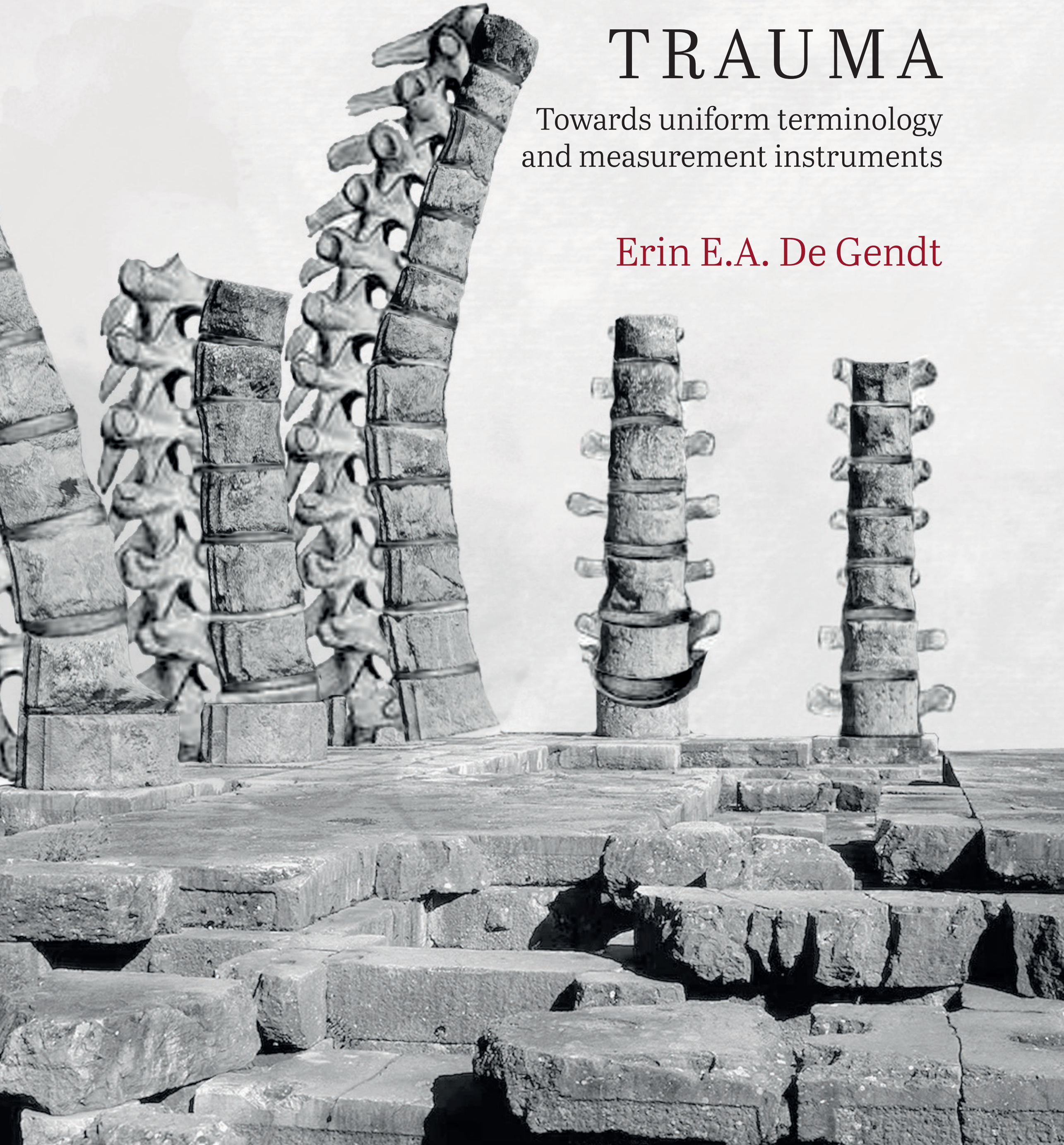
OUTCOME AFTER SPINE TRAUMA

Towards uniform terminology and measurement instruments

Erin E.A. De Gendt



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Erin Elisabeth Anna De Gendt

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Outcome After Spine Trauma:
Towards uniform terminology and measurement instruments

Uitkomsten na een wervelkolomtrauma:
Naar uniforme terminologie en meetinstrumenten

(met een samenvatting in het Nederlands)

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Erin Elisabeth Anna De Gendt
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Promotoren:

Prof. dr. F.C. Oner
Prof. dr. L.M. Benneker

Copromotor:

Dr. S.P.J. Muijs

Beoordelingscommissie:

Prof. dr. J. Hendrikse (voorzitter)
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Prof. dr. L.W. van Rhijn
Prof. dr. M.H.J. Verhofstad

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Chapter 1

General introduction and outline thesis

A trauma to the spinal column is a known injury in both low and high energy trauma in the current medical practice. A significant amount of patients who visit the emergency department in the Netherlands with a serious injury (Abbreviated Injury Scale ≥3) suffer from a trauma to the spinal column. (5-6% of total serious injuries in 2016-2020).[1] Historically, traumatic injuries to the spinal column have already been described by the Ancient Egyptian and Greek physicians. Hippocrates (460-370 BC), who studied medicine in the Asklepion of Kos, and wrote many medical books, described 'spinal deformities' in five of these books. [2] The five main reasons of spinal deformity, according to Hippocrates, were:

1) kyphosis as a result of a disease or a trauma,
2) scoliosis,
3) concussion (probably meaning a burst fracture),
4) dislocations of the vertebrae and,
5) fractures of the spinous processes.

In his books he described treatments that have been adapted throughout the following centuries. For example, figures 1 and 2 show different treatments suggested by Hippocrates. Through the application of traction and local external compression, he envisioned that the deformity of the spinal column could be reduced.

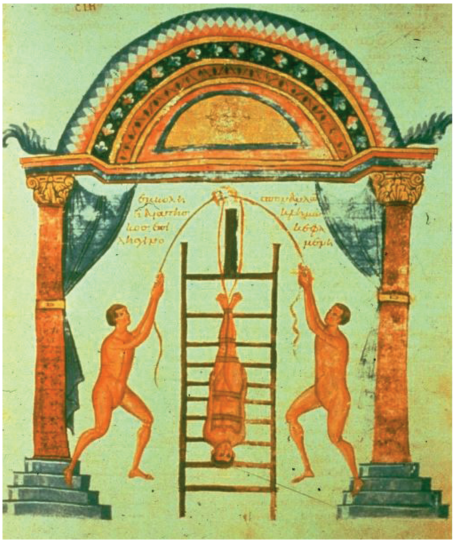

Figure 1. An illustration of Hippocratic board by Apollonius of Kitium showing correction of a spinal deformity by applying force to restore the anatomy of the spine, by using a plank. One end of this plank is adjusted to a cavity in the wall or in the post embedded in the ground. With the hump lying below the plank, one or two assistants press down its opposite end. Bibliotheca Medica Laurenziana, Florence

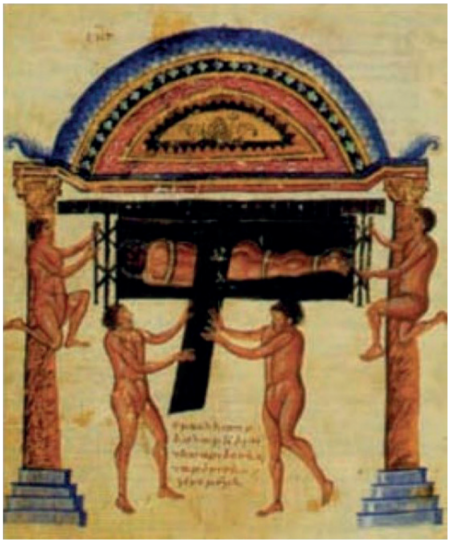

Figure 2. The Hippocratic ladder; From the illustrated comments of Apollonius of Kitium on the Hppocratic treatise On Articulations. Bibliotheca Medica Laurenziana, Florence.

Throughout the centuries, the treatment of trauma in general and, specifically, trauma to the spinal column evolved. Both World War I and II led to leaps in knowledge of treatments, because these wars resulted in a high number of patients. Also, the development and implementation of Rontgen examination resulted in better understanding and treatment options for patients with a trauma to the spinal column. [3] Examples of the evolving treatments are depicted in figures 3,4 and 5. They show the Bohler reduction technique, plaster-of-paris casting and exercises, and a leap in surgical treatment with the Harrington distraction rods, consecutively. With increasing knowledge and rising possibilities for treatment the odds of survival of these patients increased dramatically in the 20th century. Rehabilitation and return to productive lives and work became possible for many of these trauma victims. This resulted in a new group of people living with long-term consequences of injury to the spinal column, as a part of society.

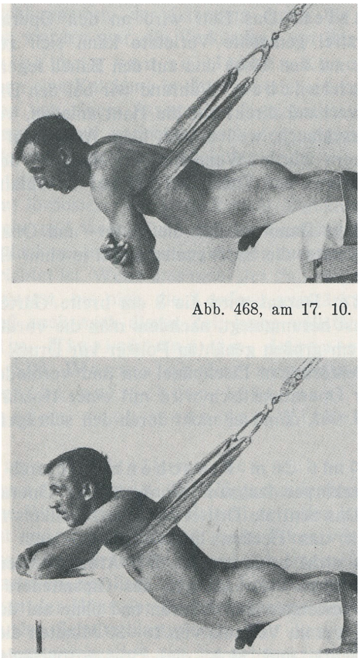

Figure 3. Bohler reduction technique

In current practice the patients' perspective is equally, if not more important, than the opinion of the surgeon. Previously, only the opinion of the surgeon combined with radiological examinations were deemed enough to monitor patients after a trauma to the spinal column and decide on their state of recovery. For example, Trojan (1971) already published a paper describing a poor outcome in patients after a spine trauma with a kyphosis of >15°, treated with for example Bohler reduction followed casting and exercises (figures 3 and 4). [4] In that time period, he did not use a Patient Reported Outcome Measurement (PROM). PROMs are essential in monitoring the quality of life and recovery of patients. Patient' specific questionnaires are used to monitor the results of treatment. The AO Spine Patient Reported Outcome Spine Trauma (PROST) was developed for this purpose as a specific outcome instrument for patients after spine trauma. The key difference between the PROST compared to the 'general Quality of Life (QoL) questionnaires' is that the PROST compares the current functioning to the pre-trauma functioning of the patient. [5, 6] The PROST went through a thorough validation and reliability testing process for the short term (up to 12 months). However, the long-term follow-up (>12 months) for patients after a trauma to the spinal column with the PROST has not yet been validated. To be able to compare treatments and monitor complications and potential problems, the questionnaire needs to be validated for the longer-term follow-up. (>12 months)

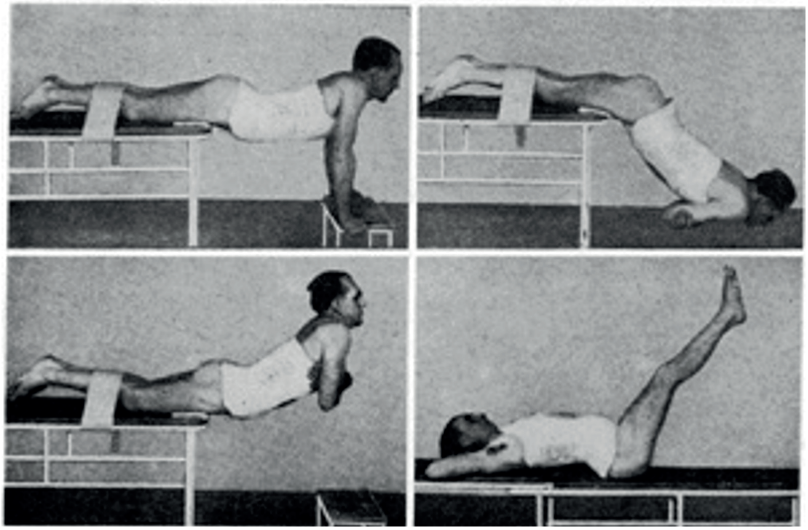

Figure 4. Minerva Casting and Excercises

As mentioned before, it is imperative to also consider the clinician' perspective in an easy-to-use and quick tool. The AO Spine Clinician Reported Outcome Spine Trauma (CROST) was developed to include the most relevant clinical and radiological parameters. The goal of the CROST was to evaluate and predict clinical outcomes of spine trauma patients. [7] A previous study showed moderate reliability when anonymized clinical cases were used in an online survey including patients' clinical information and radiological examinations. [7]

After a trauma to the spinal column there will often be some degree of deformity at the level of injury, regardless of the type of treatment administered. [8] This deformity after a trauma to the spinal column was already described by Hippocrates using different terms. For example, he mentioned that a (post-)traumatic kyphosis had low mortality, if the spinal cord was not involved. And Hippocrates himself also used the term scoliosis to describe most kinds of spinal curvatures, including those resulting from injuries. [2, 9]

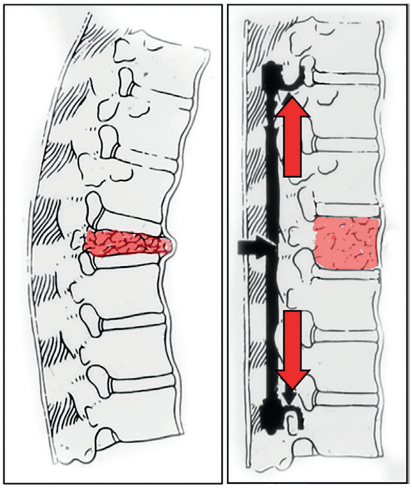

Figure 5. Harrington distraction system (1962)

Similarly, spine surgeons in following centuries used different terms and definitions for this deformity after a trauma to the spinal column. The use of different terms typically implies corresponding variations in their definitions. An earlier study from Schoenfeld et al. revealed a limited consensus on the definition of a deformity of the spine after trauma. Their consensus definition between experts was 'a painful kyphotic deformity'. [10] Despite different terms and definitions used, this condition has been recognized, described and treated in different ways. And in the last decades the treatment of a such a symptomatic deformity after a trauma to the spinal column has become more extensive and specialized. However, the comparison of these treatments is difficult because of the variety of terms and definitions used.

The indication for a surgical treatment of a deformity after trauma to the spinal column is diverse in literature. [11, 12] The key question that remains is: when is a deformity after a trauma to the spinal column clinically relevant? And when and how should it be treated? If you want to answer these essential questions, a uniform and internationally accepted term and definition is necessary.

There are multiple ways to reach consensus on a term or definition. Single expert or a small group of experts was historically an accepted and usual way of defining or stating a new entity. [2, 9, 13, 14] However, a new entity needs to be defined and redefined until broader consensus is achieved. [10] This consensus can be reached using a Delphi method. This type of study uses multiple rounds to reach consensus in a larger group of experts. Information is collected, summarized, and returned to the participants in iterative rounds, using face-to-face meetings, surveys, discussion panels and voting. The methodology can be adjusted to different study subjects. In this thesis, the decision-oriented Delphi process was used to achieve consensus on the definition of clinically relevant deformity after a trauma to the spinal column. [15]

Aims and outline of this thesis

The main aims of this thesis are to provide an insight in outcome of patients after a trauma to the spinal column using a patient specific and clinician specific measurement instrument and to develop a uniform and internationally accepted term and definition of a deformity after a trauma to the spinal column.

This thesis consists of three parts to reach these main aims. Part 1 is dedicated to the validation and implementation of the AO Spine PROST and the AO Spine CROST in the clinical practice. It focusses on the validation of the long-term reliability and outcomes of patients' perspective with the AO Spine PROST and the reliability in a clinical setting of the clinicians' perspective with the AO Spine CROST. Part 2 focusses on the development of a term and definition of a clinically relevant deformity of the spine after a traumatic injury. It contains different steps of the decision-oriented Delphi process. Part 3 assesses the presence of Posttraumatic Spinal Deformity in a group of patients with poor outcome in PROMs.

In Chapter 2 a cohort of patients treated in the UMC Utrecht after trauma to the spine completed the AO Spine PROST, EuroQoL 5D-5L (EQ-5D-5L), and either Oswestry disability index (ODI) or neck disability index (NDI) to test for reliability and validity on the long-term follow-up of the AO Spine PROST.

