.** Second level ICF categories identified as definitely relevant by ≥ 80% of the experts. Relative frequencies are shown, along with their 95% bootstrapped confidence intervals (CI) and range among the different world regions.

| ICF code | Description | % of experts | (95% CI) | (range) |
|---|---|---|---|---|
| s120 | Spinal cord and related structures | 96.5 | (93.0-99.3) | (89.7-100.0) |
| b730 | Muscle power functions | 93.3 | (89.3-96.7) | (86.7-100.0) |
| d410 | Changing basic body position | 91.4 | (86.4-95.7) | (85.7-100.0) |
| d415 | Maintaining a body position | 91.4 | (86.4-95.7) | (83.3-100.0) |
| d420 | Transferring oneself | 90.0 | (84.3-95.0) | (83.3-100.0) |
| d530 | Toileting | 88.6 | (83.6-93.6) | (76.2-96.7) |
| d450 | Walking | 87.9 | (82.1-96.6) | (82.1-93.3) |
| b280 | Sensation of pain | 86.0 | (80.0-91.3) | (77.3-96.9) |
| d445 | Hand and arm use | 85.7 | (79.3-90.7) | (79.5-93.3) |
| b620 | Urination functions | 84.7 | (78.7-90.0) | (80.0-86.7) |
| b735 | Muscle tone | 84.7 | (78.7-90.7) | (75.0-93.8) |
| d455 | Moving around | 82.9 | (76.4-89.3) | (71.4-93.3) |
| d550 | Eating | 82.9 | (76.4-89.3) | (76.2-93.3) |

**Description of responses**

Of the 143 ICF categories included in the survey, 13 (9.1%) were identified as 'definitely relevant' by more than 80% of the participants. As shown in Table 2, most of these categories were related to the ICF component *activities and participation* (n=8), followed by *body functions* (n=4) and *body structures* (n=1). For the categories *spinal cord and related structures* (s120), *muscle power functions* (b730), *changing basic body position* (d410), *maintaining a body position* (d415) and *transferring oneself* (d420), the participants of one or more world regions were in full agreement on the relevance for adult spinal trauma patients. None of the ICF categories in the component *environmental factors* reached a consensus of 80%. With a relative frequency of 71.5%, *immediate family* (e310) was considered the most relevant environmental factor. In addition, the participants excluded none of the surveyed categories convincingly. An overview of the categories identified as 'definitely relevant' by at least 50% of the participants is included in the Appendix in this Chapter.

**Regional differences**

Analyses of the responses according to each world region revealed only some minor regional differences in the pattern of answers, especially when taking the response option 'probably relevant' into account.

The responses to the categories of the components *body functions* and body structures showed the least variation among the five world regions. Significant differences were only observed for the single categories *consciousness* (b110; p=0.040), *language* (b167; p=0.019), *sensations related to muscles and movement functions* (b780; p=0.045), *reproductive system* (s630; p=0.039), and *pelvic region* (s740; p=0.042).

In contrast, the responses to the categories of the component *environmental factors* showed the highest variation. Overall, the environmental factors received the

weakest endorsement from European and Latin American participants. All categories from the ICF chapters products and *technology* (e1) and *services, systems and policies* (e3) were most heavily endorsed by participants from the Middle East.

Concerning the component activities and participation, most regional differences were observed for the chapters concerning *domestic life* (d6) and community, social and civic life (d9). Overall, categories from these two chapters were least strongly endorsed by participants from Latin America and Europe, respectively. The responses to the chapters *mobility* (d4) and *self-care* (d5) varied the least, except for the categories *driving* (d475) and *looking after one's health* (d570; p=0.010).

**Comments**

Although only a few participants used the free text fields to explain their responses, these comments illustrated that some categories are not specifically relevant to spinal trauma patients, but may remain relevant to outcome assessment in general. This mainly applied to the categories related to communication, sensation and mental functions. Categories related to the cardiovascular, hematological, immunological and respiratory system were indicated as possibly relevant co-morbidities.

## DISCUSSION

To the best of our knowledge, this is the first survey exploring the perspective of worldwide experts on aspects that they deem relevant to the measurement of outcomes after spinal trauma. The ICF system was used as a reference since it provides a comprehensive and standardized framework for the description of all of the domains of human function and health status.

A total of 150 members of AOSpine International participated in this survey. All five AOSpine International world regions were represented, which contributes to the generalizability of our findings and more broadly supports the development of a global perspective. The majority of the participants is directly involved in the care of spinal trauma patients and has a substantial level of experience.

Out of the 143 ICF categories included in the survey, 13 were identified as 'definitely relevant' by more than 80% of the participants, indicating an acceptable level of consensus among professionals. The majority of these categories are related to the ICF component *activities and participation*, followed by the components *body functions* and *body structures*. These results reflect the fact that spinal trauma is multifaceted, causing loss of functioning and restrictions in the very broad categories of activities and participations.[17-20]

The categories related to neurological status, i.e. *muscle power functions* (b730), *urination functions* (b620), and *muscle tone* (b735), were identified by the participants as the most relevant categories of the component *body functions*. This is in line with previous

publications, as many studies from all over the world report neurological status as a strong determinant of outcome in spinal trauma.[17-24] Although this survey excluded patients with complete paralysis, the participants agree that even minor and subtle neurologic injuries can contribute profoundly to substantial loss of function. Many authors have gone so far as to suggest that the definitive management of patients with spinal fractures should be directed primarily on the presence or absence and extent of neurologic injury, while others have highlighted the influence of neurological injury as a predictor of complications after surgery.[21,23] The category *sensation of pain* (b280) was also identified as 'definitely relevant' by more than 80% of the participants, a finding that confirms the importance of the experience of pain as an outcome measure.[18-20,22-26]



The identified functional impairments in the component *body functions* reflect the overwhelming endorsement of the *body structures* category spinal cord and *related structures* (s120). Traumatic spinal cord injury may lead to catastrophic events for individuals who develop motor, sensory, and autonomic deficits.[27,28] In the case of spinal trauma patients with incomplete paralysis, neurologic deterioration may necessitate renewed investigations and conversion to another treatment option.[18]

Finally, none of the ICF categories of the component *environmental factors* were identified as 'definitely relevant' by more than 80% of the participants. Categories from this component may be of greater value for chronic conditions and long-term contexts.[29] Traumatic spinal injury without severe neurological deficit is a life-altering event with a more defined period of disability in comparison to patients with persistent neurologic symptoms.[28]

Overall, only minor differences in the response patterns between the world regions were observed. The largest variations were observed for the *component environmental factors*, followed by *activities and participation*. These variations are most likely related to the interpretation of the ICF categories and may reflect cultural underpinnings or value systems. Moreover, the differences in the responses related to environmental factors may be explained by interregional differences, since almost all of the related environmental categories responses were highly endorsed only by participants from the Middle East while these same categories were least strongly endorsed by participants from Europe and Latin America.

We do recognize that this study has some limitations. First, there might be a selection bias in the sample of experts, which should be taken into account when generalizing the results. The survey was sent only to those AOSpine International members who stated spine trauma as one of their areas of expertise, with fluency in English as eligibility criteria. Secondly, in contrast to similar surveys, only surgeons were involved in this survey and no distinction was made between the different phases of care.[29-31] Patients with traumatic spinal fractures, without complete paralysis, are mainly treated and followed by surgeons during a relatively short period. Because of this, no distinction was made between the acute and the post-acute phases in this survey. Thirdly, the questionnaire included a selection of

categories instead of open-ended questions or an invitation to participate in a Delphi type process. We believe that the used compilation of ICF categories facilitates comparisons between our findings and those of other studies.[29-32] Finally, the high frequency of the response 'probably relevant' might be related to the limited three-point response scale.

In conclusion, more than 80% of an international group of health care professionals experienced in the clinical care of adult spinal trauma patients, indicated 13 out of 143 ICF categories as 'definitely relevant' to measure outcomes after spinal trauma. The minor differences in the responses between the five world regions support the universal applicability of the ICF and outcome instrument under development. Together with the findings of the other preparatory studies, i.e. an empirical (patient reported) study and a systematic review of the literature, this study creates an evidence base for a consensus meeting, whose aim will be to define a core set of ICF categories for the future development of a validated outcome measurement applicable for adult spinal trauma patients.

## ACKNOWLEDGMENT

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## APPENDIX

**Appendix.** Second level ICF categories identified as definitely relevant by ≥ 50% (and <80%) of the experts. Relative frequencies are shown, along with their 95% bootstrapped confidence intervals (CI) and range among the different world regions.

| ICF code | Description | % of experts | (95% CI) | (range) |
|---|---|---|---|---|
| b710 | Mobility of joints | 79.3 | (72.7-85.3) | (72.7-87.5) |
| d465 | Moving around using equipment | 79.3 | (72.1-85.7) | (66.7-92.9) |
| d510 | Washing oneself | 79.3 | (72.9-85.7) | (64.3-86.7) |
| d560 | Drinking | 79.3 | (72.9-85.7) | (71.4-93.3) |
| d520 | Caring for body parts | 77.9 | (71.4-85.0) | (61.9-86.7) |
| s750 | Lower extremity | 76.1 | (69.0-83.1) | (69.8-92.9) |
| b260 | Proprioceptive function | 74.7 | (67.3-82.0) | (66.7-93.3) |
| d540 | Dressing | 74.3 | (67.1-81.4) | (61.9-92.9) |
| s710 | Head and neck region | 73.9 | (66.9-81.0) | (60.0-79.1) |
| d430 | Lifting and carrying objects | 72.9 | (65.0-80.0) | (64.1-92.9) |
| e310 | Immediate family | 71.5 | (63.5-78.1) | (55.3-82.8) |
| d440 | Fine hand use | 71.4 | (63.6-78.6) | (66.7-86.7) |
| d470 | Using transportation | 71.4 | (64.3-78.6) | (59.5-85.7) |
| s730 | Upper extremity | 70.4 | (62.7-78.2) | (65.1-78.6) |
| s760 | Trunk | 70.4 | (62.7-77.5) | (53.3-80.6) |
| b780 | Sensations related to muscles and movement functions | 70.0 | (62.7-77.3) | (56.8-87.5) |
| s610 | Urinary system | 69.7 | (62.0-77.5) | (64.3-77.4) |
| d230 | Carrying out daily routine | 67.9 | (60.0-75.7) | (61.5-80.0) |
| s430 | Respiratory system | 67.6 | (59.2-75.4) | (42.9-77.4) |
| b640 | Sexual functions | 67.3 | (59.4-74.7) | (52.3-86.7) |
| b440 | Respiration functions | 66.7 | (58.7-74.7) | (46.7-78.1) |
| b740 | Muscle endurance functions | 66.7 | (59.3-74.0) | (52.3-86.7) |
| s740 | Pelvic region | 65.5 | (57.7-73.2) | (46.7-92.9) |
| s720 | Shoulder region | 62.7 | (54.9-70.4) | (51.2-85.7) |
| e410 | Individual attitudes of immediate family members | 62.0 | (54.0-70.1) | (44.7-73.3) |
| b110 | Consciousness | 62.0 | (54.0-70.7) | (50.0-86.7) |
| s110 | Brain | 62.0 | (53.5-69.7) | (43.6-79.1) |
| b420 | Blood pressure | 60.0 | (52.7-68.0) | (40.0-75.0) |
| e580 | Health services, systems and policies | 59.9 | (51.1-67.9) | (50.0-76.9) |
| b525 | Defecation | 59.3 | (51.3-67.3) | (40.0-66.7) |
| b755 | Involuntary movement reaction functions | 59.3 | (51.3-67.3) | (43.2-73.3) |
| b765 | Involuntary movement | 58.7 | (51.3-66.7) | (47.7-80.0) |
| d570 | Looking after one's health | 58.6 | (50.7-67.1) | (35.7-86.7) |
| s410 | Cardiovascular system | 57.7 | (49.3-65.5) | (42.9-64.5) |
| e355 | Health professionals | 57.7 | (49.6-65.7) | (47.4-66.7) |
| e120 | Products and technology for personal indoor and outdoor mobility and transportation | 54.7 | (46.0-63.5) | (39.5-84.6) |
| e450 | Individual attitudes of health professionals | 54.0 | (45.3-62.0) | (34.2-65.5) |
| d475 | Driving | 53.6 | (45.7-62.1) | (33.3-78.6) |
| d240 | Handling stress and other psychological demands | 52.9 | (44.3-61.4) | (41.0-66.7) |
| e320 | Friends | 52.6 | (44.5-61.3) | (39.5-66.7) |
| d760 | Family relationships | 52.1 | (44.3-60.7) | (43.6-59.5) |
| b810 | Protective functions of the skin | 51.3 | (43.4-60.0) | (45.5-62.5) |
| e440 | Individual attitudes of personal care providers and personal assistants | 51.1 | (43.1-59.9) | (34.2-62.1) |

# Chapter 4

## Toward developing a specific outcome instrument for spine trauma: an empirical cross-sectional multicenter ICF-based study by AOSpine Knowledge Forum Trauma

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## ABSTRACT

*Study Design.* Empirical cross-sectional multicenter study.
*Objective.* To identify the most commonly experienced problems by patients with traumatic spinal column injuries, excluding patients with complete paralysis.
*Summary of Background Data.* There is no disease or condition specific outcome instrument available that is designed or validated for spine trauma patients, contributing to the present lack of consensus and ongoing controversies in the optimal treatment and evaluation of many types of spine injuries. Therefore, AOSpine Knowledge Forum Trauma started a project to develop such an instrument using the International Classification of Functioning, Disability and Health (ICF) as its basis.
*Methods.* Patients with traumatic spinal column injuries, within 13 months after discharge from hospital were recruited from nine trauma centers in seven countries, representing four AOSpine International world regions. Health professionals collected the data using the general ICF Checklist. The responses were analyzed using frequency analysis. Possible differences between the world regions, and also between the subgroups of potential modifiers were analyzed using descriptive statistics and Fisher's exact test.
*Results.* 187 patients were enrolled. A total of 38 (29.7%) ICF categories were identified as relevant for at least 20% of the patients. Categories experienced as a difficulty/impairment were most frequently related to *activities and participation* (n=15), followed by *body functions* (n=6), and *body structures* (n=5). Furthermore, 12 *environmental factors* were considered to be a facilitator in at least 20% of the patients.
*Conclusions.* Out of 128 ICF categories of the general ICF Checklist, 38 ICF categories were identified as relevant. Loss of functioning and limitations in daily living seem to be more relevant for patients with traumatic spinal column injuries rather than pain during this timeframe. This study creates an evidence base to define a core set of ICF categories for outcome measurement in adult spine trauma patients.

## INTRODUCTION

Although vertebral column fractures represent only a minority of all traumatic injuries, their influence on the individual's social and financial situation is more significant than other traumatic injuries.[1,2] Moreover, an associated neurological injury can be disabling or life threatening with devastating long-term consequences and a significant financial burden on the health care system.[3,4] As more individuals survive serious trauma, the measurement of function, health, and treatment effectiveness is becoming increasingly important. However, in the absence of a validated and reliable disease specific outcome instrument for patients with traumatic spinal column injuries, it is difficult to compare outcomes of different treatments within observational or randomized cohort studies. This contributes to the present lack of consensus and wide variation in the evaluation and optimal treatment of different types of spine injuries.[5]

Therefore, AOSpine Knowledge Forum Trauma initiated a project to develop and validate disease specific outcome instruments for spine trauma patients including both the patients' and health professionals' perspectives.[6] These instruments would be helpful tools for comparing various treatment options and thus improving the quality of health care. For the development of an outcome instrument from the perspective of spine trauma patients that can be used on a global scale, a comprehensive and systematic approach is necessary. For this reason, we have decided to use the World Health Organization's (WHO) International Classification of Functioning, Disability, and Health (ICF) as the basis, as it relies on a globally accepted framework to describe and classify functioning, disability and health.[7-9] Including 1454 categories, the ICF recognizes that functioning and disability result from the interactions between different components: *body functions (b), body structures (s), activities and participation (d),* and *environmental factors (e),* and personal factors. Figure 1 shows the components of the ICF and how the categories are hierarchically organized into different levels of detail.

The preparatory phase of this methodology focuses on identifying the most relevant ICF categories for patients with traumatic spinal column injuries from different perspectives. Beside the research and expert perspective, it is crucial to empirically identify the patient perspective in order to have a better understanding of the actual problems and impairments these patients are facing after trauma.[10] Consequently, the objective of this study was to identify the most common problems and impairments in functioning and health experienced by patients with traumatic spinal column injuries (excluding patients with complete paralysis), using the ICF as a reference.

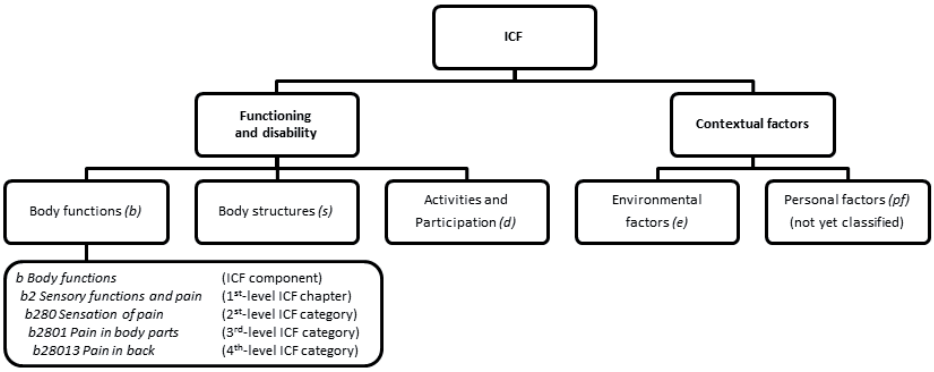


***Figure 1.*** Illustration of the bio-psycho-social model of the International Classification of Functioning, Disability and Health (ICF), along with an example of the hierarchical structure.

## MATERIALS AND METHODS

### Study design

An empirical cross-sectional multicenter study was conducted, including 9 trauma centers from 7 countries. These centers were recruited via the members of the AOSpine Knowledge Forum Trauma to ensure the involvement of different AOSpine world regions: Asia Pacific (1 center from India), Europe and Sub Saharan Africa (Germany, The Netherlands and South Africa, 1 center each), Latin America (1 center from Brazil), and North America (Canada and the USA, 2 centers each). The study was approved locally by the institutional review board of each participating center and performed in accordance with the Declaration of Helsinki.

### Study population

In order to focus on the effect of spinal column injury on health and functioning and exclude confounding factors as much as possible, the inclusion criteria were defined as spine trauma as a main diagnosis, outpatient (or telephone) follow-up within 13 months post-trauma, age ≥18 years and informed consent. Poly-trauma patients (Injury Severity Score>15), patients with complete motor paralysis at discharge/transfer from hospital (American Spinal Injury Association (ASIA) impairment grade A or B), and patients with pre-existing psychiatric conditions were excluded.

### Measures

The functioning and health of the study population was described with the ICF Checklist version 2.1a, developed by the WHO.[11] This checklist consists of a selection of 128 first and second level ICF categories that are most relevant for general clinical purposes. The presence of problems was denoted for each ICF category of the components body functions, body structures and activities and participation using the qualifiers 0 for 'no impairment/

difficulty', 1 for 'mild to moderate impairment/difficulty' and 2 for 'severe to complete impairment/ difficulty'.

Categories in the component environmental factors can be either a facilitator or a barrier, indicating a positive or negative impact on functioning or levels of disability, respectively. Facilitators were coded with +1 for 'mild to moderate facilitator' and +2 for 'severe to complete facilitator', while barriers were coded with -1 for 'mild to moderate barrier' and -2 for 'severe to complete barrier'. The qualifier 0 denoted a category neither as a facilitator, nor as a barrier. In addition, the qualifier '8' ('not specified') was used when available information was not sufficient and '9' ('not applicable') when the category was not appropriate. Problems owing to a comorbidity not associated with spine trauma were assigned qualifier 'C', comorbidity. In addition, patients were asked to rate their general health and functioning on a scale from 0 (poor health/complete problems in functioning) to 10 (excellent health /no problems in functioning), and to list the most important issues they had been facing since their injury.



**Data collection**

Patient recruitment and data collection were performed by health professionals (research coordinators) trained in the principles and application of the ICF, and study specific procedures. Eligible patients were selected consecutively, and enrolled in the study after informed consent. The majority of the information required to complete the ICF Checklist was obtained from a semi-structured interview with the patient, either at the outpatient clinic or via telephone. Prior to the interview, the medical record was checked for relevant information to identify problems in functioning, as well as socio-demographic data, main diagnosis, injury details, treatment and comorbidities. All data were entered de-identified in a central electronic database via a secured and specially designed electronic tablet (iPad) application, to ensure data quality and integrity.

**Statistical Analysis**

Characteristics of the study population and the patient reported ratings for general health and functioning were analyzed using descriptive statistics. For the ICF components body functions, body structures and activities and participation, absolute frequencies and relative frequencies of impairment/difficulty were calculated, along with their 95% confidence intervals (CI). The same was calculated for environmental factors, regarded as either a facilitator or a barrier. The response options 'not specified', 'not applicable' or 'comorbidity' were not taken into account. The ICF categories denoted as an impairment/difficulty or as a facilitator/barrier in at least 20% of the patients were reported. Furthermore, the influence of age (median divided), gender, fracture level (patients with cervical fractures compared to patients with thoracic and lumbar fractures), neurological status (patients with ASIA impairment grade C and D compared to grade E), and treatment (conservatively treated patients compared to surgically treated) as potential modifiers were investigated. The

**Table 1.** Socio-demographic and clinical characteristics of the study population.

| | Overall (n=187) | Asia Pac (n=40) | Eur/ SS Afr (n=67) | Latin Am (n=14) | North Am (n=66) |
|---|---|---|---|---|---|
| Male (%) | 116 (62.0) | 30 (75.0) | 40 (59.7) | 11 (78.6) | 35 (53.0) |
| Age, mean ± SD (range) in years | 49.6±18.5 (18-88) | 42.0±13.4 (19-73) | 47.6±20.3 (18-85) | 55.6±20.3 (18-81) | 54.9±17.1 (18-88) |
| Cohabiting (%) | 128 (68.4) | 33 (82.5) | 33 (49.3) | 11 (78.6) | 51 (77.3) |
| Years of formal education, mean ± SD (range) | 12.3±4.6 (0-22) | 8.9±5.0 (0-18) | 12.9±3.5 (6-22) | 9.2±5.7 (0-20) | 14.3±3.6 (3-20) |
| *Employment (%)* | | | | | |
| Employed | 94 (50.3) | 29 (72.5) | 30 (44.8) | 10 (71.4) | 25 (37.9) |
| Unemployed | 23 (12.3) | 0 | 13 (19.4) | 0 | 10 (15.2) |
| Retired | 40 (21.4) | 1 (2.5) | 17 (25.4) | 3 (21.4) | 19 (28.8) |
| Other | 30 (16.0) | 10 (25.0) | 7 (10.4) | 1 (7.1) | 12 (18.2) |
| *Comorbidities (%)* | | | | | |
| No medical history | 82 (43.9) | 28 (70.0) | 25 (37.3) | 7 (50.0) | 22 (33.3) |
| 1≥ comorbidities | 105 (56.1) | 12 (30.0) | 42 (62.7) | 7 (50.0) | 44 (66.7) |
| Total comorbidities | 203 | 15 | 86 | 10 | 92 |
| Cardiovascular | 39 | 6 | 14 | 1 | 18 |
| Metabolic | 37 | 6 | 4 | 4 | 23 |
| Orthopaedic[1] | 59 | 0 | 35 | 1 | 23 |
| Respiratory | 14 | 1 | 6 | 2 | 5 |
| Other | 54 | 2 | 27 | 2 | 23 |
| Time after trauma, mean ± SD (range) in months | 4.7±3.4 (0-13) | 4.2±3.1 (1-12) | 4.6±3.5 (0-12) | 2.7±2.6 (0-8) | 5.5±3.5 (0-13) |
| *Cause of trauma (%)* | | | | | |
| Falling | 89 (47.6) | 21 (52.5) | 25 (37.3) | 9 (64.3) | 34 (51.5) |
| Motor vehicle / traffic accident | 50 (26.7) | 18 (45.0) | 18 (26.9) | 4 (28.6) | 10 (15.2) |
| Sports/recreation | 33 (17.6) | 0 | 13 (19.4) | 0 | 20 (30.3) |
| Violence | 6 (3.2) | 0 | 6 (9.0) | 0 | 0 |
| Other | 9 (4.8) | 1 (2.5) | 5 (7.5) | 1 (7.1) | 2 (3.0) |
| *Fracture details* | | | | | |
| Total, mean ± SD (range) | 245, 1.3±0.7 (1-6) | 40, 1.0±0.0 (1-1) | 83, 1.2±0.7 (1-6) | 16, 1.1±0.5 (1-3) | 106, 1.6±0.8 (1-4) |

| | Overall (n=187) | | Asia Pac (n=40) | | Eur/ SS Afr (n=67) | | Latin Am (n=14) | | North Am (n=66) | |
|---|---|---|---|---|---|---|---|---|---|---|
| *Fracture level (%)* | | | | | | | | | | |
| Cervical spine | 107 (43.7) | | 9 (22.5) | | 26 (31.3) | | 5 (31.3) | | 67 (63.2) | |
| Thoracic and lumbar spine | 138 (56.3) | | 31 (77.5) | | 57 (68.7) | | 11 (68.8) | | 39 (36.9) | |
| Fracture type[24] | C | TL | C | TL | C | TL | C | TL | C | TL |
| Type A | 35 | 112 | 3 | 19 | 10 | 51 | 1 | 10 | 21 | 32 |
| Type B | 50 | 21 | 5 | 10 | 14 | 5 | 3 | 0 | 28 | 6 |
| Type C | 13 | 5 | 1 | 2 | 2 | 1 | 1 | 1 | 9 | 1 |
| Unclassified | 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 9 | 0 |
| *Treatment (%)* | | | | | | | | | | |
| Conservative | 77 (41.2) | | 9 (22.5) | | 35 (52.2) | | 10 (71.4) | | 23 (34.8) | |
| Surgical | 97 (51.9) | | 31 (77.5) | | 30 (44.8) | | 4 (28.6) | | 32 (48.5) | |
| Both | 13 (7.0) | | 0 | | 2 (3.0) | | 0 | | 11 (16.7) | |
| *ASIA impairment grade at discharge (%)* | | | | | | | | | | |
| C | 18 (9.9) | | 11 (27.5) | | 4 (6.0) | | 1 (7.1) | | 2 (3.0) | |
| D | 37 (20.3) | | 6 (15.0) | | 9 (13.4) | | 0 | | 22 (33.3) | |
| E | 127 (69.8) | | 23 (57.5) | | 54 (80.6) | | 13 (92.9) | | 37 (56.1) | |
| General health, mean ± SD (range) | 7.3±1.7 (1-10) | | 8.1±5.0 (5-10) | | 7.0±1.6 (3-10) | | 7.5±1.7 (4-10) | | 7.0±2.0 (1-10) | |
| Functioning , mean ± SD (range) | 6.7±2.2 (1-10) | | 7.7±1.5 (4-10) | | 6.5±2.0 (3-10) | | 7.1±2.6 (2-10) | | 6.2±2.6 (1-10) | |

Asia Pac= Asia Pacific; Eur/ SS Afr= Europe and Sub Saharan Africa; Latin Am= Latin America; North Am= North America; SD= standard deviation; C= cervical spine; TL= thoracic and lumbar spine
[1] 11 patients (10 from Eur/ SS Afr, and 1 from North Am) had trauma-related injuries (e.g. rib fracture or ankle fracture)

answers to the open question about the most important issues patients have been facing since the spine trauma were linked to ICF categories, using standardized linkage rules.[12,13] Linkage was performed independently by two researchers trained in the principles and application of the ICF, and the linkage rules. Possible differences between the world regions, and also between the subgroups of each modifier were analyzed using descriptive statistics and Fisher's exact test (significance level 0.05).

## RESULTS

### Patient characteristics

Between March 2013 and August 2014, 187 patients were enrolled in this study. Most of the patients were from the AOSpine International world region Europe and Sub Saharan Africa (n=67; 35.8%), followed by North America (n=66; 35.3%), Asia Pacific (n=40; 21.4%), and Latin America (n=14; 7.5%). The basic patient and clinical characteristics, along with the patient rated general health and current functioning status, are shown in Table 1. The median age was 53 years.

### ICF categories

In total, 38 (29.7%) out of the 128 ICF categories included in this study, were identified as relevant for at least 20% of the patients. Table 2 shows ICF categories experienced as mild to complete impairment/difficulty due to the spine trauma by at least 20% of the patients. Most of these categories were related to *activities and participation* (n=15), followed by *body functions* (n=6), and *body structures* (n=5). Table 3 shows the ICF categories of the component *environmental factors* (n=12) considered to be a facilitator in at least 20% of the patients. In 18.2% of patients surveyed, the environmental factor *climate (e225)* formed the highest barrier. Out of the 38 identified ICF categories, 9 were relevant for at least 20% of the patients in each world region, and 24 for at least 20% of the patients in all subgroups of modifiers. (indicated in Table 2 and Table 3). Problems due to a comorbidity not associated with the index trauma were most frequently denoted for *blood pressure functions* (*b420;* 17.1%), the *cardiovascular system* (*s410;* 16.6%) and *eye, ear and related structures* (*s2;* 13.4%).

The key issues experienced by patients since the spine trauma corresponded with the identified impairments/difficulties outlined in Table 2, except for the categories *changing a basic body position (d410)* and *maintaining a basic body position (d415)*, which are not part of the general ICF Checklist.

### Modifiers

Sub-analyses according to the modifiers revealed some more relevant ICF categories experienced as an impairment/difficulty or facilitator/barrier by the following subgroups of patients: age ≥53 years; female patients; surgically treated patients; patients with cervical fractures; and patients with mild neurological deficit (ASIA impairment grade C or D). The ICF categories experienced as an impairment/difficulty with at least 20% difference between the subgroups for each modifier are shown in Table 4. Regarding the fracture level, only the category *trunk (s760)* showed significantly ($p<0.001$) more problems in patients with thoracic and lumbar fractures (64.3% versus 23.5%). Furthermore, 4 additional ICF categories were identified as an impairment/difficulty in at least 20% of the patients only in these subgroup analyses: *undertaking multiple tasks (d220), emotional functions (b152), memory (b144),* and *defecation (b525),* with respectively 17.1%, 16.0%, 15.0%, and 12.3% in the overall analysis.

**Table 2.** Second level ICF categories qualified as mild to complete impairment/difficulty by at least 20% of the patients. Relative frequencies are shown, along with their 95% bootstrapped confidence intervals (CI) and range among the different world regions.

| ICF code | ICF code | Asia Pac (n=40) | Eur/ SS Afr (n=67) | Latin Am (n=14) |
|---|---|---|---|---|
| d430 | Lifting and carrying objects [a,b] | 69.0 | (62.0-75.4) | (50.7-95.0) |
| d920 | Recreation and leisure [a,b] | 57.8 | (50.8-64.7) | (42.9-75.8) |
| s760 | Trunk [a,b] | 48.1 | (40.6-55.6) | (33.3-75.0) |
| b730 | Muscle power functions [b] | 42.2 | (34.8-49.7) | (12.5-68.2) |
| b130 | Energy and drive functions [b] | 39.6 | (32.6-46.5) | (7.1-67.5) |
| d640 | Doing housework [b] | 39.6 | (32.6-46.5) | (12.5-57.6) |
| b710 | Mobility of joints [b] | 38.0 | (30.5-44.9) | (2.5-63.6) |
| b134 | Sleep [b] | 36.9 | (29.9-44.4) | (19.4-56.1) |
| d475 | Driving [b] | 36.9 | (30.5-43.9) | (14.3-50.0) |
| d450 | Walking [a,b] | 35.3 | (28.9-42.2) | (25.0-43.9) |
| d620 | Acquisition of goods and services [b] | 34.2 | (27.3-40.6) | (17.5-47.0) |
| d910 | Community life [a,b] | 33.7 | (26.7-40.6) | (21.4-42.5) |
| d510 | Washing oneself [a,b] | 30.5 | (24.1-37.4) | (20.0-42.9) |
| d470 | Using transportation [b] | 27.8 | (21.9-34.2) | (19.4-45.0) |
| b280 | Sensation of pain [b] | 26.7 | (20.3-33.2) | (0.0-50.0) |
| s710 | Head and neck region | 26.2 | (19.8-32.6) | (10.0-43.9) |
| b735 | Muscle tone | 24.1 | (17.6-30.5) | (7.5-53.5) |
| s750 | Lower extremity[a] | 23.5 | (17.6-29.4) | (20.9-27.3) |
| d540 | Dressing | 23.0 | (17.1-29.4) | (7.5-42.9) |
| d630 | Preparing meals | 22.5 | (16.6-28.3) | (14.9-33.3) |
| d850 | Remunerative employment | 22.5 | (17.1-29.4) | (12.5-30.3) |
| d520 | Caring for body parts | 21.9 | (16.1-27.8) | (10.0-35.7) |
| s740 | Pelvic region | 21.4 | (15.5-27.3) | (2.5-27.3) |
| s730 | Upper extremity | 20.9 | (15.0-26.2) | (10.4-37.9) |
| d660 | Assisting others | 20.9 | (15.0-26.7) | (7.5-31.8) |
| d440 | Fine hand use | 20.3 | (14.4-26.2) | (7.1-34.8) |

[a] ICF category experienced as an impairment/difficulty by at least 20% of the patients in all regions.
[b] ICF category experienced as an impairment/difficulty by at least 20% of the patients in all subgroups of modifiers.