The feasibility, internal consistency, interrater reliability, and prospective validity of the AO Spine CROST in the clinical setting is assessed in Chapter 3. Also, the correlation between the clinicians' perspective with the AO Spine CROST and the patients' perspective with the AO Spine PROST was investigated.

Chapter 4 is an introduction as well as the first step into the Delphi process. It consists of a systematic literature review which investigated all the different terms and definitions used in the historic and current literature for a deformity after a spine trauma. All newly proposed or mentioned terms and definitions were included and no languages were excluded. This was then used to develop an internationally accepted term and definition.

In Chapter 5 an expert survey was conducted to explore the different opinions and views of internationally acknowledged experts in the field of spine trauma. It was set up to explore potentially pre-existing agreements on certain aspects of a deformity after a trauma.

The diagnostic process of 7 patients was investigated and analyzed in Chapter 6. The key question was if agreement existed between experts on the presence of a clinically relevant deformity after a spine trauma. Seven patients were presented as if they would visit the clinician in the outpatient clinic: aspects of the anamnesis and the physical examination are provided, followed by radiological examinations and measurements. Subsequently, the experts were asked if a clinically relevant deformity was present or not.

In Chapter 7 all the preparatory studies were used to construct the decision-oriented Delphi process. The goal was to create and decide on a uniform and internationally accepted term and definition for a clinically relevant deformity of the spine after trauma to the spine.

Finally, in Chapter 8, the new term and definition were tested on a specific patient-population from the existing patient cohort of the long-term validation study of the AO Spine PROST (Chapter 2). The patients with an ODI>40, meaning severely disabled, were selected for this study and the correlation between patient reported outcomes (ODI, AO Spine PROST) and radiological deformity was analysed.

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Part I:

Follow-up of function and health outcomes of spine trauma patients

2

Chapter 2

Long-Term Reliability and Validity of the AO Spine PROST (Patient-Reported Outcome Spine Trauma)

George S. Buijs, MD, Erin E.A. de Gendt, MD., Said Sadiqi, MD, PhD, Marcel W. Post, PhD, Sander P.J. Muijs, MD, PhD, and F. Cumhur Oner, MD, PhD

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Abstract

Study Design. Cross-sectional validation study.

Objective. The aim was to validate the AO Spine Patient- Reported Outcome Spine Trauma (PROST) at a minimum of 12 months post-trauma and to evaluate patient characteristics, types of spine fractures, and treatment strategies as determinants of AO Spine PROST scores.

Summary of Background Data. The reliability and validity of the AO Spine PROST as a measure of health-related quality of life for more than 12 months after onset of spine trauma is unclear.

Materials and Methods. Patients with a traumatic spine injury were recruited from a level-1 trauma center. They were asked to complete the AO Spine PROST, EuroQoL 5D-5L (EQ-5D-5L), and either Oswestry disability index (ODI) or neck disability index (NDI) for concurrent validity. Internal consistency was assessed by calculating the Cronbach α and item-total correlation coefficients. Test-retest reliability was evaluated using intraclass correlation coefficients. Spearman correlation tests were performed for the AO Spine PROST in correlation with the EQ-5D-5L, and either ODI or NDI. Determinants for AO Spine PROST score were analyzed using multivariate regression models.

Results. A total of 175 patients participated in the cross-sectional arm and 49 in the test-retest arm of the study. Median duration of follow-up was 94.5 months. No floor or ceiling effects were seen. Internal consistency was excellent (α = 0.98, item-total correlation coefficient. 0.73–0.91) as well as test-retest reliability (intraclass correlation coefficient=0.81). Satisfactory correlations were seen for the EQ-5D-5L (0.76; $P < 0.001$), ODI (0.69; $P < 0.001$), and NDI (0.68; $P<0.001$) with the AO Spine PROST. Multivariate linear regression models showed that having ≥ 1 comorbidities, duration of return to work within the range of 7 to 43 months and no return to work were significant independent determinants for a worse AO Spine PROST score.

Conclusions. Very good long-term reliability and validity results were found for the AO Spine PROST.

Key words: AO spine PROST, spine trauma, long-term, validation study

INTRODUCTION

In 2019, a traumatic spine injury was registered in 5% of all injuries at emergency departments in the Netherlands. [1] Spine fractures often result in considerable long-term consequences. [2] Measurement of the impact of interventions on individuals' health-related quality of life (HRQoL) is relevant in multiple facets, for example, in search of optimal treatment strategies and cost-effectiveness of provided treatments. Outcomes of spine trauma have traditionally been limited to reporting of neurological deficits and mortality, or presented with HRQoL outcomes derived from generic measures or measures developed for degenerative spine diseases. [3–5] A degenerative spine disease is considered a different entity and has a different prognosis for both the short-term and long-term quality of life. [6]

Therefore, the AO Spine Knowledge Forum Trauma, therefore, developed a new HRQoL questionnaire: the Patient-Reported Outcome Spine Trauma (AO Spine PROST). [7] This tool is developed specifically to measure the function and health status in patients after their spine trauma. Previous validation studies on the Dutch and English language versions of the AO Spine PROST had a follow-up until 12 months. [8,9]

However, the validity of the AO Spine PROST for a follow-up period longer than twelve months is unknown. To enable evaluation of long-term function and treatment outcomes after spine trauma, further validation in patients with long-term consequences of spinal trauma is necessary. Therefore, the primary aim of this study is to investigate the psychometric properties of the AO Spine PROST for long-term follow-up.

No previous studies are available that used the AO Spine PROST to study long-term follow-up of spine trauma. Therefore, the secondary aim of this study is to evaluate the potential relation between patient characteristics, different types of spine fractures, and treatment strategies compared with patients' HRQoL outcomes using the AO Spine PROST.

MATERIALS AND METHODS

Target Population

Adult patients (≥18 y of age at onset of trauma) with a trauma to the spine who received either surgical or conservative treatment at the University Medical Center Utrecht in the Netherlands between 2003 and 2018 were included in this study. Patients had to have a follow-up visit at the outpatient clinic of at least 12 months. Subsequently, patients had to master the Dutch language and not have cognitive impairments. In accordance with previous vali- dation studies of the AO Spine PROST, patients with ASIA Impairment Scale (AIS) grade C, D, and E were included. [8,9] Patients with AIS grade A and B were excluded as the AO Spine PROST was specifically designed to measure HRQoL in patients with AIS grade C, D, and E. [8,9] Patients suffering polytrauma (injury severity score > 15) were excluded due to the different cause influencing HRQoL.

Study Procedures

Patients in this study were recruited from a large database including all spine trauma patients of a level-1 trauma center in The Netherlands. Eligible patients were invited to participate. After informed consent, they received the questionnaires either online or on paper. For test-retest purposes a group of 75 patients within this group was randomly selected and asked to fill-out the AO spine PROST twice with an interval of 14 days.

Instruments

Patients were asked about their sociodemographic characteristics and pre-trauma work status, as well as duration of return to work after trauma. Additional clinical characteristics (ie, year of injury, type of treatment received, comorbidities, and previous spine surgeries other than the primary surgery) were extracted from the patient records.

For the purpose of concurrent validity, the AO Spine PROST should be compared with a validated outcome instrument specifically designed for patients with traumatic injuries to the spine. Since there is no such instrument available, the EuroQoL 5D-5L (EQ-5D-5L) [10] and Oswestry disability index (ODI) [11,12] or neck disability index (NDI) [13,14] were used as reference standard.

The AO Spine PROST is designed to measure HRQoL outcomes in spine trauma patients. It consists of nineteen questions on a broad range of aspects of functioning (eg, household activities, urinating, sexual function) on a 0 to 100 numeric rating scale with 0 indicating no function at all and 100 the pre-trauma functional level. [15] The EQ-5D- 5L is a commonly used generic HRQoL instrument for describing and valuing HRQoL. Respondents have to report their health status in 5 dimensions of health. Within each dimension there are 5 levels of severity, resulting in a 5 digit code stating the resulting health status. [10] The ODI is a patient-reported outcome measure to quantify the disabling effect of pain during typical daily activities in patients with degenerative lower back pain. It consists of 10 questions with a 6-point scale, ranging from 0 (no disability) to 5 (maximum disability). The sum score of all questions is expressed on a 0 to 100 sum score scale. [16] The NDI is a modification of the ODI, where the items and response categories have been adjusted for people with neck com- plaints. The NDI measures self-reported pain intensity and limitations in performing daily work-related activities and nonwork-related activities, also on a 0 to 100 sum score scale. [14]

Statistical Analysis

Patient characteristics were analyzed using descriptive statistics. Normally distributed continuous data were presented as mean with SD and not normally distributed data as median with interquartile range (IQR). Floor and ceiling effects were analyzed, which could occur if >15% of patients achieved either the lowest or highest possible score, respectively. [17] The internal consistency was assessed by calculating the Cronbach α and item-total correlation coefficients (ITCCs). It is suggested that the value of α should be > 0.70 and ITCC values should be > 0.40 for satisfactory internal consistency. [18,19]

Test-retest reliability was estimated using intraclass correlation coefficients, with moderate, good, and excellent reliability indicated by values of 0.5 to 0.75, 0.75 to 0.90, and > 0.90,

respectively. [20] The correlations between the AO Spine PROST and EQ-5D-5L, ODI or NDI were analyzed using Spearman correlation coefficient (rs) as some outcomes of the questionnaires were discrete-ordinal. The rs ranges from values −1 to +1, with 1 indicating a perfect positive association, 0 no association and −1 perfect negative association of ranks. [21] Concurrent validity is supported with a coefficient of 0.70 or higher. [19]

To analyze potential determinants for AO Spine PROST scores, first univariate linear regression was performed using all collected variables. For multivariable analyses, stepwise backward selection was performed to select variables. [22] Potential determinants were expressed using hazard ratios with 95% confidence intervals. Duration of return to work and AIS scores were dichotomized to approach equal groups.

A P-value <0.05 was considered statistically significant. Missing data was handled by pairwise deletion. Data were analyzed using R for Windows (version 4.0.1.0.). [23] .

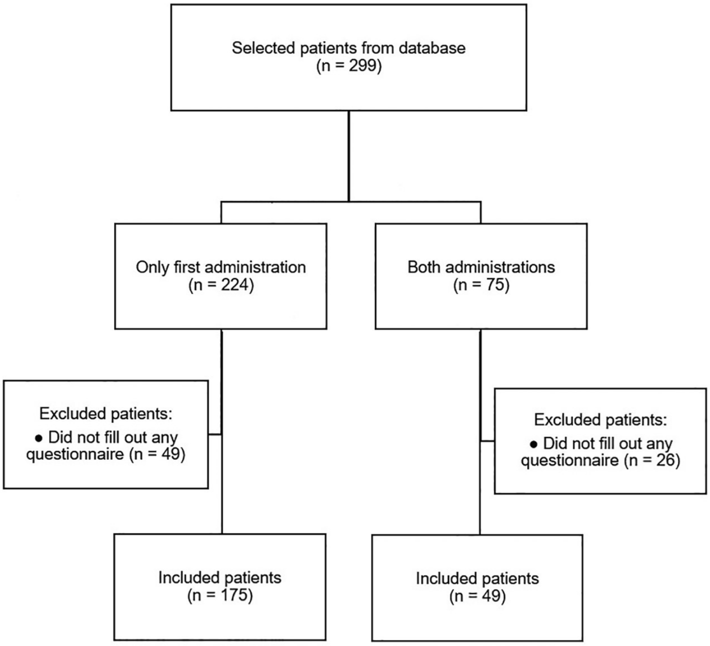

Figure 1. Flowchart for patient inclusion

Ethical Statement

This study was approved by the Institutional Review Board of the University Medical Center Utrecht (19/457). This study was executed in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans as well as the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals and reported in accordance to the STROBE guidelines (Supplementary File 1, Supplemental Digital Content 1, http://links.lww.com/BRS/B883). [24,25]

RESULTS

Patient Characteristics

All 768 patients within the database were approached, of whom 299 initially responded in consent. Out of those, 224 patients were allocated to the cross-sectional arm and 75 to the test-retest arm. In the cross-sectional arm 175 patients (78.1%) were included as they completed all questionnaires. In the test-retest arm 49 patients (65.3%) were included. Median follow-up time after spine trauma was 94.5 months (IQR: 56.6–131.7). Patients had a mean age of 50.8 years (SD 16.3) at the time of trauma and 68.8% were male. The majority (71.4%) had no pre-existent comorbidities. A total of 405 fractures were diagnosed, with a mean number of fractures of 1.81 per patient. Of all fractures, 65.4% were located in the thoracic and/or lumbar spine as opposed to 34.6% in the cervical spine. The majority of patients did not suffer neurological deficit (AIS E 92.0%). A slight majority of patients (56.7%) underwent surgical treatment (Table 1).

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

Characteristics	**Overall (n = 224)**
Age at trauma in years, mean (SD)	50.8 (16.9)
Age at final follow-up in years, mean (SD)	58.9 (16.4)
Gender (%)	
Male	154 (68.8)
Female	70 (31.2)
Overall follow-up duration in months, median (IQR)	94.5 (56.5 – 131.7)
Pre-trauma employment (%)	
Fulltime	159 (71.0)
Parttime	43 (19.2)
Unemployed (other reason)	22 (9.8)
Unemployed (health reason)	0 (0.0)
Pre-trauma comorbidities (%)	
No medical history	160 (71.4)
≥1 comorbidities	64 (28.6)
Total number of fractures	405 (100.0)
Fracture region (%)	
Cervical spine	140 (34.6)
Thoracic and/or lumbar spine	265 (65.4)
Fracture type (%) [b]	
Type A	248 (61.2)
Type B	112 (27.7)
Type C	30 (7.4)
Type F	15 (3.7)
Treatment (%)	
Conservative	97 (43.3)
Surgical	127 (56.7)
ASIA impairment grade (%)	
C	1 (0.4)
D	17 (7.6)
E	206 (92.0)

a. The percentage of each characteristic is based on the available total number of patients for the certain characteristic
b. According to the AO Spine Injury Classification Systems

During follow-up, 32 patients (14.3%) needed additional surgery after initial surgical treatment. In the majority of patients needing additional surgery, removal of osteosynthesis material was performed due to associated pain com- plaints. Overall, 71.0% of patients occupied a fulltime job and 19.2% occupied a parttime job pre-trauma,

pertaining to 53,6% and 27.7% post-trauma, respectively. Median duration of return to work was 4.0 months (IQR: 3.0–6.5) post-trauma (Table 1).

Content Validity

As no patient had the minimum score and only 10 patients (4.5%) had the maximum total score of the AO Spine PROST, no floor and ceiling effects were observed. Overall, median AO Spine PROST total score was 86.0 (IQR: 66.8–78.9; skewness −1.19; kurtosis 3.66).

Internal Consistency

Internal consistency of the AO Spine PROST total score was excellent (Cronbach α = 0.98) and all separate items within the AO Spine PROST exceeded the minimum reliability standard of α=0.70. All AO Spine PROST items showed good ITCC values, with a range of 0.73 to 0.91. The lowest values were seen for "Urinating" (0.73) and "Sexual function" (0.73). The Cronbach α did not improve or worsen if an item was removed. Internal consistency testing results are shown in Table 2.

Test-Retest Reliability

Out of the 75 patients who were asked to fill-out the AO spine PROST twice, a total of 49 patients (65.3%) completed both administrations of the AO Spine PROST (Fig. 1). The median time after trauma was 57.9 months (IQR: 51.8–102.6) when completing the first administration. All responding patients completed the second administration 14 days after completing the first administration. Good test-retest reliability was seen (intraclass correlation coefficient = 0.81; IQR: 0.67–0.89) for the total score. All individual AO Spine PROST items showed moderate to excellent test-retest reliability results (Table 2).

Table 2. Results for internal consistency for AO Spine PROST items.

AO Spine PROST items	mean (SD)	Item-total correlation	Cronbach's α if item is deleted	ICC (95% CI)*
1. Household activities	78 (25)	0.87	0.97	0.70 (0.48 – 0.83)
2. Work/study	76 (29)	0.82	0.97	0.84 (0.70 – 0.91)
3. Recreation and leisure	72 (27)	0.89	0.97	0.81 (0.67 – 0.90)
4. Social life	86 (21)	0.81	0.97	0.78 (0.60 – 0.87)
5. Walking	80 (25)	0.88	0.97	0.82 (0.68 – 0.90)
6. Travel	83 (24)	0.89	0.97	0.81 (0.66 – 0.89)
7. Change posture	78 (24)	0.91	0.97	0.73 (0.52 – 0.85)
8. Maintaining posture	75 (24)	0.83	0.97	0.79 (0.63 – 0.88)
9. Lifting and carrying	72 (27)	0.89	0.97	0.87 (0.77 – 0.93)
10. Personal care	87 (21)	0.84	0.97	0.74 (0.55 – 0.86)
11. Urinating	84 (25)	0.73	0.97	0.87 (0.77 – 0.93)
12. Bowel movement	87 (23)	0.74	0.97	0.75 (0.56 – 0.86)
13. Sexual function	75 (33)	0.73	0.97	0.71 (0.48 – 0.84)
14. Emotional function	83 (24)	0.74	0.97	0.81 (0.66 – 0.89)
15. Energy level	76 (25)	0.88	0.97	0.84 (0.71 – 0.91)
16. Sleep	82 (23)	0.78	0.97	0.76 (0.58 – 0.87)
17. Stiffness of neck and/or back	68 (26)	0.87	0.97	0.75 (0.55 – 0.86)
18. Loss of strength in arms and/or legs	79 (26)	0.87	0.97	0.83 (0.70 – 0.90)
19. Back and/or neck pain	76 (26)	0.83	0.97	0.75 (0.54 – 0.86)

° Cronbach α for total AO Spine PROST score was 0.98

Concurrent Validity

The AO Spine PROST was most strongly correlated with the EQ-5D-5L (0.76; P < 0.001). Correlations between the AO Spine PROST and ODI or NDI were 0.69 (P < 0.001) and 0.68 (P < 0.001), respectively. As shown in Table 3, extended subscale correlation analyses showed that the tool most strongly correlated with the "Usual activities" item of the EQ-5D-5L (0.71; P < 0.001).

Potential Determinants

Univariate Linear Regression Models

Resulting from univariate regression analysis, age at the time of trauma, having ≥ 1 comorbidities as opposed to no medical history and additional surgery as opposed to no additional surgery were significantly associated with a worse AO Spine PROST score. Also duration of return to work within the range of 7 to 43 months and no return to work as opposed to return to work within the range of 0 to 5 months were significantly associated with a worse AO Spine PROST score (Table 4).

Chapter 2

Multivariate Linear Regression Models

Backward stepwise selection was performed using all collected patient characteristics: age, history of comorbidities, region of fracture, total number of fractures, type of treatment, additional surgery, AIS grade at the end of follow-up, and duration of return to work. Subsequentially, the final multivariate regression model included age, comorbidities, type of treatment, additional surgery, AIS score, and duration of return to work. Multivariate regression analysis identified 3 variables as significant independent determinants for a worse AO Spine PROST score: ≥ 1 comorbidities, duration of return to work within the range of 7 to 43 months and no return to work (Table 4).

Table 3. Spearman correlations (rs) between AO Spine PROST and EQ-5D-5L, ODI and NDI.

	rs	p-value
EQ-5D-5L total	0.76	<.001
EQ-5D-5L subscales		
Mobility	0.67	<.001
Self-care	0.54	<.001
Usual activities	0.71	<.001
Pain/discomfort	0.69	<.001
Anxiety/depression	0.38	<.001
Visual Analogue Scale	0.66	<.001
ODI total	0.69	<.001
ODI subscales		
Severity of pain	0.62	<.001
Self-care	0.32	<.001
Lifting	0.70	<.001
Walking	0.40	<.001
Sitting	0.44	<.001
Standing	0.57	<.001
Sleeping	0.43	<.001
Sex life	0.44	<.001
Social life	0.55	<.001
Traveling	0.50	<.001
NDI total	0.68	<.001
NDI subscales		
Pain	0.42	<.001
Self-care	0.38	0.001
Lifting	0.63	<.001
Reading	0.45	<.001
Headache	0.33	0.005
Focus	0.48	<.001
Work	0.68	<.001
Driving	0.51	<.001
Free time	0.45	<.001

Table 4. Outcomes of univariate- and multivariate linear regression models analyzing potential determinants for AO Spine PROST score.

Patient characteristics	Univariate linear regression Change in AO Spine PROST		Multivariate linear regression Change in AO Spine PROST*	
	Estimate [95% CI]	p-value	Estimate [95% CI]	p-value
Intercept			68.082 [28.93 - 107.23]	< 0.001
Age at time of trauma	-0.25 [-0.41 - -0.08]	0.003	0.15 [-0.33 - 0.03]	0.106
Comorbidities at time of trauma				
No medical history	Reference		reference	
≥1 comorbidities	-9.68 [-15.56 - -3.80]	0.001	-6.70 [-12.74 - -0.65]	0.030
Fracture region				
Cervical	Reference			
Thoracic and/or lumbar spine	3.96 [-1.75 - 9.68]	0.173		
Total number of fractures	-0.81 [-2.87 - 1.25]	0.441		
Type of treatment				
Conservative	Reference		reference	
Surgical	-5.33 [-10.78 - 0.11]	0.055	-3.52 [-8.75 - 1.72]	0.187
Additional surgery				
No	Reference		reference	
Yes	-9.29 [-16.90 - -1.67]	0.017	-6.58 [-14.05- -0.88]	0.084
ASIA impairment grade at time of trauma				
C or D	Reference		reference	
E	34.26 [-5.48 - 74.00]	0.091	31.49 [-2.57 - 73.35]	0.096
Duration of return to work				
0 - 5 months	Reference			
5 – 7 months	-3.77 [-11.82 - 4.29]	0.358	-2.46 [-10.14 - 5.23]	0.529
7 – 43 months	-21.37 [-21.37 - -5.54]	< 0.001	-13.62 [-21.32 - -5.92]	<0.001
No return to work	-13.71 [20.11 - -7.31]	< 0.001	-8.23 [-14.78 - -1.66]	0.014

* adjusted r^2 = 0.18

DISCUSSION

To the best of our knowledge, this study is the first to investigate and report the long-term psychometric proper- ties of the AO Spine PROST, a disease-specific outcome measure for spine trauma patients. In addition, this study investigated potential patient characteristics affecting HRQoL outcomes measured by the AO Spine PROST.

Very good internal consistency and test-retest reliability were found. Satisfactory Cronbach α scores (α>70) were reported for all items. Also moderate to excellent test-retest reliability was obtained for all individual items. This is in agreement with findings from Sadiqi et al [8,9] in the previous psychometric studies for the AO Spine PROST with a follow-up up to 12 months.

For concurrent validity, patients were asked to fill-out several HRQoL questionnaires (ie, EQ-5D-5L, ODI or NDI) next to the AO Spine PROST. In preparation of this study, the SF-36, ODI, and NDI were identified in a systematic literature review as the most frequently used instruments in spine trauma studies. [3] With the expectation that it would increase participation, it was chosen to use the EQ-5D-5L instead of the SF-36 due to the abundance of items within the SF-36. Also using the EQ-5D-5L is more informative, since the validity of the AO Spine PROST was already tested in correlation to the SF-36 in previous vali- dation studies. [8,9] In the current study good concurrent validity for the AO Spine PROST was found in comparison to the EQ-5D-5L ($r = 0.76$; $P < 0.001$), while slightly lower concurrent validity was found for both the ODI ($r=0.69$; $P<0.001$) and NDI ($r=0.68$; $P<0.001$). This may be explained by the fact that comparing measures of both function and pain using the AO Spine PROST to measures of only pain using the ODI or NDI is inaccurate. [5,26]

This study is the first to report determinants effecting HRQoL outcomes by using the AO Spine PROST and identified the presence of comorbidities as well as increased duration of return to work as significant determinants for a worse outcome. A study by Schouten et al [27] identified comorbidity status (measured by the Charlson comorbidity index) as an independent determinant of SF-36 scores in patients with thoracic fractures. Although this determinant was compared with a different HRQoL questionnaire and comorbidity status was registered differently in the current study, this outcome may suggest agreement.

The current study analyzed a unique group of spine trauma patients with a median follow-up of 94.5 months (IQR: 56.6–131.7) and achieved an total completion rate of 29.2%. As indicated by Terwee et al [19] a minimum sample of 50 patients is appropriate to test-retest for reliability. The current study chose to exceed this minimum by 150%, thus decided to select 75 patients randomly. In total, 49 patients were included within the test-retest reliability arm. After sending reminders, authors decided to accept this number of patients as it was approaching this requirement.

This study has several limitations. First, no prospective responsive analysis was performed as it has already been done in a previous study investigating the AO Spine PROST up to 12 months follow-up. This study showed excellent responsive results. [28] A second limitation of the current study may result from the cross-sectional design. Due to this design and a reported moderate to low variance of 18%, the reported determinants may not derive from causal relation- ship and may indicate that other variables of importance could have an impact on the reported scores. These results should therefore be interpreted as a suggestion for future research. [29] A third limitation is considered the heterogenous patient population. Patient characteristics showed a relatively high mean age and high percentage of males. Nevertheless, similar men/woman ratios together with an aging spine trauma patient population are seen in clinics today and are corroborated in several publications. [30–32] A fourth limitation may derive from the single-center design of this validation study. Further validation done in multicenter and international manner would be desirable to enhance prove of validation. Finally, patients were asked to indicate their current function as opposed to their pre-trauma function with a median follow-up of 94.5 months, which may have resulted in recall bias. [33] Nevertheless, the reported correlation between the EQ-5D-5L, ODI, NDI, and AO Spine PROST in the current study suggests a low probability of recall bias, especially for reliability and validity testing, since these questionnaires do not ask patients to recall their pre-trauma function.

In conclusion, this study aimed to analyze the psycho- metric properties of the AO Spine PROST for long-term follow-up and showed very good results for both reliability and validity. The presence of comorbidities, duration of return to work between 7 and 43 months and no return to work were identified as potential significant and independent determinant for worse outcome. This study contributes to the long-term outcomes evaluation of spine trauma patients in a valid and reliable fashion using the AO Spine PROST. Treating physicians and researchers are encouraged to use the AO Spine PROST as a validated tool to evaluate long-term HRQoL of spine trauma patients.

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Chapter 3

Validation of the AO Spine CROST (Clinician Reported Outcome Spine Trauma) in the clinical setting

Said Sadiqi, Erin E. A. de Gendt, Sander P. J. Muijs, Marcel W. M. Post, Lorin M. Benneker, Martin Holas, Jin W. Tee, Christoph E. Albers, Sonja Häckel, Juraj Svac, Richard J. Bransford, Mohammad M. El-Sharkawi, Frank Kandziora, Shanmuganathan Rajasekaran, Klaus J. Schnake, Alexander R. Vaccaro, F. Cumhur Oner

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Abstract

Purpose. To evaluate feasibility, internal consistency, inter-rater reliability, and prospective validity of AO Spine CROST (Clinician Reported Outcome Spine Trauma) in the clinical setting.

Methods. Patients were included from four trauma centers. Two surgeons with substantial amount of experience in spine trauma care were included from each center. Two separate questionnaires were administered at baseline, 6-months and 1-year: one to surgeons (mainly CROST) and another to patients (AO Spine PROST—Patient Reported Outcome Spine Trauma). Descriptive statistics were used to analyze patient characteristics and feasibility, Cronbach's α for internal consistency. Interrater reliability through exact agreement, Kappa statistics and Intraclass Correlation Coefficient (ICC). Prospective analysis, and relationships between CROST and PROST were explored through descriptive statistics and Spearman correlations.

Results. In total, 92 patients were included. CROST showed excellent feasibility results. Internal consistency (α=0.58–0.70) and reliability (ICC=0.52 and 0.55) were moderate. Mean total scores between surgeons only differed 0.2–0.9 with exact agreement 48.9–57.6%. Exact agreement per CROST item showed good results (73.9–98.9%). Kappa statistics revealed moderate agreement for most CROST items. In the prospective analysis a trend was only seen when no concerns at all were expressed by the surgeon (CROST=0), and moderate to strong positive Spearman correlations were found between CROST at baseline and the scores at follow-up (rs=0.41–0.64). Comparing the CROST with PROST showed no specific association, nor any Spearman correlations (rs=−0.33–0.07).

Conclusions. The AO Spine CROST showed moderate validity in a true clinical setting including patients from the daily clinical practice.

Keywords: Outcome instrument, Clinician perspective, AO Spine CROST, Spine trauma, Health, Function

INTRODUCTION

The influence of spine fractures on patients' functioning, including social and financial situation, is considered very significant compared to other injuries [1]. Currently, the decision-making between non-operative management and surgical care is far from settled for various types of spine fractures. In this perspective, measurement of outcomes is relevant in order to compare different treatment options, and thereby develop more rational choices for treatment strategies [2]. To address this void, the AO Spine Knowledge Forum Trauma developed the first disease-specific outcome measure for spine trauma patients, the Patient Reported Outcome Spine Trauma (AO Spine PROST) [3]. An important note is that there may be discrepancies when comparing patients' perspective with clinicians' perspective on what is considered as a good outcome of a specific treatment [4, 5]. It is imperative to also capture the perspective of the clinicians in a simple, reliable and quick to administer tool. Including the most relevant clinical and radiological parameters, this tool would be able to evaluate and predict clinical outcomes of spine trauma patients. This led to the development of a separate, unique tool that is rated by clinicians: the Clinician Reported Outcome Spine Trauma (AO Spine CROST) [6]. An initial reliability study, using anonymized clinical cases from daily clinical practice through an online system, showed moderate results [6]. It was hypothesized that a more adequate evaluation of the CROST would be possible when patients were seen and assessed by the clinician in a true clinical setting. Therefore, the aim of the current study was to evaluate the feasibility, internal consistency, interrater reliability, and prospective validity of the CROST in the clinical setting. Also, the correlation between the clinician reported CROST and patient reported PROST was investigated.

MATERIALS AND METHODS

Study design

An international multicenter cross sectional study with prospective follow-up until 1-year post-trauma was performed in four centers, recruited through the AO Spine Knowledge Forum (KF) Trauma. The participating centers included trauma hospitals from Australia (The Alfred Hospital, National Trauma Research Institute, Monash University, Clayton), the Netherlands (University Medical Center, Utrecht), Slovakia (Slovak Medical University, F. D. Roosevelt University General Hospital, Banska Bystrica), and Switzerland (Inselspital, University of Bern). Data were gathered through the online system REDCap, using study identification codes. According to the Medical Ethics Committee of the participating centers, 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.

Surgeons

Two spine surgeons with at least 3 years of experience in spine trauma care participated from each center. Surgeon 1 was a member of the AO Spine KF Trauma, and was considered as the most experienced among these two surgeons. Surgeon 2 was recruited by Surgeon 1 at each center.

Patients

Adult patients (≥18 years) sustaining traumatic spine fractures and within 3 months post-trauma were included. They had to have mild or no neurological deficit (American Spinal Injury Association (ASIA) Severity score (AIS) C, D or E) at the time of discharge from hospital. In line with the target patient population in previous validation studies of PROST, patients with motor complete paralysis (AIS A or B) and hospitalized patients were excluded [3]. The desired sample size was 100 patients (25 per center), based on recommendations for this type of study [7]. Instruments Two separate questionnaires were administered: one to the surgeons and another to the patients. Surgeons completed CROST for each patient at their center. As shown in Appendix 1, this tool consists of 10 parameters. Eight parameters are rated for both surgically and non-surgically treated patients, while 2 parameters are only applicable to surgically treated patients ('Wound healing' and 'Implants'). Each parameter is rated both for the short-term (<12 months) and long-term (≥12 months). A 'yes'-answer provides 1 point, and expresses any expected problems or adverse events for the parameters. The total recorded score is the sum of the 'yes'-answers with a maximum achievable score being 8 points for non-surgically and 10 points for surgically treated patients. A higher score indicates worse expected outcome.