**Regional differences**

Analyses of the responses according to each world region revealed that, in general, patients from North America experienced the greatest number of impairments/difficulties and endorsed most strongly environmental factors.

The responses to the categories related to body structures showed the least variation among the world regions. Large variations in this component were only observed for *spinal cord and related structures (s120;* $p<0.001$) and all categories from the chapter *structures related to movement (s7;* $p<0.05$), except for *lower extremity (s750;* $p=0.839$). Patients from North America reported most of their impairments in the categories related to this chapter, while patients from Asia Pacific experienced the least number of body structure impairments, except for the category *trunk (s760;* $p<0.001$).

Also in the component body functions most variations were seen in movement related categories, with patients from Asia Pacific and Latin America experiencing the least impairment.

In the component activities and participation, regional differences were limited to a selection of chapters, including *mobility (d4), self-care (d5), domestic life (d6),* and *community, social and civic life (d9).* Although *lifting and carrying objects (d430)* showed the highest variation ($p<0.001$) in this component, this specific category was experienced as an impairment by a majority of the patients in all regions (range: 50.7%-95.0%).

Very minor interregional differences were observed for environmental factors as a barrier, but the same categories showed the largest variations when experienced as a facilitator by the patients, except for the categories from the chapter *natural environment and human-made changes to environment (e2;* $p>0.05$). Patients from Asia Pacific and Latin America least frequently endorsed almost all environmental factors.

## DISCUSSION

Using the ICF as a reference, this empirical cross-sectional multicenter study identified the problems in functioning and health most commonly encountered by patients with traumatic spinal column injuries(excluding patients with complete paralysis), as well as the physical and social environment issues that most profoundly influence them. Categories from all four ICF components were found to be relevant for this patient population. The socio-demographic and clinical characteristics of our sample of 187 patients are comparable to the characteristics of spine trauma patients described in various epidemiological studies.[1,14,15] Along with the representation of four out of five AOSpine International world regions, our findings reflect the worldwide perspective of spine trauma patients with respect to their functioning, disability and health.

Out of the 128 ICF categories included in this study, 38 were identified as relevant for at least 20% of the patients. Categories from the component *activities and participation* covered a wide range of chapters, mainly related to mobility, self-care, domestic life, and social life. These results state the large variety of functional problems that may be experienced by spine trauma patients.[16,17] *Remunerative employment (d850)* was found to be relevant as well, in line with the literature describing spine injury as one of the strongest determinant of return to work after a major trauma.[18]

**Table 3.** Second level environmental factors qualified as facilitator by at least 20% of the patients. Relative frequencies are shown, along with their 95% bootstrapped confidence intervals (CI) and range among the different world regions.

| ICF code | ICF code | Asia Pac (n=40) | Eur/ SS Afr (n=67) | Latin Am (n=14) |
|---|---|---|---|---|
| e310 | Immediate family [a,b] | 65.2 | (58.3-72.2) | (40.0-87.9) |
| e320 | Friends [a,b] | 56.1 | (48.7-63.1) | (25.0-80.3) |
| e355 | Health professionals [b] | 52.9 | (45.5-59.9) | (12.5-80.3) |
| e410 | Individual attitudes of immediate family members [b] | 40.1 | (33.2-47.1) | (15.0-71.2) |
| e325 | Acquaintances, peers, colleagues, neighbours and community members [b] | 38.5 | (31.0-45.5) | (5.0-69.7) |
| e580 | Health services, systems and policies [b] | 37.4 | (30.5-43.9) | (2.5-68.2) |
| e420 | Individual attitudes of friends [b] | 35.8 | (28.9-42.2) | (5.0-72.7) |
| e450 | Individual attitudes of health professionals [b] | 33.2 | (26.7-40.1) | (2.5-74.2) |
| e115 | Products and technology for personal use in daily living [b] | 27.8 | (21.4-34.8) | (5.0-45.5) |
| e110 | Products or substances for personal consumption | 24.6 | (18.7-31.0) | (0.0-42.4) |
| e330 | People in positions of authority | 23.5 | (17.6-29.9) | (2.5-51.5) |
| e340 | Personal care providers and personal assistants | 20.3 | (15.0-26.2) | (0.0-31.8) |

[a] ICF category experienced as a facilitator by at least 20% of the patients in all regions
[b] ICF category experienced as a facilitator by at least 20% of the patients in all subgroups of modifiers



The majority of the relevant body functions and all relevant body structures were related to movement, confirming the optimization of mobility as an important tool for improving the quality of life after spine trauma.[19] Relevant categories from the component body functions also included *energy and drive functions (b130)* and *sleep (b134),* indicating the importance of mental functioning in the recovery process after spine trauma.[20] Interestingly, problems related to the *perception of pain (b280)* were much less prominent in the experiences of patients compared to various function related categories. This may be attributed to not including patients with chronic spine conditions in this study.[21,22]

It is notable that none of the environmental factors were relevant for at least 20% of the patients when experienced as a barrier, while the same 12 categories were relevant when experienced as a facilitator by the patients. The most frequently reported facilitators were *immediate family (e310), friends (e320),* and *health professionals (e355),* in accordance with reports showing the importance of social support for functional ability.[23] Sub-analyses of the potential modifiers showed the largest differences between the subgroups of patients with different spine fracture levels, and different neurological status.

**Table 4.** Second level ICF categories with at least 20% difference between the subgroups of each modifier. Relative frequencies for the overall analysis and for the subgroups of each modifier are shown, along with the level of significance.

| Modifier | ICF code | Description | % overall | % subgroup 1 | % subgroup 2 | p-value |
|---|---|---|---|---|---|---|
| Age (years) | | | (n=187) | <53 (n=93) | ≥53 (n=94) | |
| | d640 | Doing housework | 39.6 | 28.0 | 51.1 | 0.002 |
| | d510 | Washing oneself | 30.5 | 20.4 | 40.4 | 0.004 |
| Gender | | | (n=187) | Male (n=116) | Female (n=71) | |
| | d640 | Doing housework | 39.6 | 29.3 | 56.3 | <0.001 |
| | d510 | Washing oneself | 30.5 | 20.7 | 46.5 | <0.001 |
| | d620 | Acquisition of goods and services | 34.2 | 25.9 | 47.9 | 0.003 |
| | d660 | Assisting others | 20.9 | 12.9 | 33.8 | 0.001 |
| Treatment | | | (n=187) | Cons (n=77) | Surg (n=97) | |
| | d440 | Fine hand use | 20.3 | 5.2 | 27.8 | 1.000 |
| Fracture level | | | (n=187) | C spine (n=68) | TL spine (n=115) | |
| | s710 | Head and neck region | 26.2 | 60.3 | 4.3 | <0.001 |
| | d440 | Fine hand use | 20.3 | 51.5 | 1.7 | <0.001 |
| | s730 | Upper extremity | 20.9 | 50.0 | 3.5 | <0.001 |
| | s760 | Structure of trunk | 48.1 | 23.5 | 64.3 | <0.001 |
| | s120 | Spinal cord and related structures | 19.8 | 42.6 | 6.1 | <0.001 |
| | s720 | Shoulder region | 18.2 | 39.7 | 5.2 | <0.001 |
| | b235 | Vestibular | 18.7 | 35.3 | 8.7 | <0.001 |
| | d570 | Looking after one's health | 17.1 | 30.9 | 8.7 | <0.001 |
| | b530 | Weight maintenance | 16.6 | 29.4 | 8.7 | <0.001 |
| | b735 | Muscle tone | 24.1 | 36.8 | 16.2 | 0.002 |
| Neurological status | | | (n=187) | ASIA C/D (n=55) | ASIA E (n=127) | |
| | d440 | Fine hand use | 20.3 | 49.1 | 6.3 | <0.001 |
| | s730 | Upper extremity | 20.9 | 45.5 | 9.4 | <0.001 |
| | s750 | Lower extremity | 23.5 | 47.3 | 13.4 | <0.001 |
| | s120 | Spinal cord and related structures | 19.8 | 41.8 | 8.7 | <0.001 |
| | d465 | Moving around using equipment | 19.8 | 40.0 | 11.0 | <0.001 |
| | b735 | Muscle tone | 24.1 | 41.8 | 14.2 | <0.001 |
| | b130 | Energy and drive functions | 39.6 | 54.5 | 32.2 | 0.008 |
| | d450 | Walking | 35.3 | 49.1 | 27.6 | 0.006 |
| | b730 | Muscle power functions | 42.2 | 56.4 | 35.4 | 0.014 |
| | b765 | Involuntary movement | 12.3 | 25.5 | 5.5 | <0.001 |

Cons= conservatively treated patients; Surg= surgically treated patients; C spine= patients sustaining a cervical fracture; TL spine= patients sustaining a thoracic and/or lumbar fracture; ASIA C/D= patients with ASIA impairment grade C or D at discharge/transfer from hospital; ASIA E= patients with ASIA impairment grade E at discharge/transfer from hospital

In general, interregional differences were limited to a number of ICF categories. These differences may be related to the interpretation of ICF categories. Also cultural differences could play a role, as the largest variations were observed in the endorsement of environmental factors. Furthermore, some interregional differences may be due to the different patient populations recruited in specific regions.

This study has some limitations. First, one AOSpine International world region was not able to participate in this study, thus the patient perspective from the region Middle East/North Africa is missing. However, considering that the differences from various regions were limited to a number of ICF categories, no major shifts are expected in the overall analysis as the perspective of patients from all other world regions were represented in this study. Second, the number and type of patients differed among the regions. Europe and Sub Saharan Africa, North America, and Asia Pacific were represented by a convenient sample of patients (67, 66 and 40, respectively), while Latin America was represented by only 14 patients. Third, information was obtained from semi-structured interviews by health professionals instead of a standardized questionnaire filled out by patients. We believe that a questionnaire including 128 ICF categories would be too abstract, but also too extensive. Moreover, a part of the ICF Checklist could be filled out in advance from information obtained from the medical record. Fourth, patients with complete paralysis (ASIA impairment grade A or B) were excluded from this study. The results of the current study, therefore, may not apply to the whole spinal cord injury population. Finally, the selection of the ICF categories was based on the arbitrary cut-off point of at least 20% of the patients.

In conclusion, 38 out of 128 ICF categories of the general ICF Checklist were identified as most relevant for at least 20% of traumatic spinal column injury patients (excluding patients with complete paralysis), reflecting their most commonly experienced problems in functioning and health, as well as the influence of environmental factors on it. The results of this empirical study show that loss of functioning and limitations in daily living are most relevant for spine trauma patients on the short term. These results, together with the results of the other preparatory studies, i.e. an expert survey and systematic review, create an evidence base for a consensus meeting during which a core set of ICF categories for outcome measurement in patients with traumatic spinal column injuries will be defined.



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# Chapter 5

## Toward a specific outcome instrument for spinal trauma: how to measure function and health

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## ABSTRACT

*Study Design.* Validation study.
*Objective.* To investigate the most valid, reliable, and comprehensible response scale for spinal trauma patients to compare their current level of function and health with their pre-injury state.
*Summary of Background Data.* In the context of a main project of the AOSpine Knowledge Forum Trauma to develop a disease specific outcome instrument for adult spinal trauma patients, the need to identify a response scale that uniquely reflects the degree to which a spine trauma patient has returned to his or her pre-injury state is crucial.
*Methods.* In the first phase, three different question formats and three different response formats were investigated in a questionnaire, which was administered twice. Based on the results of the first phase, in the second phase a modified questionnaire was administered once to a second group of patients to investigate five different response formats: 0-10 Numeric Rating Scale (NRS-11), 0-100 Numeric Rating Scale (NRS-101), Visual Analog Scale (VAS), Verbal Rating Scale (VRS), and Adjective Scale (AS). All patients were interviewed in a semi-structured fashion to identify their preferences. Multiple statistical analyses were performed: test-retest reliability, internal consistency, and discriminant validity.
*Results.* Twenty eligible patients were enrolled in the first phase and 59 in the second phase. The initial phase revealed the highest preference for one specific question format (60.0% and 86.7% after the first and second administration of the questionnaire, respectively). The second phase showed the VRS as the most preferred response format (35.6%). The semi-structured interviews revealed that overall, a subgroup of patients preferred a verbal response format (42.4%), and another group a numerical response format (49.1%). The statistical analysis showed good to excellent psychometric properties for all formats.
*Conclusions.* The most preferred question and response formats were identified for use in a disease specific outcome instrument for spinal trauma patients.

## INTRODUCTION

Among survivors of major trauma, those with spinal trauma comprise a significant proportion, both in number and in the amount of care they require. Epidemiological studies from different countries have reported an incidence of spinal injury in 4.6% to 33% of all trauma patients.[1-5] As more individuals survive serious trauma, the measurement of the effectiveness of treatment and the influence of spinal column injury on the individuals' health-related quality of life are becoming more and more important. Additionally, the overall strain on medical services is making evidence-based justification of different treatment strategies imperative, and this justification cannot occur without a specific measure to apply to spinal trauma patients in comparative effectiveness analyses.[1-8] However, there are currently no such measures available, contributing to the present lack of consensus and ongoing controversies regarding the optimal treatment and evaluation of many types of spinal injuries.[7]



Therefore, the AOSpine Knowledge Forum Trauma started a project to develop and validate such an instrument, which is proposed to include both the patients' and health professionals' perspective on health and function.[9] The systematic ICF Core Set approach of the World Health Organization's International Classification of Functioning, Disability and Health (ICF)[10-12] is the basis for the development of the patient reported part of this outcome instrument.[13,14]

The development of an outcome instrument designed specifically for spinal trauma patients presents several challenges.[7,15] First, the pre-injury health status of the spinal trauma patient is unknown, which creates difficulty in assessing the impact of spinal trauma due to the lack of a baseline or pre-injury measurement. Comparing the health and function of spinal trauma patients to normative standardized data is not straightforward since the characteristics of spinal trauma patients may very well deviate substantially from those of the general population.[16,17] Consequently, for the development of a disease specific outcome, the need to identify a response scale that uniquely reflects the degree to which a spinal trauma patient has returned to his or her pre-injury state of health and function is crucial. The aim of the current study, therefore, is to assess various response scales for their validity and reliability, but also to analyze the degree to which they are understandable for spinal trauma patients, thus enabling them to accurately compare their current level of function and health with their pre-injury state.

## MATERIALS AND METHODS

### Study design

This study consisted of two phases.

In the first phase , a questionnaire was administered twice to a group of individuals for the purpose of test-retest reliability. In this phase, all patients were interviewed in a semi-structured fashion after completing the first questionnaire to identify their preferences between the various question and response formats.

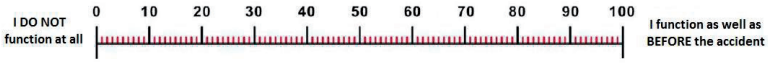
The second phase of this study involved the creation of a modified questionnaire, based to a great extent on the feedback received from participants in the first phase. This modified questionnaire was subsequently administered to a second cohort of individuals. This second sample filled out the questionnaire only on one occasion and had a telephone structured interview to again assess their preferences afterwards.

*Question formats used in the first phase*

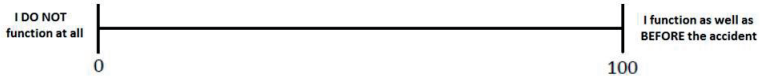
| | |
|---|---|
| Question format A | Please indicate your level of functioning NOW [*item*] compared to BEFORE the accident. |
| Question format B | How are you doing NOW [*item*] compared to BEFORE the accident? |
| Question format C | This category includes activities that have to do with [*item*]. |

*Response formats used in the first phase*

NRS-101




VAS

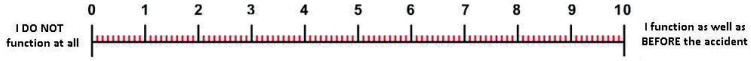



VRS

- ❑ Not possible at all
- ❑ Much worse
- ❑ Worse
- ❑ Somewhat worse
- ❑ Same as BEFORE the accident

*Added response formats in the second phase*

NRS-11




AS

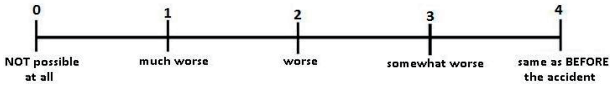



***Figure 1.*** The different question and response formats used in the first phase and the second phase. NRS-101=0-100 Numeric Rating Scale. VAS= Visual Analog Scale. VRS=Verbal Rating Scale. NRS-11= 0-10 Numeric Rating Scale. AS=Adjective Scale

**Instruments**

The questionnaire administered in the first phase consisted of five series of the same items, testing three different question formats and three different response formats (see Figure 1). To enhance the contrast between the questions, the most diverse formats were used to compare the current level of functioning with the pre-injury state. The response formats were a 0-100 Numeric Rating Scale (NRS-101), a Visual Analog Scale (VAS), and a Verbal Rating Scale (VRS). The items of functioning and health included in the question formats were: work or other daily activities, self-care, mobility, sports, hobbies, social functioning, sexual functioning and psychological functioning. These items, along with the question and response formats, were selected from the most commonly used generic outcome instruments and instruments designed for the assessment of populations of spine patients, such as chronic degenerative back-pain and poly-trauma patients.[7, 18-36]

Based on the results of the first phase, the questionnaire was adapted for the second phase. Question format A was adopted in all five parts of the questionnaire, measuring the same eight items of functioning and health, and two additional response formats were added; a 0-10 Numeric Rating Scale (NRS-11) and an Adjective Scale (AS) (Figure 1). The sequence of the five parts was randomized to reduce the risk of bias due to order-effects.

**Patients**

Adults (>18 years) with a diagnosis of spinal trauma and outpatient follow-up within 12 months post-trauma were included. Poly-trauma patients (International Severity Score >15) and patients with complete motor paralysis (American Spinal Injury Association score A or B) were excluded, in order to exclude confounding factors and focus on patients with spine fractures as the main diagnosis, thus, the effect of spinal column injury on health and functioning.

**Study procedures**

Patients were recruited from the Orthopaedic outpatient department of the University Medical Center Utrecht, a level-1 trauma center in The Netherlands.

In the first phase of this study, patients were selected consecutively. Eligible patients were informed about the study via telephone and invited to participate. Once informed consent was given, the questionnaire was mailed to the individuals to fill out at home and bring it along to their regular outpatient appointment. Subsequently, patients were interviewed at the outpatient department, and the same questionnaire was given to fill out once more at home for the purpose of test-retest reliability. The mean response time between the first and second questionnaire was 10.7±9.5 (range: 1-36 days).

In the second phase, the same recruitment method was used, except that patients were recruited by reviewing all outpatient appointments from the previous year, the questionnaire was filled out only on one occasion, and patients had a telephone structured

interview. To reduce the risk of bias, patients from the first phase were not included in the second phase.

Background data was partly collected from the medical record and partly completed during the evaluation interviews. Background data consisted of socio-demographic variables (date of birth, gender, education level, living situation) and variables concerning diagnosis and other health conditions (date of trauma, cause of trauma, main diagnosis, treatment, comorbidities).

According to the Medical Ethics Committee of the University Medical Centre Utrecht, this protocol did not need ethical approval under the scope of the Medical Research Involving Human Subjects Act, because participants were not subjected to procedures nor were they required to follow any specific protocol.

**Statistical analysis**

Patient characteristics were analyzed using descriptive statistics. Patient preferences were analyzed using frequency analysis. Furthermore, the influence of potential determinants of preferences (gender, age and educational level) was analyzed for dichotomized preferences, i.e. either a numerical response format (NRS-11 and NRS-101) or a verbal response format (VRS and AS). Possible differences between the subgroups of each determinant were analyzed using Chi square test.

Test-retest reliability was assessed using Intraclass Correlation Coefficients (ICC), with good and excellent reliability indicated by values of 0.70-0.85 and >0.85, respectively.[37] The internal consistency of each part of the questionnaire was assessed by calculating Cronbach's α and item-total correlation coefficients. It is suggested that the value of α should be above 0.70 for acceptance as satisfactory internal consistency.[38-40]

In the second phase, as external criterion for discriminant validity, the degree of recovery was assessed for each patient by thoroughly evaluating the most recent reports and radiographic findings in the medical record. The degree of recovery was subdivided into four categories: 'not recovered at all', 'somewhat recovered', 'mainly recovered', and 'completely recovered'. Subsequently, the discriminative ability of each response format was analyzed by calculating the mean scores for each category and performing F tests (significance level 0.05). Finally, the effect size of the difference between the two largest categories was calculated for each response format using Cohen's d. The standard interpretation of d was used: 0.20 is considered a small effect, 0.50 a moderate effect, and 0.80 is considered a large effect.[41]

**Table 1.** Patient and clinical characteristics of the study populations are shown.

| | First phase (n=20) | Second phase (n=59) |
|---|---|---|
| Male (%) | 14 (70.0) | 37 (62.7) |
| Age, mean ± SD (range) in years | 46.3 ± 18.6 (22-82) | 51.2 ± 19.9 (18-85) |
| Time after trauma in months ± SD (range) | 4.1 ± 2.8 (1.0-11.5) | 4.9 ± 3.8 (0-12.0) |
| Cohabiting (%) | 18 (90.0) | 46 (78.0) |
| High educational level (%)[a] | 6 (30.0) | 20 (33.9) |
| No medical history (%) | 14 (70.0) | 36 (61.0) |
| Comorbidities | | |
| Cardiovascular/respiratory (%) | 4 (20.0) | 12 (20.3) |
| Orthopaedic diagnosis (%) | 1 (5.0) | 7 (11.9) |
| Multiple (%) | 1 (5.0) | 4 (6.8) |
| Cause of trauma | | |
| Road traffic accidents (%) | 11 (55.0) | 22 (37.3) |
| (High) falls (%) | 9 (45.0) | 32 (54.2) |
| Other (%) | 0 | 5 (8.5) |
| No. of fractures, mean ± SD (range) | 34, 1.7 ± 1.4 (1-6) | 89, 1.5 ± 1.0 (1-8) |
| Fracture level | | |
| Cervical spine (%) | 15 (44.1) | 33 (37.1) |
| Thoracic and lumbar spine (%) | 19 (55.9) | 54 (60.7) |
| Sacral spine (%) | 0 | 2 (2.2) |
| Fracture type[62] | | |
| Type A (%) | 26 (76.5) | 58 (65.2) |
| Type B (%) | 5 (14.7) | 25 (28.1) |
| Type C (%) | 0 | 0 |
| Odontoid (%) | 2 (5.9) | 2 (2.2) |
| Hangman (%) | 1 (2.9) | 2 (2.2) |
| Sacral (%) | 0 | 2 (2.2) |
| Treatment | | |
| Non-surgical (%) | 13 (65.0) | 41 (69.5) |
| Surgical (%) | 7 (35.0) | 18 (30.5) |

SD = standard deviation.
[a] Higher and academic education, according to the Dutch education system[60]

## RESULTS

### Patient characteristics

In the first phase of this study, 20 (74.1%) out of 27 eligible patients were enrolled. Of these patients, 15 (75.0%) returned the second questionnaire for test-retest reliability. In the second phase, 59 (77.6%) out of 76 eligible patients were enrolled. Exclusion of 7 patients in the first phase and 17 patients in the second phase was based on either unwillingness to participate or not returning the questionnaire. One patient returned a partly completed questionnaire. The basic patient and clinical characteristics for both study populations are shown in Table 1.

### Patient preferences

The first phase revealed the highest preference for question format A (60.0% and 86.7% after the first and second administration of the questionnaire, respectively), followed by question format B (15.0% and 13.3%), and question format C (15.0% and 0%). The remaining 10.0% of the participants in the first round of the first phase stated 'no preference' for a question format. However, there was no strong preference for one response format. The most preferred response format was the VRS (55.0% and 53.3%), followed by the NRS-101 (45.0% and 46.7%), while the VAS was not chosen at all. The mean self-reported time to complete the questionnaire in the first phase was 13.2±7.4 minutes (range: 5-30 minutes).

The distribution of the most preferred response format in the second phase is shown in Figure 2. The VRS was most often preferred by the patients, followed by the NRS-101, NRS-11, the AS, and the VAS. Two patients had no preference. Surprisingly, the order of the series made a large difference: the preferred response format was most frequently in Part 1 of the questionnaire (36.8%), followed by Part 2 (22.8%), Part 5 (21.1%), Part 3 (14.0%) and Part 4 (5.3%). The most preferred response format subdivided according to the patient's educational level is shown in Figure 3. The semi-structured interviews revealed that 49.1% of the patients preferred a numerical response format (NRS-11 or NRS-101), while 42.4% preferred a verbal response format (VRS or AS). The mean self-reported time to fill out the questionnaire in the second phase was 12.2±7.1 minutes (range: 5 to 45 minutes).

### Determinants

There were no statistically significant differences in preferences for response format according to gender, age or education. The numerical response format was somewhat more often preferred by male patients(60.6% versus 42.9%; p=0.202), patients younger than the median age of 53 years (60.7% versus 46.2%; p=0.284), and patients with lower educational (60.6% versus 36.8%; p=0.099).

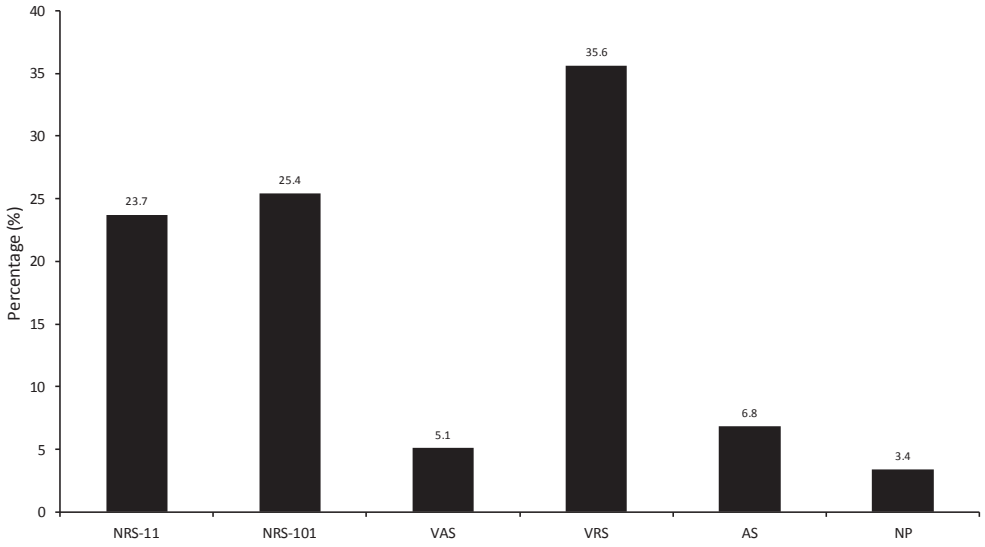



***Figure 2.*** Distribution of the most preferred response formats in the second phase.
NRS-11 = 0-10 Numeric Rating Scale; NRS-101 = 0-100 Numeric Rating Scale; VAS = Visual Analog Scale; VRS = Verbal Rating Scale; AS = Adjective Scale; NP = no preference.

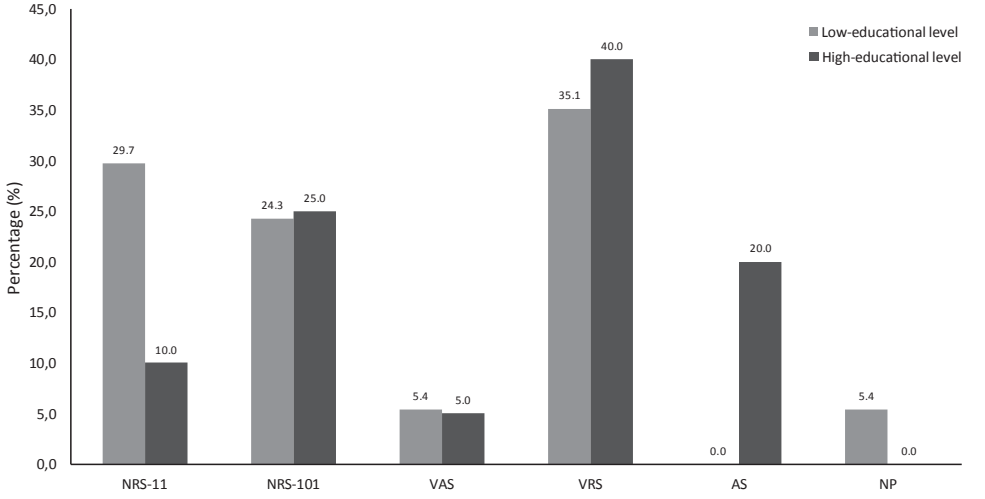



***Figure 3.*** Distribution of the most preferred response formats in the second phase subdivided into low- and high-educational level.
NRS-11 = 0-10 Numeric Rating Scale; NRS-101 = 0-100 Numeric Rating Scale; VAS = Visual Analog Scale; VRS = Verbal Rating Scale; AS = Adjective Scale; NP = no preference..

### Test-retest reliability

The first phase showed satisfactory to excellent test-retest reliability results for all question and response formats, with the ICC ranging from 0.73 to 0.98 (Table 2).

### Internal consistency

Both in the first phase and the second phase, internal consistency of all formats was excellent with a range of Cronbach's α from 0.91 to 0.93 and high item-total correlations (Table 3).

### Discriminant validity

According to the external criterion, 11 patients were 'somewhat recovered', 39 patients were 'mainly recovered' and 8 patients were 'completely recovered'. The statistical analysis revealed that all response formats discriminated well between the different degrees of recovery ($p < 0.001$ for all response formats), with the NRS-11 having the best discriminative ability (Table 4; Figure 4 A-E). The effect size between the two largest subgroups, i.e. 'somewhat recovered' and 'mainly recovered' patients, is also shown in Table 4.

**Table 2.** Test-retest reliability, assessed by using Intraclass Correlation Coefficient, is shown for overall analysis and each item of the questionnaire in the first phase.

| Combinations of formats | Overall | Work | Self-care | Mobility | Sport | Hobby | Social | Sexual | Psychological |
|---|---|---|---|---|---|---|---|---|---|
| A_NRS-101 | 0.97 | 0.90 | 0.93 | 0.83 | 0.95 | 0.95 | 0.98 | 0.84 | 0.96 |
| B_NRS-101 | 0.96 | 0.92 | 0.90 | 0.93 | 0.96 | 0.96 | 0.97 | 0.84 | 0.96 |
| C_NRS-101 | 0.96 | 0.91 | 0.93 | 0.90 | 0.97 | 0.94 | 0.98 | 0.84 | 0.94 |
| A_VAS | 0.97 | 0.91 | 0.93 | 0.83 | 0.97 | 0.96 | 0.94 | 0.83 | 0.94 |
| A_VRS | 0.92 | 0.91 | 0.73 | 0.74 | 0.74 | 0.84 | 0.86 | 0.93 | 0.93 |

A = question format A; B = question format B; C = question format C; NRS-101 = 0-100 Numeric Rating Scale; VAS = Visual Analog Scale; VRS = Verbal Rating Scale.

**Table 3.** Internal consistency of each part of the first- (1) and second (2) questionnaire in the first phase, and each part of the questionnaire in the second phase are shown (number of items = 8).

| Combinations in the first phase | Cronbach's α | Range of Item-Total Correlation | Combinations in the second phase | Cronbach's α | Range of Item-Total Correlation |
|---|---|---|---|---|---|
| A_NRS-101 (1) | 0.93 | 0.61 – 0.89 | A_NRS-11 | 0.93 | 0.71 - 0.85 |
| A_NRS-101 (2) | 0.93 | 0.58 – 0.93 | A_NRS-101 | 0.93 | 0.67 – 0.85 |
| B_NRS-101 (1) | 0.93 | 0.64 – 0.89 | A_VAS | 0.92 | 0.60 – 0.87 |
| B_ NRS-101 (2) | 0.93 | 0.56 – 0.93 | A_VRS | 0.92 | 0.63 – 0.87 |
| C_NRS-101 (1) | 0.92 | 0.60 – 0.91 | A_AS | 0.91 | 0.68 – 0.77 |
| C_NRS-101 (2) | 0.93 | 0.57 – 0.93 | | | |
| A_VAS (1) | 0.92 | 0.65 – 0.87 | | | |
| A_VAS (2) | 0.93 | 0.57 – 0.94 | | | |
| A_ VRS (1) | 0.91 | 0.45 – 0.84 | | | |
| A_VRS (2) | 0.93 | 0.27 – 0.90 | | | |

A = question format A; B = question format B; C = question format C; NRS-11= 0-10 Numeric Rating Scale; NRS-101 = 0-100 Numeric Rating Scale; VAS = Visual Analog Scale; VRS = Verbal Rating Scale. AS=Adjective Scale.