Additionally, surgeons were also asked to complete patients' background data, as well as evaluation questions in order to assess the feasibility: time to complete CROST, if it was considered as an easy and useful tool, if any difficulties were encountered when filling out, and if there were any redundant or missing parameters. Finally, the AO Spine KF Trauma surgeon was asked to assess the overall patient outcome in various prospective time points. The patient part of the questionnaire consisted of PROST, which includes 19 questions on a broad range of aspects of functioning [3, 8–12]. Each item has a 0–100 Numeric Rating Scale, with 0 indicating no function at all and 100 the pre-injury level of function. The item "Work/ Study" is optional. The total score is calculated by the mean of the answered questions. A higher score indicates improved outcome.

Study procedure

Eligible patients were identified and screened either just before discharge from hospital or at their first outpatient clinic appointment. Patients were enrolled in the study after informed consent was given. They were seen at three time points: baseline (i.e., the first outpatient clinic visit), 6-months, and 1-year after the trauma that caused their spine injury. At all these time points, patients were asked to complete PROST.

In order to assess the reliability of CROST, the two surgeons located at the same center independently made clinical assessments, and completed the tool for the same patient at the baseline visit. Concerning the prospective evaluation, CROST was also scored at 6-months and 1-year visits. At these time points, the questionnaire was only completed by Surgeon 1 (i.e., the AO Spine KF Trauma member). This surgeon was also asked to judge the overall outcome of the patient at 6-months and 1-year with a binary definition: 'same or better outcome than expected' or 'worse outcome than expected'. A 'same or better outcome than expected' was scored if the treatment goals were achieved, and 'worse outcome than expected' if they were not. For example, conversion of a conservatively treated patient to a surgical case, a surgically treated patient that undergoes a re-operation, or a patient highly dysfunctional in daily activities could be considered as 'worse outcome than expected'.

Statistical analysis

Descriptive statistics were used to analyze patient characteristics and the feasibility of CROST. The internal consistency of the tool was analyzed by calculating Cronbach's α. An α>0.70 is accepted as satisfactory result [7]. Inter-rater reliability analysis was performed both for individual CROST items as well as for the total score. Kappa statistics was used for the individual CROST items, with0.85 indicating good and excellent reliability, respectively [7]. The prospective analysis was performed by comparing outcomes as assessed at the baseline to the outcomes at 6-months and 1-year follow-up. The CROST scores at baseline were compared to the actual outcomes (same/better versus worse outcome) at 6-months and 1-year follow-up. Also, Spearman correlation coefficients (rs) between CROST scores at baseline and the scores at 6-months and 1-year follow-up were analyzed. The rs ranges from+1 to −1, with+1 indicating a perfect association, 0 no association, and −1 perfect negative association [7]. Finally, correlations between the clinician-reported CROST scores and patient-reported PROST scores were explored. Descriptive statistics were used to correlate CROST scores at baseline to PROST scores at different prospective time points. The change in CROST and PROST scores over time was analyzed using Spearman correlations. Also, the association between the 'actual' binary outcome (same/better versus worse outcome) was compared to PROST scores at 6-months and 1-year follow-up.

RESULTS

Patient characteristics

A total of 92 patients were included in the study: 24 (26.1%) from Australia, 27 (29.3%) Dutch patients, 15 (16.3%) from Slovakia, and 26 (28.3%) Swiss patients. Table 1 shows the overall patient characteristics, as well as stratified for the provided treatment and per participating center.

Feasibility

The questions concerning the feasibility of the CROST were completed by 7 surgeons. Five surgeons stated that it took less than 5 min to complete the tool; while, two surgeons mentioned 5–10 min. All agreed the tool was easy to use and no difficulties were experienced in completing. No parameter was deemed difficult, redundant or missing. All surgeons expected that the CROST would be a useful tool in the clinical setting.

Internal consistency

As shown in Table 2, the internal consistency of CROST total score was moderate with Cronbach's α ranging from 0.58 and 0.70.

Inter-rater reliability

The inter-rater reliability results for the total CROST scores as well as for each item are shown in Tables 3 and 4, respectively. Moderate reliability results were found for the total scores, both for the short-term anticipated scores (ICC=0.55) and long-term anticipated scores (ICC = 0.52). Subanalysis showed better reliability results for conservatively treated patients (ICC=0.59–0.81) compared with surgically treated patients (ICC=0.34–0.39). As shown in Table 4, analyses of the mean scores per CROST item showed very good exact agreement results ranging from 73.9% ('Range of motion impairment') to 98.9% ('Sagittal alignment problems') for the short-term anticipated scores. Comparable results were seen for the long-term anticipated scores: 81.5% (rage of motion impairment) to 100.0% (wound healing problems). Additional analysis including Kappa values showed somewhat varying results. Except poor agreement for 'Implants adverse events' (κ = −0.4 both for the short-term and long-term anticipated scores), most other CROST items showed moderate agreement; while, 'Sagittal alignment problems' showed an almost perfect agreement (κ=0.85).

Prospective analysis

The CROST scores at baseline were divided into 3 scoring subcategories: 0, 1, and≥2. As shown in Table 5, none of those subcategories showed a specific correlation to the actual assessed outcomes at the follow-up. Nevertheless, a trend was seen when CROST was scored 0 (indicating no concerns at all), in which the vast majority of patient outcomes (87.0–93.8%) were classified as 'same or better than expected'. Moderate to strong positive Spearman correlations were found between CROST scores at baseline and the scores at 6-months and 1-year follow-up, with significant rs values ranging from 0.41 to 0.64 (Table 6).

Correlation AO Spine CROST and PROST

No specific correlation was observed between the clinician-reported CROST scores at baseline as compared to the patient-reported PROST scores at different time points (baseline, 6-monts, and 1-year follow-up). Higher CROST scores (i.e., more concerned from clinical perspective) did not result in worse PROST scores nor were the differences statistically significant (Table 7). As shown in Table 8, no Spearman correlations were found between the change in CROST scores and change in PROST scores when compared at the baseline relatively to the scores at 6-months and 1-year follow-up (rs=-0.33 – 0.07). Finally, there seemed to be a statistically significant correlation between the PROST score and the assessed outcome by the surgeon (same/better versus worse outcome than expected). Table 9 reflects this with worse patient-reported PROST scores when the overall outcome is assessed as worse than expected.

DISCUSSION

This study investigated the validation of the AO Spine CROST (Clinician Reported Outcome Spine Trauma) in the clinical setting. In contrast to a previous validation study that included online cases [6], the current study was performed in an actual clinical setting including patients from daily clinical practice. Excellent feasibility and acceptable internal consistency results were found. This indicates that the tool is deemed useful in the clinical setting and that its content measures the intended concept of assessing clinical outcomes from the perspective of the clinicians.

The inter-rater reliability analysis showed moderate results. Although only minor differences were found for the total CROST scores between Surgeon 1 and Surgeon 2 (0.2–0.9 difference), the agreement percentages were relatively low (48.9–57.6%). This may be explained by the high amount of variations in scoring the same exact score with a total ranging from 0 to 10. Additional subanalysis per CROST item showed very good exact agreement results (73.9–100.0%). On the other hand, varying Kappa values were found with the most agreements being moderate. These Kappa results may be skewed, and not fully representative, due to the very high number of CROST items that were responded with a 'no'-answer (i.e., no concerns were expected with those items).

Prospective evaluation analysis of the CROST scores did not show a specific correlation to the overall outcomes as assessed by the surgeon at follow-up time points (same/better versus worse than expected). It is interesting to explore the clinicians' perspective relative to the patients' perspective on health and functioning. In the case of the treatment of spinal trauma patients, several clinical and radiological parameters are generally used by treating surgeons to evaluate treatment results. The most relevant parameters among spine trauma patients were identified in two preparatory studies in the developmental process of CROST [14, 15]. An estimation of any expected problems with respect to those parameters are made by the treating surgeons in order to determine the further course of treatment. The surgeon's assessment may differ substantially from the patient's perception [16, 17]. These discrepant views have also been addressed for a variety of other diseases, including metastatic diseases [18], multiple sclerosis [19], rheumatoid arthritis [20], and peripheral artery diseases [21]. The current study substantiates the discrepant views, and therefore the need for the clinician-reported CROST.

The patient-reported PROST analysis was not the main focus of the current study and, therefore, not further detailed in the Results section. Nevertheless, it is worth to mention that during the follow-up a gradual increase is seen in the mean PROST scores, indicating gradual recovery of the patients over time. This is in line with previous validation studies in which the PROST was crossculturally translated and validated in the Dutch, English, German, Nepali and Slovak versions [8–11, 12]. A very recent publication states that translations have been, or are being, performed in a total of 17 languages [22]. This facilitates a worldwide use of the patient-reported outcome measure. As the clinician-reported CROST is assessed by the treating surgeons or clinicians, the authors recommend no additional translations besides the original English version.

This study has several limitations. The intra-rater reliability was not assessed due to the study procedures, as it was considered very challenging to see patients back at multiple additional time points across 4 different centers. Secondly, the number of included patients was lesser than initially anticipated, and the contribution of included patients from the 4 centers was not equal. The different amount of spine trauma exposure and local practical difficulties at the centers contributed to this limitation. Also, the patient population was somewhat heterogeneous. Finally, the binary outcome as assessed by the treating surgeon may be somewhat arbitrary. However, we believe this is a valid strategy to assess clinical outcomes, as judged by a highly experienced spine trauma surgeon.

In conclusion, the AO Spine CROST showed moderate results in the current validation study in a true clinical setting including patients from the daily clinical practice. In future studies, the validation will be further investigated among larger patient and clinician samples. With its unique approach as a clinician-rated outcome measure, this tool has the potential to be valuable for use in clinics and research.

Table 1. Patient characteristics. Also stratified per type of treatment as well as per center.

	Total (n=92)	Conservative (n=48)	Surgical (n=44)	Australia (n=24)	Netherlands (n=27)	Slovakia (n=15)	Switzerland (n=26)
Male (%)	64.1	62.5	65.9	62.5	66.7	66.7	61.5
Age, mean (SD)	52.0 (19.7)	54.1 (20.1)	49.7 (19.2)	60.1 (16.7)	44 (20.5)	51.5 (16)	53.1 (20.9)
Trauma cause (%)							
Traffic	19.6	22.9	15.9	33.3	18.5	6.7	15.4
Fall	56.5	62.5	50.0	41.7	66.7	73.3	50.0
Sports	22.8	14.6	31.8	25	14.6	13.3	34.6
Other	1.1	0	2.3	0	0	6.7	0
Surgical treatment (%)	47.8	NA	NA	8.3	55.6	13.3	96.2
Fracture levels							
C spine	22.8	20.8	25.0	37.5	18.5	0	26.9
T spine (T1-T10)	19.6	10.4	29.5	12.5	33.3	6.7	19.2
TL spine (T11-L2)	51.1	60.4	40.9	41.7	44.4	86.7	46.2
L spine (L3-L5)	6.5	8.3	4.5	8.3	3.7	6.7	7.7
Fracture type[a] (%)							
A	80.2	94.9	66.7	77.8	88.0	100	62.5
B	33.3	2.6	61.9	16.7	44.0	0	54.2
C	2.5	0	4.8	0	0	0	8.3
F	4.9	2.6	7.1	5.6	0	0	12.5
Related injuries[b] (%)	50.0	58.3	41.7	45.8	74.1	6.7	53.8
≥1 comorbidities[c] (%)	47.8	52.1	43.2	62.5	55.6	20.0	42.3
ASIA at discharge (%)							
A-C	0	0	0	0	0	0	0
D	9.8	4.2	15.9	12.5	3.7	0	19.2
E	90.2	95.8	84.1	87.5	96.3	100	80.8

[a] fracture type according to the AO Spine Injury Classification system (F= facet fracture in cervical spine). More than one option possible, displayed are percentages of cases.
[b] e.g., costal fractures, soft tissue lesions to extremities, abdominal or thorax trauma, trauma to the skull/cerebrum
[c] e.g., pulmonary, cardiovascular, neurological diseases, diabetes, alcohol abuse, osteoporosis.
NA: not applicable

Table 2. Internal consistency results (Cronbach's α), shown for the AO Spine CROST scores at different study time points (baseline, 6-months, and 1-year follow-up), stratified for the short-term (<12 months) and long-term (≥12 months) anticipated CROST scores, as well as stratified for surgeons (Surgeon 1 and Surgeon 2). Results are shown for all patients (conservative and surgically treated patients, i.e. 8 CROST items scored) and only surgically treated patients (i.e. 10 CROST items scored).

Study time point	Surgeon 1		Surgeon 2	
	All patients (8 items) (n=92)	Surgical only (10 items) (n=44)	All patients (8 items) (n=92)	Surgical only (10 items) (n=44)
Baseline				
Short-term (<12m) CROST scores	0.63	0.60	0.64	0.44
Long-term (≥12m) CROST scores	0.61	0.57	0.69	0.49
6-months follow-up				
Short-term (<12m) CROST scores	0.67	0.71		
Long-term (≥12m) CROST scores	0.70	0.75		
1-year follow-up				
Short-term (<12m) CROST scores	0.59	0.68		
Long-term (≥12m) CROST scores	0.58	0.56		

Table 3. Descriptive and agreement statistics for AO Spine CROST total score, between Surgeon 1 and Surgeon 2 at baseline study time point.

	Surgeon 1 - Mean (SD)	Surgeon 2 - Mean (SD)	% Exact agreement	ICC (95% CI)
Short-term (<12m) CROST scores				
Total sample (n=92)	1.0 (1.4)	0.7 (1.2)	48.9	0.55 (0.38 - 0.68)
Conservative (n=48)	0.7 (1.2)	0.9 (1.4)	64.6	0.81 (0.68 - 0.89)
Surgical (n=44)	1.4 (1.5)	0.5 (0.9)	31.8	0.34 (0.02 - 0.58)
Long-term (≥12m) CROST scores				
Total sample (n=92)	0.9 (1.3)	0.4 (1.0)	57.6	0.52 (0.31 - 0.67)
Conservative (n=48)	1.0 (1.4)	0.5 (1.2)	64.6	0.59 (0.34 - 0.76)
Surgical (n=44)	0.8 (1.2)	0.4 (0.8)	50.0	0.39 (0.11 - 0.61)

Table 4. Descriptive and agreement statistics for each AO Spine CROST item, between Surgeon 1 and Surgeon 2 at baseline study time point (n=92).

	Short-term (<12m) CROST scores				Long-term (≥12m) CROST scores			
CROST item	Surgeon 1, yes-answer (%)	Surgeon 2, yes-answer (%)	% Exact agreement	Kappa	Surgeon 1, yes-answer (%)	Surgeon 2, yes-answer (%)	% Exact agreement	Kappa
1 Neurological deterioration	2	0	97.8	X**	2	0	97.8	X
2 Sagittal alignment problems	4	3	98.9	.85	14	5	89.1	.40
3 Bone quality adverse events	16	10	86.9	.43	21	10	84.8	.42
4 Mechanical stability adverse events	10	4	92.4	.43	8	4	92.4	.33
5 Range of motion impairment	15	13	73.9	.23	18	4	81.5	.13
6 General physical condition	10	13	88.0	.41	9	10	92.4	.55
7 General psychological condition	2	7	93.5	.23	2	2	95.7	-.02
8 Functional recovery problems	22	15	82.6	.43	18	4	83.7	.23
9* Wound healing problems	5	2	97.8	.66	0	0	100	X
10* Implants adverse events	14	2	84.1	-.04	2	7	90.1	-.04

* Only surgical patients (n=44)

** Kappa cannot be computed because one or both variables are a constant

Table 5. AO Spine CROST scores for the short-term (<12-months) as scored at baseline study time point compared to assessed outcomes ('same/better' versus 'worse' outcome than expected) at the follow-up: 6-months (n=89) and at 1-year (n=75) study time points. Results are shown for the total patient sample as well as for conservatively and surgically treated patients.

	Total sample				Conservative				Surgical			
	6M follow-up, n (%)		1Y follow-up, n (%)		6M follow-up, n (%)		1Y follow-up, n (%)		6M follow-up, n (%)		1Y follow-up, n (%)	
CROST score	Same/ better (n=76)	Worse (n=13)	Same/ better (n=63)	Worse (n=12)	Same/ better (n=38)	Worse (n=8)	Same/ better (n=31)	Worse (n=4)	Same/ better (n=38)	Worse (n=5)	Same/ better (n=32)	Worse (n=8)
0	40 (87.0)	6 (13)	34 (87.2)	5 (12.8)	25 (83.3)	5 (16.7)	20 (87.0)	3 (13)	15 (93.8)	1 (6.3)	14 (87.5)	2 (12.5)
1	17 (89.5)	2 (10.5)	15 (78.9)	4 (21.1)	6 (75.0)	2 (25.0)	6 (85.7)	1 (14.3)	11 (100)	0 (0)	9 (75.0)	3 (25.0)
≥2	19 (79.2)	5 (21.8)	14 (82.4)	3 (17.6)	7 (87.5)	1 (12.5)	5 (100)	0 (0)	12 (75)	4 (25)	9 (75.0)	3 (25.0)

Table 6. Spearman correlations (r_s) between AO Spine CROST scores at baseline and 6-months and 1-year follow-up study time points. Results are shown for the total patient sample as well as for conservatively and surgically treated patients.

	Total sample		Conservative		Surgical	
	6M follow-up (n=89)	1Y follow-up (n=75)	6M follow-up (n=46)	1Y follow-up (n=35)	6M follow-up (n=43)	1Y follow-up (n=40)
Short-term (<12m) CROST scores	.61***	.41***	.58***	.28	.63***	.46***
Long-term (≥12m) CROST scores	.58***	.41***	.51***	.20	.64***	.62***

*** p<.001

Table 7. Relationships between short-term (<12 months) AO Spine CROST as scored at baseline study time point, in comparison to AO Spine PROST scores at baseline and follow-up study time points (6-months and 1-year). Results are shown for the total patient sample as well as for conservatively and surgically treated patients.

	Total sample			Conservative			Surgical		
Short-term (<12m) CROST scores	PROST baseline (n=84)	PROST at 6M (n=74)	PROST at 1Y (n=67)	PROST baseline (n=48)	PROST at 6M (n=42)	PROST at 1Y (n=32)	PROST baseline (n=36)	PROST at 6M (n=32)	PROST at 1Y (n=35)
0	59.4 (19.3)	79.5 (17.6)	84.5 (15.4)	54.9 (19.6)	76.9 (19.3)	82.1 (17.4)	69.1 (14.8)	85.2 (12.0)	88.0 (11.6)
1	63.7 (19.4)	83.0 (10.1)	87.1 (12.1)	62.5 (19.5)	81.0 (10.6)	82.7 (15.2)	64.7 (20.2)	84.6 (10.1)	90.4 (8.8)
≥2	54.1 (20.4)	72.3 (21.6)	78.7 (17.9)	51.0 (20.2)	76.0 (17.6)	78.4 (19.8)	56.6 (21.2)	69.7 (24.5)	78.8 (17.9)
All	59.1 (19.6)	78.6 (17.5)	83.6 (15.5)	55.6 (19.6)	77.4 (17.6)	81.6 (16.9)	63.9 (18.8)	63.9 (18.8)	85.4 (14.1)

NB: none of the differences in PROST scores are statistically significant

Table 8. Spearman correlations between change in AO Spine CROST scores and change in AO Spine PROST scores as compared between baseline to 6-months and 1-year follow-up study time points. Results are shown for the total patient sample as well as for conservatively and surgically treated patients.

	Total sample		Conservative		Surgical	
	Baseline to 6M	Baseline to 1Y	Baseline to 6M	Baseline to 1Y	Baseline to 6M	Baseline to 1Y
Short-term (<12m) CROST scores	0.07	-0.30	0.02	-0.33	0.06	-0.30

Table 9. Relationships between assessed outcomes ('same/better' versus 'worse' outcome than expected) in comparison to mean AO Spine PROST scores (SD) at 6-months and at 1-year follow-up study time points. Results are shown for the total patient sample as well as for conservatively and surgically treated patients.

	Total sample		Conservative		Surgical	
Assessed outcome	PROST 6M (n=73)	PROST 1Y (n=65)	PROST 6M (n=42)	PROST 1Y (n=32)	PROST 6M (n=31)	PROST 1Y (n=33)
Same/better	82.6 (13.3)	87.5 (11.9)	81.3 (14.4)	84.3 (14.4)	84.3 (12.2)	90.1 (7.3)
Worse	51.0 (20.2)*	60.0 (15.8)*	53.8 (19.5)*	55.4 (19.1)*	45.5 (24.8)*	62.8 (15.1)*

* p<.001

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Supplement 1 AO Spine Clinician Reported Outcome Spine Trauma

AO SPINE

AO Spine Clinician Reported Outcome Spine Trauma (AO Spine CROST)

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

Patient Name: ________________________

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

Patient ID: ________________________
(to be filled in by the health professional)

Please rate the following parameters:

Parameter	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

Study identification code: ____________
(To be filled in by the health professional)

Source: Sadiqi, S., de Gendt, E.E.A., Muijs, S.P.J. et al. Validation of the AO Spine CROST (Clinician Reported Outcome Spine Trauma) in the clinical setting. Eur Spine J 33, 1607-1616 (2024). https://doi.org/10.1007/s00586-024-08145-5

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Parameter	In the next 12 months		From 12 months onwards	
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 only if the patient is treated surgically				
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
	In the next 12 months		**From 12 months onwards**	
Total score:				

Each 'yes'-answer provides 1 point.

The total score is the sum of each 'yes'-answer, with a maximum of 8 points for non-surgically treated patients, and 10 points for surgically treated patients.

A higher score indicates worse expected outcome.

The score guides the treating surgeon in anticipating a change to the current treatment plan.

Study identification code: ________________

(To be filled in by the health professional)

Part II:

Spinal Posttraumatic Deformity: creating a uniform term and definition

4

Chapter 4

The Current Status of Spinal Posttraumatic Deformity: A Systematic Review

Erin E. A. De Gendt, MD , Timon F. G. Vercoulen, MD , Andrei F. Joaquim, MD, PhD, Wei Guo, MD, PhD , Emiliano N. Vialle, MD, PhD , Gregory D. Schroeder, MD, PhD , Klaus S. Schnake, MD, PhD , Alexander R. Vaccaro, MD, PhD , Lorin Michael Benneker, MD, PhD , Sander P. J. Muijs, MD, PhD , and F. Cumhur Oner, MD, PhD

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Abstract

Study Design. Systematic Review. Objective: To systematically analyze the definitions and descriptions in literature of "Spinal Posttraumatic Deformity" (SPTD) in order to support the development of a uniform and comprehensive definition of clinically relevant SPTD.

Methods. A literature search in 11 international databases was performed using "deformity" AND "posttraumatic" and its synonyms. When an original definition or a description of SPTD (Patient factors, Radiological outcomes, Patient Reported Outcome Measurements and Surgical indication) was present the article was included. The retrieved articles were assessed for methodological quality and the presented data was extracted.

Results. 46 articles met the inclusion criteria. "Symptomatic SPTD" was mentioned multiple times as an entity, however any description of "symptomatic SPTD" was not found. Pain was mentioned as a key factor in SPTD. Other patient related parameters were (progression of) neurological deficit, bone quality, age, comorbidities and functional disability. Various ways were used to determine the amount of deformity on radiographs. The amount of deformity ranged from not deviant for normal to >30°. Sagittal balance and spinopelvic parameters such as the Pelvic Incidence, Pelvic Tilt and Sacral Slope were taken into account and were used as surgical indicators and preoperative planning. The Visual Analog Scale for pain and the Oswestry Disability Index were used mostly to evaluate surgical intervention.

Conclusion. A clear-cut definition or consensus is not available in the literature about clinically relevant SPTD. Our research acts as the basis for international efforts for the development of a definition of SPTD.

Keywords: spinal posttraumatic deformity, posttraumatic kyphosis, systematic review, spine trauma

INTRODUCTION

A trauma to the spine was registered in 17% (144.909/861.888 incidents) of total traumatic incidents of the population in the USA in 2015.[1] Some degree of deformity is common after spine trauma, regardless of the treatment.[2–13] According to White et al. and Whitesides et al., even a small degree of kyphosis, by increasing the moment arm, can lead to a progressive deformity over the years; [14,15] however, at which point a posttraumatic deformity of the spine becomes clinically 'relevant' or symptomatic is still up for debate. This 'Spinal Posttraumatic Deformity' (SPTD) can require extensive surgery with high risk of complications and is more aggressive than treatment of the primary injury itself.[16–18] Indications for such surgical interventions for patients suffering from SPTD differ in literature.

The etiology of SPTD is multifactorial and the key factors are still unknown. Some examples of the factors involved are wrong or delayed fracture diagnosis, failure of treatment (either non-surgical or surgical), intervertebral disc (IVD)-injury and diseases influencing the bone quality.[12,16–22] SPTD has been described in various ways using clinical symptoms, kyphotic angles and other spine-related measurements on radiographs and Patient Reported Outcomes Measures (PROMs).

A decade ago, Schoenfeld et al. published a survey to reach consensus about SPTD. A definition on which consensus between experts was reached was 'a painful kyphotic deformity', but no further specifics related to define SPTD reached a consensus.[23] This basic definition results in no practical conclusion to be used in clinical practice. Moreover, this definition does not consider the different spine regions. The absence of a clear definition of 'clinically relevant' SPTD limits the possibilities to compare different treatments and prognostic factors involved. The aim of this study is to systematically review and evaluate the current definitions and descriptions of SPTD and which patient factors, radiological assessments and surgical indications are part of SPTD in literature. This will be the first step in gathering broad information to support the development of a uniform and comprehensive definition of SPTD in follow-up research.

METHODS

Protocol and registration

This review was structured using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Statement (PRISMA-statement).[24] The protocol was registered in PROSPERO (registration number:CRD42019122293).

Eligibility criteria, Information sources and search strategy

A literature search in Pubmed, Embase, Scopus and eight other international databases was performed using the search terms deformity and posttraumatic and its synonyms (Table 1), from 1950 until the present (date of search:23-12-2019). The search was limited to title and abstract using the correct field description. No language was excluded.

Study selection

All articles were screened on title and abstract by two independent observers (EDG, TV) after removal of duplicates using Rayyan QRCI (web application, Qatar Computing Research Institute (Data Analytics), Doha, Qatar). Articles were included if they concerned adults (≥18 years) and if: a definition of SPTD was given; the indication for treatment was SPTD; SPTD was mentioned as a diagnosis; or when recurrent kyphosis was evident after acute fracture. Any discrepancies between the two observers were resolved by discussion and if necessary, by consulting a senior independent author (SPJM). The full texts were screened on the in- and exclusion criteria and included on consensus by the two observers. The first author was contacted when a full text was not available. Exclusion criteria were absent full text, review articles, patients <18 years, no mention of SPTD and congress abstracts. A cross-reference check was performed.

Data collection process & Data items

The characteristics of the articles were assessed by extracting year of publication, type of study, spine level of interest and number of patients included. All the data was extracted by two independent observers. Discrepancies were resolved by discussion. The descriptions of SPTD were extracted and placed in four categories: Patient factors(e.g. pain, neurology), Radiological Outcomes (e.g. amount of deformity, radiographic diagnosis entity), PROMs and Surgical indication.

Risk of bias per study

Methodological quality was reviewed using the PRISMA-statement.[24] Because of the nature of the research questions the articles were critically appraised by our own system and applied by two observers independently. The quality assessment was based on the presence of an original description or definition of SPTD. If: no original description or definition; just mentioning of SPTD without a description or recurrent kyphosis without additional information was given; the study was excluded based upon poor quality for the aim of this study. All types of study design were considered.

Summary & Synthesis

The terms/descriptions per category of SPTD were extracted from the included articles and placed in a table by both observers. As the data is qualitative data a narrative synthesis was drafted, when certain terms were stated by multiple articles cumulative results were given.

RESULTS

Search, Study Selection

In total, 1.675 articles were found in the searched databases of which 332 articles were included in full text analysis, Figure 1 displays the full search strategy. The cross-reference check showed one article which only mentioned SPTD and was excluded for the analysis. The included articles were placed in two categories: 'Definition of SPTD' (9 articles) and 'SPTD Surgical Indication' (37 articles). The study designs were: Expert opinion, Survey, Case reports, Case-series and Cohort studies. A chronological overview of the included articles and the extracted data can be found in Tables 2, 3a and 3b.

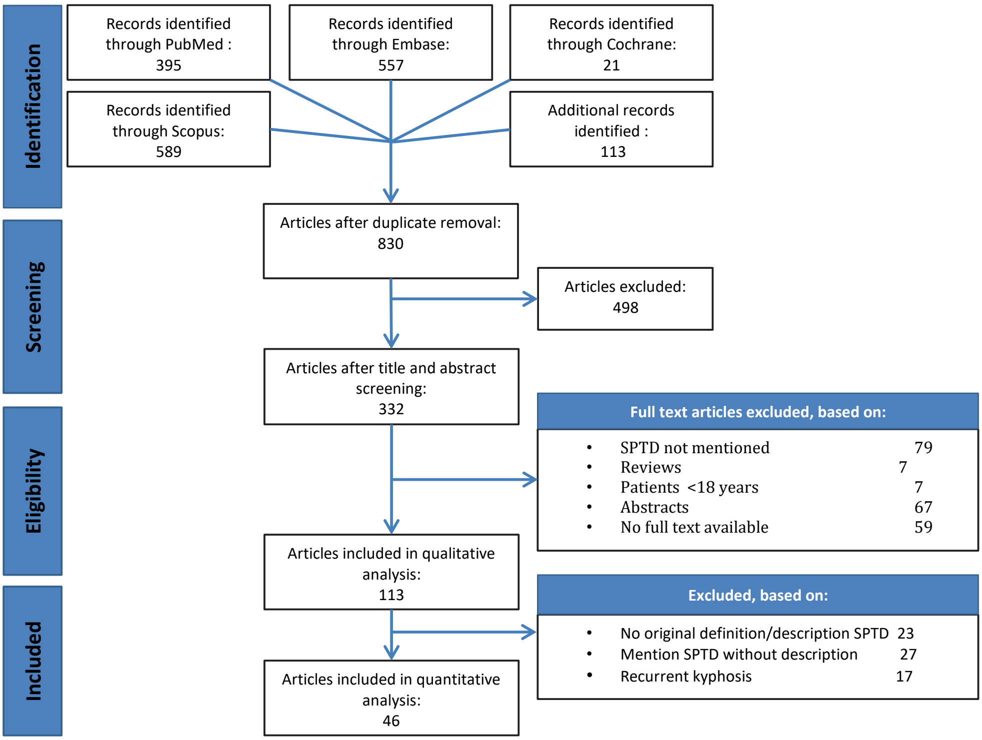

Figure 1. Flow chart of the conducted search for the definition or description of SPTD following the PRISMA-statement.

Table 1: Full search strategy for the PubMed-database. The search string was adjusted accordingly to fit each different database. The search was performed on 23-12-2019.

Database	
PubMed	(((scolio*[Title/Abstract]) OR kypho*[Title/Abstract]) OR spinal deform*[Title/Abstract]) AND ((post[Title/Abstract] AND trauma*[Title/Abstract]) OR posttrauma*[Title/Abstract] OR postrauma*[Title/Abstract])
All databases	Pubmed, Embase, Scopus, Global Clinical Trial Data, Cochrane library, SUDOC, Red de Revistas Científicas de América Latina y el Caribe, España y Portugal, eLibrary.ru, J-Stage and CNKI.net

Table 2: Overview of the study characteristics of the 46 articles included in the quantitative analysis. The first nine articles gave a specific definition of SPTD, the other 37 articles presented an original description of SPTD.