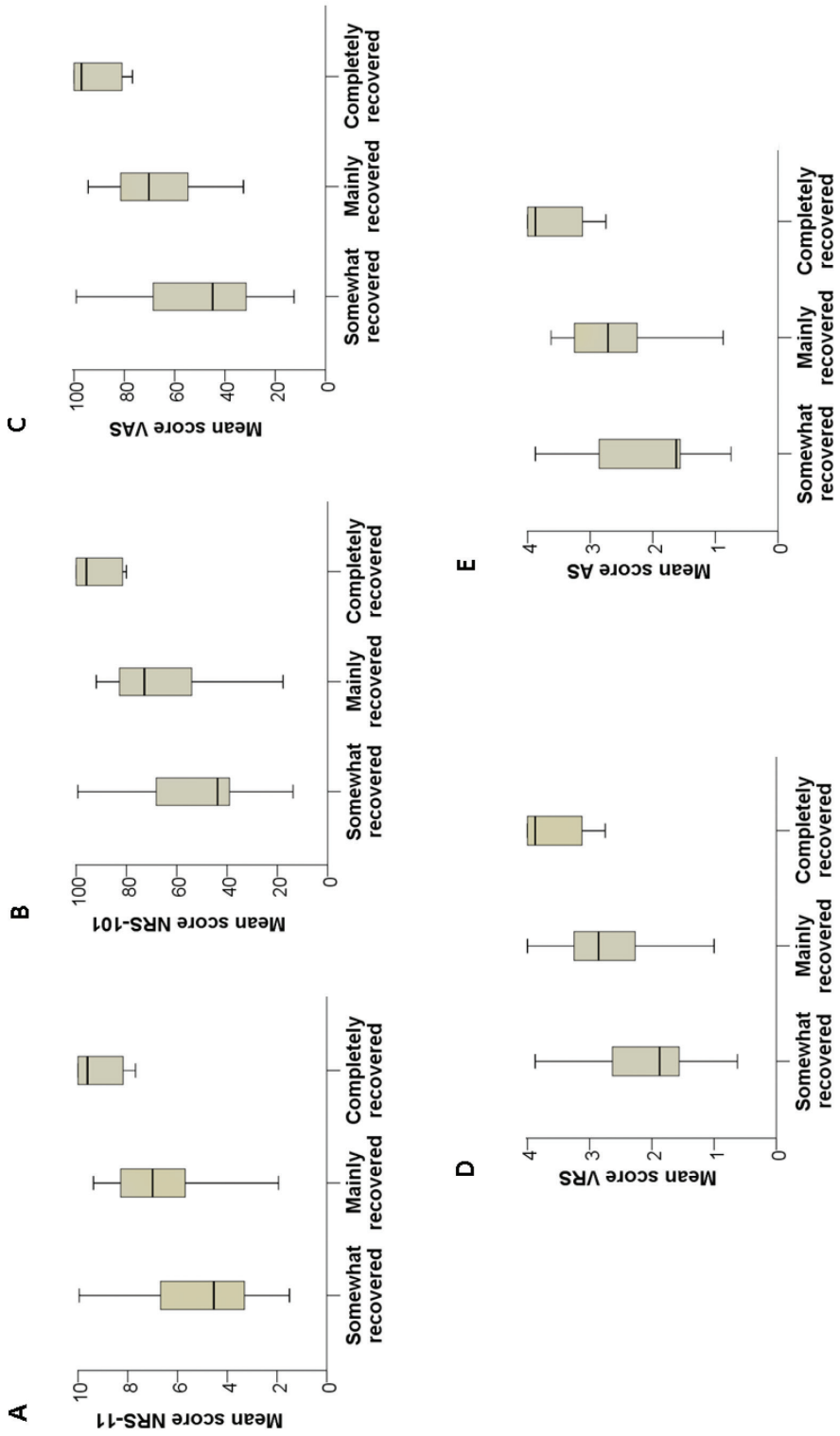



***Figure 4.*** (A-E) Box-whisker plots for the response formats are shown for three subsets of patients with different degrees of recovery, according to the external criterion.

## DISCUSSION

To the best of our knowledge, this is the first study investigating how to measure function and health in spinal trauma patients, in terms of question and response format. Moreover, it is one of the few studies comparing various questionnaire formats and taking the patient's view into account. Since spinal trauma is an acute often life-threatening event leading to a loss of function, this study focused specifically on the comparison of individuals current level of function and health with their pre-injury state.[16,42] In the literature that describes the development of questionnaires for partly overlapping, but dissimilar, patient populations, the selection of the question or response format was either based on the author's opinion or not mentioned at all.[27,31,43-45] Although the NRS, VRS and VAS have been compared in different patient populations, most studies investigated only psychometric properties.[46,47] The few studies also investigating the preference from the patient perspective showed most frequently a NRS as the preferred response format.[48-51]

The first phase of our study showed a clear preference for question format A ('Please indicate your level of functioning NOW [*item*] compared to BEFORE the accident'). However, there was no strong preference for one specific response format. After adapting the questionnaire and investigating it in a larger patient sample, the semi-structured interviews revealed that slightly more patients preferred a numerical response format (NRS-11 or NRS-101) than a verbal response format (VRS or AS).

Also several other findings obtained from the interviews are of great value for the development of the outcome instrument. Patients stated that question format A was the most comprehensible and most easy to understand when comparing their current level of function with their pre-injury state. The VRS was the preferred response format since it was perceived as easy and well-structured with conveniently arranged response options. The NRS-11 was viewed as a school mark, possibly due to the standard practice in the Netherlands of providing students with grades between 0 and 10 during their elementary and secondary schooling. On the other hand, the NRS-101 was viewed by participants as a percentage scale. Despite its simplicity and extensive use in medicine to assess a variety of constructs, e.g. pain,[52] mood,[53] and functional capacity,[27,54] the VAS was least endorsed as response format. Our finding of patients preferring the NRS-101 over the VAS because of the display of the intervals, is supported by several studies.[48,55-58]

Multiple statistical analyses showed that all response formats had good psychometric properties and that all are capable of discriminating between the different degrees of recovery, with the NRS-11 having a slightly better discriminative ability. Although in a different patient population, Brunelli et al. also showed a higher discriminatory capability for the NRS compared to the VRS.[59]

**Table 4.** Discriminative ability for each response format was calculated.

| | Degree of recovery[a] | Mean | SD | *F* | *d* |
|---|---|---|---|---|---|
| NRS-11 | Somewhat recovered | 5.1 | 3.0 | 10.001* | 0.712 |
| | Mainly recovered | 6.8 | 1.7 | | |
| | Completely recovered | 9.2 | 1.0 | | |
| NRS-101 | Somewhat recovered | 52.1 | 29.6 | 9.312* | 0.652 |
| | Mainly recovered | 67.6 | 18.1 | | |
| | Completely recovered | 91.9 | 9.2 | | |
| VAS | Somewhat recovered | 51.0 | 30.6 | 9.126* | 0.642 |
| | Mainly recovered | 66.8 | 18.5 | | |
| | Completely recovered | 91.6 | 10.2 | | |
| VRS | Somewhat recovered | 2.1 | 1.1 | 9.924* | 0.768 |
| | Mainly recovered | 2.7 | 0.6 | | |
| | Completely recovered | 3.6 | 0.5 | | |
| AS | Somewhat recovered | 2.1 | 1.1 | 9.274* | 0.652 |
| | Mainly recovered | 2.7 | 0.6 | | |
| | Completely recovered | 3.6 | 0.5 | | |

[a]Arbitrary based on the most recent reports and radiographic findings in the medical record, i.e. the reported level of functioning, level of pain, radiological assessments, and the future surgeon decided time point to see the patient again at the outpatient department
* = p<0.001
d= Cohen's d effect size between the subgroups 'somewhat recovered' and 'mainly recovered'
NRS-11= 0-10 Numeric Rating Scale; NRS-101 = 0-100 Numeric Rating Scale; VAS = Visual Analog Scale; VRS = Verbal Rating Scale; AS= Adjective Scale; SD= standard deviation.



More patients with lower educational levels preferred the responses with numerical formats in our sample, although this difference did not reach statistical significance. The educational profile of our patient population corresponds with the Dutch population.[60] However, since literacy can be an issue in developing countries,[61] a numeric scale is expected to be most suitable for an international outcome instrument.

Our study has some limitations, including the selection of the most preferred question format based on the results of an initial study with a small number of participants. However, it is highly unlikely that a different question format would result from a larger patient sample since 86.7% of the participants preferred this question format. Secondly, examination of test-retest reliability was not repeated in the second phase, as it was excellent in the first phase. This analysis can be repeated in a later phase of the outcome development process, when the core ICF categories are selected. Thirdly, the degree of recovery from the surgeons' perspective was arbitrarily based on the most recent clinical reports of the patients' health and function, but the patients' situation could have changed since their last visit to the outpatient clinic. Nevertheless, this was the most feasible way to make an assessment of the degree of recovery in order to test the external criterion. Finally, the fact that this study included only individuals from the Netherlands does to some degree limit its generalizability. We acknowledge that corroborating these findings in a heterogeneous international study cohort will be important.

In conclusion, the unique challenges of designing a disease specific outcome instrument for spinal trauma patients requires that all patients understand both the question format and the response format and that these are valid and reliable. We have identified what is the most preferred question format and the preferred response format for use in a disease specific outcome instrument for adult spinal trauma patients which is currently under development. Since both response formats have also shown good psychometric properties, selection of the response format should depend on ease of use in the international setting. The items of the questions will be based on a selection of ICF categories that are by consensus most relevant for this patient population. After implementation of the items in the questionnaire, in future studies the instrument will be subjected to further validation for measuring function and health in adult spinal trauma patients.

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# Chapter 6

## The selection of core International Classification of Functioning, Disability and Health (ICF) categories for patient-reported outcome measurement in spine trauma patients: results of an international consensus process

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## ABSTRACT

*Background context:* There is no outcome instrument specifically designed and validated for spine trauma patients without complete paralysis, which makes it difficult to compare outcomes of different treatments of the spinal column injury within and between studies.
*Purpose:* To report on the evidence-based consensus process that resulted in the selection of core International Classification of Functioning, Disability and Health (ICF) categories, as well as the response scale for use in a universal patient reported outcome measure for traumatic spinal column injury patients.
*Study Design/Setting:* A formal decision-making and consensus process.
*Patient sample:* Patients with traumatic spinal column injury as primary diagnosis, excluding completely paralyzed and poly-trauma patients.
*Outcome measures:* The wide array of function and health status of traumatic spinal column injury patients was explored through the identification of all potentially meaningful ICF categories.
*Methods:* A formal decision-making and consensus process integrated evidence from four preparatory studies. Three studies aimed to identify relevant ICF categories from three different perspectives. The research perspective was covered by a systematic literature review identifying outcome measures focusing on the functioning and health of spine trauma patients. The expert perspective was explored through an international web-based survey among spine surgeons from the five AOSpine International world regions. The patient perspective was investigated in an international empirical study. A fourth study investigated various response scales for their potential use in the future universal outcome instrument. This work was supported by AOSpine. AOSpine is a clinical division of the AO Foundation—an independent medically guided nonprofit organization. The AOSpine Knowledge Forums are pathology focused working groups acting on behalf of AOSpine in their domain of scientific expertise.
*Results:* Combining the results of the preparatory studies, the list of ICF categories presented at the consensus conference included 159 different ICF categories. Based on voting and discussion, eleven experts from six countries selected a total of 25 ICF categories as core categories for patient reported outcome measurement in adult traumatic spinal column injury patients (9 body functions, 14 activities and participation, and 2 environmental factors). The experts also agreed to use the Numeric Rating Scale 0-100 as response scale in the future universal outcome instrument.
*Conclusions:* A formal consensus process integrating evidence and expert opinion led to a set of 25 core ICF categories for patient reported outcome measurement in adult traumatic spinal column injury patients, as well as the response scale for use in the future universal disease-specific outcome instrument. The adopted core ICF categories could also serve as a benchmark for assessing the content validity of existing and future outcome instruments used in this specific patient population.

## INTRODUCTION

Traumatic spinal column injuries remain a major public health concern. Although these injuries comprise only a minority of all traumatic injuries, they have a significant influence on the individual's social, functional, and financial situation.[1,2] A subset of these patients are dealing with an associated neurological injury, which contributes to substantial disability with long-term consequences and associated considerable health care related costs.[3-5]

Currently, there is a lack of consensus regarding the evaluation and optimal treatment of many types of spinal column injuries.[6,7] Although a number of outcome instruments have been developed and validated for individuals with traumatic spinal cord injury, these tend to focus on the impact of paralysis.[8] In the absence of an outcome instrument specifically designed and validated for spine trauma patients without complete paralysis, it is difficult to compare outcomes of different treatments of the spinal column injury within and between studies.



In reflection of this dilemma, the AOSpine Knowledge Forum Trauma initiated a project to develop and validate universal disease-specific outcome instruments for adult spine trauma patients that include both the patients' and clinicians' perspectives.[9] In the developmental phase and initial validation of the patient reported part of this outcome instrument, completely paralyzed (American Spinal Injury Association (ASIA) impairment grade A or B) and poly-trauma patients (Injury Severity Score > 15) were excluded, in order to exclude confounding factors and to maintain the focus on a well-defined patient population with traumatic spinal column injury as primary diagnosis.

We have decided to use the systematic and comprehensive approach of the International Classification of Functioning, Disability and Health (ICF) of the World Health Organization [10-12] as the basis for the development of this disease-specific patient reported outcome instrument.[13] The bio-psycho-social perspective of the ICF relies on a globally accepted framework to describe and classify functioning, disability and health in people with a variety of diseases, conditions or health states. As shown in Fig. 1, the ICF recognizes that problems in functioning can be understood and described using different components: *body functions (b)*, *body structures (s), activities and participation (d), environmental factors (e),* and *personal factors (pf;* not yet further classified).

With more than 1400 categories hierarchically organized into different levels across these components, the ICF is too comprehensive for use in daily practice. Therefore, the preparatory phase of the project focused on identifying potentially meaningful ICF categories for traumatic spinal column injury patients from different perspectives. A fourth preparatory study investigated different response scales for use in the future universal disease-specific patient reported outcome instrument. The results of these studies created the necessary background for an international consensus conference during which a selection of core ICF categories and response scale was decided on for universal outcome measurement in adult traumatic spinal column injury patients (Fig. 2). The objective of this paper is to report on the results of this consensus process.

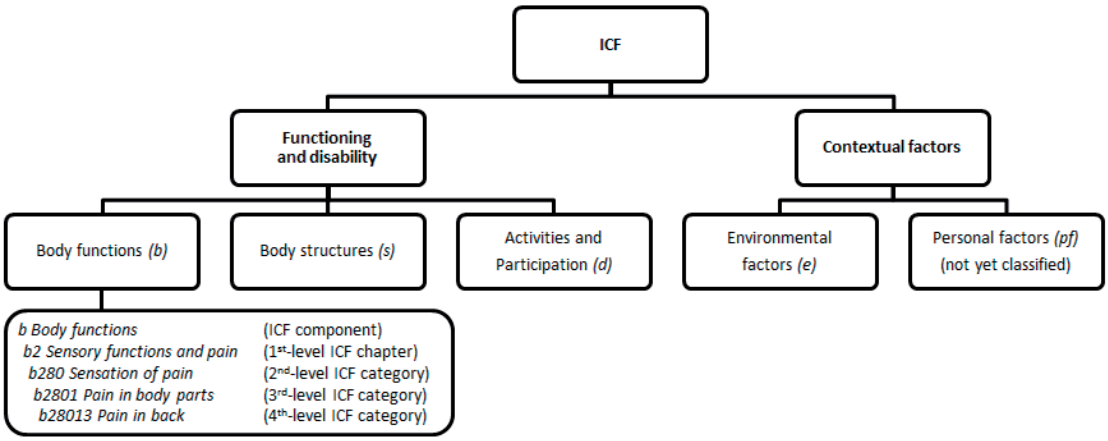



***Figure 1.*** The bio-psycho-social perspective of the International Classification of Functioning, Disability and Health (ICF), along with an example of the hierarchical fashion in different levels.

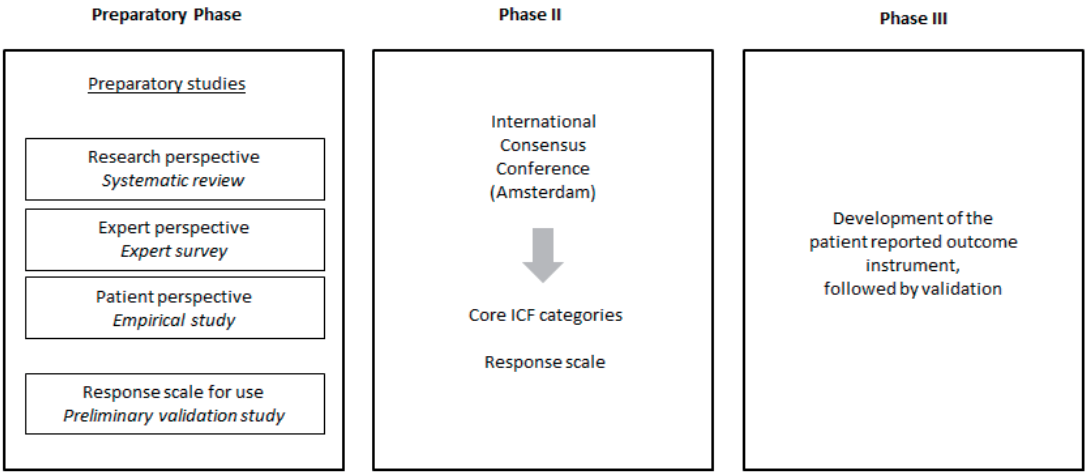



***Figure 2.*** Phases of the project to develop and validate an international disease-specific patient reported outcome instrument for traumatic spinal column injury patients.

## MATERIALS AND METHODS

The consensus conference took place on August 30, 2014 in Amsterdam, The Netherlands, and was attended by a panel of internationally renowned experts on spinal trauma.

### Preparatory studies

Three preparatory studies aimed to identify relevant ICF categories for traumatic spinal column injury patients from three different perspectives, i.e. research, expert, and patient perspectives. The results of these studies have been described in detail elsewhere.[14-16]

1) The research perspective was covered by a systematic literature review in which the outcome measures used in spine trauma research were evaluated.[14] The contents of the identified measures were linked to the ICF using established linking rules.[17,18]

2) The expert perspective was explored through an international cross-sectional web-based survey among 150 experienced spine trauma surgeons from the five AOSpine International world regions.[15] They were asked to rate the relevance of a compilation of 143 ICF categories for traumatic spinal column injury patients.

3) The patient perspective was investigated in an international cross-sectional empirical study, including 187 traumatic spinal column injury patients from 9 trauma centers in 7 countries (covering 4 AOSpine International world regions).[16] The generic ICF Checklist, consisting of 128 ICF categories, was used in semi-structured interviews to describe their most commonly experienced problems. This study was approved by the institutional review board of each participating center and performed in accordance with the Declaration of Helsinki.

At a level-1 trauma center in The Netherlands, a fourth preparatory study among adult traumatic spinal column injury patients was conducted, to investigate various question and response formats for their potential use in the future patient reported outcome instrument (Table 1).[19] According to the local Medical Ethics Committee, the protocol of this questionnaire on response scales did not require ethical approval under the scope of the Medical Research Involving Human Subjects Act.

### Recruitment of conference participants

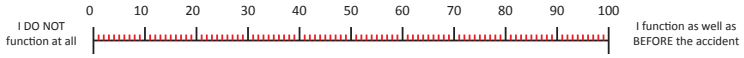
Potential participants for the consensus conference were selected by AOSpine International from a pool of candidates already involved or interested in the project. This pool consisted of members of the AOSpine Knowledge Forums Trauma and Spinal Cord Injury, as well as experts involved in the preparatory studies. In total, eleven international spine trauma experts from six countries (i.e. Brazil, Canada, India, Netherlands, South Africa, and USA) attended the conference; nine spine surgeons, one epidemiologist, and one senior researcher and professor in spinal cord injury rehabilitation with an academic background in psychology. The members of these international groups of spine surgeons are recognized as thought leaders and are globally renowned for their contributions that have advanced the field of spine trauma research and care.

**Table 1.** The question and response formats investigated in one of the preparatory studies.

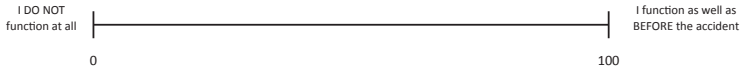
| | |
|---|---|
| *Question formats* | |
| Question format A | Please indicate your level of functioning NOW [item] compared to BEFORE the accident. |
| Question format B | How are you doing NOW [item] compared to BEFORE the accident? |
| Question format C | This category includes activities that have to do with [item]. |

*Response formats*

NRS-101




VAS




VRS

- ☐ Not possible at all
- ☐ Much worse
- ☐ Worse
- ☐ Somewhat worse
- ☐ Same as BEFORE the accident

NRS-11


AS


NRS-101=0-100 Numeric Rating Scale. VAS= Visual Analog Scale. VRS=Verbal Rating Scale. NRS-11= 0-10 Numeric Rating Scale. AS=Adjective Scale.

## Consensus procedure

In preparation of the conference, all participants were provided with a document containing the background of the project and essential details of the preparatory studies. At the beginning of the conference, the participants were trained in the structure, principles and nomenclature of the ICF in general. Subsequently, an overview of the project followed by the design and results of the preparatory studies was presented. Before the consensus process started, participants were trained in the principles and rules that would be applied during the consensus process. The process was moderated and facilitated by a research manager of AOSpine International. The operating language during the conference was English.

The consensus process consisted of a plenary session and a decision-making process among the experts. Each ICF category and its relevance based on the preparatory studies was presented by the moderator, following which the experts discussed whether it should be selected as a core ICF category. An ICF category was only selected as a core category after consensus was reached among the experts. In this context, a core category was defined as an ICF category being 1) relevant for adult traumatic spinal column injury

**Table 2.** Illustration of ICF categories including the relative frequency resulting from each preparatory study, as presented at the consensus conference, that required different amount of discussions among the conference participants.

| ICF code | Description | Systematic review (% of articles) | Expert survey (% relevant) | Empirical study (% impairment) |
|---|---|---|---|---|
| *ICF categories affirmed as core category by ≥80% of the participants* | | | | |
| *d430* | Lifting and carrying objects | 43.0 | 72.9 | 69.0 |
| *d920* | Recreation and leisure | 43.5 | 39.3 | 57.8 |
| *b730* | Muscle power functions | 54.4 | 93.3 | 42.2 |
| *ICF categories discussed in detail* | | | | |
| *s120* | Spinal cord and related structures | 52.7 | 96.5 | 19.8 |
| *b152* | Emotional functions | 18.1 | 26.7 | 16.0 |
| *d550* | Eating | 12.2 | 82.9 | 5.3 |
| *ICF categories not included as core category without discussion* | | | | |
| *d720* | Complex interpersonal interactions | 7.6 | 22.1 | 4.3 |
| *b420* | Blood pressure | x | 60.0 | 2.1 |
| *d177* | Making decisions | x | 40.0 | X |

x = not measured in this preparatory study



patients, 2) relevant for clinical and functional recovery during the acute and post-acute time frame, and 3) meaningful to include in the universal patient reported outcome instrument. Once the core ICF categories were defined, the results of the response scales study were discussed. Subsequently, the participating experts agreed on the scale for use in the future universal outcome instrument.

## RESULTS

### Preparatory studies

The systematic literature review identified 17 frequently used outcome measures in 245 articles.[14] The contents of these measures were linked to 57 different ICF categories. The expert survey yielded 13 ICF categories as most relevant for traumatic spinal column injury patients from the perspective of spine surgeons.[15] The empirical study identified 38 ICF categories as most relevant to be included in the spinal column injury outcome instrument.[16] The list of ICF categories presented at the conference included all unique first- and second-level ICF categories from the preparatory studies, sorted on the relevance from the empirical study. In total, 159 different categories were presented (46 *body functions,* 16 *body structures,* 64 *activities and participation,* and 33 *environmental factors)*. A fraction of this list is shown in Table 2.

**Table 3.** The selected core ICF categories (n=25) for outcome measurement in adult traumatic spinal column injury patients.

| | |
|---|---|
| *Body functions (n=9)* | |
| b130 | Energy and drive functions |
| b134 | Sleep functions |
| b152 | Emotional functions |
| b280 | Sensation of pain |
| b525 | Defecation functions |
| b620 | Urination functions |
| b640 | Sexual functions |
| b710 | Mobility of joints |
| b730 | Muscle power functions |
| *Activities and participation (n=14)* | |
| d410 | Changing basic body position |
| d415 | Maintaining a body position |
| d430 | Lifting and carrying objects |
| d450 | Walking |
| d470 | Using transportation |
| d475 | Driving |
| d510 | Washing oneself |
| d530 | Toileting |
| d540 | Dressing |
| d630 | Preparing meals |
| d640 | Doing housework |
| d850 | Remunerative employment |
| d910 | Community life |
| d920 | Recreation and leisure |
| *Environmental factors (n=2)* | |
| e110 | Products or substances for personal consumption |
| e3 | Support and relationships |

**Core ICF categories**

Based on voting and discussion, a total of 25 first- and second-level ICF categories were selected as core ICF categories for patient reported outcome measurement in adult traumatic spinal column injury patients (Table 3). Those include 9 (36.0%) categories from the component *body functions,* 14 (56.0%) from the component *activities and participation,* and 2 (8.0%) from the component *environmental factors*. No ICF category from the component *body structures* was selected. All core ICF categories belong to the second-level of the ICF except for *Support and relationships (e3),* which is a first-level category.

Some ICF categories were discussed in more detail, especially those related to the component *body structures,* e.g. *Spinal cord and related structures (s120)* and categories from the chapter *Structures related to movement (s7).* Those categories were considered to be more relevant for the future outcome instrument from the clinicians' perspective.

Also some other categories were discussed in detail, but not selected as core categories for outcome measurement in traumatic spinal column injury patients. ICF categories such as *Eating (d550), Drinking (d560),* and *Protective functions of the skin (b180)* were found to be more relevant for severe spinal cord injured patients who are dealing with long-term consequences and rehabilitation.

**Response scale**

From the investigated formats shown in Table 1, the question format A combined with the Numeric Rating Scale 0-100 (NRS-101) was chosen as the response scale for use in the future universal outcome instrument. In this response format, 0 indicates ''I DO NOT function at all'' and 100 indicates ''I function as well as BEFORE the accident''. In the preparatory study, this response scale showed excellent results.[19] Moreover, the experts agreed on this response scale being the most appropriate for use in all items, as well as for combining item scores to a total score.



## DISCUSSION

A formal consensus process, which integrated evidence from preparatory studies as well as the opinions of a group of recognized content experts at the consensus conference led to the definition and formal adoption of a set of 25 core ICF categories for outcome measurement in adult traumatic spinal column injury patients. The participating experts also agreed on the response scale to be used in the future universal disease-specific patient reported outcome instrument.

Our systematic review addressed the lack of unanimity regarding patient and clinician reported instruments to assess spine trauma outcomes.14 This is in line with the results of a review by Stadhouder et al. which identified 21 different outcome instruments.[8] In addition, they proposed a list of ICF categories that could be used when evaluating outcome measures in spinal trauma. Consisting of 14 first-level ICF categories from all 4 components, this list differs substantially from the core ICF categories presented in the current study. The list of ICF categories as suggested by Stadhouder et al. was mainly based on authors' opinions and the identified literature discussing the implementation of the ICF to spinal trauma, while the findings of the current consensus process have a formal and solid base from different preparatory studies. Taking the formally adopted core ICF categories into account, it would be interesting to re-evaluate the results of Stadhouder et al. regarding the outcome domains measured by the instruments they identified. Thus, the core ICF categories presented here could serve as a benchmark when assessing the content validity of existing and future outcome instruments applied to this specific patient population.

Comparison of the results of the preparatory studies yielded some interesting findings. The systematic review showed that the most frequently used outcome measures

in spine trauma research focused primarily on pain.[14] Also clinician based neurological classifications [20,21] were frequently used. This is in line with many studies from all over the world reporting neurological status as a strong determinant of outcome in spine trauma, and the intensity of pain experienced by the patient as an outcome measure.[22-27] Interestingly, the most relevant ICF categories identified in the expert survey related to the same issues.[15] However, the most relevant ICF categories identified from the patient perspective in the empirical study related to loss of function and limitations in activities of daily living.[16] Problems related to the perception of pain were much less prominent. These findings were very valuable for the definition of the core ICF categories, and should be taken into consideration when developing a universal outcome instrument for adult traumatic spinal column injury patients.

Consequently, the core ICF categories reflect a wide array of functional impairments that may be encountered by adult patients sustaining traumatic injuries to the spinal column. This is emphasized by the fact that the majority of the categories are related to the component *activities and participation*. Also mental functioning was included with most of the categories from the component *body functions* being related to the chapter *Mental functions (b1)*. Although *Sensation of pain (b280)* was included as a core category as well, the participating experts agreed that pain should not be the main focus of the future patient reported outcome instrument, rather functional impairment and its related problems should be more prominent. Our systematic review showed that the current most frequently used patient reported outcome measures in this specific population, e.g. the Oswestry Disability Index (ODI), mainly focus on pain-related disabilities.[14] On the other hand, generic outcome measures such as the Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) are not designed for measuring disability in this specific patient population. Moreover, many relevant items are lacking, including urination and sexual functions.[8,14] Neurological classification systems such as the Frankel scale [20] or ASIA impairment scale [21] only measure motor/sensory deficits due to spinal cord injury, and do not focus on the functional impairments in daily living. Since spinal column injury patients may sustain neurological symptoms, also categories such as *Defecation functions (b525), Urination functions (b620), Sexual functions (b640),* and *Muscle power functions (b730)* were included as core categories. Some other categories such as *Eating (d550), Drinking (d560),* and *Protective functions of the skin (b180)* were found to be more relevant for severe spinal cord injured patients. These categories are indeed included in the ICF Core Sets 28 that have been defined for individuals with severe spinal cord injury in the early post-acute context 29 and long-term context.[30] The influence of *environmental factors* was considered to be important as well. More specifically, support from the individuals in the patients' environment was reflected by the chapter *Support and relationships (e3),* while *Products or substances for personal consumption (e110)* was selected to indicate the use of analgesic drugs. There were no categories from the component body structures selected. Those categories were considered to be more relevant for the future outcome instrument

from the clinicians' perspective. This so-called surgeon reported outcome measure will be mainly based on clinical and radiological parameters.

The preparatory systematic review showed that many of the disease-specific outcome instruments used in spine trauma research, which are designed for non-traumatic patient populations, focus on one specific anatomic spine region. Some were designed for measuring neck specific disability [31,32], while others focus on low back disability.[33-37] Based on the defined core ICF categories, our future patient reported outcome instrument should be able to measure functioning and disability of the entire spinal column in traumatic conditions.

The defined core ICF categories describe what to measure, not how to measure it. This transition process presents several challenges for this specific patient population. As the pre-injury physical, psychological, and general health related characteristics of spinal column injury patients may very well deviate from those of the general population, there is an acknowledged lack of baseline or pre-injury measurement.[38,39] Therefore, one of the preparatory studies investigated various response scales. Not only for their validity and reliability, but also the degree to which they are understandable for adult traumatic spinal column injury patients to accurately compare their current level of function and health with their pre-injury state.[19]

We do recognize several limitations of the consensus process. First, completely paralyzed and poly-trauma patients were excluded in the developmental phase and initial validation of the patient reported outcome instrument. We found this to be a thoughtful decision prompted by our intent to present a rather well-defined target group, while minimizing the confounding and overwhelming influence of profound paralysis as much as possible. The new outcome instrument covers important outcomes of spinal cord damage, such as bladder and bowel function and thereby may nevertheless be a valid outcome measure in this subgroup. Furthermore, in future research it can be investigated whether it is useful to add other categories from the ICF Core Sets that have been defined for severe spinal cord injury [29,30] and several other neurological and musculoskeletal diseases. [40-43] Second, there was a lack of representation from patient advocacy organizations and other disciplines involved in spine trauma care. However, the patient perspective was identified in the preparatory empirical study, and once the outcome instrument is developed, it will be rigorously tested on patients for many aspects of validity within the target patient population. Finally, another group of experts might have come up with a slightly different set of core ICF categories. However, we believe that the participating experts represent an appropriate panel involved in the treatment of traumatic spinal column injury patients.

## CONCLUSIONS

In conclusion, a formal consensus process integrated evidence and expert opinion, and has led to a set of 25 core ICF categories for universal patient reported outcome measurement in adult traumatic spinal column injury patients, as well as what we feel is a clear and understandable response scale that is relevant to spine trauma patients. The adopted core ICF categories could also serve as a benchmark when assessing the content validity of existing and future outcome instruments used for this specific patient population. In the next phase of this project, a draft version of the outcome instrument will be created by combining the core ICF categories with the selected response scale, followed by international multicenter studies to further validate and cross-culturally adapt it. We believe that this disease-specific outcome instrument will have the potential to be applied universally in clinical and research settings.