Reference ***SPTD Definition***	Year	Study type	Spine region of interest	Number of patients with SPTD
White et al[14]	1977	Expert Opinion	C, Th, L	NA
Malcolm et al[31]	1979	Expert Opinion	Whole spine	NA
Rusu et al[33]	2007	Expert Opinion	ThL	NA
Kandziora et al[36]	2009	Expert Opinion	ThL	NA
Munting et al[34]	2010	Expert Opinion	Th, L	NA
Schoenfeld et al[23]	2010	Survey, Expert Opinion	CTh, Th, L	NA
Suchomel et al[53]	2010	Expert Opinion	Upper C	NA
Cecchinato et al[48]	2014	Expert Opinion	ThL	NA
Boehm et al[44]	2017	Expert Opinion	Th, L	NA
SPTD Surgical indication				
Malcolm et al[32]	1981	Retrospective Cohort	Th, L	48
McBride et al[28]	1983	Case Series	ThL	6
Boni et al[57]	1984	Retrospective Cohort	C	10
Kostuik et al[69]	1984	Retrospective Cohort	Th, L	20
Roberson et al[70]	1985	Cohort	Th, L	34
Dick et al[71]	1987	Cohort	-	20
Kostuik et al[47]	1989	Retrospective Cohort	Th, L	37
Gertzbein et al[67]	1992	Case Series, Expert Opinion	Th	3
Chang et al[72]	1993	Case Series	ThL, L	17
Wu et al[29]	1996	Case Series	ThL, L	13
Atici et al[37]	2004	Retrospective Cohort	Th, L	10
Been et al[38]	2004	Retrospective Cohort	Th, L	25
Robertson et al[73]	2004	Case Series	-	10
Stoltze et al[51]	2008	Retrospective Cohort, Expert opinion	Th, L	268
Chou et al[74]	2009	Case Report	ThL	2
Zhang et al[39]	2010	Case Series	ThL	5
El-Sharkawi et al[40]	2011	Prospective cohort with retrospective control	ThL, L	80
Wang et al[75]	2012	Retrospective Cohort	ThL	21
Noor et al[76]	2013	Expert opinion	Th, ThL	NA
Omidi-Kashani et al[77]	2013	Retrospective Cohort	ThL	26
Xi et al[25]	2013	Retrospective Cohort	ThL	19
He et al[54]	2013	Retrospective Cohort	ThL	10
Obeid et al[41]	2013	Case Report	High Th	1

Table 2: Continued

Reference	Year	Study type	Spine region of interest	Number of patients with SPTD
Soultanis et al[42]	2014	Retrospective Cohort	Th, L, S	32
Shigematsu et al[43]	2014	Case Report	Th12	1
Yagi et al[26]	2015	Retrospective Cohort	NA	158
Gao et al[78]	2015	Retrospective Cohort	Th11-L2	89
Bourghli et al[49]	2015	Retrospective Cohort	ThL	10
Liu et al[35]	2015	Case Report	L1	1
Hu et al[55]	2016	Retrospective Cohort	ThL	46
Chen et al[27]	2016	Prospective Cohort	Th-L	58
Wang et al[56]	2016	Randomized Controlled Trial	ThL	43
Li et al[30]	2017	Retrospective Cohort	ThL	12
Rerikh et al[46]	2017	Retrospective Cohort	Th-L	45
El Nagger et al[52]	2018	Prospective Cohort	ThL	12
Matsumoto et al[45]	2018	Retrospective Cohort	ThL	20
Avila et al[79]	2019	Prospective multiple cohort	Th9-L3	30

SPTD = Spinal Posttraumatic Deformity;
C = cervical spine, Th = thoracic spine; L = lumbar spine; S = sacral spine; NA = not available

General

Used synonyms of SPTD were: late kyphotic deformity, chronic vertebral instability, (severe) posttraumatic kyphosis and symptomatic posttraumatic deformity. Asymptomatic SPTD exists according to Schoenfeld et al.[23] The presentation of patients with SPTD was between 3 months and 36 years after the primary spine injury. Only four articles addressed the cervical spine.

Patient factors

Multiple patient factors were described as an element of SPTD in the included articles. The most common factor was pain which was mentioned in 38 of the 46 articles. Pain may be originating from different regions: the injured vertebra itself due to mechanical instability/pseudoarthrosis, other regions of the spine due to degeneration of the compensatory segments, IVD-lesions, or due to the fatigue of the tendinomuscular apparatus as a compensatory mechanism. Another patient factor mentioned in 29 of the 48 articles was the presence of a (pre-existing or increasing) neurological deficit. Clinical neurology was classified and evaluated using the American Spinal Injury Association Impairment Scale (ASIA)[25–27] or Frankel grade.[28–30]

Other factors mentioned were, in order of frequency; noticeable progression of deformity, functional disability, cosmetic appearance, diseases affecting bone quality, skin ulceration, inability to maintain a forward gaze, respiratory insufficiency, spinal crepitus, impaired sitting or standing, body habitus, inability to work and problems with hygiene.[29–43]

Radiology

Diagnostic tests, amount of deformity and surgical planning

The radiological workup to diagnose SPTD or for surgical planning was not clearly differentiated; therefore the results were combined. Regional and full standing lateral and anteroposterior radiographs of the spine were used by all but one article. Five different ways to measure the amount of deformity were described and 16 articles did not mention the way of measurement. The majority of the deformity angles were measured as proposed by Cobb (25 articles), between the upper endplate of the vertebra cranial of the affected vertebra and the lower endplate of the vertebra caudal to the affected vertebra. Other measurements were: between the upper and lower endplate of the injured vertebra (sometimes called 'wedge angle'), between the lower or the upper endplate of the vertebra cranial and the lower endplate of the injured vertebra.

The amount of deformity to diagnose or treat SPTD was very diverse and depended on the way of measurement. The cut-off deformity angles for SPTD ranged from 'different from the normal anatomy of the spine' to >30^0. The majority of the articles included patients with deformities on different levels of the spine (i.e. T3-L2) but used the same cut-off value for each individual patient regardless of level of deformity. Some articles only gave a median or average of the angular deformities at different levels. Three articles used the SRS-criteria for adult spinal deformity to see if the deformity exceeded the normal anatomy of the spine.[44–46] All these different amounts of deformity were defined as SPTD.

Other methods to diagnose SPTD or plan a surgery were: flexion-extension radiographs (11 articles), myelography (three articles), Computerized Tomography (CT) scan (19 articles) and Magnetic Resonance Imaging (MR) scan (13 articles). Flexion-extension radiographs were used to assess mechanical instability and the rigidity of the deformity. Myelography was used to depict the neurological anatomy.[36,37,47] CT scan was used to assess the presence of pseudoarthrosis (i.e. non-union or non-healed fracture), pre-operative bony anatomy, to assess the facet joints and the spinal canal encroachment and to use 3D images for planning. MR scan was used to evaluate the neurological involvement, the posterior ligamentous complex (PLC) injury and to exclude a syrinx.

Spinopelvic parameters in SPTD

In recent papers, spinopelvic parameters were included in the definition, diagnosis and treatment of SPTD. The spinopelvic parameters were: the C7-plumbline or the Sagittal Vertical Alignment (SVA) for sagittal balance; and the pelvic parameters such as the Pelvic Tilt (PT), Sacral Slope (SS) and Pelvic Incidence (PI) to assess compensation in the pelvis.[44,48–50] All parameters were measured on standing full spine lateral radiographs, including the hip joints and preferably the base of the skull. The C7-plumbline was described in seven articles. Imbalance was present when the plumbline fell outside the sacrum. A SVA >50 mm was scored as an imbalance in six articles. Compensation was suspected in three articles if deviation of the normal spinal alignment, as stated by the Scoliosis Research Society, was present.[44–46] Other signs of compensation mechanisms were: a PT >20 or a PT higher than expected; and an increased PT with flexion of the hips.[48,51] Kandziora et al. and Boehm et al. stated that the spinopelvic parameters could discern between two types of SPTD: 1. the compensated and/or sagittal balanced; 2. the sagittal imbalanced.[41,44]

Patient Reported Outcomes Measurements

Different PROMs were performed to evaluate a treatment in 23 articles. The PROMs used were: Visual Analogue Scale (VAS) for pain, Oswestry Disability Index (ODI), patient satisfaction, Japanese Orthopedic Association (JOA) score of back pain and back pain scoring by Greenough and Fraser. Cecchinato et al. stated that a patient with VAS pain scale of <70/100 and an ODI of <20/100 would less likely benefit from surgical intervention. A patient with VAS pain scale >70/100 or an ODI >40/100 would benefit from surgical intervention.[4]8 El Nagger et al. only included patients in his study with severe SPTD and back pain affecting quality of life defined as a VAS>5 and an ODI >40.[52]

Surgical indication

Surgical indications of patients with SPTD are described in 42 articles. Description of the indication range from 'symptomatic' or 'rigid' SPTD [29,32,37] to explicit requirements on patient factors, radiological parameters and PROMs. Refractory pain or increasing pain after conservative therapy was described in nine articles.[25,41,43,48,52–56] Nineteen articles considered a progressive neurological deficit an absolute indication for surgical intervention. Progression can result from tension on the spinal cord, stenosis or a syrinx. Stoltze et al. recommended differentiating between vertebral pain and neurological pain, to avoid disappointing results after surgical treatment.[51] Boni et al. indicated surgical treatment when a cervical myelopathy due to stenosis, without specific kyphosis, was present in a patient.[57]

DISCUSSION

In this systematic review, we gave an overview of the descriptions of 'Spinal Posttraumatic Deformity'. We explored four different domains that were used to describe SPTD. A clear-cut definition was absent in the literature.

We displayed the heterogeneity in the reported factors: the amount of deformity and method measurement, the use of spinopelvic parameters and the use of PROM's. This great heterogeneity can be attributed to different study formats and the fact that no specific description of SPTD was sought, in all but two articles.[14,58]

There is a relative lack of articles describing Cervical SPTD. This can be explained by the fact that most fractures occur in the thoracic and lumbar spine.[59] Another potential reason may be that cervical fractures are more prone for surgical treatment and are not influenced by the body weight, suggested as a factor of progressive deformity.[36,60]

The existence of asymptomatic SPTD is plausible as 'symptomatic' SPTD is mentioned often. Schoenfeld et al. concluded that asymptomatic SPTD does exist with agreement from all respondents.[58] However patients with SPTD almost exclusively suffer back pain in literature.

The amount of deformity in SPTD is measured in many different ways and the amount of deformity varies greatly, this is in agreement with a survey performed by Sadiqi et al.[61] The methods used most in our review (Cobb and wedge angle) have been shown to have a high intra- and interrater reliability.[62]

A major concern is the reporting of a mean or median kyphotic angle combining different spine regions within the same study. The regions of the spine have a different alignment, which means that an angle 30° in the high thoracic spine or the lumbar spine has different consequences. Some articles addressed this by using the Sagittal Index, the SRS-criteria or the Effective Regional Deformity.[31,39,44–46,48,52,55]

Spinopelvic parameters are of great importance to assess the spine and are extensively studied in the context of degenerative spine diseases as opposed to the context of a traumatic spine. Already, the use of various spinopelvic parameters in Adult Spinal Deformity is encouraged for surgical planning.[63,64] Matsumoto et al. suggested that if patients with SPTD compensated by increasing lumbar lordosis and thus maintained a SVA <50mm, achieved good global spinal balance after surgical intervention combined with a decrease in lumbar lordosis.[45] Koller et al. looked for correlations between spinal alignment and regional kyphosis in 146 patients treated conservatively after a thoracolumbar burst fracture. They found that lumbo-sacral lordosis had a significant correlation with regional kyphosis and segmental kyphosis at follow-up (average 9,5 years).[65] Rousseau et al. looked at sagittal rebalancing after pedicle subtraction osteotomy in the lumbar spine for a multitude of etiologies, including SPTD. They found that patients with SPTD responded differently with a local lumbar lordosis gain, but no real reorientation of the pelvis was seen.[66] Spinopelvic parameters show promising correlation with SPTD, the question remains if certain values increase the risk of development of SPTD.

Contradictory correlations between SPTD and different factors were found. For example, a correlation between SPTD, pain and kyphosis>30 degree was found [67], however others disagree.[68] Malcolm et al. stated that body habitus and IVD injury play a role in the development of SPTD.[36] Rerikh et al. found an inverse correlation of hyperlordosis/hyperkyphosis with the amount of thoracic kyphosis and lumbar lordosis. Also, a correlation was found between the deviation of SVA and the ODI and VAS of pain.[46] All these correlations were studied with different definitions of SPTD and are therefore difficult to interpret, compare and repeat.

Surgical indication of patients with SPTD was based on factors such as pain, progression of neurology, amount of deformity or 'symptomatic' patients. Buchowski et al. concluded in their review that pain was not an absolute indication for a surgical intervention contrary to some articles in our review.[17] Of note, pain without radiological deformity after a spine trauma would be out of the context of SPTD. Due to the great variance in the surgical indications and definitions of SPTD, comparing effectiveness of interventions is not possible.

This review reflects the evolving concepts of SPTD over the last decades. For example, more recently PROMs are used increasingly in evaluation of patients with SPTD. Another striking point was the radiological assessments used to diagnose or describe SPTD. Some imaging techniques were not widely available and specific in the second half of the 20th century and were therefor not part of the description of SPTD. The way we see spinal trauma and treat it evolved throughout the last decades, this also influences the meaning of a posttraumatic spinal deformity. The evolving vision on SPTD could partly explain the differences in descriptions throughout the years.

International efforts resulted in translation of all foreign languages by natives or capable readers. Two possible limitations of this study are both related to the nature of our research question. First, we searched for a description of SPTD which can be an opinion of an author. A risk-assessment as proposed by the PRISMA-statement was not applicable in our research. Normally Expert Opinion and Case Reports are rated as a high risk of bias, but in our study, it was occasionally the 'best available evidence'. The quality of the articles that only mentioned SPTD without a description were considered low because they did not add value to the understanding of SPTD. The 'recurrent kyphosis after fracture' articles could provide some insights on the possible risk factors in SPTD. They were also considered as low quality because a clear description to the recurrent kyphosis was not given other than that is was significantly different than before primary treatment. A second limitation of this study was the narrative character of the review. It is however not possible to find a definition or description by meta-analysis in this case. A last limitation is the number of articles excluded for inability to retrieve the full texts.

Kyphosis (or synonym) is used multiple times as a part of the definition of SPTD in current literature. A deformity after trauma, however, can be of a different shape. We propose, for future clinicians and researchers, that the more neutral Spinal Posttraumatic Deformity will be used to avoid inaccuracy.

Future research should focus on reaching a consensus on the definition of SPTD. Armed with a new definition, factors can be identified which lead to SPTD in an, ideally prospective, observational cohort of patients with vertebral fractures. In the ideal situation SPTD can be prevented if the contributing factors are addressed accordingly and timely.

Table 3a

Reference	Patient factors	Radiology	Cutoff values	Spinopelvic	Cutoff values	Patient Reported Outcome Measurements	Surgical indication
White et al[14]	-	- - Cobb	Th >30° C/L > 5° or any posterior curvature	-	-	-	-
Malcolm et al[31]	Body habitus, pain (partly discs), spinal crepitus, impaired sitting/ standing, ulceration, respiratory insufficiency, increased neurological deficit,	X Standing/sitting FS AP+Lat X flex/ext, lat bending Tomography Myelography (decompression) CAT-scan	-	-	-	-	Chronic cases depending on severity of presenting signs and symptoms
Rusu et al [33]	Pain, inability to work, deformities in clinical exam, neurological deficit (spasticity)	X Th/L AP+Lat - Cobb - Wedge angle - Segmental angle CT: planning surgery MRI: soft tissue, neurologic involvement	-	-	-	-	Clinical symptoms most important: pain, neurological deficit Cobb>20 °
Kandziora et al[36]	Osteoporosis, refusal of therapy. Cardiac, pulmonic and abdominal dysfunction	X Standing FS AP+Lat X flex/ext: MRI exclude syrinx CT surgical planning and excl non union	-	C7plumbline, ThK (T2-T12); LL (T12-S1)/ (L2-S1); ThL (T10-L2)	Deviation from normal ThK: +35° (20°-50°) LL -55°(-45°-65°) LL -50° (-40°-60°) ThL 0°	-	Pain unresponsive to therapy and physiotherapy; Neurological deficit (radiculopathy, myelopathy with claudication); Posttraumatic syrinx; Instability because of non-union Cosmetic appearance

Table 3a: Continued

Reference	Patient factors	Radiology	Cutoff values	Spinopelvic	Cutoff values	Patient Reported Outcome Measurements	Surgical indication
Munting et al[34]	Nociceptive sensitivity, age, pain, deformity, function, forward gaze, psychosocial problems, neurological deficit, cosmetic	X Standing FS: - SI	>20 °		Hyperlordosis L, hypo-/ or hyperkyphosis Th	Altered function	
Schoenfeld et al[23]	Pain, progressive deformity and deteriorating neurology (rare), A3/B1/B2 fractures Asymptomatic SPTD does exist	X regional flex/ext - Cobb - Wedge angle MRI: Posterior Ligament Complex, spinal cord, Intervertebral discs CT: bony anatomy, non-union, facet joints Discography	5-30 °	C7 plumbline	Imbalance relative to sacral endplate	-	Proposed definition: Painful kyphotic deformity in posttraumatic spine.
Suchomel et al[53]	Pain dependent on neck rotation, occipital pain, reduced neck mobility, myelopathy, vascular compromise; No specific clinical presentation	X C AP+Lat, Flex/ext CT: anatomy MRI: capacity spinal canal, neural compression	-	-	-	-	Cons: mild and stable deformity without neurological symptoms. Elderly and multiple comorbidities. Surg: neurological compromise, intractable pain as result of malalignment
Cecchinato et al[48]	-	X FS AP+Lat	SI <15° compensation possible; SI >20° symptoms and in need of management	C7 plumbline, C7/SVA, PI, PT, ThK, LL	PT > 20° or high compared to expected PT	VAS <70/100 or ODI <20/100 less likely to benefit from surgery; VAS high or ODI >40 more benefit from surgery	No response conservative treatment Sagittal index >20° PT > 20° or high compared to expected PT Lumbar hyper-/ OR hypolordosis

Table 3a: Continued

Reference	Patient factors	Radiology	Cutoff values	Spinopelvic	Cutoff values	Patient Reported Outcome Measurements	Surgical indication
Boehm et al[44]	Load dependent pain, compensatory mechanisms, deviations of physiological curves during standing and walking, neurological deficit	X standing FS AP+Lat X functional (rigid, instability, correction potential) MR: ligaments, neurological structures, canal compromise CT: nonunion, anatomy	Deviation from SRS: T1–5: ≥20° T5–12: ≥50° T10–L2: ≥20° T12–S1: ≥40°	C7-plumbline ThK ThL LL PI, PT, SS	-	-	Cons: Pain free deformity Surg: deformity, instability, stenosis >20° at former fracture site, pain at index level or other locations, neurological deficit. >15-20° should be corrected.

X: radiograph; AP+Lat: anteroposterior and lateral views; C: Cervical, Th: thoracic vertebra, L: lumbar

CT: Computer Tomography; MR: magnetic resonance imaging; FS: full spine

Cobb: upper endplate of vertebra cranial and lower endplate of vertebra caudal

SRS-criteria: Scoliosis Research Society criteria

SVA: Sagittal Vertical Axis; PT: Pelvic tilt, SS: Sacral Slope, PI: Pelvic Incidence; ThK: thoracic kyphosis, LL: lumbar lordosis, ThL: thoracolumbar

ERD: Effective Regional Deformity, SI: Sagittal index

VASpain: visual analogue scale of pain, ODI: Oswestry Disability Index,

Cons: Conservative treatment, Surg: surgical treatment

Table 3b

Reference	Patient factors	Radiology	Cutoff values	Spinopelvic	Cutoff values	Patient Reported Outcome Measurements	Surgical indication
Malcolm et al[32]	Pain: apical constant aching, reduced by recumbency, ThL deformity had radiation to buttocks, progression of kyphosis, spinal crepitus; neurological deficit	X Standing/sitting FS AP+Lat Cobb X flex/ext X lateral bending in scoliosis Tomography Myelography: neurology	-	-	-	pain	Symptomatic PTK
McBride et al[28]	Back pain at the apex of kyphosis, radicular pain or hypesthesia, urinary incontinence/urgency, rectal tenesmus or spasm, focal motor weakness (Frankel)	X Standing FS AP+Lat, flex/ext CAT, lateral planograms: spinal canal encroachment Myelography: neurological involvement	-	-	-	-	1. persistent or increasing neurological deficit or radicular pain, with anterior bony impingement, compromising at least 25% of spinal canal; 2. failed posterior instrumentation and fusion attempts with unstable, painful pseudarthrosis and kyphosis
Boni et al[57]	Neurological deficit	X C AP-Lat X C dynamic: residual mobility	-	-	-	-	Stenosis of 3 or more intersomatic spaces with myelopathy
Kostuik et al[69]	Pain, progressive deformity, with/without neurological involvement	X regional AP+Lat CAT	-	-	-	Pain	Painful and/or progressive kyphotic deformities with or without neurologic involvement
Roberson et al[70]	Pain, deformity, neural embarrassment, incomplete rehabilitation	X regional Tomography Occasionally CT	-	-	-	Pain relieve poor, fair or good	Increasing kyphotic deformity, pain, or increasing neurologic deficit
Dick et al[71]	Severe pain	X Reg: kyphosis angle: upper endplate of vertebra above and lower endplate of fractured vertebra	-	-	-	-	Severe pain with failure of previous treatment

Table 3b: Continued

Reference	Patient factors	Radiology	Cutoff values	Spinopelvic	Cutoff values	Patient Reported Outcome Measurements	Surgical indication
Kostuik et al[47]	Pain at apex and/or levels below, neurological deficit, limited walking	X regional AP+Lat Kyphosis angle: measured between cranial and caudal instrumented levels CAT Myelography Discography	-	-	-	Pain	Kyphosis angle >30° Symptomatic PTK
Gertzbein et al[67]	With or without neurology, with or without mechanical back pain, facet pain	X regional AP+Lat 'Cobb' (lower endplate cranial vertebra and lower endplate of fractured vertebra)		-	-	-	Symptomatic PTK with Cobb >30°, for the described procedure; but Cobb <30° is not excluding factor for other surgical treatment
Chang et al[72]	Neurological deficit (Eismont muscle strength evaluation), progressive back pain, fatigue	X Standing AP+Lat: Cobb X flex/ext: rigidity CT or Tomography: neurological topography	-	-	-	-	Progression of deformity and low back pain, constant fatigue with rigid kyphosis on flex/ext radiographs
Wu et al[29]	Pain, neurologic compromise (Frankel), disabled, pressure sores, fatigue, progressive deformity	X reg AP/Lat Cobb X Flex/ext	-	-	-	-	Rigid PTK
Atici et al[37]	Back pain at apex, neurological deficit, cosmetic	X-ray: Cobb	Th >30 ° L > 20 °	-	-	-	Th > 30°, L >20° or neurological deficit
Been et al[38]	Pain (apex or compensatory), neurological damage or progression, skin problems	X regional Standing AP+Lat Cobb Scoliotic angle (Cobb method) CT: spinal canal	-	-	-	back pain scoring: Greenough and Fraser. VAS pain, same surgery again?	Symptomatic ThL PTK, pain not responding to conservative treatment.

Table 3b: Continued

Reference	Patient factors	Radiology	Cutoff values	Spinopelvic	Cutoff values	Patient Reported Outcome Measurements	Surgical indication
Robertson et al[73]	-	X regional AP+Lat Cobb Coronal plane deformity	-	-	-	-	Late reconstruction for PTD and pain
Stoltze et al[51]	Vertebral (deformity, iatrogenic instability, stenosis, compensation/ tendinosis) vs neurological (radiculopathy, tethered cord, atrophy/myelopathy, syrinx)	X Standing FS: Arthrosis hips, total balance X regional function: segmental mobility CT: bony anatomy MR: neurological involvement	-	-	Compensation: increased PT and flexion hips	-	Vertebral pain syndrome because of deformity or instability or neurological deficit
Chou et al[74]	Pain (non-healed fracture or kyphosis)	X Standing FS AP+Lat CT: healed fracture			Positive balance or compensatory hyperlordosis	VAS pain	Refractory to conservative treatment, debilitating pain. Kyphosis =40˚; no osteoporosis
TABLE 3b.2 Reference	Patient factors	Radiology	Cutoff values	Spinopelvic	Cutoff values	Patient Reported Outcome Measurements	Surgical indication
Zhang et al[39]	Back pain, Neurology, progressive deformity	X Standing AP+Lat, flex/ext, - Cobb--> ERD= Cobb-physiological cobb for level (Stagnara et al) CT: 3D reconstruction; MRI: spinal canal influence	Severe PTK ERD >60˚	-	-	VAS pain, ODI	Symptomatic PTK, ERD >60˚ still worsening with/without neurological defect, no osteoporosis/ endocrine or metabolic disease
El-Sharkawi et al[40]	Persistent low back pain, cosmetic	X Standing FS AP+lat - wedge angle	-	-	-	VAS pain, ODI, patient satisfaction	Symptomatic PTK

Table 3b: Continued

Reference	Patient factors	Radiology	Cutoff values	Spinopelvic	Cutoff values	Patient Reported Outcome Measurements	Surgical indication
Wang et al[75]	Painful kyphotic angulation, back pain, neurological function	X lat: - Cobb - Ant. and post. vertebral body height CT MRI: Disc injury	-	-	-	JOA Back pain scores	Rigid PTK with: progression of kyphosis >5°, kyphosis >30° with significant low back pain and deterioration of neurological function
Noor et al[76]	Severe back pain, sagittal imbalance, compression myelum or nerve roots, pseudarthrosis	-	-	-	-	-	Severe complaints with kyphosis >15°-30°
Omidi-Kashani et al[77]	Fatigue and pain	X standing FS AP+Lat: - Cobb - MRI	-	-	-	VAS pain, ODI, patient satisfaction	Cons: mild cases Symptomatic PTK, no neurological deficit, no osteoporosis, Excl: Cobb>50° relative to normal, neurological deficit requiring ant. Decompression, age >60
Xi et al[25]	Local muscle fatigue or pain, focal deformity, neurological deficit (ASIA)	X AP+Lat - Cobb - ThK - LL CT: 3D planning	-	SVA (cm)	-	VAS pain	progressive increase in Cobb, pitched trunk clinically OR follow-up revealed intractable back pain and increase neurological deficit consider: 1. Cobb>30° with persisting pain after cons treatment 2. nerve compression or progressive aggravation of symptoms 3. progressive kyphosis deformity 4. urgent cosmetic requirement

Table 3b: Continued

Reference	Patient factors	Radiology	Cutoff values	Spinopelvic	Cutoff values	Patient Reported Outcome Measurements	Surgical indication
He et al[54]	Severe back pain, kyphosis	X standing FS AP+Lat	-	C7 plumbline ThK LL	-	VAS pain, ODI	Severe backpain, kyphosis, conservative failed to alleviate symptoms Absolute indication: progression of deformity
Obeid et al[41]	Neck or high Th deformity, impaired horizontal gaze, chronic pain	X Standing FS AP+Lat - Kyphosis Angle (-), - Scoliosis, Coronal head shift CT	-	-	-	-	Unbearable neck and high thoracic deformity with horizontal visual impairment; kyphosis 80°
Soultanis et al[42]	Residual kyphosis, can be asymptomatic, back pain, osteoporosis	X regional AP+Lat - Wedge angle - loss of Vertebral body height	-	-	-	VAS pain, ODI	10 patients with progressive deformity and back pain 22 patients: mild residual kyphosis, asymptomatic. Treated conservatively All patients had low energy trauma
Shigematsu et al[43]	Back pain, cosmetic deformity, late neurological deficit	Plain AP+Lat radiographs: - Fracture healing - Cobb (upper endplate of vertebra above and lower endplate fractured vertebra); MRI: neurological involvement	-	Sagittal balance: SVA	-	-	Difficulty with daily activities caused by severe sagittal imbalance, back pain or neurological disturbance
Yagi et al[26]	ASIA A-D	X Standing FS AP: - Scoliosis Cobb angle	>10° lateral curve coronal plane	-	-	-	-

Table 3b: Continued

Reference	**Patient factors**	**Radiology**	**Cutoff values**	**Spinopelvic**	**Cutoff values**	**Patient Reported Outcome Measurements**	**Surgical indication**
Gao et al[78]	Intractable pain, stooping, rapid fatigue, progressive neurologic deficits	X regional: - Cobb CT: 3D reconstruction MRI: neurological involvement	>30°	-	-	VAS pain, ODI	Symptomatic PTK, focal ThL kyphosis >30°
TABLE 3b.3 Reference	Patient factors	Radiology	Cutoff values	Spinopelvic	Cutoff values	Patient Reported Outcome Measurements	Surgical indication
Bourghli et al[49]	Painful, rigid, flexion of the knees	X Standing FS AP+Lat - ThL kyphosis (T10-L2) - Upper local kyphosis (lower endplate vertebra below, upper endplate of fractured vertebra) X Dynamic: stiffness CT: anatomy (shape and osteophytes)	-	Frontal C7 Sagittal C7 ThK LL PT, SS, PI	-	-	Non-flexible ThL deformity with local kyphosis >30° on dynamic views and degenerated discs around fracture level
Liu et al[35]	Overall loss of sagittal balance, back pain, cosmetic, could interfere with personal hygiene and daily physical life	X Regional AP+Lat: - Cobb CT: 3D reconstruction MRI: spinal cord compression	45°	-	-	-	Progressive back pain with kyphosis
Hu et al[55]	Pain, neurological impairment	X Standing FS - Cobb X Pelvis	>30°	SVA PT, SS, PI	-	VAS pain, ODI	Cobb >30° of SI; Significant pain refractory to conservative treatment; Increasing neurologic deficit
Chen et al[27]	Neurological impairment (ASIA), some with obvious back pain	X Regional AP+Lat - Cobb CT	-	-	-	VAS pain, ODI	Chronic pain in segment, some with progressive kyphosis.

Table 3b: Continued

Reference	Patient factors	Radiology	Cutoff values	Spinopelvic	Cutoff values	Patient Reported Outcome Measurements	Surgical indication
Wang et al[56]	Related to kyphosis: intractable pain, stooping, rapid fatigue, progressive neurological deficit, refractory after 3 months conservative therapy; no osteoporosis	X Regional AP+Lat - Cobb	>30˚	-	-	VAS pain, ODI	Symptomatic late PTK, no osteoporosis
Li et al[30]	Back pain, neurological deficit (Frankel) Functional disability	X standing ThL AP+Lat: - Cobb - LL	-	-	-	VAS pain	Cons: Cobb <20˚, without obvious pain or neurological deficit Surg: Cobb >20˚ with pain, progressive nerve damage
Rerikh et al[46]	Painful deformity	X FS AP+Lat - Cobb	Deviation from SRS-criteria	ThK(T1-T12) LL(L1-S1) ThL(T10-L2) PT, SS, PI Roussouly	Deviation from SRS-criteria	VAS pain, ODI	
El Nagger et al[52]	Back pain, local deformity with neurology	X Standing FS AP+Lat: - Cobb Occasional: CT: evaluate deformity MRI: neurological involvement	Severe: Cobb>50	SVA ThK (T5-T12) LL (-)	>25mm	VAS pain, ODI	Inclusion of Severe PTK: Back pain affecting QoL (ODI>40, VAS >5), neurological symptoms, Cobb >50˚, SVA>25mm Surg: refractory back pain, deteriorating neurology and SI>20˚

Table 3b: Continued

Reference	Patient factors	Radiology	Cutoff values	Spinopelvic	Cutoff values	Patient Reported Outcome Measurements	Surgical indication
Matsumoto et al[45]	Back pain	X Standing FS AP+Lat - Local kyphosis (lower endplate cranial, upper endplate caudal vertebra)	-	SVA LL (fracture-S) ThK (T5-fracture) Segmental LL (L3-S/L4-S) PT, SS, PI	SRS-criteria	-	Rigid kyphotic deformity + symptoms including non-flexible deformity and very mild vertebral instability with local kyphosis and severe low back pain
Avila et al[79]	-	X Standing FS AP+Lat - Cobb	-	C7 plumbline	-	ODI	Loss of spinal balance with PTK

X: radiograph; AP+Lat: anteroposterior and lateral views; C: Cervical spine; T: Thoracic spine; L: Lumbar spine; S: Sacral spine
CT: Computer Tomography; MR: magnetic resonance imaging; FS: full spine
Cobb: upper endplate of vertebra cranial and lower endplate of vertebra caudal
SRS-criteria: Scoliosis Research Society criteria
ThK: thoracic kyphosis, LL: lumbar lordosis; SVA: Sagittal Vertical Axis; PT: Pelvic tilt, SS: Sacral Slope, PI: Pelvic Incidence;
ERD: Effective Regional Deformity, SI: Sagittal index
VAS pain: visual analogue scale of pain, ODI: Oswestry Disability Index
Cons: Conservative treatment, Surg: surgical treatment; PTK: posttraumatic kyphosis; QoL: quality of life

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Chapter 5

Spinal Posttraumatic Deformity: An international expert survey among AO Spine Knowledge Forum members

Erin E.A. De Gendt, MD, Greg D. Schroeder, MD, PhD, Andrei Joaquim, MD, PhD, Jin Tee, MD, PhD, Rishi M. Kanna, MD, Frank Kandziora, MD, PhD, Gaurav R. Dhakal, MD, Emiliano N. Vialle, MD, PhD, Mohammad El-Sharkawi, MD, PhD, Klaus J. Schnake, MD, PhD, Shanmuganathan Rajasekaran, MD, PhD, Alex R. Vaccaro, MD, PhD, Sander P.J. Muijs, MD, PhD, Lorin M. Benneker, MD, PhD and F. Cumhur Oner, MD, PhD

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Abstract

Study Design. survey amongst spine experts

Objective. To investigate the different views and opinions of clinically relevant spinal posttraumatic deformity (SPTD)

Summary of Background Data. There is no clear definition of clinically relevant SPTD. This leads to a wide variation in characteristics used for diagnosis and treatment indications of SPTD. In order to understand the current concepts of SPTD a survey was conducted among spine trauma surgeons.