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# Chapter 7

## Development of the AOSpine Patient Reported Outcome Spine Trauma (AOSpine PROST): a universal disease-specific outcome instrument for individuals with traumatic spinal column injury

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## ABSTRACT

*Purpose.* To report on the multi-phase process used in developing the AOSpine Patient Reported Outcome Spine Trauma (AOSpine PROST), as well as the results of its application in a pilot study.

*Methods.* The International Classification of Functioning, Disability and Health (ICF) methodology was used as the basis for the development of this tool. Four preparatory studies and a consensus conference were performed, and resulted in the selection of 25 core ICF categories as well as the scale for use. The first draft of the Dutch version of AOSpine PROST was pilot tested among a consecutively selected representative sample of 25 spine trauma patients, using the 'think aloud' and 'probing' methods.

*Results.* Of the 25 core ICF categories, 9 related to *body functions,* 14 *activities and participation,* and 2 *environmental factors.* Those 25 core categories were implemented into the selected response scale, and resulted in a draft version of AOSpine PROST consisting of 19 items. From the pilot study, very satisfactory results were obtained for comprehensibility, relevance, acceptability, feasibility and completeness, as well as high internal consistency (Cronbach's alpha = 0.926).

*Conclusions.* Following the ICF methodology and including the results of 4 different preparatory studies and a consensus conference, the AOSpine PROST is developed. Taking the results from the subsequent pilot study into account, a definite version to be further validated will be developed. The AOSpine PROST has the potential to be a helpful tool in clinical practice and research to compare various treatments and improve the quality of health care.

## INTRODUCTION

The AOSpine Knowledge Forum Trauma initiated a project to develop universal disease-specific outcome instruments for spine trauma patients. Because of the possible discrepancies when comparing outcomes from the patients' perspective to clinical and radiological assessments by the clinicians, two separate tools were developed: the Patient Reported Outcome Spine Trauma (AOSpine PROST) to represent the patients' perspective, and the Clinician Reported Outcome Spine Trauma (AOSpine CROST) to cover the perspective of the treating surgeons.[1]

Although a number of outcome measures have been used in individuals with traumatic spine injuries, these tend to focus on the impact of paralysis.[2] In the absence of an instrument that is specifically designed and validated for spine trauma patients without complete paralysis, it is difficult to compare outcomes of different treatments of the spinal column injury within and between studies.[3] Because of the persisting controversies on the optimal treatment of many types of these injuries, there is a real need for such an instrument.[4-6]

The systematic approach and methodology of the International Classification of Functioning, Disability, and Health (ICF) of the World Health Organization (WHO) was used as the basis for the development of the AOSpine PROST.[7,8] The ICF recognizes that functioning and disability are multi-dimensional concepts relating to different components: *body functions (b), body structures (s), activities and participation (d),* and *environmental factors (e).* Figure 1 shows the components of the ICF and the hierarchical organization of more than 1400 categories into different levels of detail. This article reports on the multi-phase process used in developing the AOSpine PROST, as well as the results of its application in a pilot study.

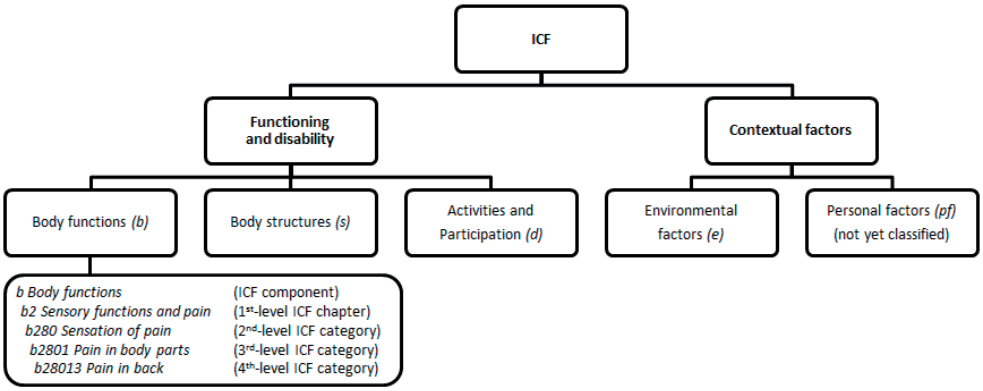



***Figure 1.*** The bio-psycho-social model of the International Classification of Functioning, Disability and Health (ICF), along with an example of the hierarchical fashion in different levels.

**Table 1.** The core ICF categories (n=25) and their relation to the defined items in the AOSpine PROST version that was pilot tested, along with examples incorporated in each item.

| ICF code | ICF title | Item in the AOSpine PROST version that was pilot tested | Examples in the AOSpine PROST version that was pilot tested |
|---|---|---|---|
| *Body functions (n=9)* | | | |
| *b130* | Energy and drive functions | Energy level and motivation | fatigue or your drive to achieve a specific goal |
| *b134* | Sleep functions | Sleeping | amount of sleep and quality of sleep |
| *b152* | Emotional functions | Emotional functioning | feeling sad, worried or anxious, and the ability to express those feelings |
| *b280* | Sensation of pain | Pain | the extent to which spinal pain limits your current level of overall function |
| *b525* | Defecation functions | Urination | having bowel movements, bowel incontinence |
| *b620* | Urination functions | Defecation | emptying the bladder, urinary incontinence |
| *b640* | Sexual functions | Sexual functioning | no examples |
| *b710* | Mobility of joints | Stiffness of your neck and/or back | the extent to which stiffness of your neck and/or back limits your current level of overall function |
| *b730* | Muscle power functions | Weakness in your arms and/or legs | the extent to which weakness in your arms and/or legs limits your current level of overall function |
| *Activities and participation (n=14)* | | | |
| *d410* | Changing basic body position | Changing your body position | lying down, sitting or standing |
| *d415* | Maintaining a body position | Maintaining your body position | maintaining a lying, sitting or standing position, as long as necessary |
| *d430* | Lifting and carrying objects | Lifting and carrying | lifting a bag of groceries or carrying a child |
| *d450* | Walking | Walking | with or without mobility aid |
| *d470* | Using transportation | Traveling | driving a car, using public transportation or any other mean of transportation |
| *d475* | Driving | Traveling | |
| *d510* | Washing oneself | Personal care | bathing or showering, toileting or dressing |
| *d530* | Toileting | Personal care | |
| *d540* | Dressing | Personal care | |
| *d630* | Preparing meals | Domestic life | cleaning the house, washing clothes or preparing meals |
| *d640* | Doing housework | Domestic life | |
| *d850* | Remunerative employment | Work / Study | no examples |
| *d910* | Community life | Social activities | maintaining relationships with family, friends and acquaintances |
| *d920* | Recreation and leisure | Recreational and leisure activities | sports or hobbies |

| | | |
|---|---|---|
| *Environmental factors (n=2)* | | |
| *E110* | Products or substances for personal consumption | No specific item |
| *e3* | Support and relationships | Social activities |

## PHASE I: PREPARATORY STUDIES

Four different studies were completed in the preparatory phase of the project, all of which have been published. Three preparatory studies aimed to identify ICF categories relevant to measure the outcomes of traumatic spinal column injuries from different perspectives. The research perspective was covered by a systematic literature review.[3] Out of 5117 screened references, 245 were included, and 17 different frequently used outcome measures used in spine trauma research were identified. The content of these measures were linked to 57 ICF categories, using established linking rules.[9,10] The expert perspective was explored through a web-based survey among 150 experienced spine trauma surgeons from all world regions, and identified 13 ICF categories as most relevant.[11] The patient perspective was investigated in an international empirical study including 187 patients from nine trauma centers in seven countries, and yielded 38 ICF categories as the most important.[12] A fourth study investigated various question and response formats for their potential use in the patient reported outcome instrument.[13]



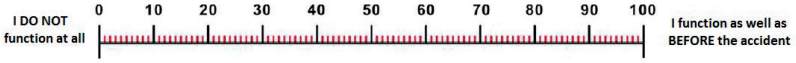
## PHASE II: INTERNATIONAL CONSENSUS CONFERENCE

In the next phase, a formal consensus process integrated evidence from the preparatory studies and expert opinion.[14]

From a pool of candidates already involved or interested in the project, eleven international spine trauma experts from six countries were selected to attend a consensus conference. The selected experts are globally renowned for their contributions that have advanced the field of spine trauma research and care. Based on voting and group discussions, 25 out of 159 relevant ICF categories were selected as core categories (Table 1). A core ICF category was defined as being a) relevant for adult traumatic spinal column injury patients, b) relevant for clinical and functional recovery during the acute and post-acute time frame, and c) meaningful to include in the outcome instrument. The attendants also agreed on one specific question format as well as the 0-100 Numeric Rating Scale (NRS-101) as the response format to use as the scale (Figure 2).

*Question and response format (NRS-101) agreed on during the consensus conference*

Please indicate your level of functioning NOW [*item*] compared to BEFORE the accident.




*Response format incorporated in the AOSpine PROST that was pilot tested*

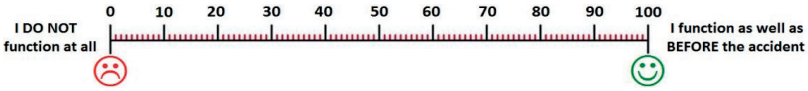



***Figure 2.*** The question and response formats initially agreed on during the international consensus conference, and the format used in AOSpine PROST that was pilot tested.
NRS-101 = 0-100 Numeric Rating Scale

## PHASE III: DEVELOPMENT AOSPINE PROST

### Methodology

Taking the results from the consensus conference as the basis, a draft version of the AOSpine PROST was developed in the Dutch language following the steps that we outline here.

First, it was investigated if and which core ICF categories could be clustered as one item. Subsequently, the defined items were implemented in the selected question and response formats. This draft version was discussed among the Dutch-native investigators, and a senior researcher and professor in spinal cord injury rehabilitation with an academic background in psychology and extensive amount of experience in the development of outcome measures. The draft version was also translated into English in order to discuss it among the AOSpine Knowledge Forum Trauma members. Based on this feedback, changes were applied accordingly to the Dutch version and a draft version was developed. Finally, this draft version was pilot tested.

### From core ICF categories to specific items

The draft version of the AOSpine PROST was developed by clustering the 25 core ICF categories into 19 items (Table 1).

The majority of the core ICF categories (n=15) were transformed into one specific item. Three items of the AOSpine PROST were formed by clustering two core ICF categories: *Using transportation (d470)* and *Driving (d475)* formed the item 'Traveling', *Preparing meals (d630)* and *Doing Housework (d640)* were combined in 'Domestic life', and *Support and Relationships (e3)* and *Community life (d910)* into 'Social activities'. One item, 'Personal care', was formed by clustering three core ICF categories: *Washing oneself (d510), Toileting*

*(d530)* and *Dressing (d540)*. *Products or substances for personal consumption (e110)* was the only core ICF category that could not be transformed into a specific item.

Subsequently, examples were added to all items, except for the items 'Work/Study' and 'Sexual functioning' (Table 1). Those examples were primarily selected from the extensive descriptions of each specific ICF category in the ICF manual.[8]

Once agreement was reached upon the examples, the next step was to implement the items into the selected question and response formats. Unlike degenerative disorders or diseases where patients express their function as compared to perfect health, patients recovering from an injury express their health status in relation to their status prior to the accident or injury. Expressing all items in the selected question format *('Please indicate your level of functioning NOW [item] compared to BEFORE the accident')* resulted for most items, however, in complicated sentences and cumbersome sentence structures. Therefore, it was decided to explain the question format at the beginning of the questionnaire instead of presenting it per item and define 'accident' as the accident that caused the spine injury.

The main focus of each item was the functional impairment and the problems in daily living related to this impairment. To stress this, the phrase 'the extent to which *[item]* limits your current level of overall function' was added to some items, e.g. the item 'Pain'.



### Scoring methodology

Each item is scored on the aforementioned NRS-101 scale. In this scale, 0 indicates no function at all while 100 represents the pre-injury level of function, which may not necessarily correspond to population normative data nor to function in a condition of perfect health. During the developmental phase of the AOSpine PROST, it was decided to visualize and support the scale by smileys at both ends of the ruler (Figure 2). The total score is the sum of all scores divided by the number of completed items. Instructions on how to score an item, and the statement that all items should be completed were added to the questionnaire.

## PILOT TESTING AOSPINE PROST

### Procedures

Patients were recruited from the Orthopaedic outpatient department of a level-1 trauma center in The Netherlands. In line with the patient population in the previous phases of the project, eligibility criteria were defined as adults with a diagnosis of spine trauma and outpatient follow-up within 13 months post-trauma. Poly-trauma (Injury Severity Score >15) and completely paralyzed patients (American Spinal Injury Association grade A or B) were excluded.

Eligible patients were informed about the study and invited to participate. Once informed consent was given, the Dutch draft version of the AOSpine PROST was filled out in a cognitive interview setting. More specifically, the 'think aloud' and 'probing' methodology was used to assess the comprehensibility, relevance, acceptability, feasibility and completeness of the questions.[15] In this context, the respondents were instructed

to complete the AOSpine PROST as they would do at home or at another place, and to verbalize their thoughts while filling out each question. Using the 'probing' methodology, the interviewer (SS) asked questions within the course of the interview in response to patients' comments to comprehend their interpretation more precisely and clearly. Background data was collected from the medical record and completed during the interviews.

The Medical Ethics Review Committee (MERC) of the University Medical Center Utrecht confirmed that the Medical Research Involving Human Subject Act (WMO) does not apply to this study and that therefore an official approval of this study by the MERC was not required under the WMO.

**Results cognitive interviews**

In total, 25 eligible patients were enrolled consecutively in January and February 2015. The basic socio-demographic and clinical characteristics are shown in Table 2.

The think aloud and probing methodology revealed that the items were very well understood and easy to read, except for some difficulties with two items. 'Work/Study' was considered as the general function of daily living by 7 out of 10 retired patients. They postulated that the time they used to spend on their previous paid work, currently was filled with many other activities. The remaining three retired patients did not provide an answer with the assumption that the question was inapplicable. The second item that patients experienced difficulties with was 'Energy level and motivation'. It was considered as two separate questions. All patients indicated that they were highly motivated to recover as soon as possible, but their energy levels were considerably lower. The score they provided was an average of these considerations.

Analyses of the rational for providing a specific score to an item revealed that the examples were most important. If one example within the same item was scored high, while another was given a low score, patients usually estimated an average score.

The NRS-101 scale was comprehended clearly by 23 out of 25 patients (92.0%) to compare their current level of function with their pre-injury functional state.

The time to fill out the AOSpine PROST could not be calculated because of probing during the course of the interview. The average total time of the cognitive interview was 14.4 minutes (range: 8-20). Patients indicated the questionnaire not to be too extensive.

**Table 2.** Patient and clinical characteristics of the study population in the pilot study (n=25).

| | |
|---|---|
| Male (%) | 13 (52.0) |
| Age, mean ± SD (range) in years | 52.5±19.3 (20-75) |
| Time after trauma in months ± SD (range) | 3.6±3.0 (0-12) |
| Cohabiting (%) | 21 (84.0) |
| High educational level (%) [a] | 7 (28.0) |
| No medical history (%) | 11 (44.0) |
| Concomitant injury | 8 (32.0) |
| Cause of trauma (%) | |
| Road traffic accidents | 5 (20.0) |
| Falling | 15 (60.0) |
| Sports / recreation | 5 (20.0) |
| No. of fractures, mean ± SD (range) | 43, 1.7±1.1 (1-5) |
| Fracture level (%) | |
| Cervical spine | 22 (51.2) |
| Thoracic and lumbar spine (T1-T10) | 19 (44.2) |
| Sacral spine | 2 (4.7) |
| Fracture type (%) [b] | |
| Type A | 30 (69.8) |
| Type B | 5 (11.6) |
| Type C | 0 |
| Other | 8 (18.6) |
| Treatment (%) | |
| Conservative | 14 (56.0) |
| Surgical | 11 (44.0) |

SD = standard deviation.
[a] Higher and academic education, according to the Dutch education system[25]
[b] Classified according to the novel AOSpine Injury Classification systems[26,27]



### Content validity

All items were considered as relevant by the patients. Two patients (8.0%) suggested that we should add the use of painkillers as an item.

### Internal consistency

The internal consistency of the questionnaire was excellent with a Cronbach's α of 0.926.[16] As shown in Table 3, a wide range of item-total correlations was seen, from 0.182 ('Urination') to 0.897 ('Personal care'). However, Cronbach's alpha became only 0.05 higher after removal of the item with the lowest item-total correlation. The highest median scores were observed for 'Urination' and 'Defecation' (Table 3).

**Table 3.** Mean scores per item along with the standard deviation, ranges and median scores, as well as the corrected item-total correlations and alpha if the item is deleted.

| Item | Mean±SD | Range | Median | Item-total correlation | Cronbach's α if item deleted |
|---|---|---|---|---|---|
| Work / Study | 58.2±32.3 | 5-100 | 70.0 | 0.55 | 0.924 |
| Domestic life | 60.1±28.9 | 12-100 | 70.0 | 0.83 | 0.917 |
| Recreational and leisure activities | 44.3±30.1 | 1-100 | 35.0 | 0.73 | 0.919 |
| Social acitivities | 82.6±21.4 | 5-100 | 84.0 | 0.72 | 0.922 |
| Walking | 66.4±27.1 | 1-100 | 70.0 | 0.67 | 0.921 |
| Traveling | 52.1±31.4 | 5-100 | 50.0 | 0.78 | 0.918 |
| Changing your body position | 60.1±25.9 | 10-100 | 60.0 | 0.77 | 0.919 |
| Maintaining your body position | 62.2±24.9 | 10-100 | 70.0 | 0.70 | 0.920 |
| Lifting and carrying | 48.3±28.7 | 5-100 | 49.0 | 0.88 | 0.916 |
| Personal care | 76.9±21.0 | 33-100 | 80.0 | 0.90 | 0.918 |
| Urination | 80.4±28.4 | 10-100 | 99.0 | 0.18 | 0.931 |
| Defecation | 85.0±24.7 | 20-100 | 99.0 | 0.47 | 0.925 |
| Sexual functioning | 67.9±37.8 | 0-100 | 80.0 | 0.36 | 0.931 |
| Emotional functioning | 82.6±20.1 | 40-100 | 90.0 | 0.54 | 0.924 |
| Energy level and motivation | 69.2±21.8 | 24-100 | 70.0 | 0.49 | 0.925 |
| Sleeping | 67.3±27.1 | 15-100 | 70.0 | 0.66 | 0.921 |
| Stiffness of your neck and/or back | 53.9±28.1 | 8-94 | 65.0 | 0.80 | 0.917 |
| Weakness in your arms and/or legs | 71.5±25.5 | 20-100 | 80.0 | 0.44 | 0.925 |
| Pain | 70.6±26.4 | 19-100 | 80.0 | 0.45 | 0.925 |

## DISCUSSION

Using the systematic approach and methodology of the ICF, and based on the results of four different preparatory studies and an international consensus conference, a disease-specific patient reported outcome instrument for traumatic spinal column injury patients has been developed. A Dutch draft version of this 19-item AOSpine PROST was pilot tested and showed very satisfactory results for comprehensibility, relevance, acceptability, feasibility, and completeness, as well as high internal consistency.

The ICF methodology as well the 'think aloud' and 'probing' methods have proven to be very good and valid methodologies for developing and refining outcome instruments.[7,8,15,17-19]

The 19 items of AOSpine PROST cover a wide range of domains, including and beyond the scope of activities of daily living. With the specific response scale, patients are able to compare their current level of function with their situation before the trauma. This makes the AOSpine PROST valuable compared to outcome measures that solely focus on the level of dependence in patients' daily activities, such as the SCIM and WISCI.[20,21] Applying these outcome instruments to patients with only mild or transient neurological deficits would result in ceiling effects. Moreover, the AOSpine PROST includes ``many items that could be very relevant for spinal cord injured patients, e.g. 'Urination', 'Defecation',

and 'Changing your body position'. In contrast to many other outcome measures used in this specific patient population, which include generic outcome measures and instruments designed for patient populations with degenerative conditions,[3] the AOSpine PROST holds promise as a useful outcome measure in patients with and without neurological deficit, making it more feasible for clinical use as well.

All 25 core ICF categories could be incorporated in the AOSpine PROST, except for *Products or substances for personal consumption (e110)*. This ICF category was defined as a core category, with the rationale of possibly including a separate item that would describe the use of opioids. During the pilot study, two patients indicated that opioid use is a missing item and should be included. However, the overall concept of the outcome instrument relates more to the functional impairment and the problems in daily living related to this impairment and not to specific treatment strategies such as the use of medication. Opioid use could be taken into account for the AOSpine CROST, the future outcome instrument from the perspective of the treating surgeons.[22,23]



The findings obtained from the pilot study are of great value for refining the AOSpine PROST prior to multicenter validation of this instrument. In the next phase, the items 'Work/Study' and 'Energy level and motivation' will be adjusted because of the difficulties experienced by the patients when answering these questions. Examples will be added to the 'Work/Study' item, and the motivation part will be removed from the item 'Energy level and motivation' as ceiling effects could be expected for 'Motivation' when separating it as an item. Another valuable finding was that patients scored their level of function by taking all provided examples into account and calculate an average score. This may lead to lower item-total correlations for the specific items. In order to abolish this obscurity, instructions will be added to base the score on the situation or example where the patient is most disabled.

We do recognize several limitations of the development process for this outcome instrument. First, this process slightly deviates from the ICF Core Set development guideline, e.g. a focus group was not included in the preparatory phase.[7] Nevertheless, the chosen process provides a solid and systematic base for the selection of the core ICF categories described in this article. Second, a specific trauma patient population was chosen. The rational was to exclude confounding factors and focus on the effect of spinal column injury on health and function in the acute and post-acute phase. Once validated in this specific patient population, the AOSpine PROST will be subjected to further validation in completely paralyzed patients as well. Third, the number of patients included in the pilot study could be debated. We believe this is a sufficient number to explore the most common obstacles experienced by the patients to fill out the AOSpine PROST. Fourth, analyses as test-retest reliability, floor and ceiling effect, or responsiveness were not performed in the pilot study. These analyses will be performed in the next phase in a multicenter validation study including a considerable larger number of patients. Finally, in the development process the Dutch version was freely translated into English in order to be reviewed by the AOSpine

Knowledge Forum Trauma. We believe this is acceptable for this phase of the project. Once a definitive Dutch version is developed and ready to be validated, a careful translation into English will be performed and the linguistic equivalence of both versions will be checked using established guidelines.[24]

In conclusion, using the ICF methodology and incorporating the results of four preparatory studies and an international consensus conference, the AOSpine Patient Reported Outcome Spine Trauma (AOSpine PROST) was developed. Taking the results from the subsequent pilot study into account, a definite version will be developed, followed by international multicenter studies to validate both the Dutch and English versions. Once validated, this tool has the potential to be useful in the clinics as well as research, to evaluate, compare and establish the effectiveness of interventions in the treatment of spine trauma patients. In this context, the patient reported outcomes as assessed by the AOSpine PROST could be related to the type of fractures, the provided treatments as well as radiological results.

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# PART II

## The development of a universal disease-specific clinician reported outcome instrument

# Chapter 8

## Surgeon reported outcome measure for spine trauma: an international expert survey identifying parameters relevant for the outcome of subaxial cervical spine injuries

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## ABSTRACT

*Study Design.* International web-based survey
*Objective.* To identify clinical and radiological parameters that spine surgeons consider most relevant when evaluating clinical and functional outcomes of subaxial cervical spine trauma patients.
*Summary of Background Data.* While an outcome instrument that reflects the patients' perspective is imperative, there is also a need for a surgeon reported outcome measure (SROM) to reflect the clinicians' perspective adequately.
Methods. A cross-sectional online survey was conducted among a selected number of spine surgeons from all five AOSpine International world regions. They were asked to indicate the relevance of a compilation of 21 parameters, both for the short term (3 months - 2 years) and long term (≥2 years), on a five-point scale. The responses were analyzed using descriptive statistics, frequency analysis and Kruskal-Wallis test.
*Results.* Of the 279 AOSpine International and International Spinal Cord Society members who received the survey, 108 (38.7%) participated in the study. Ten parameters were identified as relevant both for short term and long term by at least 70% of the participants. *Neurological status, implant failure within 3 months,* and *patient satisfaction* were most relevant. *Bony fusion* was the only parameter for the long term, while 5 parameters were identified for the short term. The remaining 6 parameters were not deemed relevant. Minor differences were observed when analyzing the responses according to each world region, or spine surgeons' degree of experience.
*Conclusions.* The perspective of an international sample of highly experienced spine surgeons was explored on the most relevant parameters to evaluate and predict outcomes of subaxial cervical spine trauma patients. These results form the basis for the development of a disease-specific SROM, which will be a helpful tool in research and clinical practice.

## INTRODUCTION

Although several outcome measure instruments are used by health professionals to assess the functional status of spine injured patients, those tend to focus on severe spinal cord injury patients only, and their long-term functional outcome in rehabilitation setting. Moreover, as the patient's functional status is assessed by only observing their activities of daily living, no professional training is required to complete observer reported outcome measures such as the Spinal Cord Independence Measure (SCIM),1 Walking Index for Spinal Cord Injury (WISCI),[2] or Functional Independence Measure (FIM).[3]

In daily clinical practice, several clinical and radiological parameters are used by treating surgeons to evaluate treatment results after traumatic spine injuries. In order to determine the further course of treatment, an estimation of any expected problems with respect to these outcomes on the short term and long term health of the patient is made. In this aspect, the surgeons' perspective may differ substantially from the patients' perspective, the latter being based on patient reported outcome measures.[4,5] These discrepant views have also been addressed for a variety of other diseases, including rheumatoid arthritis,[6] multiple sclerosis,[7] as well as metastatic breast and prostate cancer.8 While an outcome instrument that reflects the patients' perspective is imperative, there is also a need for a tool that incorporates the most relevant clinical and radiological parameters that reflects the clinicians' perspective adequately. Together with independent patient reported outcome, this tool will provide a holistic view of patients' health in relation to their spine injury.

Therefore, besides the development of a patient reported outcome instrument, the AOSpine Knowledge Forum Trauma adopted the development of a new concept of a surgeon reported outcome measure (SROM).[9] This tool can be used by the treating surgeons during the follow-up period, after patients' initial treatment. Based on the results of the treatment as assessed during follow-up, this tool would enable treating surgeons to estimate and predict clinical and functional outcomes of spine trauma patients incorporating the content expertise of the surgeon.

However, it is not clear which clinical and radiological parameters should be implemented in a SROM tool to reflect the surgeons' perspective adequately. In order to identify the most relevant parameters, a previous study including an international survey was conducted to identify relevant parameters for the thoracic and lumbar spine.[10] This current study aimed to explore the perspective of a worldwide sample of spine surgeons on relevant clinical and radiological parameters when evaluating clinical and functional outcomes of subaxial cervical spine trauma patients.

**Table 1.** The general case as provided at the start of the second part.

| |
|---|
| ''You see a patient with a traumatic subaxial cervical fracture (C3-C7) in the period of 6 weeks to 3 months after discharge at the outpatient department. This patient had a traumatic injury and has been treated either nonsurgically (collar, halo-vest immobilization or functional) or surgically (with any kind of technique; anterior, posterior or both, with or without less invasive techniques).'' |

## MATERIALS AND METHODS

### Design

A cross-sectional web-based survey was conducted among spine surgeons from all world regions (Asia Pacific, Europe and Sub Saharan Africa, Latin America, Middle East and North Africa, and North America).

### Participant recruitment

A panel of experts was recruited through AOSpine International, and consisted of a worldwide sample of spine surgeons with substantial expertise in spine trauma care, as well as an interest in outcome assessment and classification for this specific patient population. Potential participants were members of the AOSpine Knowledge Forums Spinal Cord Injury and Trauma (n=10),9 members of the spine trauma study group of the International Spinal Cord Society (ISCoS) (n=10),11 responders in the preparatory expert survey of the patient reported outcome development (n=200),12 and experts involved in the international validation of the novel AOSpine Thoracolumbar Spine Injury Classification System (n=100).13 Taking the overlap between these groups into account and excluding experts without any contact details, a personal email invitation was sent to a total of 279 experts. To take part in the survey, the responder had to be an orthopedic-, trauma- or neurosurgeon with at least five years of experience in the treatment of adult spine trauma patients. Also sufficient command of the English language was required to start the survey.

### Survey

The survey questionnaire consisted of two parts. The first part explored the professional background of the participants. The second part started with a general case of a patient at the outpatient clinic who had sustained a traumatic injury to the subaxial cervical spine (C3-C7), treated either conservatively or surgically (Table 1). Subsequently, a predefined compilation of 21 clinical and radiological parameters was listed (Table 2). These parameters were based on: 1) parameters included in the AOSpine Subaxial Cervical Spine Injury Classification System,14 2) parameters identified in a systematic literature review15 and 3) results obtained from another survey which focused on the identification of relevant parameters for the thoracic and lumbar spine.10 The relevance of each parameter was indicated for the clinical and functional outcome of adult (≥18 years) subaxial cervical spine trauma patients, both for the short term (3 months - 2 years) and long term (≥2 years) post-trauma. Responses were provided on a five-point scale: 'definitely not relevant', 'probably

**Table 2.** The surveyed clinical and radiological parameters (n=21).

- Age
- Ankylosed spine
- Bony fusion as seen and assessed on radiographs taken in the clinic today
- Co-morbidity not associated with the index trauma i.e. diabetes or heart disease
- Disc height loss on radiographs taken in the clinic today
- Facet fracture (displaced or non-displaced) on the trauma radiographs
- Implant failure after 6 months (in case surgical fixation was chosen as treatment option)
- Implant failure within 3 months (in case surgical fixation was chosen as treatment option)
- Lateral mass fracture on the trauma radiographs
- Ligamentous injury on the trauma MR imaging
- Misplacement of implants (in case surgical fixation was chosen as treatment option)
- Mobility of the subaxial cervical spine
- Neurological status
- Osteoporosis
- Patient satisfaction with the treatment
- Patient's current level of pain
- Spinal canal encroachment on the trauma CT or MR imaging
- Subaxial cervical sagittal alignment (kyphosis) on radiographs taken in the clinic today
- Subaxial cervical scoliotic alignment on radiographs taken in the clinic today
- Surgical site infections (in case surgical fixation was chosen as treatment option)
- Vertebral body height loss on radiographs taken in the clinic today



not relevant', 'possibly relevant', 'probably relevant', and 'definitely relevant'. An additional open question asked for the *age,* that in the absence of serious medical comorbidities, may have an influence on patients' outcome. Free text fields for general comments or any missing parameters were provided at the end of the survey.

**Data collection and analysis**

The survey was conducted in April and May 2015. A reminder was sent to all invited experts after two and three weeks. The participants in the region with the lowest response rate received one additional reminder.

All responses were recorded and analyzed anonymously. Descriptive statistics were used to analyze the characteristics of the participants and the additional open question about the possible influential age. The response options 'probably relevant' and 'definitely relevant' were combined to indicate the relevance of each parameter. Absolute and relative frequencies of relevance were calculated, along with their 95% confidence interval. Descriptive statistics and Kruskal-Wallis test (significance level 0.05) were performed to investigate any differences in responses between the five world regions, as well as the influence of surgeons' clinical experience (up to 10 years, 11-20 years or more than 20 years).

## RESULTS

### Response rate and characteristics

In total, 124 (44.4%) out of 279 experts responded to the survey invitation. Responders who did not meet the inclusion criteria (n=3) or only completed the background data (n=13) were excluded, resulting in a total of 108 (38.7%) participants. Except for one, all participants were males (99.1%), on average 47 years of age and with 17 years of experience. The participants were from 41 different countries, representing all AOSpine International world regions. Active clinical surgical practice was reported as the main category of work (90.7%). Table 3 shows the socio-demographic characteristics of the participants.

### Relevance of parameters

The relevance of each parameter for the short term and long term time period post-trauma is shown in Tables 4 and 5, respectively.

In total, 10 parameters were identified as relevant both for the short term and long term post-trauma by at least 70% of the participants. *Neurological status, implant failure within 3 months,* and *patient satisfaction* were found to be most relevant. Out of those 10 parameters, 5 were selected as more relevant for the short term, i.e. *ankylosed spine, ligamentous injury on trauma MRI, misplacement of implants, osteoporosis,* and *implant failure after 6 months*. *Sagittal alignment (kyphosis)* was equally relevant for the short term and long term (73.1% and 75.0% of the participants, respectively). The only parameter identified as considerably more relevant for the long term was *bony fusion* (83.3% vs 72.2%).

Five parameters were thought to be relevant for the short term only: *surgical site infections, spinal canal encroachment on trauma CT/MRI, facet fracture on trauma radiographs, age,* and *lateral mass fracture on trauma radiographs.* The remaining 6 parameters were not identified as relevant for any time period post-trauma, i.e. *co-morbidity, patient's current level of pain, mobility, vertebral body height loss, scoliotic alignment,* and *disc height loss*.

The indicated age that may have an influence on patients' outcome was comparable for the short term and long term (mean: 56.4 and 58.2 years respectively; median: 60 years for both time periods post-trauma).

### Regional differences

In general, minor differences were observed for the parameters found to be relevant on the short term, when analyzing the responses according to each world region. It was notable that for some parameters the responses of the North American participants

**Table 3.** Characteristics of surveyed experts (n=108).

| | |
|---|---|
| Male (%) | 107 (99.1%) |
| Age, mean ± SD (range) in years | 47.1±8.0 (30-65) |
| AOSpine world region (%) | |
| Asia Pacific | 23 (21.3%) |
| Europe / Sub Saharan Africa | 28 (25.9%) |
| Latin America | 28 (25.9%) |
| Middle East / North Africa | 12 (11.1%) |
| North America | 17 (15.7%) |
| Profession (%) | |
| Neurosurgeon | 35 (32.4%) |
| Orthopaedic surgeon | 65 (60.2%) |
| Trauma surgeon | 8 (7.4%) |
| Spine fellowship completed (%) | 96 (88.9%) |
| Main working field (%) | |
| Clinic | 98 (90.7%) |
| Education | 7 (6.5%) |
| Other | 3 (2.8%) |
| Years of practice, mean ± SD (range) in years | 17.1±8.4 (5-40) |



deviated from the responses from the other world regions. *Spinal canal encroachment on trauma CT/MRI* was relevant for 41.2% of the North American participants, while the relevance among other world regions ranged from 83.3% to 100.0% (p<0.001). The same pattern was seen for *vertebral body height loss,* being relevant among 17.2% of the North American participants and 53.6-78.3% of participants from other world regions (p=0.002).

Also for the long term, no large regional differences were observed for parameters identified as relevant in the overall analysis. Other parameters showed some more variations, with the highest variations for *surgical site infections* (range: 29.4-83.3%; p=0.005) and *vertebral body height loss* (range: 23.5-75.0%; p=0.003).

Parameters identified as relevant by at least 70% of the participants among all world regions are indicated in Tables 4 and 5.

**Experiential influence**

Even less differences were observed when analyzing the responses according to the spine surgeons' degree of experience, both for the short term and long term. Significant differences were only seen for *implant failure after 6 months* in the short term analysis (range: 71.9-94.6%; p=0.029), and for *co-morbidity* on both the short term (range: 50.0-82.1%; p=0.015) and long term (range: 37.5-70.3%; p=0.011). These parameters were considered the least relevant by the surgeons with the least experience.

**Table 4.** The relevance of the parameters for the subaxial cervical spine (C3-C7) on the short term (3 months - 2 years) post-trauma.

| Parameter | % of experts | (95% CI) | (range – regions) | (range – experience) |
|---|---|---|---|---|
| Implant failure within 3 months[a] | 96.3 | (92.6-99.1) | (91.7-100.0) | (93.8-100.0) |
| Neurological status[a] | 95.4 | (90.7-99.1) | (92.9-100.0) | (90.6-100.0) |
| Ankylosed spine[a] | 92.6 | (88.0-97.2) | (89.3-96.4) | (90.6-94.6) |
| Surgical site infections[a] | 91.7 | (86.1-96.3) | (70.6-100.0) | (89.2-93.8) |
| Ligamentous injury[a] | 88.0 | (81.5-93.5) | (70.6-96.4) | (78.1-92.3) |
| Misplacement of implants | 88.0 | (81.5-93.5) | (58.8-96.4) | (81.3-91.9) |
| Patient satisfactiona | 86.1 | (78.7-92.6) | (75.0-95.7) | (82.1-89.2) |
| Spinal canal encroachment | 83.3 | (75.0-89.8) | (41.2-100.0) | (76.9-93.8) |
| Osteoporosis[a] | 81.5 | (74.1-88.9) | (75.0-82.6) | (78.4-84.4) |
| Implant failure after 6 months | 80.6 | (73.1-88.0) | (66.7-85.7) | (71.9-94.6) |
| Facet fracture | 80.6 | (72.2-87.0) | (64.7-91.3) | (75.7-87.2) |
| Age | 75.0 | (67.6-83.3) | (58.3-88.2) | (65.6-84.6) |
| Lateral mass fracture | 74.1 | (65.7-82.4) | (58.8-83.3) | (67.6-82.1) |
| Sagittal alignment (kyphosis) | 73.1 | (63.9-81.5) | (58.3-92.9) | (66.7-78.4) |
| Bony fusion | 72.2 | (63.9-80.6) | (47.1-82.1) | (66.7-81.1) |
| Co-morbidity | 68.5 | (60.2-76.9) | (58.3-82.4) | (50.0-82.1) |
| Mobility | 63.9 | (54.6-73.1) | (52.9-91.3) | (54.1-71.8) |
| Patient's current level of pain | 62.0 | (52.8-72.2) | (52.9-73.9) | (56.4-65.6) |
| Vertebral body height loss | 58.3 | (49.1-67.6) | (17.6-78.3) | (48.7-67.6) |
| Scoliotic alignment | 51.9 | (41.7-62.0) | (46.4-60.9) | (43.2-62.5) |
| Disc height loss | 41.7 | (32.4-50.9) | (23.5-60.9) | (35.1-53.1) |

Relative frequencies are shown, along with their 95% bootstrapped confidence intervals (CI), and range among the different world regions (range-regions) and different degrees of experience (range-experience).
[a] Relevant for at least 70% of the participants in all AOSpine world regions

### Provided comments

Participants who provided comments (n=29; 26.9%) repeated one or more of the surveyed parameters to emphasize their importance. Some other comments referred to factors more relevant for the patient reported outcome, such as daily activities and work status. No additional parameters were provided in the comments section.

## DISCUSSION

We believe this is the first study to have explored the perspectives of a highly generalizable cohort of worldwide experts on clinical and radiological parameters most relevant to evaluate clinical and functional outcomes of subaxial cervical spine trauma patients.

In total, 108 experts from 41 different countries, representing all five AOSpine International world regions, participated in the current study. This provides global validity and an international perspective on the most relevant parameters to be implemented in the future SROM for spine trauma patients. Moreover, only minor differences in responses were observed between the world regions, especially for those parameters that were identified

**Table 5.** The relevance of the parameters for the subaxial cervical spine (C3-C7) on the long term (≥2 years) post-trauma.

| Parameter | % of experts | (95% CI) | (range – regions) | (range – experience) |
|---|---|---|---|---|
| Neurological statusa | 90.7 | (85.2-96.3) | (75.0-95.7) | (81.3-97.3) |
| Patient satisfactiona | 86.1 | (79.6-92.6) | (76.5-91.7) | (79.5-91.9) |
| Bony fusion | 83.3 | (75.9-89.8) | (64.7-91.3) | (78.1-89.2) |
| Implant failure within 3 monthsa | 82.4 | (75.0-89.8) | (75.0-87.0) | (78.1-89.7) |
| Ankylosed spine | 79.6 | (72.2-86.1) | (66.7-82.6) | (70.3-87.5) |
| Sagittal alignment (kyphosis) | 75.0 | (66.7-82.4) | (66.7-85.7) | (69.2-83.8) |
| Osteoporosis | 74.1 | (65.7-82.4) | (58.3-82.1) | (69.2-84.4) |
| Ligamentous injury | 73.1 | (64.8-81.5) | (50.0-82.6) | (62.5-82.1) |
| Implant failure after 6 months | 73.1 | (64.8-81.5) | (50.0-82.6) | (62.5-81.1) |
| Misplacement of implants | 72.2 | (63.9-80.6) | (47.1-91.3) | (68.8-78.4) |
| Age | 69.4 | (61.1-77.8) | (58.3-82.4) | (56.3-76.9) |
| Spinal canal encroachment | 69.4 | (60.2-77.8) | (41.2-78.6) | (62.5-73.0) |
| Mobility | 65.7 | (56.5-74.1) | (41.2-78.3) | (62.2-68.8) |
| Surgical site infections | 60.2 | (50.9-69.4) | (29.4-83.3) | (56.8-62.5) |
| Facet fracture | 60.2 | (51.9-69.4) | (35.3-78.3) | (54.1-66.7) |
| Vertebral body height loss | 60.2 | (50.9-69.4) | (23.5-78.3) | (53.8-67.6) |
| Patient's current level of pain | 59.3 | (50.9-68.5) | (42.9-78.6) | (54.1-62.5) |
| Co-morbidity | 59.3 | (50.0-67.6) | (46.4-71.4) | (37.5-70.3) |
| Lateral mass fracture | 53.7 | (44.5-63.0) | (35.3-73.9) | (46.9-56.8) |
| Scoliotic alignment | 51.9 | (41.7-61.1) | (46.4-58.8) | (40.5-59.4) |
| Disc height loss | 45.4 | (36.1-55.6) | (23.5-65.2) | (43.6-46.9) |

Relative frequencies are shown, along with their 95% bootstrapped confidence intervals (CI), and range among the different world regions (range-regions) and different degrees of experience (range-experience).
[a] Relevant for at least 70% of the participants in all AOSpine world regions



as being most relevant. Even less differences were seen when analyzing the responses according to the spine surgeons' degree of experience.

Out of the 21 surveyed parameters, 10 were found to be relevant for the clinical and functional outcomes of subaxial cervical spine trauma patients on both the short and long term post-trauma. Consistent with the results of a similar survey focusing on relevant parameters for the thoracic and lumbar spine, *neurological status* was considered as most relevant.[10] This parameter is important in many aspects. A neurological injury can have significant impact on patients' quality of life with restrictions in daily activities, health and well-being.16 Patients' neurological status plays a key role in decision making in the clinical setting,[17,18] and has been extensively used as an outcome measure in spine trauma research.[19,20] Although *co-morbidity* was not identified as relevant, some other related parameters were indeed considered as relevant both for the short term and long term, i.e. *ankylosed spine* and *osteoporosis*. These parameters are related to bone quality, which was identified as the missing parameter in the thoracic and lumbar survey.[10] Several participants provided comments, however, no new parameter was indicated in the current study. The indicated factors more relevant for the patient reported outcome (e.g. work and daily activities) are already incorporated in the newly developed AOSpine patient reported

outcome measure. Currently, this instrument is being subjected to further validation in a multicenter study.[9] Bone quality plays a key role in multiple ways. It may clarify the type of injury a patient has suffered, e.g. a severe cervical spine injury after a mild trauma by an *ankylosed spine* patient.[21] In an *osteoporotic* patient, a sub-optimal anchorage due to the decreased bone quality influences the decision if and which type of surgery will be performed because of the potential risk of *misplaced implants* and *implant failure*.[22] After the initial management, treatment results may be evaluated by assessing *bony fusion* rates and the degree of *sagittal alignment (kyphosis)*. Parameters related to the stability of the spine, such as *facet fracture* and *ligamentous injury,* seemed to be more relevant for the short term. These parameters have demonstrated to be dominant stabilizers for axial rotation.[23] Therefore, it was surprising that *mobility of the subaxial cervical spine* was not considered as relevant. Also *pain* was not deemed relevant, while it is frequently used in the clinical practice to evaluate treatment results and it has been related to disability in daily activities of spinal cord injury patients.[24] Unsurprisingly, *scoliotic alignment* was not identified as relevant. Some participants commented this parameter as a very rare post-traumatic condition in the cervical spine trauma patient. Although the compilation of surveyed parameters was slightly different in another study focusing on the thoracic and lumbar spine10, the relevance of the parameters was in general comparable. This contributes to the development of a SROM for the whole spine.

This study has several limitations. First, the survey was sent to the same selected panel of experts as another study which focused on the identification of relevant parameters to evaluate outcomes of thoracic and lumbar spine trauma. Nevertheless, we believe that this international panel represents a sample of highly experienced spine surgeons with interest in, and knowledge of, spine trauma patients in daily clinical practice. Indeed, a higher complete response rate is preferred, but it is comparable to many other surveys.[25-27] Second, the selection of the surveyed parameters might be a point of discussion. However, different perspectives were incorporated to identify potential parameters. Moreover, free text fields were added in order to enable participants to indicate any missing parameters. Finally, an arbitrary response cut-off point of 70% was selected to indicate a parameter as relevant. We believe that a large majority of the participants' views are represented by taking this cut-off point into account.

In conclusion, this study explored the perspective of an international sample of highly experienced spine surgeons on the most relevant clinical and radiological parameters to evaluate and predict clinical and functional outcomes of patients sustaining traumatic injuries to the subaxial cervical spine. Combining the results of the current study and another survey focusing on the identification of relevant parameters for thoracic and lumbar spine trauma patients, a surgeon reported outcome measure for adult spine trauma patients will be developed. Once subjected to further validation, this tool will be helpful in research and clinical practice.

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# Chapter 9

## Universal disease-specific outcome instruments for spine trauma: a global perspective on relevant parameters to evaluate clinical and functional outcomes of thoracic and lumbar spine trauma patients

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## ABSTRACT

*Purpose.* Besides a patient reported outcome measure, the AOSpine Knowledge Forum Trauma aims to develop a new concept of a surgeon reported outcome measure (SROM) for spine trauma patients. This study aims to identify parameters that spine surgeons consider relevant to evaluate clinical and functional outcomes of thoracic and lumbar spine trauma patients.

*Methods.* An international cross-sectional web-based survey was conducted among spine surgeons from the five AOSpine International world regions. They were asked to evaluate the relevance of a compilation of 16 clinical and radiological parameters for thoracic and lumbar spine trauma patients, both for the short term (3 months-2 years) and long term (≥2 years), on a five-point scale. The responses were analyzed using descriptive statistics, frequency analysis, and Kruskal-Wallis test.

*Results.* Out of the 279 invited members of AOSpine International and the International Spinal Cord Society, 118 (42.3%) participated in this study. Of the 16 surveyed parameters, 5 were identified as relevant by at least 70% of the participants. *Neurological status* was identified as most relevant. In contrast, five parameters were not deemed relevant for any spine region or time period, except for *comorbidity*. Only minor differences were observed when analyzing the responses according to each world region, spine surgeons' clinical experience, or professional background.

*Conclusions.* Including a large and representative sample of spine trauma experts, this study identified parameters to evaluate clinical and functional outcomes of thoracic and lumbar spine trauma patients. The results form the basis for the development of a SROM for this specific patient population.

## INTRODUCTION

Controversy remains regarding the evaluation and optimal treatment of many types of spine injuries.[1-4] In the absence of an outcome instrument specifically designed and validated for spine trauma patients, it is difficult to compare different treatment options, and to develop more rational choices for treatment strategies. Therefore, the AOSpine Knowledge Forum Trauma aims to develop and validate such instruments for adult spine trauma patients that reflect both the patients' and clinicians' perspectives.[5] The patient reported part, named AOSpine Patient Reported Outcome Spine Trauma (AOSpine PROST), has already been developed and being validated in international multicenter studies. Besides this AOSpine PROST, the Knowledge Forum decided to develop a new concept of a surgeon reported outcome measure (SROM) to reflect the perspective of the treating surgeons. Their perspective is predominantly based on clinical and radiological assessments, and may differ substantially from the patients' perspective.[6,7] A SROM tool is needed to formalize the most relevant assessment parameters as a simple, reliable and quick to administer tool that is completed by the treating surgeons, and is able to predict the clinical outcomes of spine trauma patients. Together with the independent patient reported outcome, the SROM provides a holistic view of patients' function and health status.

First, it should be investigated what the SROM would consist of in order to reflect the surgeons' perspective adequately. Therefore, surveys were conducted among international spine trauma experts in order to identify relevant clinical and radiological parameters. Considering the anatomical and functional differences and treatment practices of different spine regions, two separate surveys were conducted: one focusing on the thoracic and lumbar spine and another on the cervical spine. The objective of this paper is to report on the results of the first survey, that aimed to identify the parameters that spine surgeons consider to be relevant when evaluating clinical and functional outcomes of patients sustaining a traumatic injury to the thoracic and lumbar spine.



## MATERIALS AND METHODS

### Study design

This study was conducted as a cross-sectional web-based survey among spine surgeons from all five AOSpine International world regions (Asia Pacific, Europe and Sub Saharan Africa, Latin America, Middle East and North Africa, and North America).

### Recruitment of participants

Potential participants were recruited through AOSpine International. We aimed to include a worldwide sample of spine surgeons with substantial expertise in spine trauma care, as well as an interest in outcome assessment and classification for this specific patient population.

Based on these prerequisites, members of the AOSpine Knowledge Forums Spinal Cord Injury and Trauma (n=10),[5] members of the spine trauma study group of the International Spinal Cord Society (ISCoS) (n=10),[8] initial responders in the preparatory expert survey of AOSpine PROST development (n=200),[9] and experts involved in the international validation of the novel AOSpine Thoracolumbar Spine Injury Classification System (n=100)[10] were considered potential participants. Taking into account the overlap between these groups and excluding experts without sufficient contact details, a personal email invitation with an electronic link to the survey was sent to a total of 279 experts. Eligibility criteria were defined as orthopedic-, trauma- or neurosurgeon with at least five years of experience in the treatment of adult spine trauma patients. Sufficient command of the English language was required to complete the survey.

**Survey instrument**

The survey questionnaire consisted of two parts. In the first part, participants were asked about their professional background.

The second part of the survey was subdivided into three parts. Each subpart focused on one specific anatomic spine region, defined as the thoracic spine (T1-T10), thoracolumbar junction (T11-L2), and lumbar spine (L3-L5), respectively. Each part started with a general case, representing a spinal trauma case after conservative or operative treatment (Appendix 1 in this Chapter), followed by a predefined compilation of 16 clinical and radiological parameters (Appendix 2 in this Chapter). These parameters were based on: 1) parameters identified in the systematic literature review of AOSpine PROST development,[11] 2) parameters used by the AOSpine Thoracolumbar Spine Injury Classification System,[12] and 3) expert interviews among three spine surgeons from a level-1 trauma center. Participants of the survey were asked to indicate the relevance of each parameter for the clinical and functional outcome of adult (≥18 years) patients who suffered an acute traumatic injury to the thoracic, thoracolumbar or lumbar spine, both for the short term (3 months - 2 years) and long term (≥2 years) post-trauma on a five-point scale: 'definitely not relevant', 'probably not relevant', 'possibly relevant', 'probably relevant', and 'definitely relevant'. Relevance was further defined by the authors as the parameter being associated with-, related to-, and considered to be important for the clinical and functional outcome of spine trauma patients. The parameter age, described as the age of patients that, in the absence of serious medical comorbidities, could influence their outcome, was surveyed in an open question. Finally, free text fields were provided at the end of each subpart to enable the respondents to add any missing parameters or general comments.

**Data collection**

The survey was conducted in November and December 2014. All invited experts received a reminder after two and three weeks. An additional reminder was sent to the region with the lowest response rate. All responses were recorded and analyzed anonymously.

**Table 1.** Characteristics of surveyed experts (n=118).

| Parameter | % of experts |
|---|---|
| Male (%) | 115 (97.5%) |
| Age, mean ± SD (range) in years | 46.3±8.5 (30-68) |
| AOSpine world region (%) | |
| Asia Pacific | 25 (21.2%) |
| Europe / Sub Saharan Africa | 34 (28.8%) |
| Latin America | 33 (28.0%) |
| Middle East / North Africa | 10 (8.5%) |
| North America | 16 (13.6%) |
| Profession (%) | |
| Neurosurgeon | 39 (33.1%) |
| Orthopaedic surgeon | 72 (61.0%) |
| Trauma surgeon | 6 (5.1%) |
| Other | 1 (0.8%) |
| Spine fellowship completed (%) | 91 (77.1%) |
| Main working field (%) | |
| Clinic | 109 (92.4%) |
| Management | 2 (1.7%) |
| Education | 4 (3.4%) |
| Research | 1 (0.8%) |
| Other | 2 (1.7%) |
| Years of practice, mean ± SD (range) in years | 16.3±8.0 (5-42) |



### Statistical analysis

The characteristics of the participants and the additional open question about the age that could influence patient outcome were analyzed using descriptive statistics. For the surveyed parameters, absolute and relative frequencies of relevance were calculated, along with their 95% confidence interval. The response options 'probably relevant' and 'definitely relevant' were analyzed to indicate the relevance of each parameter. Furthermore, various subanalyses were performed using descriptive statistics and Kruskal-Wallis test (significance level 0.05) to identify possible differences in responses between: 1) world regions, 2) degree of clinical experience (up to 10 years, 11-20 years or more than 20 years), 3) perspectives of orthopedic surgeons and neurosurgeons, and 4) surgeons with and without a completed spine fellowship.

## RESULTS

### Response rate

Out of 279 experts who received the survey, 147 (52.7%) responded to the study invitation. A total of 118 (42.3%) participated in this study as some of the responders did not meet the inclusion criteria (n=8) or only completed the background data (n=21). The socio-demographic characteristics of the participants are shown in Table 1. The majority of the

participants were males (97.5%), consistent with the demographics of spine surgeons. The mean age was 46.3 years and the mean years of experience 16.3 years (range: 5-42 years). The experts were from 44 different countries, representing all AOSpine International world regions. With 92.4%, the main working field of the participants was the clinical practice.

**Relevance of parameters**

The relevance of each parameter for patients with traumatic thoracic, thoracolumbar, and lumbar spine injuries is shown in Table 2-4, respectively. *Neurological status* was identified as the most relevant parameter for all defined spine regions, as well as for the short term and long term. Although less relevant than *neurological status,* four other parameters were also identified as relevant by at least 70% of the participants for all defined spine regions and time periods: *implant failure within 3 months, patient satisfaction, sagittal alignment (kyphosis),* and *age. Patient's current level of pain* and *mobility* seemed to be relevant for the thoracolumbar and lumbar spine only. Furthermore, three parameters *(surgical site infections, misplacement of implants,* and *implant failure after 6 months)* were found to be relevant specifically for the short term and one parameter *(bony fusion)* for the long term, regardless of the spine region. The remaining five parameters *(comorbidity, coronal alignment (scoliosis), vertebral body height loss, spinal canal encroachment on trauma CT/MRI,* and *disc height loss)* were not identified as relevant, except for *comorbidity* being relevant for the lumbar spine in the short term.

As shown in Table 5, no large differences were observed for the age that, in the absence of serious medical comorbidities, substantially may influence outcome of the defined group of patients (range of means: 50.1-54.1 years).

**Regional differences**

Minor differences were observed when analyzing the responses according to each world region. In general, the North American participants were most likely to consider parameters as least relevant. Parameters identified as relevant by at least 70% of the participants among all world regions are indicated in Table 2-4.

Concerning the thoracic spine, for the short term the largest differences in responses were observed for the parameters *vertebral body height loss* (range: 6.3%-72.7%; $p<0.001$) and *spinal canal encroachment on the trauma CT/MRI* (range: 18.8-84.8%; $p<0.001$), being least relevant for North American participants and most relevant for Latin American participants. For the long term, besides these two parameters ($p<0.05$), *surgical site infections* also showed large interregional differences (range: 31.3-87.9%; $p<0.001$).

For the thoracolumbar spine, it was notable that the parameters *mobility* and *vertebral body height loss* were found much less relevant by the North American participants compared to the other world regions, both for the short term ($p\leq0.004$), and long term ($p\leq0.038$).

**Table 2.** The relevance of the parameters for the thoracic spine (T1-T10), on the short term and long term post-trauma.

| Parameter | % of experts | (95% CI) | (range – regions) | (range – experience) |
|---|---|---|---|---|
| *Short term (3 months – 2 years)* | | | | |
| Neurological status[a] | 95.8 | (91.5-99.2) | (90.9-100.0) | (93.3-96.3) |
| Implant failure within 3 months[a] | 92.3 | (87.3-97.4) | (81.3-97.1) | (90.0-97.1) |
| Surgical site infections | 90.7 | (85.6-95.8) | (68.8-100.0) | (88.9-94.1) |
| Patient satisfaction[a] | 81.4 | (73.8-89.0) | (75.8-92.0) | (73.3-85.3) |
| Implant failure after 6 months | 77.1 | (68.6-84.7) | (66.7-100.0) | (75.9-79.4) |
| Misplacement of implants | 74.6 | (67.8-82.2) | (43.8-90.0) | (68.5-86.7) |
| Sagittal alignment (kyphosis) | 73.7 | (66.1-80.5) | (56.3-87.9) | (60.0-87.0) |
| Age | 71.2 | (62.7-79.6) | (62.5-100.0) | (63.3-79.4) |
| Patient's current level of pain | 68.7 | (60.2-76.3) | (62.5-76.0) | (60.0-74.1) |
| Bony fusion | 68.7 | (60.2-77.1) | (37.5-78.8) | (46.7-79.4) |
| Co-morbidity | 61.1 | (52.5-69.5) | (40.0-72.7) | (50.0-70.6) |
| Spinal canal encroachment | 58.4 | (49.2-67.8) | (18.8-84.8) | (55.6-64.7) |
| Vertebral body height loss | 54.2 | (44.9-62.7) | (6.3-72.7) | (40.0-61.1) |
| Mobility | 38.1 | (29.7-46.6) | (18.8-60.0) | (29.4-42.6) |
| Coronal alignment (scoliosis) | 38.2 | (30.5-47.5) | (18.8-60.0) | (26.5-48.1) |
| Disc height loss | 32.2 | (23.7-40.7) | (6.3-52.0) | (26.5-38.9) |
| *Long term (≥2 years)* | | | | |
| Neurological status[a] | 91.5 | (85.6-95.8) | (81.8-100.0) | (90.7-93.3) |
| Sagittal alignment (kyphosis)[a] | 85.6 | (78.8-91.5) | (80.0-88.2) | (80.0-88.9) |
| Patient satisfaction[a] | 83.9 | (77.1-89.8) | (81.3-90.0) | (79.6-90.0) |
| Bony fusion | 78.0 | (70.3-85.6) | (56.3-91.2) | (76.5-80.0) |
| Implant failure within 3 months | 72.9 | (64.4-80.5) | (68.8-76.5) | (72.2-73.5) |
| Age | 71.2 | (62.7-78.8) | (60.6-80.0) | (70.0-73.5) |
| Implant failure after 6 months | 65.2 | (56.8-73.7) | (58.8-80.0) | (63.0-70.6) |
| Patient's current level of pain | 62.7 | (54.2-71.2) | (56.3-66.7) | (58.8-73.3) |
| Surgical site infections | 61.9 | (53.4-70.3) | (30.0-87.9) | (57.4-70.0) |
| Misplacement of implants | 56.8 | (47.5-65.3) | (31.3-72.0) | (51.9-66.7) |
| Co-morbidity | 54.3 | (44.9-63.5) | (30.0-68.0) | (51.9-60.0) |
| Spinal canal encroachment | 52.5 | (44.1-61.9) | (18.8-72.7) | (48.1-56.7) |
| Coronal alignment (scoliosis) | 50.8 | (41.5-59.3) | (25.0-70.0) | (44.1-55.6) |
| Vertebral body height loss | 49.2 | (39.8-58.5) | (12.5-68.0) | (40.0-55.9) |
| Mobility | 44.1 | (34.7-53.4) | (18.8-50.0) | (32.4-53.3) |
| Disc height loss | 35.6 | (28.0-44.9) | (12.5-50.0) | (26.5-40.7) |

Relative frequencies are shown, along with their 95% bootstrapped confidence intervals (CI), and range among the different world regions (range-regions) and different degrees of experience (range-experience).
[a] relevant for at least 70% of the participants in all AOSpine International world regions

The same pattern was seen for the lumbar spine. For the short term, *misplacement of implants* was relevant for 53.3% of the North American participants, while the relevance among the other world regions ranged from 82.8% to 90.0% (p=0.069). The largest differences among all world regions were seen for *vertebral body height loss*, both on the short term (range: 13.3-79.2%; p<0.001) and long term (range: 20.0-75.0%; p=0.012).

**Table 3.** The relevance of the parameters for the thoracolumbar junction (T11-L2), on the short term and long term post-trauma.

| Parameter | % of experts | (95% CI) | (range – regions) | (range - experience) |
|---|---|---|---|---|
| *Short term (3 months – 2 years)* | | | | |
| Neurological status[a] | 94.5 | (89.9-98.2) | (87.5-100.0) | (92.9-96.4) |
| Implant failure within 3 months[a] | 92.7 | (87.2-97.2) | (73.3-100.0) | (92.5-92.9) |
| Patient satisfactiona | 88.0 | (81.7-93.6) | (80.6-100.0) | (82.1-92.9) |
| Surgical site infections | 86.3 | (79.8-92.7) | (60.0-100.0) | (83.0-89.3) |
| Implant failure after 6 months | 85.3 | (78.0-91.7) | (66.7-91.7) | (83.0-89.3) |
| Misplacement of implants | 79.8 | (71.6-87.2) | (53.3-100.0) | (71.4-85.7) |
| Age[a] | 78.9 | (70.6-86.2) | (75.0-90.0) | (67.9-85.7) |
| Sagittal alignment (kyphosis) | 75.2 | (67.0-83.5) | (53.3-93.5) | (60.7-83.0) |
| Patient's current level of pain | 70.7 | (62.4-78.9) | (53.3-90.0) | (64.3-73.6) |
| Bony fusion | 68.8 | (60.6-77.1) | (40.0-80.0) | (64.3-71.7) |
| Co-morbidity | 67.9 | (58.7-77.1) | (58.6-79.2) | (60.7-78.6) |
| Mobility | 64.3 | (55.0-72.5) | (20.0-75.0) | (57.1-67.9) |
| Spinal canal encroachment | 60.6 | (51.4-69.7) | (33.3-87.1) | (50.0-66.0) |
| Vertebral body height loss | 56.9 | (47.7-66.1) | (13.3-77.4) | (46.4-66.0) |
| Coronal alignment (scoliosis) | 53.2 | (44.0-62.4) | (41.4-70.0) | (39.3-60.4) |
| Disc height loss | 39.5 | (31.2-47.7) | (6.7-54.2) | (35.7-43.4) |
| *Long term (≥2 years)* | | | | |
| Neurological status[a] | 92.7 | (88.1-97.2) | (87.1-100.0) | (85.7-96.4) |
| Patient satisfaction[a] | 87.1 | (80.7-93.6) | (80.0-100.0) | (84.9-89.3) |
| Sagittal alignment (kyphosis)[a] | 86.2 | (78.9-91.7) | (66.7-90.3) | (82.1-90.6) |
| Bony fusion | 77.1 | (68.8-84.4) | (60.0-83.3) | (67.9-85.7) |
| Implant failure within 3 months | 77.0 | (68.8-85.3) | (53.3-82.8) | (75.0-79.2) |
| Agea | 75.2 | (67.0-83.5) | (66.7-82.8) | (64.3-82.1) |
| Patient's current level of pain | 73.4 | (64.2-81.7) | (53.3-83.3) | (71.4-78.6) |
| Mobility | 72.5 | (63.3-80.7) | (40.0-90.0) | (69.8-75.0) |
| Implant failure after 6 months | 68.8 | (60.6-77.1) | (53.3-79.2) | (64.2-75.0) |
| Surgical site infections | 65.2 | (56.0-74.3) | (33.3-77.4) | (60.4-78.6) |
| Coronal alignment (scoliosis) | 63.3 | (53.2-72.5) | (46.7-80.0) | (50.0-67.9) |
| Co-morbidity | 63.3 | (54.1-72.5) | (58.1-75.0) | (62.3-64.3) |
| Misplacement of implants | 62.4 | (53.2-70.6) | (40.0-70.8) | (50.9-75.0) |
| Vertebral body height loss | 56.0 | (13.3-80.0) | (13.3-80.0) | (50.0-58.5) |
| Spinal canal encroachment | 46.8 | (26.7-64.5) | (26.7-64.5) | (42.9-53.6) |
| Disc height loss | 44.9 | (13.3-70.0) | (13.3-70.0) | (41.5-50.0) |

Relative frequencies are shown, along with their 95% bootstrapped confidence intervals (CI), and range among the different world regions (range-regions) and different degrees of experience (range-experience).
[a] relevant for at least 70% of the participants in all AOSpine International world regions

## Influence of experience and professional background

Differences in response where considerably less when investigating the influence of spine surgeons' degree of experience and professional background.

Concerning the different degrees of clinical experience, some differences were observed for *sagittal alignment (kyphosis)* (range: 60.0-87.0%; p=0.010) and *bony fusion*

**Table 4.** The relevance of the parameters for the lumbar spine (L3-L5), on the short term and long term post-trauma.

| Parameter | % of experts | (95% CI) | (range – regions) | (range – experience) |
|---|---|---|---|---|
| *Short term (3 months – 2 years)* | | | | |
| Neurological status[a] | 89.9 | (84.4-95.4) | (82.8-100.0) | (85.7-92.9) |
| Implant failure within 3 months[a] | 88.1 | (81.7-93.6) | (86.2-90.3) | (84.9-92.9) |
| Surgical site infections | 85.3 | (78.0-91.7) | (66.7-100.0) | (81.1-89.3) |
| Sagittal alignment (kyphosis)[a] | 84.4 | (78.0-90.8) | (73.3-90.3) | (71.4-92.5) |
| Patient satisfaction[a] | 82.5 | (75.2-89.9) | (86.7-90.0) | (78.6-92.9) |
| Misplacement of implants | 80.7 | (73.4-88.1) | (53.3-90.0) | (78.6-85.7) |
| Implant failure after 6 months[a] | 78.9 | (71.6-86.2) | (77.4-86.7) | (75.0-81.1) |
| Mobility | 78.9 | (71.6-86.2) | (46.7-87.5) | (60.7-88.7) |
| Age[a] | 78.0 | (70.6-86.2) | (72.4-90.0) | (67.9-83.0) |
| Patient's current level of pain | 75.2 | (67.0-82.6) | (60.0-90.0) | (64.3-79.2) |
| Co-morbidity | 70.6 | (61.5-78.9) | (66.7-80.0) | (64.3-73.6) |
| Bony fusion | 64.2 | (54.1-72.5) | (40.0-79.2) | (57.1-71.4) |
| Coronal alignment (scoliosis) | 60.6 | (51.4-69.7) | (26.7-70.8) | (46.4-69.8) |
| Vertebral body height loss | 56.0 | (46.8-64.2) | (13.3-79.2) | (39.3-62.3) |
| Spinal canal encroachment | 52.3 | (43.1-61.5) | (26.7-64.5) | (42.9-60.7) |
| Disc height loss | 47.7 | (39.4-57.8) | (13.3-70.8) | (42.9-52.8) |
| *Long term (≥2 years)* | | | | |
| Neurological status[a] | 90.8 | (85.3-95.4) | (80.0-100.0) | (86.8-100.0) |
| Patient satisfaction[a] | 85.3 | (78.9-91.7) | (80.0-91.7) | (81.1-92.9) |
| Mobility | 84.4 | (78.0-90.8) | (66.7-93.1) | (75.0-89.3) |
| Sagittal alignment (kyphosis)[a] | 81.7 | (74.3-88.1) | (60.0-91.7) | (79.2-85.7) |
| Bony fusion | 80.8 | (73.4-87.2) | (66.7-86.2) | (78.6-85.7) |
| Age[a] | 77.0 | (68.8-84.4) | (72.4-90.0) | (71.4-79.2) |
| Patient's current level of pain | 76.2 | (67.9-83.5) | (60.0-91.7) | (67.9-85.7) |
| Implant failure within 3 months | 75.3 | (67.9-83.5) | (53.3-87.5) | (71.4-77.4) |
| Implant failure after 6 months | 68.8 | (59.6-77.1) | (60.0-79.2) | (67.9-71.4) |
| Surgical site infections | 67.0 | (57.8-75.2) | (33.3-87.1) | (58.5-82.1) |
| Misplacement of implants | 65.1 | (55.1-73.4) | (40.0-75.0) | (62.3-71.4) |
| Coronal alignment (scoliosis) | 61.5 | (51.4-70.6) | (46.7-75.0) | (53.6-67.9) |
| Co-morbidity | 59.6 | (50.5-67.9) | (48.4-75.0Å | (54.7-67.9) |
| Vertebral body height loss | 56.0 | (46.8-64.2) | (20.0-75.0) | (46.4-64.3) |
| Disc height loss | 51.4 | (42.2-60.6) | (13.3-66.7) | (50.0-52.8) |
| Spinal canal encroachment | 41.3 | (32.1-50.5) | (13.3-54.2) | (39.3-46.4) |

Relative frequencies are shown, along with their 95% bootstrapped confidence intervals (CI), and range among the different world regions (range-regions) and different degrees of experience (range-experience).
[a] Relevant for at least 70% of the participants in all AOSpine International world regions

(range: 46.7-79.4%; p=0.010) for the thoracic spine on the short term. Both parameters were considered least relevant by the surgeons with more than 20 years of clinical experience. For the thoracolumbar spine, even less differences were observed between the surgeons with different degrees of experience. Moreover, none of the parameters showed statistically

significant differences. *Mobility of the lumbar spine* showed some differences for the short term (range: 60.7-88.7%; p=0.014).

Comparing the responses of orthopedic surgeons and neurosurgeons for all spine regions, parameters were, in general, considered more relevant by orthopedic surgeons. Neurological status was most relevant for both groups of professionals.

Almost no differences were seen when comparing the responses between surgeons with and without a completed spine fellowship, except for one parameter. In the thoracic spine, *spinal canal encroachment on the trauma CT/MRI,* was substantially more relevant for surgeons without a completed spine fellowship, both for the short term (77.8% vs. 52.7%; p=0.021) and the long term (81.5% vs. 44.0%; p=0.001).

**Comments**

Although a large number of participants (n=52; 44.1%) provided extra comments, the majority repeated one or more of the surveyed parameters to emphasize their importance. A considerable number of comments were related to factors more relevant for the patient reported outcome such as daily activities, return to work, and urinary and bowel function. The novel variables provided in the comments section and not indicated in the questions were related to *bone quality,* including *bone density* and *osteoporosis,* which are relevant in osteoporosis and ankylotic conditions.

## DISCUSSION

To our knowledge, this is the first survey exploring the perspective of worldwide experts on parameters they find most relevant to evaluate the clinical and functional outcomes of adult patients sustaining traumatic injuries to the thoracic and lumbar spine.

A representative sample of 118 experts from all five AOSpine International world regions and with substantial experience in the clinical practice of spine trauma was surveyed in this study. This contributes to the multinational and multicultural perspective in the identification of the most relevant clinical and radiological parameters for outcome measurement.

Of the 16 surveyed parameters, 5 were identified as relevant by at least 70% of the participants for all spine regions, both for the short term and long term. *Neurological status* was identified as most relevant parameter. This was not a surprising finding as neurological injury can be devastating with an abrupt change in patients' quality of life, as well as long-term clinical consequences. Moreover, many studies report on neurological status as a strong determinant of outcome in spine trauma patients.[13-16] Also some radiographic findings were found to be relevant for all spine regions and time periods. These parameters could be related to occult instability of the injured spine level with gradual post-traumatic deformities, which may very well influence patients' outcome and result in conversion of

**Table 5.** The age that, in the absence of serious medical comorbidities, substantially may influence the outcome of patients with traumatic thoracic and lumbar spine injuries, on the short term and long term post-trauma.

| Parameter | T spine | TL spine | L spine |
|---|---|---|---|
| Age, mean ± SD (range) in years | | | |
| *Short term (3 months – 2 years)* | 51.7±16.7 (18-85) | 50.1±16.3 (18-85) | 50.9±15.8 (18-85) |
| *Long term (≥2 years)* | 54.1±14.0 (18-80) | 52.5±14.8 (18-80) | 53.8±14.6 (18-80) |
| Age, median in years | | | |
| *Short term (3 months – 2 years)* | 55.0 | 50.0 | 50.0 |
| *Long term (≥2 years)* | 60.0 | 55.0 | 60.0 |

T=Thoracic spine (T1-T10); TL=Thoracolumbar spine (T11-L2); L=Lumbar spine (L3-L5).

the treatment.[17-19] Another relevant parameter for all spine regions and time periods was age. As increased age may be associated with multiple comorbidities along with their influence on patients' function and health,[20,21] it was surprising that *comorbidity* was not identified as relevant. These findings were partly clarified by the free text comments. Some participants found age to be relevant because of the potential risk of osteoporosis in women over 50 years of age. Probably this pattern of thoughts also explains the indicated age that could influence outcomes of these patients, ranging from a mean of 50 to 54 years. Combining all these findings supports that *bone quality* was reported as missing parameter. Bone quality plays a key role in aspects such as whether a patient should undergo surgery and subsequently the choice of surgical treatment, but also for the potential risk of implant failure and the possibility for gradual neurological deterioration.[22,23]

In general, the various subanalyses revealed only minor differences between world regions, degree of experience and professional background. However, it was notable that for some parameters, most of which were not identified as relevant by at least 70% of the participants, the responses of the North American participants deviated from the responses of the other world regions. An obvious explanation for this finding is lacking, but it may be possible that only few parameters are used by the North American participants to evaluate the treatment outcomes. Interestingly, a recently conducted study showed no regional differences when looking at the perceived severity of thoracolumbar spine trauma.[24] The minimal differences in our study regarding experience and professional background may be explained by the inclusion of spine surgeons with a substantial amount of experience in spine trauma care.

We do recognize several limitations of the current study. First, the survey was sent to a selected panel of experts. It is possible that including other experts might lead to different results. However, we believe that the participants represent a sample of spine surgeons with knowledge of and interest in outcome assessment in this specific patient population. Second, the definition of the short term and long term post-trauma was somewhat arbitrarily defined by the initiators of this project. However, the participants did not comment on this categorization. Finally, the selection of relevant parameters was based

on the arbitrary response cut-off point of at least 70%, representing a large majority of the participants.

In conclusion, including a representative sample of highly experienced spine surgeons from around the world, this study identified clinical and radiological parameters relevant to evaluate clinical and functional outcomes of patients sustaining traumatic injuries to the thoracic and lumbar spine. Together with the results of another expert survey focusing on the identification of relevant parameters for cervical spine trauma patients, this study forms the basis for the development of a SROM for adult spine trauma patients. After further validation, this tool should be useful to the spine surgeons for the purposes of guiding patient care and future research.

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**Appendix 1.** The general case as provided at the start of each subpart.

| |
|---|
| ''You see a patient with a traumatic [T/TL/L] fracture in the period of 6 weeks to 3 months after discharge at the outpatient department. This patient had a traumatic injury and has been treated either nonsurgically (brace, cast or functional) or surgically (with any kind of technique; posterior, anterior, circumferential with or without less invasive techniques).'' |

T=Thoracic spine (T1-T10); TL=Thoracolumbar spine (T11-L2); L=Lumbar spine (L3-L5)

**Appendix 2.** The surveyed clinical and radiological parameters (n=16).

- Age
- Bony fusion as seen and assessed on radiographs taken in the clinic today
- Co-morbidity not associated with the index trauma i.e. diabetes or heart disease
- [T/TL/L] coronal alignment (scoliosis) on radiographs taken in the clinic today
- Disc height loss on radiographs taken in the clinic today
- Implant failure after 6 months (in case surgical fixation was chosen as treatment option)
- Implant failure within 3 months (in case surgical fixation was chosen as treatment option)
- Misplacement of implants (in case surgical fixation was chosen as treatment option)
- Mobility of the [T/TL/L] spine
- Neurological status
- Patient satisfaction with the treatment
- Patient's current level of pain
- [T/TL/L] sagittal alignment (kyphosis) on radiographs taken in the clinic today
- Spinal canal encroachment on the trauma CT or MRI
- Surgical site infections (in case surgical fixation was chosen as treatment option)
- Vertebral body height loss on radiographs taken in the clinic today

T=Thoracic spine (T1-T10); TL=Thoracolumbar spine (T11-L2); L=Lumbar spine (L3-L5)

# Chapter 10

## Measurement of kyphosis and vertebral body height loss in traumatic spine fractures: an international study

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## ABSTRACT

*Purpose.* To investigate whether wide variations are seen in the measurement techniques preferred by spine surgeons around the world to assess traumatic fracture kyphosis and vertebral body height loss (VBHL).

*Methods.* An online survey was conducted at two time points among an international community of spine trauma experts from all world regions. The first survey (TL-survey) focused on the thoracic, thoracolumbar and lumbar spine, the second survey (C-survey) on the subaxial cervical spine. Participants were asked to indicate which measurement technique(s) they used for measuring kyphosis and VBHL. Descriptive statistics, frequency analysis and the Fisher exact test were used to analyze the responses.

*Results.* Of the 279 invited experts, 107 (38.4%) participated in the TL-survey, and 108 (38.7%) in the C-survey. The Cobb angle was the most frequently used for all spine regions to assess kyphosis (55.6-75.7%), followed by the wedge angle and adjacent endplates method. Concerning VBHL, the majority of the experts used the vertebral body compression ratio in all spine regions (51.4-54.6%). The most frequently used combination for kyphosis was the Cobb and wedge angles. Considerable differences were observed between the world regions, while fewer differences were seen between surgeons with different degrees of experience.

*Conclusions.* This study identified worldwide variations in measurement techniques preferred by treating spine surgeons to assess fracture kyphosis and VBHL in spine trauma patients. These results establish the importance of standardizing assessment parameters in spine trauma care, and can be taken into account to further investigate these radiographic parameters.

## INTRODUCTION

A significant proportion of major trauma patients suffer spine injuries, which can contribute to disability with long-term consequences and associated health related costs. Epidemiological studies have reported annual incidences of traumatic spine fractures between 19 and 88 per 100.000 population.[1,2] The reported annual incidence of spinal cord injured patients varies from 13.9 to 19.4 per million population in Europe, and 43.3 to 51.0 in North America.[3-5] In the trauma setting as well as during follow-up, different clinical and radiological parameters are taken into account by the treating surgeons as a guide to decide on treatment strategy. Clinical parameters may include patients' neurological status as a critical indicator, and injury morphology.[6-9] Also radiographic measurements are crucial, including sagittal alignment (kyphosis) and the amount of vertebral body height loss (VBHL).[10-12] Changes in the kyphotic angle may indicate the degree of instability of the injured spinal segment and progression of deformity. Increasing VBHL has the potential to contribute to and enhance this instability, which can result in changes in the treatment plan. In the thoracolumbar spine, various studies have shown a kyphotic angle of 15˚ to 30˚ or VBHL of more than 50% to be associated with instability.[13-16]

Different measurement techniques have been described to assess these radiographic parameters. It is not known which specific measurement technique, or combination of techniques, is preferred by spine surgeons around the world. We hypothesize that different measurement techniques are used to assess fracture kyphosis and vertebral body height loss. The use of different techniques could result in different measurements and thereby lead to treatment variability for certain types of spine fractures.[17-19] Moreover, the use of a standardized technique would facilitate a universal language, both in research and clinical settings. Therefore, the aim of the current study is to investigate whether wide variations are seen in the measurement techniques preferred by spine surgeons around the world to assess traumatic fracture kyphosis and vertebral body height loss in both the thoracolumbar spine and the cervical spine.

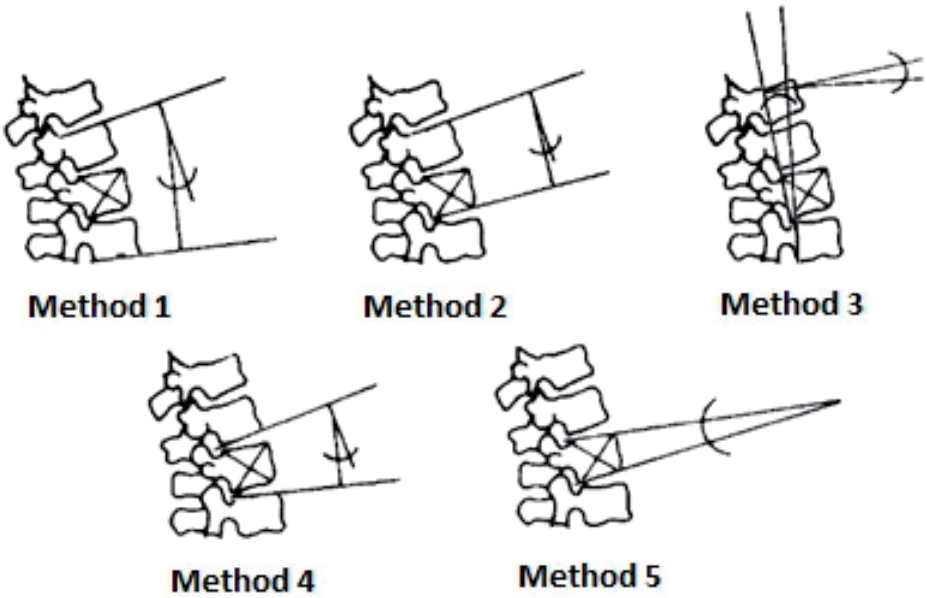


***Figure 1.*** Surveyed measurement techniques for assessing fracture kyphosis.

Method 1 = Cobb angle (bisegmental)
Method 2 = Gardner's method (monosegmental)
Method 3 = posterior walls angle
Method 4 = adjacent endplates method
Method 5 = wedge angle

## MATERIALS AND METHODS

### Study design

A cross-sectional web-based survey was conducted at two time points, with an interval of three months, among spine surgeons from all world regions (Asia Pacific, Europe and Sub Saharan Africa, Latin America, Middle East and North Africa, and North America).

### Recruitment of participants

The recruitment of potential participants was performed through AOSpine International. As it was aimed to include a worldwide sample of surgeons experienced in spine trauma care, an international pool of 279 experts from the AOSpine and International Spinal Cord Society (ISCoS) was identified. They could only participate if they were an orthopedic-, trauma- or neurosurgeon with at least five years of experience in the treatment of adult spine trauma patients. Also fluency in English was required to complete the surveys. The current survey was combined with two surveys of an AOSpine project that focuses on the development of a surgeon reported outcome instrument for spine trauma patients.[20,21]

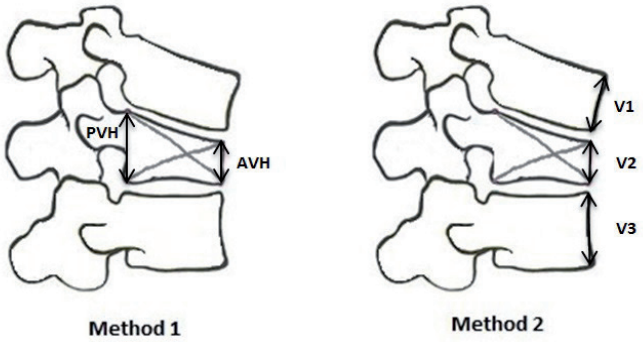


***Figure 2.*** Surveyed measurement techniques for assessing vertebral body height loss.

Method 1 = Anterior/Middle Column Vertebral Body Compression Ratio (VBCR) = AVH/PVH
Method 2 = Anterior Vertebral Body Compression Percentage (AVBC%) = V2 / [(V1+V3)/2] x 100%
AVH = anterior vertebral height
PVH = posterior vertebral height

**Survey instrument**

The first survey (TL-survey) focused on the measurement techniques in the thoracic (T1-T10), thoracolumbar (T11-L2) and lumbar spine (L3-L5), while the second survey (C-survey) focused on the subaxial cervical spine (C3-C7). In the first part of both surveys, participants were asked about their professional background. In the second part, they were asked to indicate which measurement technique(s) they used to assess fracture kyphosis and VBHL. The surveyed measurement techniques were based on the previously described Radiographic Measurement Manual of the Spine Trauma Study Group,[22] and included five techniques for measuring fracture kyphosis and two methods for VBHL. Participants could indicate whether they use one specific technique, a combination of techniques, some other technique or do not measure that spinal parameter. The response option 'another technique' required a specification. At the end, free text fields were provided for any general comments. All data were recorded and analyzed anonymously.



**Surveyed measurement techniques kyphosis**

As shown in Figure 1, the five surveyed methods to measure fracture kyphosis were: 1) 'Cobb angle', from the superior endplate of the adjacent cranial vertebral body to the inferior endplate of the adjacent caudal body (bisegmental angle); 2) 'Gardner's method', using the superior endplate of the vertebral body above and inferior endplate of the fractured vertebral body (monosegmental angle); 3) 'posterior walls angle', measuring the angle between the posterior walls of the vertebral bodies above and below the injured vertebra; 4) 'adjacent endplates method', from the inferior endplate of the vertebra above and the superior endplate of the vertebra below the fracture; and 5) 'wedge angle', measuring from the superior endplate to the inferior of the injured vertebra.

**Table 1.** Characteristics of surveyed experts.

| | TL-survey (n=107) | C-survey (n=108) |
|---|---|---|
| Male (%) | 104 (97.2%) | 107 (99.1%) |
| Age, mean ± SD (range) in years | 46.6±8.2 (30-67) | 47.1±8.0 (30-65) |
| AOSpine world region (%) | | |
| Asia Pacific | 24 (22.4%) | 23 (21.3%) |
| Europe / Sub Saharan Africa | 29 (27.1%) | 28 (25.9%) |
| Latin America | 30 (28.0%) | 28 (25.9%) |
| Middle East / North Africa | 10 (9.3%) | 12 (11.1%) |
| North America | 14 (13.1%) | 17 (15.7%) |
| Profession (%) | | |
| Neurosurgeon | 35 (32.7%) | 35 (32.4%) |
| Orthopaedic surgeon | 63 (58.9%) | 65 (60.2%) |
| Trauma surgeon | 6 (5.6%) | 8 (7.4%) |
| Other | 3 (2.8%) | 0 |
| Spine fellowship completed (%) | 84 (78.5%) | 96 (88.9%) |
| Main working field (%) | | |
| Clinic | 98 (91.6%) | 98 (90.7%) |
| Education | 4 (3.7%) | 7 (6.5%) |
| Management | 2 (1.9%) | 0 |
| Research | 1 (0.9%) | 0 |
| Other | 2 (1.9%) | 3 (2.8%) |
| Years of practice, mean ± SD (range) in years | 16.5±7.7 (5-42) | 17.1±8.4 (5-40) |

TL-survey = first survey focusing on the thoracic, thoracolumbar and lumbar spine
C-survey = second survey focusing on the subaxial cervical spine

**Surveyed measurement techniques VBHL**

The two surveyed methods for measuring VBHL were (see Figure 2): 1) Anterior/Middle Column Vertebral Body Compression Ratio ('VBCR'), i.e. the ratio of anterior vertebral height (AVH) to posterior vertebral height (PVH) with the formula VBCR= AVH/PVH; and 2) the Anterior Vertebral Body Compression Percentage ('AVBC%'), consisting of the percentage of anterior vertebral body compression with respect to the average height of the anterior vertebral bodies immediately cephalad and caudad to the injury level (formula: V2 / [(V1+V3)/2] x 100%).

**Statistical analysis**

Descriptive statistics were used to analyze the characteristics of the participants. For each measurement technique, absolute and relative frequencies along with their 95% confidence interval were calculated for the different spine regions. If a combination of techniques was indicated by an expert, each technique was counted independently. Hence, with relative frequencies being analyzed relative to the total number of participants, the sum of relative frequencies could exceed 100%. Descriptive statistics and the Fisher exact test (significance level $\alpha$=0.05) were used to analyze any differences between the five world regions, and the influence of clinical experience (≤10 years, 11-20 years or >20 years).

## RESULTS

### Response rate

Out of 279 invited experts, 107 (38.4%) from 43 different countries participated in the first survey (TL-survey), and 108 (38.7%) from 41 different countries in the second survey (C-survey). The number of experts that participated in both surveys was 64 (22.9%). Comparable socio-demographic characteristics and results were observed between this group and the total number of participants from each survey. In order to have a larger number of participants for the subanalyses, the results presented are for the total responders from each survey (n=107 for TL-survey and n=108 for C-survey). The socio-demographic characteristics of the participants are shown in Table 1.

### Measurement techniques

As shown in Figure 3 and Table 2, the Cobb method (Method 1) was the most frequently used technique for all spine regions to assess fracture kyphosis, although considerably less frequent for the subaxial cervical spine (55.6%) compared with the other spine regions (71.0-75.7%). Also the wedge angle (Method 5) was used by a considerable number of experts, followed by the adjacent endplates method (Method 4). The least frequently used method in the subaxial cervical spine was Gardner's method (Method 2; 4.6%), while the posterior walls method (Method 3) in the thoracic (0.9%), thoracolumbar (1.9%), and lumbar spine (0.9%). In both surveys, only one expert indicated to use another technique to assess kyphosis. These were not the same participants. In the C-survey, the other technique was 'measuring from the superior endplates of the cephalad and caudad vertebral body'. In the TL-survey, 'T2 superior endplate to T10 inferior endplate' was the other measurement technique in the thoracic spine, 'T10 superior endplate to L2 inferior endplate' in the thoracolumbar junction, and 'L3 superior endplate to sacrum superior endplate' in the lumbar spine.

The results of the measurement techniques used to assess VBHL are shown in Figure 4 and Table 3. The majority of the experts used the VBCR (Method 1) in all spine regions (51.4-54.6%). Compared to kyphosis, a larger proportion of participants indicated not to measure VBHL (range among spine regions: 13.0-15.9%). No participant used a different technique to assess VBHL.

All identified combinations of techniques to assess kyphosis along with their absolute and relative frequencies are shown in Table 4, as well as for the combination of VBCR and AVBC% for VBHL. In total, 13 combinations of measurement techniques for kyphosis were identified, but the most frequently used combination for all spinal regions was the assessment of the Cobb and wedge angles. Only 3 surgeons (2.8%) indicated to use a combination of VBCR and AVBC% to assess VBHL.

**Table 2.** Results for the assessment of fracture kyphosis.

| | % of experts[a] | 95% CI | (range – regions) | (range – experience) |
|---|---|---|---|---|
| *Subaxial cervical spine (C3-C7)* | | | | |
| None | 6.5 | 2.8 – 11.1 | (0.0-8.7) | (5.4-7.7) |
| Method 1 | 55.6 | 46.3 – 63.9 | (46.4-60.9) | (48.7-65.6) |
| Method 2 | 4.6 | 0.9 – 9.3 | (0.0-10.7) | (0.0-10.8) |
| Method 3 | 8.3 | 3.7 – 13.9 | (0.0-11.8) | (3.1-10.8) |
| Method 4 | 20.4 | 13.0 – 28.7 | (8.3-47.1) | (6.3-28.2) |
| Method 5 | 21.3 | 13.0 – 29.6 | (5.9-41.7) | (10.8-31.3) |
| Other | 0.9 | 0.0 – 2.8 | (0.0-3.6) | (0.0-2.6) |
| *Thoracic spine (T1-T10)* | | | | |
| None | 3.7 | 0.9 – 7.5 | (0.0-8.3) | (0.0-7.1) |
| Method 1 | 75.7 | 67.3 – 83.2 | (40.0-80.0) | (67.9-80.8) |
| Method 2 | 4.7 | 0.9 – 9.3 | (0.0-10.3) | (0.0-7.7) |
| Method 3 | 0.9 | 0.0 – 2.8 | (0.0-4.2) | (0.0-1.9) |
| Method 4 | 9.3 | 4.7 – 15.0 | (6.7-20.0) | (7.1-11.5) |
| Method 5 | 18.7 | 12.1 – 27.1 | (8.3-40.0) | (7.7-29.6) |
| Other | 0.9 | 0.0 – 2.8 | (0.0-3.3) | (0.0-3.6) |
| *Thoracolumbar junction (T11-L2)* | | | | |
| None | 4.7 | 0.9 – 9.3 | (0.0-8.3) | (0.0-7.1) |
| Method 1 | 72.0 | 63.6 – 80.4 | (50.0-79.2) | (60.7-76.9) |
| Method 2 | 8.4 | 2.8 – 14.0 | (0.0-12.5) | (3.7-11.5) |
| Method 3 | 1.9 | 0.0 – 4.7 | (0.0-8.3) | (0.0-3.6) |
| Method 4 | 13.1 | 7.5 – 19.6 | (0.0-30.0) | (11.1-17.9) |
| Method 5 | 15.0 | 9.3 – 22.4 | (6.7-24.1) | (7.7-22.2) |
| Other | 0.9 | 0.0 – 2.8 | (0.0-3.3) | (0.0-3.6) |
| *Lumbar spine (L3-L5)* | | | | |
| None | 6.5 | 1.9 – 11.2 | (0.0-10.3) | (0.0-7.1) |
| Method 1 | 71.0 | 61.7 – 79.4 | (40.0-83.3) | (67.9-73.1) |
| Method 2 | 7.5 | 2.8 – 13.1 | (0.0-10.3) | (3.7-9.6) |
| Method 3 | 0.9 | 0.0 – 2.8 | (0.0-4.2) | (0.0-3.6) |
| Method 4 | 11.2 | 5.6 – 17.8 | (4.2-20.0) | (7.4-13.5) |
| Method 5 | 17.8 | 11.2 – 25.2 | (8.3-40.0) | (9.6-29.6) |
| Other | 0.9 | 0.0 – 2.8 | (0.0-3.3) | (0.0-3.6) |

Relative frequencies are shown, along with their 95% bootstrapped confidence intervals (CI), and range among the different world regions (range-regions) and different degrees of experience (range-experience).
[a] The total percentage exceeds 100% as a combination of measurement techniques was indicated by some participants.

## Regional differences

Analysis of the responses according to each world region showed that fracture kyphosis was most frequently assessed using the Cobb method. It was remarkable that for the subaxial cervical spine, the adjacent endplates method was considerably more often used by North American participants (47.1%) compared to the other world regions (8.3-21.4%; p=0.069). For the thoracic spine, the Cobb method was less frequently used in the Middle East / North Africa (40.0% vs. 78.6-80.0%; p=0.155), while the wedge angle was more often used (40.0% vs. 8.3-27.3%; p=0.145). Comparable patterns of regional variations were seen for

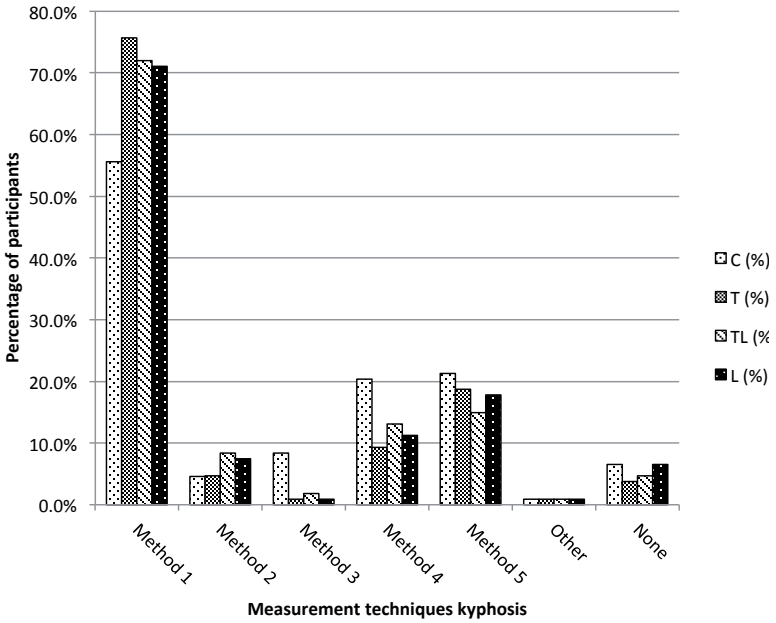


***Figure 3.*** Measurement techniques used by the percentage of experts to assess fracture kyphosis. C=Subaxial cervical spine (C3-C7); T=Thoracic spine (T1-T10); TL=Thoracolumbar junction (T11-L2); L=Lumbar spine (L3-L5)



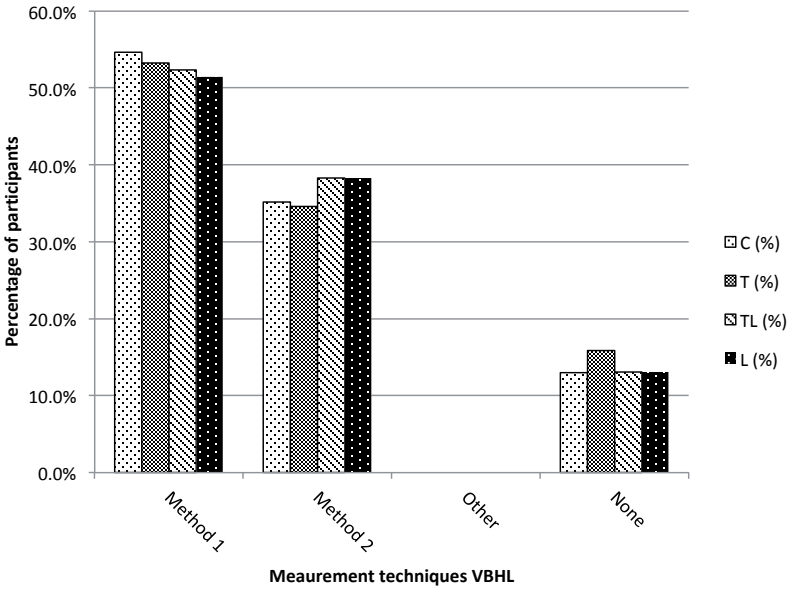


***Figure 4.*** Measurement techniques used by the percentage of experts to assess vertebral body height loss. C=Subaxial cervical spine (C3-C7); T=Thoracic spine (T1-T10); TL=Thoracolumbar junction (T11-L2); L=Lumbar spine (L3-L5)

**Table 3.** Results for the assessment of vertebral body height loss.

| | % of experts[a] | 95% CI | (range – regions) | (range – experience) |
|---|---|---|---|---|
| *Subaxial cervical spine (C3-C7)* | | | | |
| None | 13.0 | 7.4 – 19.4 | (0.0-25.0) | (6.3-20.5) |
| Method 1 | 54.6 | 45.4 – 63.9 | (42.9-83.3) | (51.3-56.8) |
| Method 2 | 35.2 | 26.9 – 45.4 | (17.9-47.1) | (32.4-40.6) |
| Other | 0.0 | n.a. | (0.0-0.0) | (0.0-0.0) |
| *Thoracic spine (T1-T10)* | | | | |
| None | 15.9 | 9.3 – 23.4 | (0.0-30.0) | (10.7-21.2) |
| Method 1 | 53.3 | 43.9 – 62.6 | (40.0-64.3) | (44.2-66.7) |
| Method 2 | 34.6 | 26.2 – 43.9 | (27.6-50.0) | (25.9-39.3) |
| Other | 0.0 | n.a. | (0.0-0.0) | (0.0-0.0) |
| *Thoracolumbar junction (T11-L2)* | | | | |
| None | 13.1 | 7.5 – 19.6 | (0.0-20.7) | (3.6-19.2) |
| Method 1 | 52.3 | 43.0 – 60.7 | (40.0-64.3) | (40.4-66.7) |
| Method 2 | 38.3 | 29.0 – 46.7 | (27.6-50.0) | (25.9-42.9) |
| Other | 0.0 | n.a. | (0.0-0.0) | (0.0-0.0) |
| *Lumbar spine (L3-L5)* | | | | |
| None | 13.1 | 7.5 – 19.6 | (0.0-20.0) | (3.6-19.2) |
| Method 1 | 51.4 | 42.1 – 60.7 | (40.0-64.3) | (38.5-66.7) |
| Method 2 | 38.3 | 29.0 – 47.7 | (27.6-50.0) | (25.9-42.9) |
| Other | 0.0 | n.a. | (0.0-0.0) | (0.0-0.0) |

Relative frequencies are shown, along with their 95% bootstrapped confidence intervals (CI), and range among the different world regions (range-regions) and different degrees of experience (range-experience).
n.a. = not applicable
[a] The total percentage exceeds 100% as a combination of measurement techniques was indicated by some participants.

the thoracolumbar junction and lumbar spine. The only significant difference between the world regions was the adjacent endplates method not being used by Asian participants, while 30% of the Middle East / North African participants indicated to use this technique in the thoracolumbar junction (p=0.026).

Compared to fracture kyphosis, more regional variations were seen in the responses to VBHL. The VBCR method was more frequently used for the subaxial cervical spine by participants from all world regions, except for Latin American participants using more often the AVBC% method (53.6% vs. 42.9%). Moreover, a wide range was observed for VBCR method (42.9-83.3%; p=0.169). Significant regional differences were seen for AVBC% method (17.9-53.6%; p=0.047), and for not measuring VBHL (0.0-25.0%; p=0.044). Also in in the thoracic, thoracolumbar and lumbar spine, the VBCR method seemed to be more frequently used than the AVBC% method, except for Middle East / North Africa using the latter more frequently in the thoracolumbar and lumbar spine (both 50% vs. 40%).

**Table 4.** Absolute and relative frequencies (%) are shown for the identified combinations of measurement techniques used in each spine region for the assessment of fracture kyphosis and vertebral body height loss.

| | C | T | TL | L |
|---|---|---|---|---|
| *Kyphosis* | | | | |
| Methods 1 and 2 | 2 (1.9) | 1 (0.9) | 3 (2.8) | 2 (1.9) |
| Methods 1 and 3 | 2 (1.9) | 1 (0.9) | 1 (0.9) | 0 |
| Methods 1 and 4 | 1 (0.9) | 1 (0.9) | 0 | 0 |
| Methods 1 and 5 | 7 (6.5) | 8 (7.5) | 6 (5.6) | 5 (4.7) |
| Methods 2 and 3 | 1 (0.9) | 0 | 0 | 0 |
| Methods 2 and 4 | 1 (0.9) | 0 | 0 | 0 |
| Methods 3 and 4 | 1 (0.9) | 0 | 0 | 0 |
| Methods 3 and 5 | 1 (0.9) | 0 | 0 | 0 |
| Methods 4 and 5 | 0 | 1 (0.9) | 1 (0.9) | 1 (0.9) |
| Methods 1,2 and 5 | 0 | 1 (0.9) | 1 (0.9) | 1 (0.9) |
| Methods 1,4 and 5 | 0 | 0 | 0 | 1 (0.9) |
| Methods 1,2,3 and 5 | 0 | 0 | 1 (0.9) | 1 (0.9) |
| Methods 1,3,4 and 5 | 1 (0.9) | 0 | 0 | 0 |
| Total | 17 (15.7) | 13 (12.1) | 13 (12.1) | 11 (10.3) |
| *VBHL* | | | | |
| Methods 1 and 2 | 3 (2.8) | 3 (2.8) | 3 (2.8) | 3 (2.8) |

C=Subaxial cervical spine (C3-C7); T=Thoracic spine (T1-T10); TL=Thoracolumbar junction (T11-L2); L=Lumbar spine (L3-L5)

### Influence of experience

Fewer differences were observed when taking the spine surgeons' degree of clinical experience into account. Regardless of the experience, most surgeons used the Cobb method to assess kyphosis in all spine regions. In the subaxial cervical spine, some variations were seen for the adjacent endplates method (6.3-28.2%; p=0.043) and the wedge angle method (10.8-31.3%; p=0.113).

Concerning the measurement techniques to assess VBHL in the subaxial cervical spine, the VBCR method was used by most surgeons in all subgroups of clinical experience. More variation was observed for the measurement techniques in the thoracic, thoracolumbar and lumbar spine, with the only significant differences for using the VBCR method in the thoracolumbar junction (40.4-66.7%; p=0.049) and lumbar spine (38.5-66.7%; p=0.031).

### Comments

No general comments concerning the measurement techniques were provided by the participants.

## DISCUSSION

To the best of our knowledge, this is the first study exploring the measurement techniques preferred by a worldwide sample of spine trauma experts to assess traumatic fracture kyphosis and vertebral body height loss. In the only previous study performed by the Spine

Trauma Study Group, a small number of 35 member surgeons were surveyed on the methods used for assessing kyphosis.[23] However, the main objective of that study was to provide an updated definition of post-traumatic kyphosis, and methods for diagnosis and treatment of post-traumatic kyphosis, rather than to survey the preferred method to measure fracture kyphosis.

Including 107 spine surgeons from 43 different countries in the first survey (TL survey), and 108 from 41 different countries in the second survey (C-survey), the results from this study are considered as a valid reflection of the current practice in spine trauma care worldwide.

The most frequently indicated technique to assess fracture kyphosis was measuring the Cobb angle (Method 1), followed by the wedge angle (Method 5). Kuklo et al. investigated the inter- and intra-rater reliability of the same five measurement techniques for kyphosis as we surveyed, and concluded that the Cobb method showed the best intra- and inter-observer reliability, followed by the wedge angle.[24] Also in the aforementioned survey by the Spine Trauma Study Group,[23] the same Cobb angle was reported to be most useful in measuring kyphosis. One other study investigated the influence of experience on reproducibility of kyphosis measurement among physicians with different degrees of experience.[25] This study found the methods not taking the fractured vertebra into account to be the most reproducible. These methods are the same as Method 1 (Cobb angle) and Method 4 (adjacent endplates method) in the current study. The posterior walls angle method (Method 3) was least frequently used. With this method, the exact location of the vertebral body may be difficult to establish. No 'gold standard' or 'true value' exists for measuring kyphosis or VBHL, but the aforementioned studies demonstrate the most satisfactory results for the Cobb angle to assess fracture kyphosis. Compared to the other measurement techniques surveyed in the current study, a larger area over which to measure is included when using this bisegmental measurement method. The potential advantages are the minimization of differences between measurements as well as the recognition of the degree of instability of the injured spinal segment.

It is worth mentioning that many studies investigating kyphosis measurement techniques only focus on the thoracic and lumbar spine.[23-26] Moreover, those studies were performed in a single center or small group setting, which makes them subjective to bias and less representative for a worldwide perspective. We investigated the preferred measurement techniques for the entire spinal column, except for the occipitocervical junction (C0-C2). The anatomy and biomechanical properties of this spine region are substantially different compared to the other regions. Very specific and useful measurement techniques for this spine region have been described in the Radiographic Measurement Manual of the Spine Trauma Study Group.[22]

Concerning vertebral body height loss, the VBCR method was most frequently used by the surveyed experts. This is a useful method to assess the structural integrity of the fractured vertebral body, specifically, that of the anterior and middle columns of the injured

vertebra. Interestingly, based on the results of a systematic literature review, the Spine Trauma Study Group recommended to routinely use the AVBC% method to assess VBHL.[26] We think that additional reliability studies are needed to substantiate such recommendations.

We do recognize several limitations of this study. First, the survey was incorporated in two other planned surveys and therefore sent on two separate occasions. This may have led to some bias when comparing the results from the two occasions. Second, the surveys were sent to a selected pool of spine surgeons. However, we believe we were able to reach a representative international sample of highly experienced spine trauma experts.

In conclusion, this study identified worldwide variations in measurement techniques preferred by treating spine surgeons to assess fracture kyphosis and vertebral body height loss in spine trauma patients. These results confirm our hypothesis that a standardized technique is currently not employed. For clinical purposes, and to provide meaningful comparisons among study reports, it is recommended to use validated tools and standardized assessment parameters. The AOSpine Knowledge Forum Trauma endorses the use of universal methods and techniques, and initiated projects to develop classification systems for spine injuries, as well as disease-specific outcome instruments for spine trauma patients.[27] The results obtained from the current study establish the importance of standardization of assessment parameters in spine trauma care, and can be taken into account to further investigate these radiographic parameters in the process toward a universal language.

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# PART III

# Chapter 11

## Summary, General Discussion and Future Perspectives

During the last two decades there has been substantial improvement in our understanding of the basic patterns of prevalent spine fractures. This led to more reliable classification and injury severity assessment systems as well as rapid developments in surgical techniques.[1-6] Despite these advancements many issues remain unresolved concerning the optimal management of spine trauma. It also became clear that there is a need for outcome instrument(s) specifically designed for spine trauma. Such instruments would make it possible to compare outcomes of spine injuries between and within studies in a valid and reliable fashion, contributing to the advancement of spine trauma care and research. At the start of our study, no outcome measure was specifically designed or validated for spinal column injury patients with only mild, transient or no neurological impairment, and that can be used for the total spectrum of neurological involvement. Similarly, no clinician-reported measure was available for spine trauma patients. This Thesis adopts the aforementioned challenges, and describes the development of such instruments, which have the potential to be applied in a worldwide setting. Two outcomes measurement instruments were developed: one from the patient's perspective (AOSpine PROST [Patient Reported Outcome Spine Trauma]), and another from the perspective of the treating surgeons (AOSpine CROST [Clinician Reported Outcome Spine Trauma]).

## DEVELOPMENT OF AOSPINE PROST

### Framework AOSpine PROST



A solid base is required for the development of a disease-specific tool to measure outcomes. Therefore, we decided to use the solid framework of the ICF classification system as the basis for development of the AOSpine PROST. This framework is described in the Introduction of this Thesis. Various ICF based instruments exist such as the ASAS Health Index, WHODAS-II, and IMPACT-S.[7-9] Moreover, ICF Core Sets have been defined for several neurological and musculoskeletal diseases, including severe spinal cord injured patients.[10-16] The ICF has also been used for the examination and comparison of outcome measures in many patient populations, e.g. stroke, stroke rehabilitation, vocational rehabilitation, traumatic brain injury, lower limb amputation, Crohn's disease, and inflammatory bowel-disease.[17-23]

In the developmental process of the AOSpine PROST, the ICF Core Set development methodology was used. The aim was to define a set of ICF categories as core categories for patient reported outcome measurement in spine trauma. In line with the Core Set development methodology, various studies were conducted in the preparatory phase to identify the most relevant ICF categories from three different perspectives: research, experts, and patients.

The developmental and initial validation phase of the AOSpine PROST described in this Thesis focused on patients sustaining injuries to their spinal column and excluded completely paralyzed (American Spinal Injury Association impairment grade A or B) and

polytrauma patients (Injury Severity Score >15). This is considered as a thoughtful decision in order to identify specific problems related to spine trauma, while minimizing the overwhelming influence of paralysis.

**Preparatory PROST studies**

Our systematic literature review described in Chapter 2 revealed great diversity in the use and content of outcome measures in traumatic spinal column injury, with the identification of 17 different patient-reported and clinician-reported outcome measures linked to 57 unique ICF categories. All ICF components were represented, with the primary focus on pain and neurological status. Many studies report on these factors as strong determinant or as an outcomes measure in spine trauma.[24-31] One generic and seven spine-specific measures were identified, including five developed for the thoracic and lumbar spine and two measuring neck-specific disability.[32-38] Furthermore, six single-parameters outcomes and three clinician-based instruments were found. The evidence on the psychometric properties of the identified measures was very limited and only available for a few instruments.

The experts' perspective was identified through an international cross-sectional online survey among 150 health care professionals experienced in the clinical care of adult spine trauma patients (Chapter 3). With the representation of all world regions, the global perspective and the generalizability of the findings are supported. Out of 143 included ICF categories, 13 were deemed most relevant to measure outcomes after spine trauma. The ICF component *environmental factors (e)* was not represented while the majority of the categories related to *activities and participation (d),* followed by *body functions (b),* and *body structures (s)*. Thus, many facets are considered as relevant by the experts when it comes to loss of function and restrictions in daily activities after spine trauma.

Surely, besides the research and expert perspectives, it is imperative to include the patients' perspective in the developmental process of a PROM. In Chapter 4, our findings from an empirical study including traumatic spinal column injury patients from different countries across the world is described. Out of 128 ICF categories of the general ICF Checklist, 38 were most relevant and reflected the most commonly experienced problems in function and health. Categories from all 4 ICF components were found to be relevant for this patient population, with the majority being related to *activities and participation (d)*. A wide range of chapters were covered from this component, indicating the large variety of functional problems that may be experienced by these patients.[39-41] Compared to the research and expert perspectives, *Sensation of pain (b280)* was much less prominent from the patients' perspective (76.4% and 86.0% versus 26.7%). The identified categories most relevant for the patients related to loss of function and limitations in activities of daily living (ADL).

While the preparatory studies described in Chapters 2-4 focus on the identification of the most relevant ICF categories for measuring outcome of traumatic spinal column injury patients from different perspectives, a fourth study was performed to investigate how to measure function and health in these patients in terms of question and response

format (Chapter 5). It is one of the few studies comparing various formats and taking the patients' preference for a questionnaire format into account. The focus was specifically on the comparison of the individuals' current level of function and health with their pre-injury state, taking into assumption that spine trauma is an acute often life-threatening event leading to a loss of function. A clear preference was shown for one specific question format, while slightly more patients preferred a numerical response format: Numeric Rating Scale 0-10 (NRS-11) or Numeric Rating Scale 0-100 (NRS-101). All response formats had good psychometric properties and were capable of discriminating between the different degrees of recovery. Interestingly, although the VAS is simple and extensively used in many constructs, we found it to be least endorsed as response format.[42-50]

**Valuable findings for consensus process**

Various relevant findings were obtained for the development of the AOSpine PROST. In general, many of the selected ICF categories related to the chapter *mobility (d4)* from the component *activities and participation (d).* Another important finding was obtained from the systematic review. It seemed that the majority of the identified disease-specific outcome instruments used in spine trauma research, which are designed for non-traumatic patient populations, focus on one specific anatomical spine region, i.e. neck-specific disability or low back disability. Concerning the AOSpine PROST, it was deemed important that the tool should be able to measure function and disability of the entire spinal column in traumatic conditions. Finally, several findings from the fourth preparatory study focusing on the question and response formats were valuable for the selection of the appropriate response scale for AOSpine PROST. In our sample of Dutch patients, a numerical rating scale was slightly more preferred, but no statistical significance was reached for either numerical or verbal response formats. Nevertheless, because literacy can be an issue in developing countries, a numerical scale is expected to be most suitable for a universal instrument. Also, because both the numerical and verbal response formats showed good psychometric properties, the selection of the response format in the AOSpine PROST was thought to be dependent on ease of use in the international setting.

All these findings from the preparatory studies were discussed in an international consensus conference, which was attended by a group of recognized content experts. This consensus process is described in Chapter 6. A selection of 25 ICF categories were formally adopted as core categories for patient reported outcome measurement in traumatic spinal column injury patients. The selected response scale was decided on the NRS-101. These results formed the basis for the development of the AOSpine PROST, while the adopted 25 core categories could also serve as a benchmark when assessing the content validity of existing and future outcome instruments used in spine trauma. Other authors have sought to provide a list of ICF categories that could be used when evaluating outcome measures in spine trauma, but this differs substantially from our list of core categories.[51] The major differences are their suggestion of a mere 14 ICF categories, as well as a lack of indicating

detailed domains by only including first-level categories. Also, the ICF categories proposed by other authors were mainly selected based on their opinions and literature discussing the implantation of the ICF to spine trauma. In contrast, we suggest our results from the consensus process have a formal and solid base from different studies, justifying its use as a benchmark.

The core ICF categories reflect a wide array of functional impairments. In line with the findings from the preparatory studies, most categories related to the component *activities and participation (d),* more specifically to the chapter *mobility (d4)*. No categories were selected from the component *body structures (s)*. Those categories are considered to be more relevant for the AOSpine CROST, which consists of radiological and clinical parameters. Several categories were included that are also deemed relevant for patients sustaining neurological symptoms, e.g. *Defecation functions (b525), Urination functions (b620),* and *Sexual functions (b640)*.

**From core ICF categories to AOSpine PROST**

The AOSpine PROST was developed by the transition of somewhat abstract core ICF categories into 19 items, and incorporating them in the selected response scale in which patients compare their current level of function with their pre-injury state on a 0-100 Numeric Rating Scale (Chapter 7). This consisted of a multiphase process by clustering ICF categories to specific items, developing a Dutch draft version, and translating it into English in a step-by-step process. The transition process of 25 core ICF categories into 19 items was as follows (described in detail in Chapter 7): fifteen categories were transformed into one specific item each, three items were formed by clustering two categories, and one item by clustering three categories while *Products or substances for personal consumption (e110)* could not be incorporated as an item. The items cover a wide range of domains, including and beyond the scope of activities of daily living. With the incorporation into the specific response scale, the AOSpine PROST is considered valuable compared to outcome measures that solely focus on the level of dependence in patients' daily activities.[52,53] The worst score for an item is indicated with 0, while 100 represents the best score. The total score is assessed by the sum of all scores divided by the number of completed items. Once the details were set, such as adding smileys to the ends of the response format to visualize the scale and adding examples per item, the Dutch version was pilot tested among a representative sample of 25 spine trauma patients from a level-1 trauma center in the Netherlands. The 'think aloud' and 'probing' methods were used, which have proven to be very good and valid methodologies for developing and refining outcomes measurement instrument.[54-57] Satisfactory results were obtained for comprehensibility, relevance, acceptability, feasibility, and completeness. The internal consistency was excellent with a Cronbach's $\alpha$ of 0.926.

The findings obtained from the pilot study were of great value for refining the AOSpine PROST. Several final minor changes were applied after it was shown that patients experienced some difficulties with a few items. Now it was time to cross-culturally adapt and translate the tool into the English language using established guidelines according to

Beaton et al.[58] Ultimately, a definitive version to be further validated in an international multicenter study was developed (see Appendices).

## DEVELOPMENT AOSPINE CROST

### Framework AOSpine CROST

The second section of this Thesis focused on the development of the AOSpine CROST. This clinician-reported outcome measurement concept is a very new concept in spine trauma care: a simple and reliable tool that formalizes the most relevant clinical and radiological parameters to reflect the clinician's perspective adequately, and predicts clinical outcomes of spine trauma patients.

The first step in the developmental process consisted of the identification of the most relevant clinical and radiological parameters to evaluate and predict clinical and functional outcomes of spine trauma patients on both the short and long term post-trauma. In this respect, two web-based surveys were conducted to explore the perspectives of a highly generalizable cohort of worldwide experts: one focusing on the identification of relevant parameters for the subaxial cervical spine, and another for the thoracic and lumbar spine.

The surveyed parameters were based on parameters identified in a systematic literature review, parameters used by the AOSpine Subaxial Cervical and Thoracolumbar Spine Injury Classification Systems, as well as expert interviews among spine surgeons from a level-1 trauma center.[5,6] Moreover, the results obtained from the first study focusing on thoracic and lumbar spine parameters contributed to a more extensive list of surveyed parameters in the second study focusing on the subaxial cervical spine. This was seen as a valid methodology and a solid base for the development of the AOSpine CROST. Furthermore, our intention was to have a tool that can be applied in a worldwide setting. The fact that more than 100 experts from more than 40 countries from all world regions participated in both preparatory surveys contributed to the multinational and multicultural perspective in the identification of the most relevant clinical and radiological parameters for outcomes measurement. Also, only minor differences in responses were observed between the world regions, especially for those parameters that were identified as most relevant.

In order to identify the most relevant parameters for the clinical and functional outcomes of the defined group of spine trauma patients, we provided the participants with cases that were very similar to what would be seen in a clinical setting. To put more emphasis on this point, also plain radiographs and/or CT images were provided along with the complete case descriptions. In line with the anatomical and functional differences and treatment practices of different spine regions, the thoracic and lumbar spine was divided into thoracic spine (T1–T10), thoracolumbar junction (T11–L2), and lumbar spine (L3–L5). Also, a distinction was made between the short-term and long-term outcomes.

**Preparatory CROST studies**

Out of the 21 surveyed parameters, 10 were found to be relevant for the subaxial cervical spine trauma patients (Chapter 8), while 5 out of the 16 surveyed parameters were identified for thoracic and lumbar spine trauma patients (Chapter 9). When looking into detail, comparable findings were found for both studies. *Neurological status* seemed to be most relevant. Throughout this Thesis, the importance of neurological status is extensively discussed. Besides that neurological status can have a significant impact on patients' quality of life with restrictions in daily activities, health, and well-being, it also plays a key role in decision making in the clinical setting.[59-61] Furthermore, various radiographic findings were found to be relevant for all spine regions and time periods. These parameters could be related to occult instability of the affected spine level which may lead to gradual deformities.[62,63] It is well known that such factors can influence patients' outcomes and ultimately may lead to conversion of treatment. In this respect, some other identified parameters could be linked to *bony fusion* and *sagittal alignment (kyphosis),* i.e. facets that are assessed to evaluate treatment outcomes. Also *bone quality* was a relevant parameter which may be very important when choosing and evaluating treatment options, e.g. the type of surgical treatment for traumatic fracture in an osteoporotic patient while taking into consideration the potential risk of implant failure.[64]

In the process toward the development of the AOSpine CROST, another challenge was the nomenclature of the parameters, especially the radiological parameters. In this concern, radiographic measurements as sagittal alignment (kyphosis) and vertebral body height loss (VBHL) are crucial and can be used by the treating surgeons as a guide to decide on treatment strategy.[65-67] Although a kyphotic angle of 15º-30º or VBHL >50% in the thoracolumbar spine are reported as being associated with instability, until today no consensus is reached on the specific degrees of kyphosis or VBHL that is related to instability.[68-71] Different measurement techniques have been indicated in the literature to assess these radiographic modalities. Our hypothesis that different measurement techniques are used by spine surgeons around the world to assess kyphosis and VBHL was established by our findings in Chapter 10. Five different techniques for measuring kyphosis and two methods for VBHL were investigated, and we identified worldwide variations. In contrast to the few other studies that investigated measurement techniques, our study focused on the entire spinal column (except for occipitocervical junction) and included a large sample of participants, contributing to a worldwide perspective and valuable findings for the development of the AOSpine CROST.[72-75]

**From parameters to AOSpine CROST**

In the next phase, formalizing the identified parameters into a simple and quick to administer tool for the treating surgeons resulted in a draft version of the AOSpine CROST. After pilot testing and multiple evaluations during expert committee meetings, a final version was developed consisting of 10 parameters (see Appendices). Eight parameters apply to both

surgically and conservatively treated patients, while two parameters (i.e., 'Wound healing' and 'Implants') should be rated for surgically treated patients only. It was decided to include the parameter 'Functional recovery', while not being surveyed in the preparatory studies. This is seen as a valuable contribution to the tool, as a direct connection is settled to the AOSpine PROST which measures the function and health status reported by the patients. Furthermore, based on our findings from Chapter 10, the included radiographic parameters (such as 'Radiographic sagittal alignment') were not further clarified in terms of a specific measurement technique or value. A question was added to each parameter with the intention to make the tool more easy for use as well as to have the same interpretability. Also, for each parameter a distinction is made between the short-term outcomes (defined as 'in the next 12 months') and long -term outcomes ('from 12 months onwards'). This reflects the daily clinical practice, as the treating surgeons evaluate the provided treatment by assessing any expected issues both on the short-term and long-term.

## FINAL REMARKS AND FUTURE PERSPECTIVES

In summary, this thesis outlines the development of disease-specific outcome instruments for spine trauma patients, i.e. the AOSpine PROST and AOSpine CROST, based on a solid methodology and various preparatory studies.

Outcome measurement is imperative in health care, both in clinical practices as well as research. In this Thesis, we showed that several measures are available and have been validated for spine trauma patients, however, these tend to focus on the impact of severe neurological deficit or complete paralysis only. No outcome measurement tool is specifically designed and validated for patients with spinal column injury dealing with only mild or no neurological impairment. We also showed that several challenges arise when an outcome instrument for this specific patient population is used or developed. In this respect, an additional valuable contribution of the AOSpine PROST is the comparison of patients' current level of function and health with their pre-injury state. Moreover, with the AOSpine CROST we introduced a new concept of clinician reported outcome measurement in spine trauma.

Currently, both the Dutch and English versions of the AOSpine PROST are being validated in an international multicenter study. The aim of this study is to investigate the validity, reliability and responsiveness of the tool among a total of 300 patients from the Netherlands, USA and Canada. Once this validation study is completed, the tool will be available for use in studies including spine trauma patients. Also, the applicability of the AOSpine PROST for use in severe spinal cord injured and polytrauma patients will be investigated. These specific patient populations were excluded in the current phase of the developmental process. Various methodologies will be evaluated to extend the tool to SCI patients, such as pilot testing the current version of the AOSpine PROST among SCI patients,

or combining our formalized core ICF categories with the ICF Core Sets that have been developed for patients with severe spinal cord injury in the early post-acute and long-term context.[12,15] Simultaneous with these evaluations, the aim is to cross-culturally translate and adapt AOSpine PROST into many languages. Currently, initiatives are being taken to develop guidelines for this translational process in order to have the same solid base as described in this Thesis. Finally, future studies will reveal if item reduction is required, or whether subscales are more suitable in the application of the tool (e.g. physical function and mental function).

Concerning the AOSpine CROST, its content validity has been tested in expert meetings including a panel of internationally renowned experts on spine trauma. Currently, an international reliability analysis among the steering committee members and associates of the AOSpine Knowledge Forums Trauma and Spinal Cord Injury is ongoing. No changes are expected to the current version of the AOSpine CROST. Once the reliability of the tool is set, further prospective validation studies will be performed to investigate its construct validity and responsiveness. The results of these studies will show if the scoring methodology of the tool should be adjusted in order to make it more and more useful to the spine surgeons for the purposes of guiding patient care. One of the possibilities that are taken into consideration concerns the weighting of the parameters. For example, deterioration of 'Neurological status' might provide a higher (or worse) score compared to a negatively affected outcome by the 'General psychological condition'.

With the development of the AOSpine PROST and AOSpine CROST, and once the validation studies are completed, there is a significant potential to eventually contribute to the standardization of outcome measures in spine trauma. Treating surgeons around the world are encouraged to use these tools in daily clinical practice and for research purposes to create and contribute to evidence-based and patient-centered care. Moreover, the defined 25 core ICF categories could serve as a benchmark when assessing the content validity of outcome instruments used in spine trauma. Using the same outcome measures that are specifically developed and validated for traumatic spine injuries will allow us to compare the outcomes of various treatments in a valid and reproducible fashion to reduce the ongoing controversies and provide the best treatments for our patients.

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# Chapter 12

## Summary in Dutch (Nederlandse samenvatting)

## INTRODUCTIE

Traumatische letsels van de wervelkolom komen frequent voor en hebben, in vergelijking met letsels van de extremiteiten, voor patiënten grotere gevolgen op sociaal, functioneel en financieel gebied. Een deel van deze patiënten heeft tevens te maken met neurologische uitval door beschadiging van het ruggenmerg met ernstige en soms blijvende gevolgen.

De laatste twee decennia is de medische kennis van traumatische wervelkolomletsels toegenomen. Dit heeft geleid tot verschillende classificatiesystemen om de ernst van letsels in te delen en tot belangrijke ontwikkelingen in (chirurgische) behandeltechnieken. Ondanks deze vorderingen bestaan er verschillende opvattingen over de optimale behandeling van patiënten met traumatische wervelkolomletsels, met of zonder neurologische uitval. Dat deze verschillende opvattingen naast elkaar kunnen bestaan heeft mede te maken met het ontbreken van goede meetinstrumenten om de uitkomsten van behandeling bij deze patiëntenpopulatie te meten en vast te leggen.

Er zijn namelijk nog geen instrumenten beschikbaar om de gevolgen van werveltrauma's en de behandeling daarvan in kaart te brengen, die specifiek ontwikkeld zijn voor patiënten met traumatische wervelkolomletsels met milde, voorbijgaande of geen neurologische uitval. Dit geldt zowel voor een meetinstrument vanuit het perspectief van de patiënten (PROM; Patient Reported Outcome Measure), als vanuit het perspectief van clinici (Clinician Reported Outcome Measure). Dergelijke meetinstrumenten zijn cruciaal om de verschillende beschikbare behandelingen op een valide en betrouwbare wijze te vergelijken in wetenschappelijk onderzoek en de klinische praktijk, en daarmee bij te dragen aan het optimaliseren van de geleverde zorg.

Het doel van dit proefschrift is het beschrijven van de ontwikkeling van ziekte-specifieke uitkomstinstrumenten voor patiënten met traumatische wervelkolomletsels. Vanwege de mogelijke discrepanties tussen de uitkomsten gemeten vanuit het patiëntenperspectief in vergelijking met de klinische en radiologische beoordelingen door clinici, zijn er twee aparte instrumenten ontwikkeld: de AOSpine PROST (Patient Reported Outcome Spine Trauma) en de AOSpine CROST (Clinician Reported Outcome Spine Trauma). De ervaringen van patiënten bij een behandeling kunnen namelijk significant verschillen ten opzichte van de interpretatie van klinische en radiologische uitkomsten door behandelaars.



## ONTWIKKELING AOSPINE PROST

In het eerste deel van dit proefschrift (Hoofdstuk 3-7) wordt de ontwikkeling van de AOSpine PROST beschreven. Als solide basis voor de ontwikkeling ervan werd het veelomvattende classificatiesysteem International Classification of Functioning, Disability, and Health (ICF) van de Wereldgezondsorganisatie (WHO) gebruikt, meer specifiek de methodologie van het ontwikkelen van ICF Core Sets. Deze methodologie is gebruikt om een set ICF categorieën

als kerncategorieën te definiëren voor het meten van de gevolgen van een bepaalde aandoening vanuit het perspectief van de patiënt. Bij de ontwikkeling en eerste validatie van de AOSpine PROST zoals beschreven in dit proefschrift was het focus op de volgende specifieke patiëntengroep: volwassen patiënten met traumatische wervelkolomletsels, met de exclusie van patiënten met complete paralyse (American Spinal Injury Association impairment graad A of B) en polytrauma (Injury Severity Score >15). Conform de Core Set ontwikkeling methodologie werden er in de voorbereidende fase verschillende studies uitgevoerd om relevante ICF categorieën vanuit drie verschillende perspectieven te identificeren: wetenschap, experts en patiënten.

In Hoofdstuk 2 wordt het wetenschapsperspectief beschreven aan de hand van een systematische review van de beschikbare literatuur. In het onderzoek werden 17 onderling sterk verschillende meetinstrumenten gebruikt om de uitkomsten te meten bij patiënten met traumatische wervelkolomletsels. De inhoud van deze instrumenten werden gelinkt aan 57 unieke ICF categorieën uit alle componenten van de ICF, met de primaire focus op pijn en neurologische status.

Het perspectief van de experts is onderzocht met een online vragenlijst die door 150 experts vanuit de hele wereld is ingevuld (Hoofdstuk 3). Van de 143 gepresenteerde ICF categorieën werden er 13 als de meest relevante om de uitkomsten van traumatische wervelkolomletsels te meten aangemerkt. Deze categorieën reflecteren verschillende aspecten van functieverlies en beperkingen in het dagelijkse leven in vooral de component activities and participation (d), gevold door body functions (b), en body structures (s). Er werden geen relevante categorieën van de component environmental factors (e) geselecteerd.

In Hoofdstuk 4 worden de resultaten van een internationale empirische studie naar het perspectief van de patiënten beschreven. Van de 128 gepresenteerde categorieën uit de ICF Checklist bleken er 38 het meest relevant. In vergelijking met het wetenschaps- en experts perspectief werd pijn door patiënten minder vaak als relevant ervaren (respectievelijk 76,4%, 86,0% en 26,7%). De meest relevante categorieën hadden te maken met functieverlies en beperkingen in activiteiten van het dagelijks leven (ADL).

Daarnaast werd in de voorbereidende fase nog een vierde studie uitgevoerd om diverse vraag- en antwoordvormen voor het toekomstige uitkomstinstrument (Hoofdstuk 5) met elkaar te vergelijken. De focus hierbij lag met name op het niveau van functioneren, meer specifiek de vergelijking van het huidige niveau van functioneren ten opzichte van vóór het ongeval die het wervelkolomletsel veroorzaakte. Eén specifieke vraagvorm had de meeste voorkeur van patiënten en als antwoordvorm was er voorkeur voor een numerieke vorm. Alle onderzochte schalen toonden goede psychometrische eigenschappen en konden goed differentiëren tussen de verschillende niveaus van herstel.

De bevindingen uit deze voorbereidende studies werden bediscussieerd gedurende een internationale consensus meeting in 2015, bestaande uit een groep vooraanstaande experts op het gebied van wervelkolomtrauma. Het consensus proces

beschreven in Hoofdstuk 6 heeft geleid tot de selectie van een set van 25 ICF categorieën als kerncategorieën voor het meten van patiënt-gerapporteerde uitkomsten bij traumatische wervelkolomletsels. Als antwoordschaal werd de Numeric Rating Scale 0-100 (NRS-101) geselecteerd. Deze bevindingen vormden de basis voor de ontwikkeling van de AOSpine PROST. De set van 25 ICF kerncategorieën kan tevens als maatstaf (benchmark) gebruikt worden om de inhoudsvaliditeit te bepalen van bestaande en toekomstige instrumenten bij patiënten met wervelkolomletsels.

In de volgende fase werd de AOSpine PROST ontwikkeld (Hoofdstuk 7). Het proces van de ontwikkeling bestond uit diverse stappen: clusteren en concretiseren van de wat abstracte ICF categorieën in specifieke items, ontwikkeling van een Nederlandse conceptversie en vertaling hiervan naar een Engelse versie. De items van de AOSpine PROST beslaan uiteenlopende domeinen in het kader van dagelijkse functioneren. Het incorporeren van de items in de geselecteerde antwoordschaal waarbij patiënten wordt gevraagd hun niveau van functioneren te vergelijken met dat van voor het werveltrauma maakt de AOSpine PROST waardevol ten opzichte van andere gebruikte uitkomstinstrumenten die alleen op het niveau van afhankelijkheid van de patiënt focussen. De score van een item varieert van 0 tot en met 100, waarbij 0 de slechtste score weergeeft en 100 de best mogelijke score. De totale score wordt berekend door de som van de score van alle items te delen door het aantal ingevulde items. Nadat de details waren afgewerkt (zoals het toevoegen van smileys en het toevoegen van voorbeelden bij een item), werd de Nederlandse conceptversie onderworpen aan een pilot test onder 25 patiënten met traumatische wervelkolomletsels uit een level-1 traumacentrum uit Nederland. Deze studie toonde zeer gunstige resultaten voor uiteenlopende betrouwbaarheidstesten en een interne consistentie van Cronbach's α van 0,926. Enkele laatste minimale wijzigingen werden toegepast waarna het instrument volgens gestandaardiseerde internationale richtlijnen in het Engels werd vertaald. Het uiteindelijke resultaat is een definitieve versie die verder gevalideerd gaat worden in een internationale multicenter studie (zie Appendix).



## ONTWIKKELING AOSPINE CROST

In het tweede deel van dit proefschrift (Hoofdstuk 8-10) wordt de ontwikkeling van de AOSpine CROST beschreven. Het concept van uitkomsten meten vanuit het perspectief van- en gerapporteerd door clinici is nieuw in de zorg voor patiënten met wervelkolomletsels, namelijk: het hebben van een simpel en betrouwbaar instrument om de voor clinici meest relevante klinische en radiologische parameters vast te leggen en daarmee het perspectief van de clinici adequaat te reflecteren. Tevens om het voorspellen van klinische uitkomsten op langere termijn van deze patiënten mogelijk te maken.

Als basis voor de onderzochte parameters diende een systematische literatuur review; de parameters gebruikt in de bestaande AOSpine Subaxial Cervical en Thoracolumbar

Spine Injury Classification systemen; en een aantal surveys met experts. Meer dan 100 experts uit meer dan 40 landen uit diverse werelddelen hebben deelgenomen aan de voorbereidende surveys. Dit gaf een multinationaal en multicultureel perspectief bij het identificeren van de meest relevante klinische en radiologische parameters voor het meten van uitkomsten. Er werden weinig verschillen in de reacties tussen de verschillende werelddelen gevonden, met name voor de parameters die als meest relevant werden geïdentificeerd. Van de 21 gepresenteerde parameters bleken er 10 relevant te zijn voor patiënten met traumatische subaxiale cervicale wervelkolomletsels (Hoofdstuk 8), terwijl in de tweede voorbereidende studie 5 van de 16 gepresenteerde parameters relevant bleken te zijn voor patiënten met traumatische letsels aan de thoracale en lumbale wervelkolom (Hoofdstuk 9). De meest relevante parameter bleek het al dan niet hebben van ruggenmergletsel te zijn. Daarnaast waren er diverse radiologische parameters als relevant bevonden voor alle wervelkolomregio's en tijdsperioden (korte en lange termijn) na het ontstaan van het letsel. Deze parameters waren gerelateerd aan instabiliteit van het aangedane deel van de wervelkolom, en daarmee aan het mogelijk ontstaan van deformiteiten. In dit opzicht konden een aantal andere geïdentificeerde parameters gelinkt worden aan fusie en sagittale uitlijning (kyfose). Ook botkwaliteit was een relevante parameter die zeer belangrijk kan zijn bij de keuze en evaluatie van behandelopties, bijvoorbeeld de type chirurgische behandeling bij een patiënt met osteoporose in verband met het potentiële risico op het falen van de osteosynthese.

Een andere uitdaging in het ontwikkelingsproces van de AOSpine CROST was de aanduiding van de parameters in de uiteindelijke tool, met name de radiologische parameters. Radiologische metingen zoals het sagittale alignement (kyfose) en hoogteverlies van het wervellichaam (VBHL – vertebral body height loss) zijn belangrijk en kunnen door de behandelende chirurgen gebruikt worden als handvat voor de keuze van behandeling. Onze hypothese dat er verschillende meettechnieken door wervelkolom chirurgen wereldwijd wordt gebruikt om kyfose en VBHL te bepalen werd bevestigd door onze bevindingen in Hoofdstuk 10. Vijf verschillende meettechnieken voor het bepalen van kyfose en twee verschillende voor het bepalen van VBHL werden gevonden.

In de volgende fase resulteerde het formaliseren van de geïdentificeerde parameters naar een simpele en gebruiksvriendelijke tool voor de behandelende chirurgen, in een conceptversie van de AOSpine CROST. Na een pilot test en meerdere evaluaties gedurende expert meetings werd een definitieve versie ontwikkeld bestaande uit 10 parameters (zie Appendix). Acht parameters zijn van toepassing op zowel chirurgisch als conservatief behandelde patiënten, terwijl twee parameters ('Wound healing' en 'Implants') alleen van toepassing zijn op chirurgisch behandelde patiënten. De parameter 'Functional recovery' werd later geïncludeerd, ondanks dat deze niet was onderzocht in de voorbereidende studies. De parameter werd een waardevolle toevoeging bevonden, aangezien er zo een direct verband ontstond met de AOSpine PROST welke de functionele en gezondheidsstatus meet zoals gerapporteerd door patiënten. Verder werd er op basis van

de resultaten uit Hoofdstuk 10 besloten de radiologische parameters (zoals 'Radiographic sagittal alignment') niet nader te specificeren in de vorm van een specifieke meetmethode of referentiewaarde. Aan iedere parameter werd een vraag toegevoegd met de intentie de tool gebruiksvriendelijker en meer eenduidig interpreteerbaar te maken. Tevens werd er bij iedere parameter een onderscheid gemaakt tussen de korte termijn (gedefinieerd als binnen 12 maanden) en de lange termijn (12 maanden en langer). Dit reflecteert de dagelijkse klinische praktijk, aangezien de behandelende chirurgen de behandeling evalueren door het bepalen van verwachte problemen op zowel de korte als lange termijn.

## SLOTOPMERKINGEN

Het meten van uitkomsten is belangrijk in de gezondheidszorg, zowel in de dagelijkse klinische praktijk als in wetenschappelijk onderzoek. In dit proefschrift hebben wij de ontwikkeling en eerste validatie van de AOSpine PROST (Patient Reported Outcome Spine Trauma) beschreven. Tevens hebben wij aangetoond dat er diverse uitdagingen bestaan wanneer een instrument voor deze specifieke groep wordt gebruikt of ontwikkeld. In het kader hiervan is een extra toegevoegde waarde van de AOSpine PROST de vergelijking van het huidige niveau van functioneren ten opzichte van vóór het ongeval die het wervelkolomletsel veroorzaakte. Voorts hebben we met de ontwikkeling van de AOSpine CROST een nieuw concept van het meten van uitkomsten vanuit het perspectief van- en gerapporteerd door clinici geïntroduceerd.

Momenteel worden zowel de Nederlandse als de Engelse versie van de AOSpine PROST onderworpen aan validatie in een internationale multicenter studie. Het doel van de studie is het onderzoeken van de validiteit, betrouwbaarheid en responsiviteit van de tool onder 300 patiënten uit Nederland, Verenigde Staten en Canada. Na het afronden van deze studie zal de tool beschikbaar komen voor gebruik in studies met wervelkolom trauma patiënten. Verder zal de toepasbaarheid van de AOSpine PROST voor patiënten met ernstige neurologische uitval en polytrauma onderzocht worden. Deze specifieke patiënten populaties zijn geëxcludeerd in de huidige fase van het ontwikkelingsproces, zodat er problemen die specifiek gerelateerd zijn aan werveltrauma worden geïdentificeerd terwijl de overweldigende invloed van paralyse wordt geminimaliseerd. Simultaan met deze evaluaties is tevens het doel de AOSpine PROST cross-cultureel te vertalen en aan te passen naar vele talen.

Wat betreft de AOSpine CROST is de inhoudsvaliditeit getest gedurende meetings met experts op het gebied van wervelkolomtrauma en wordt er momenteel de internationale betrouwbaarheid onderzocht. Er worden geen veranderingen van de huidige AOSpine CROST versie meer verwacht. Nadat de betrouwbaarheid van de tool is bevestigd, zullen er prospectieve validatiestudies volgen om de construct validiteit en responsiviteit te onderzoeken.

Met de ontwikkeling van de AOSpine PROST en AOSpine CROST, en straks met het completeren van de validatie studies, hebben wij een significante bijdrage geleverd aan het standaardiseren van uitkomstinstrumenten bij wervelkolom trauma. Chirurgen over de gehele wereld kunnen deze instrumenten gebruiken in de dagelijkse klinische praktijk en in onderzoeksverband om zo bij te dragen aan evidence-based en patiënt-gecentreerde zorg.

# APPENDICES

# AOSpine PROST

# AOSpine PROST (Patient Reported Outcome Spine Trauma)

## Your function NOW compared to BEFORE the accident

*This questionnaire contains 19 questions about aspects of your life after the accident that caused your spine injury. Please read the questions and the description of the scale carefully. Please answer ALL questions and answer each question with one cross (" X ") on the scale. This should reflect how you function NOW compared to BEFORE the accident.*

*The scale ranges from 0 to 100. It is important to realize that 0 indicates a level at which you are NON-FUNCTIONAL. 100 indicates the level BEFORE the accident, no matter how well or poorly you functioned before the accident.*

*Below is an example.*

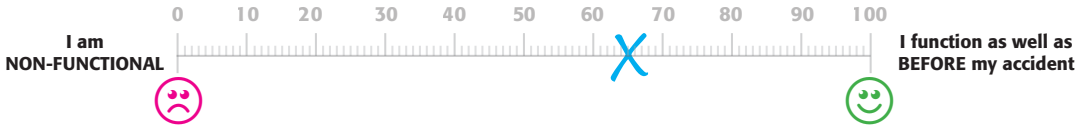
**Patient Name:** _____

**Date (MM/DD/YY):** _____ / _____ / _____

**Patient ID:** _____

(to be filled in by the health professional)

**0. Reading** **EXAMPLE**

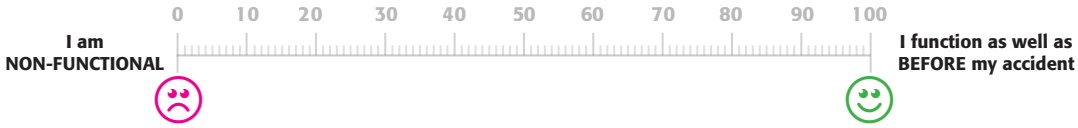



**To be completed by the PATIENT**

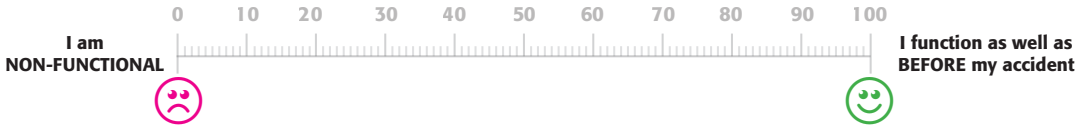
*The questionnaire begins here.*

In almost all questions, a number of situations or examples are shown in brackets.
Please base your answer on the situation or example where you are most disabled.

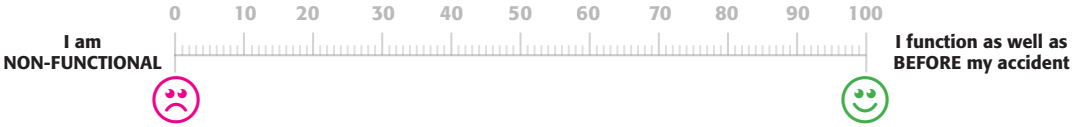
**1. Household activities (such as cleaning in and around the house, doing laundry or preparing a meal)**



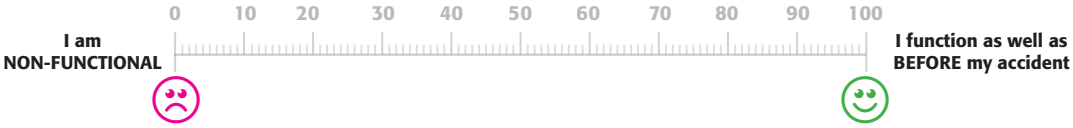

**2. Work/study (if you were not working or studying BEFORE the accident, please skip this question)**



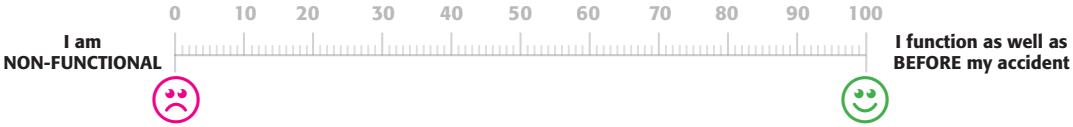
**3. Recreation and leisure (such as hobbies or sports)**



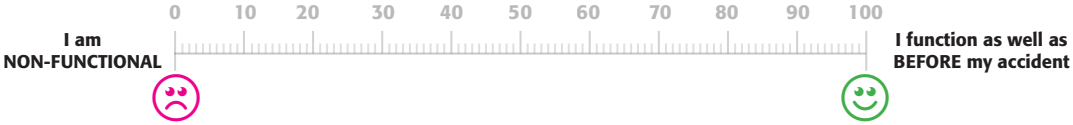

**4. Social life (such as maintaining relationships with family, friends and acquaintances)**



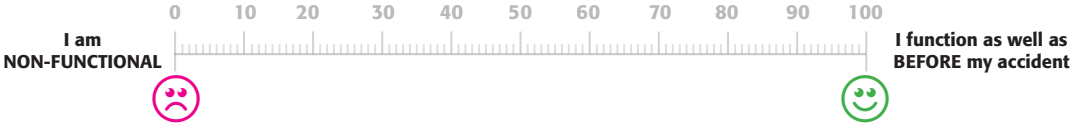

**5. Walking (with or without an aid)**



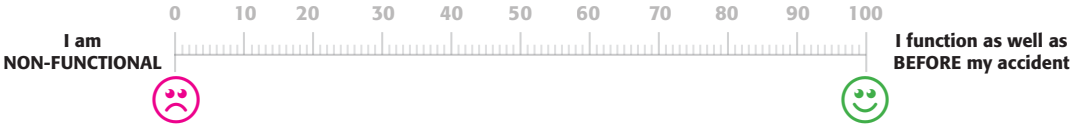

**6. Travel (such as driving yourself, using public transportation or other means of transport)**



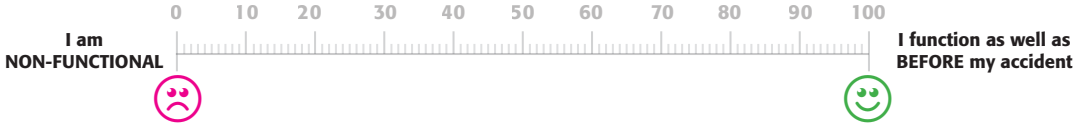

**7. Changing posture (such as lying down, sitting or standing)**



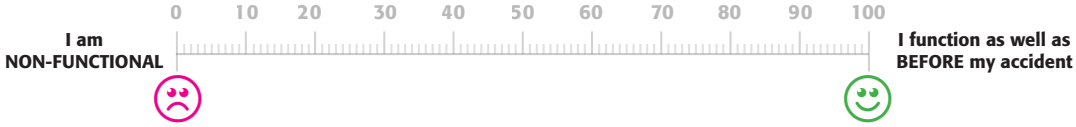

**8. Maintaining posture (such as lying down, sitting or standing, for as long as necessary)**



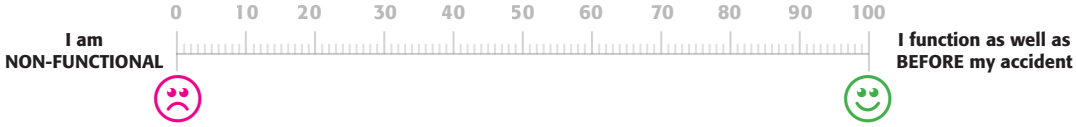
**9. Lifting and carrying (such as lifting a bag of groceries or carrying a child)**



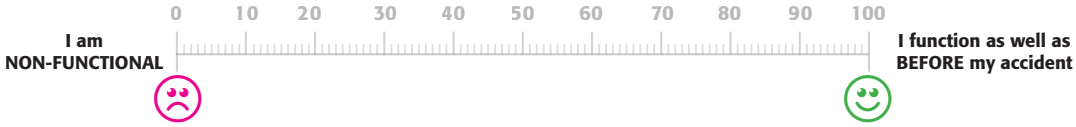

**10. Personal care (such as taking a bath or shower, using the toilet or dressing and undressing)**



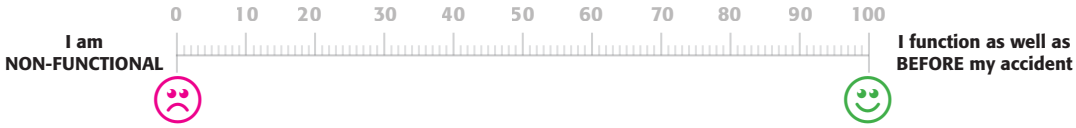

**11. Urinating (are you able to urinate; can you hold your urine)**



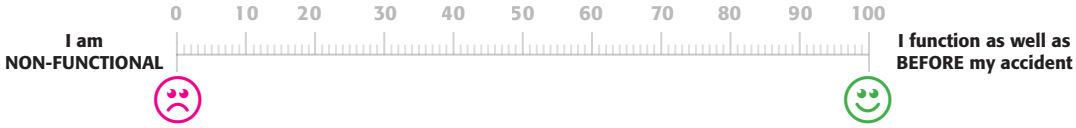

**12. Bowel movement (are you able to have a bowel movement; can you hold your bowel movement)**



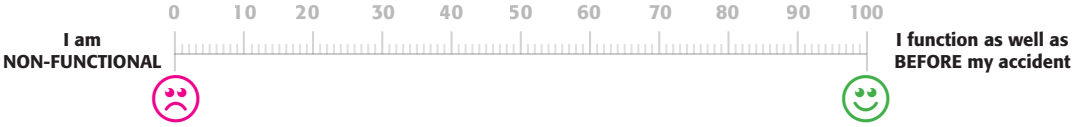

**13. Sexual function**



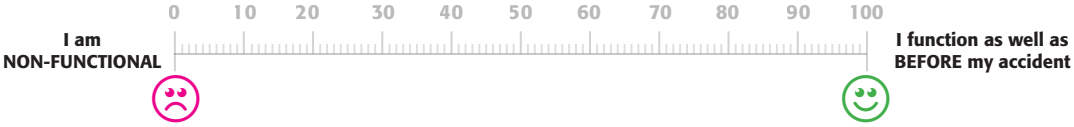

**14. Emotional function (such as gloomy, worried or anxious feelings)**



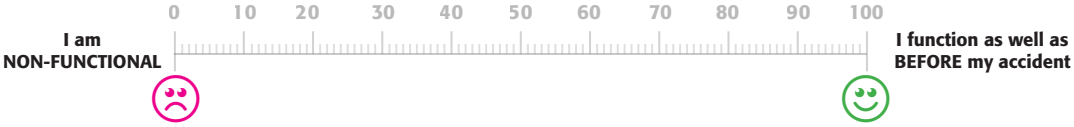
**15. Energy level (such as fatigue or listlessness)**



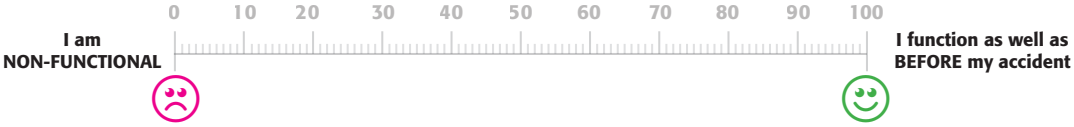

**16. Sleep (such as number of hours and quality)**



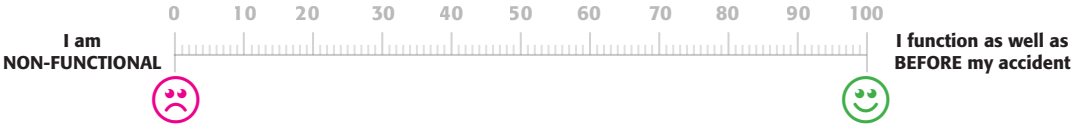

**17. Stiffness of your neck and/or back (in terms of disability in overall performance)**




**18. Loss of strength in your arms and/or legs (in terms of disability in overall performance)**




**19. Back and/or neck pain (in terms of disability in overall performance)**



# AOSpine CROST

# AOSpine CROST (Clinician Reported Outcome Spine Trauma)

*The AOSpine CROST is applied after the initial treatment, and allows you as the treating surgeon to evaluate and predict clinical outcomes of spine trauma patients.*

**To be completed by the CLINICIAN**

***Please rate the following parameters:***

| | | *In the next 12 months* | *From 12 months onwards* |
|---|---|---|---|
| **1. Neurological status** | Do you expect a neurological deterioration? | □ No □ Yes | □ No □ Yes |
| **2. Radiographic sagittal alignment** | Do you expect clinically relevant problems from sagittal alignment? | □ No □ Yes | □ No □ Yes |
| **3. General bone quality** | Do you expect adverse events related to the general bone quality? | □ No □ Yes | □ No □ Yes |
| **4. Stability of the injured spine level** | Do you expect adverse events related to mechanical instability of the injured spinal level(s)? | □ No □ Yes | □ No □ Yes |
| **5. Spinal column mobility** | Do you expect a functionally relevant impairment related to spinal column range of motion? | □ No □ Yes | □ No □ Yes |

| | | | |
|---|---|---|---|
| **6. General physical condition** | Do you expect the clinical outcome to be negatively affected by the general physical condition? | ☐ No ☐ Yes | ☐ No ☐ Yes |
| **7. General psychological condition** | Do you expect the clinical outcome to be negatively affected by the general psychological condition? | ☐ No ☐ Yes | ☐ No ☐ Yes |
| **8. Functional recovery** | Do you expect problems in functional recovery? | ☐ No ☐ Yes | ☐ No ☐ Yes |
| ***Please rate parameters 9 and 10 <u>only if the patient is treated surgically:</u>*** | | | |
| **9. Wound healing** | Do you expect problems with wound healing or persistent infection? | ☐ No ☐ Yes | ☐ No ☐ Yes |
| **10. Implants** | Do you expect any implant related adverse events? | ☐ No ☐ Yes | ☐ No ☐ Yes |
| **Do you anticipate a change in the current treatment plan?** | | | ☐ No ☐ Yes |

# List of publications

## LIST OF PUBLICATIONS

**This thesis**

Chapter 2: Oner FC, Jacobs WCH, Lehr AM, **Sadiqi S**, Post MW, Aarabi B, Chapman JR, Dvorak MF, Fehlings MG, Kandziora F, Rajasekaran S, Vaccaro AR. Towards the development of a universal outcome instrument for spine trauma – A systematic review and content comparison of outcome measures used in spine trauma research using the ICF as reference.
*Spine (Phila Pa 1976). 2016 Feb;41(4):358-67.*

Chapter 3: Oner FC, **Sadiqi S**, Lehr AM, Dvorak MF, Aarabi B, Chapman JR, Fehlings MG, Kandziora F, Rajasekaran S, Vaccaro AR. Towards the development of an outcome instrument for spinal trauma: an international survey of spinal surgeons.
*Spine (Phila Pa 1976). 2015 Jan 15;40(2):E91-6*

Chapter 4: Oner FC, **Sadiqi S**, Lehr AM, Aarabi B, Dunn, RN, Dvorak MF, Fehlings MG, Kandziora F, Post MW, Rajasekaran S, Vialle, LR, Vaccaro AR. Towards developing a specific outcome instrument for spine trauma - An empirical cross-sectional multicenter ICF-based study by AOSpine Knowledge Forum Trauma.
*Spine (Phila Pa 1976). 2015 Sep 1;40(17):1371-9*

Chapter 5: **Sadiqi S**, Lehr AM, Post MW, Vaccaro AR, Dvorak MF, Oner CF. Towards a specific outcome instrument for spinal trauma - How to measure function and health.
*Spine (Phila Pa 1976). 2015 May 15;40(10):E578-86*

Chapter 6: **Sadiqi S**, Lehr AM, Post MW, Jacobs WCH, Aarabi B, Chapman JR, Dunn, RN, Dvorak MF, Fehlings MG, Rajasekaran S, Vialle, LR, Vaccaro AR, Oner FC. The selection of core International Classification of Functioning, Disability and Health (ICF) categories for patient reported outcome measurement in spine trauma patients - results of an international consensus process.
*Spine J. 2016 Aug;16(8):962-70.*

Chapter 7: **Sadiqi S**, Lehr AM, Post MW, Dvorak MF, Kandziora F, Rajasekaran S, Schnake KJ, Vaccaro AR, Oner FC. Development of the AOSpine Patient Reported Outcome Spine Trauma (AOSpine PROST): a universal disease-specific outcome instrument for individuals with traumatic spinal column injury.
*Eur Spine J. 2017 May;26(5):1550-1557.*

Chapter 8: **Sadiqi S**, Verlaan JJ, Lehr AM, Dvorak MF, Kandziora F, Rajasekaran S, Schnake KJ, Vaccaro AR, Oner FC. Surgeon reported outcome measure for spine trauma - An international survey identifying parameters relevant to evaluate outcomes of subaxial cervical spine trauma patients.
*Spine (Phila Pa 1976). 2016 Dec 15;41(24):E1453-E1459.*

Chapter 9: **Sadiqi S**, Verlaan JJ, Lehr AM, Dvorak MF, Kandziora F, Rajasekaran S, Schnake KJ, Vaccaro AR, Oner FC. Universal disease-specific outcome instruments for spine trauma - A global perspective on relevant parameters to evaluate clinical and functional outcomes of thoracic and lumbar spine trauma patients.
*Eur Spine J. 2017 May;26(5):1541-1549.*

Chapter 10: **Sadiqi S**, Verlaan JJ, Lehr AM, Chapman JR, Dvorak MF, Kandziora F, Rajasekaran S, Schnake KJ, Vaccaro AR, Oner FC. Measurement of kyphosis and vertebral body height loss in traumatic spine fractures - an international study.
*Eur Spine J. 2017 May;26(5):1483-1491.*

**Other journal publications and submitted papers**

van Rein EAJ, **Sadiqi S**, Lansink KWW, Lichtveld RA, van Vliet R, Oner FC, Leenen LPH, van Heijl M. The role of emergency medical service providers in the decision-making process of prehospital trauma triage. *Submitted*

de Guerre LEVM, **Sadiqi S**, Leenen LPH, Oner FC, van Gaalen SM. Injuries related to bicycle accidents: an epidemiological study in the Netherlands. *Submitted*

Rajasekaran S, Kanna RM, Schnake KJ, Vaccaro AR, Schroeder GD, **Sadiqi S**, Oner FC. Osteoporotic thoracolumbar fractures-how are they different?-classification and treatment algorithm.
*J Orthop Trauma. 2017 Sep;31 Suppl 4:S49-S56 (Focus Issue Paper)*

Oner FC, **Sadiqi S**, Lehr AM, Schroeder GD, Vaccaro AR. The need of validated disease-specific outcome instruments for spine trauma.
*J Orthop Trauma. 2017 Sep;31 Suppl 4:S33-S37 (Focus Issue Paper)*

Oner FC, Rajasekaran S, Chapman JR, Fehlings MG, Vaccaro AR, Schroeder GD, **Sadiqi S**, Harrop J. Spine trauma - what are the current controversies?
*J Orthop Trauma. 2017 Sep;31 Suppl 4:S1-S6 (Focus Issue Paper)*

**Sadiqi S**, Oner FC, Kim JS, Baird EO. What is the best treatment for a thoracolumbar burst fracture in a neurologically intact patient in the absence of posterior ligamentous disruption: Surgical treatment.
*Clin Spine Surg. 2016 Nov;29(9):359-362 (Invited Paper)*

**Sadiqi S**, Lehr AM, Jacobs WCH, Post MW, Oner FC, AOSpine Knowledge Forum Spinal Cord Injury and Knowledge Forum Trauma. Reply to the Letter to the Editor regarding 'Towards the development of a universal outcome instrument for spine trauma - A systematic review and content comparison of outcome measures used in spine trauma research using the ICF as reference.''
*Spine (Phila Pa 1976). 2016 Mar;41(5):E302-3.*

**Sadiqi S**, Oner FC, Dvorak MF, Aarabi B, Schroeder GD, Vaccaro AR. The influence of spine surgeons' experience on the classification and intraobserver reliability of the novel AOSpine Thoracolumbar Spine Injury Classification System – an international study.
*Spine (Phila Pa 1976). 2015 Dec;40(23):E1250-6*

**Book chapter**
**Sadiqi S** and Oner FC. Outcome Measures in Spinal Trauma.
In: *Textbook of Spinal Surgery, 4th edition. Editors: KH Bridwell, MC Gupta. In press*

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# Curriculum Vitae

## CURRICULUM VITAE

Said Sadiqi was born on July 1st 1988 in Kabul, Afghanistan. He fled from war and came to the Netherlands at the end of the 1990s. After graduating high school (VWO, 't Hooghe Landt College, Amersfoort) in 2006, he studied biomedical sciences for one year. In 2007 he started medical school at the VU University Amsterdam. After obtaining his bachelor's degree in 2010, he co-founded a company which he owned until 2015. This company led him to the department of Orthopaedics of the University Medical Center Utrecht for his final research internship. After receiving his medical degree in April 2014, he started working as a full-time researcher at the same department on the development of disease-specific outcome instruments for spine trauma patients under supervision of prof. dr. F.C. Oner, prof. dr. M.W.M. Post and dr. J.J. Verlaan. The research projects were performed in close collaboration with the AOSpine Knowledge Forum Trauma, consisting of a panel of internationally renowned experts on spine trauma. This work resulted in several publications, presentations at national and international conferences, and this thesis.

In 2015, he won the Travel Grant for Eurospine. In 2016, he was awarded the Dutch Spine Society Annual Award for the best publication in the Netherlands. Furthermore, in the same year he was nominated for the Best Paper Award at the Eurospine as well as the Global Spine Congress.

In May 2016 he started working as a non-training resident at the departments of Orthopaedics and Neurosurgery of the OLVG hospital Amsterdam (supervisors: dr. R.W. Poolman and dr. G.J. Bouma). Since April 2017 he is working as a resident in training at the department of Surgery of the OLVG hospital Amsterdam (supervisors: dr. M.F. Gerhards and dr. B.C. Vrouenraets), as part of his training in Orthopaedic surgery. In October 2018 he will return to the University Medical Center Utrecht to continue his Orthopaedic residency.