Methods. Members of the AO Spine Knowledge Forum Trauma participated in an online survey. The survey was divided in four domains: Demographics, criteria to define SPTD, risk factors and management. The data was collected anonymously and analyzed using descriptive statistics, absolute and relative frequencies. Consensus on dichotomous outcomes was set to 80% of agreement.

Results. Fifteen members with extensive experience in treatment of spinal trauma participated, representing the five AO Spine Regions. Back pain was the only criterion for definition of SPTD with complete agreement. Consensus (≥80%) was reached for kyphotic angulation outside normative ranges and impaired function. 87% and 100% agreed that a full-spine conventional radiograph was necessary in diagnosing and treating SPTD respectively. The 'missed B-type injury' was rated at most important by all but one participant. There was no agreement on other risk factors leading to clinically relevant SPTD. Concerning the management, all participants agreed that an asymptomatic patient should not undergo surgical treatment and that neurological deficit is an absolute surgical indication. For most of the participants the preferred surgical treatment of acute injury in all spine regions but the subaxial region is posterior fixation.

Conclusion. Some consensus exists among leading experts in the field of spine trauma care concerning the definition, diagnosis, risk factors and management of SPTD. This study acts as the foundation for a Delphi study amongst the global spine community.

Keywords: Spinal Posttraumatic Deformity, consensus, spine trauma, diagnosis, expert survey, Delphi study

INTRODUCTION

Spinal posttraumatic deformity (SPTD) is a complication of a traumatic injury of the spinal column. After trauma, some deformity of the spine may be present in different amount, but when and how a specific deformity in a specific region of the spine becomes 'clinically relevant' SPTD is poorly understood. It is known that SPTD can lead to impairment of the quality of life and decrease in function in daily life.[1,2] Over a decade ago, a survey was held by Schoenfeld et al among experienced spine trauma surgeons to reach a consensus on what constitutes a SPTD.[3] Consensus of the definition of SPTD was a 'painful kyphotic deformity after a spine trauma'. However, clinically relevant SPTD was not distinguished from asymptomatic SPTD and no consensus was reached on more specific patient factors or treatment factors.[3]

In clinical practice and in research, the lack of a clear definition of SPTD causes confusion. First, since SPTD is a complication of a traumatic spine injury, one could argue that SPTD should be preventable by better management of the spine injury itself. To compare the management of the acute injuries and even predict the chance of development of SPTD you need to have a good defined outcome. This definition of SPTD is however non-existing. Second, patients with SPTD may need high risk surgical procedures with unpredictable outcomes. In order to compare the different treatments of SPTD (surgical and non-surgical) the diagnosis of SPTD should be uniform.[4,5]

A new project of the AO Spine Knowledge Forum (KF) Trauma focusses on defining clinically relevant SPTD. In the first phase of this project, a systematic review was conducted to search the literature for a description of definition of SPTD. Literature is still inconclusive on what exactly constitutes a 'clinically relevant' SPTD.[6] This review did identify relevant different domains in the literature such as patient factors (e.g. pain and neurological deficits), radiologic parameters (e.g. Cobb angle, sagittal balance and Roussouly profile), Patient Reported Outcome Measurements (PROMs) and indications for surgical intervention in patients with SPTD.

We aim to investigate the expert opinion of the different domains of SPTD. This will lead to the development of a Delphi study which will be held among the global AO Spine community to create a widely supported definition of clinically relevant SPTD.

METHODS

Study design and recruitment of participants.

An online survey was developed and distributed to the members of the AO Spine KF Trauma. The survey was developed based on the results of the systematic review and discussion among the experts and included all factors deemed important. The AO Spine KF Trauma is a group of 18 leading experts in the field of Spine Trauma. This group consists of orthopedic surgeons and neurosurgeons from all five AO Spine regions (Europe and Southern Africa, Asia Pacific, Latin America, Middle East and Northern Africa, North America).

Expert Survey

The full survey is available as supplementary data. The survey consisted of four 'Domains'; Domain 1: Demographics, Domain 2: Criteria to define SPTD and radiological assessment, Domain 3: Risk factors and Domain 4: Management.

Demographics

The first domain consisted of five questions on the demographics of the participants: their region, years of experience, subspecialty (orthopedic or neurosurgical) and work setting (academic hospital, general hospital, private).

Criteria to define SPTD and radiological assessment

The second domain consisted of 13 questions about the different criteria that needed to be fulfilled to define a clinically relevant SPTD (answers per factor: should be fulfilled or not fulfilled). The factors that were included for definition of SPTD were: amount of deformity, disturbance of sagittal balance (including most relevant parameter), back pain (including a VAS of pain), impaired function (including Oswestry Disability Index and walking distance), secondary progression after treatment of the acute spine trauma (surgical vs bracing), persisting instability or non-union, disc degeneration, and the time frame of development of SPTD after trauma. The preference on the type of radiologic exams was explored (standing local conventional radiogram (CR), dynamic CR, full spine CR, CT-scan, MR-scan and bone quality assessment) for diagnosis and treatment of SPTD. The radiologic exams were rated on a 2-point scale: 'optional' or 'strongly necessary'.

Table 1. Criteria that need to be fulfilled to define SPTD

Criteria		Fulfilled#	Not fulfilled#
Kyphotic angulation outside normative ranges *		14	1
Degree of angulation:	*>10°*	*3*	
	>20°	*5*	
	>30°	*6*	
Sagittal imbalance		10	5
Most relevant measurement	*SVA >5cm*	*6*	
	Pelvic rotation	*4*	
Back pain*		15	0
Visual Analogue Scale of pain	*>1*	*0*	
	*>4**	*12*	
	>7	*3*	
Impaired function*		13	2
Oswestry Disability Index	*>40%*	*9*	
	>60%	*4*	
Walk distance	*Unlimited*	*5*	
	< 1 km	*2*	
	< 100 m	*6*	
Secondary progression		9	6
Persisting instability or non-union		6	9
Disc degeneration *		2	13
Development of SPTD:	Irrelevant	2	
	Within 0-2 months	3	
	Within 2-6 months	7	
	Within 6-12 months	1	
	After 12 months	2	

#: number of participants;*Agreement ≥80% is reached; SPTD indicates spinal post-traumatic deformity; SVA: sagittal vertical axis

Risk factors

The third domain contained four questions: three ranking questions (radiological/ morphological, patient-related and treatment of spine trauma) about the risk factors for development of SPTD and one multiple choice question on the degree of risk per spine region. The question on radiology/morphology contained six factors, the question on patient-related factors contained nine factors and the question on treatment of spine trauma contained eight factors. The ranking was from 'most important'(assigned number 1) to 'least important' and the number of ranks equaled the number of factors per question. The factor with the lowest mean is rated the most important. The risk per spine region (subaxial, cervicothoracic, mid-thoracic, thoracolumbar, lumbar) was rated on a three-point scale: low risk, moderate risk or high risk.

Management of the primary injury and indications for surgery in SPTD

The last domain contained questions about the consequences of type of management of acute spine trauma on the development of SPTD and the indications for treatment of patients with SPTD. The first seven questions assessed if certain treatments of acute spine trauma have an impact on the development of SPTD. The experts were asked which treatment they preferred (bracing, posterior, anterior or combined surgery) in a neurologically intact patient with an unstable spine injury for the different regions of the spine. To further specify on which surgical treatment (anterior or posterior alone) for acute spine trauma could increase the risk on SPTD in the different spine regions, the participants were asked to score the risk on a 3-point scale (yes, possible or no). If yes or possibly was indicated, an additional question per spine region was opened to ask if this risk was dependent on fracture type, bone quality or something else. The following question of the survey assessed if there are certain Roussouly type sagittal profiles that increase the risk of development of SPTD.[7] The answers were yes, no or possibly for each of the different sagittal profiles according to Roussouly. The last question was about the different indications (relative or absolute) for surgical treatment of patients with SPTD. The following indications were considered: asymptomatic, pain, progressive radiological deformity, physical dysfunction, neurological deficits and cosmetic concerns.

Table 2. The radiographic assessment necessary to perform for diagnosis and for treatment of SPTD.

	Strongly necessary		**Optional**		**No answer**	
Radiographic assessment	Diag.	Treat.	Diag.	Treat.	Diag.	Treat.
Standing local CR *	13	11	2	3	0	1
Dynamic CR	3	7	12	7	0	1
Full Spine CR*	13	15	2	0	0	0
CT-scan	10	10	5	4	0	1
MR-scan *	6	12	9	3	0	0
Bone quality assessment	2	6	12	9	1	1

Diag. = Diagnosis; Treat.= Treatment; CR= conventional radiography;

* Agreement ≥80% is reached

Data collection and analysis

The survey was distributed with RedCap (REDCap Software - Version 6.5.2 - © 2020 Vanderbilt University) between 23 January 2020 and 29 February 2020. Reminders were sent out weekly until the survey was completed. The response of each participant was assigned a study identification number for anonymous analysis of the collected data. The analysis was performed by a blinded researcher for the identification code of the participants

The data of Domains 1, 2 and 4 was analyzed using descriptive statistics, absolute and relative frequencies. Consensus for dichotomous outcomes was set at 80% agreement between participants.[8–10] The data of Domain 3 was analyzed with frequency analysis and means for the rating questions.

RESULTS

Domain 1: Demographics

The survey was distributed to 18 KF Trauma members and completed by 13 orthopedic surgeons and 2 neurosurgeons; 1 member completed the survey partially. Six were from Europe and Southern Africa, three from North America, three from Asia Pacific, two from Latin America and one from the Middle East and Northern Africa. The experience of the participants ranged from 5-10 years to more than 20 years. Of the participants 73% worked at an Academic medical institution, 20% at a general hospital and 7% in private practice.

Domain 2: Criteria to define SPTD and radiological assessment of SPTD

The participants reached unanimous agreement on the presence of 'Back pain' as a necessary criterion to define clinically relevant SPTD and agreement that the Visual analogue scale of pain (80%) should be ≥4 out of 10. The items 'kyphotic angulation' (93%) and 'impaired function' (87%) also reached agreement. On 'disc degeneration' the participants agreed that it was not a necessary criterion (87%).

Concerning the radiological assessment for the diagnosis of SPTD standing local CR and Full Spine CR were strongly necessary for the diagnosis of SPTD. For treatment choices of SPTD agreement was reached for the necessity for a full spine CR and an MR-scan. The results are summarized in Table 1 and 2.

Domain 3: Risk factors for development of SPTD

Figure 1 shows the radiographic/ morphological factors, no factor reached a consensus. Overall, the 'kyphotic angulation' was rated as the most important factor (mean 2.4; ranking interval 1-6) and the 'Spinal Curvature' as the least important (mean 4.9; ranking interval 1-6).

Figure 2 shows the different patient-related risk factors, no consensus was reached. 'Bone quality'(mean 2.7; ranking interval 1-5) and 'Neurological deficit' (mean 2.9; range 1-6) were rated most important and 'Medical comorbidities' as least important (mean 7.5; ranking interval 3-9).

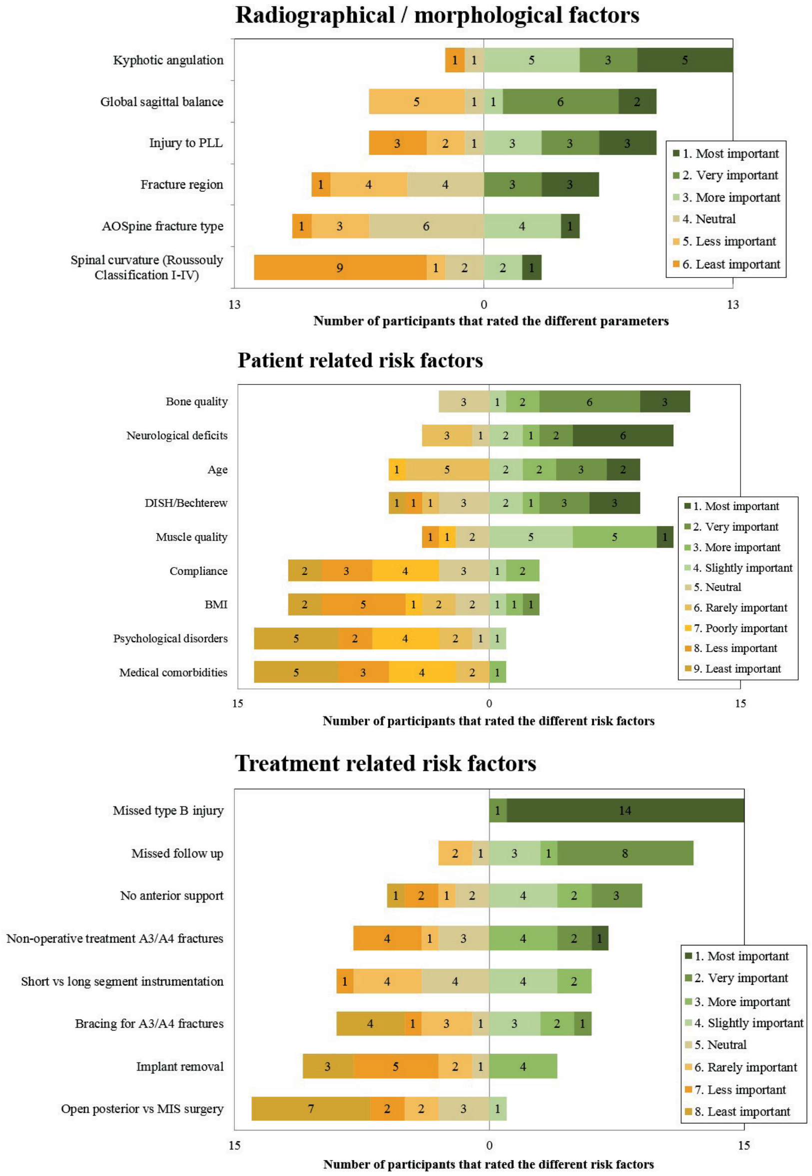

Figure 1, 2, 3. The factor at the top of the figure had the lowest mean, thus was rated as most important and the factor at the bottom had the highest mean (rated least important). 1: the six radiological/morphological factors are displayed; 2: the nine patient related factors are displayed; 3: the eight treatment related factors are displayed.

Figure 3 shows the ranking of the treatment related risk factors. The factor 'missed type B-injury' (mean 1.1; ranking interval 1-2) was ranked by 14 out of the 15 participants as most important factor.

When comparing the risk probability of the various spine regions to develop SPTD, thoracolumbar spine was ranked as high risk by 80%. (Figure 4)

Domain 4: Management of the primary injury and indications for surgery in SPTD

Table 3 shows the results which treatment of an acute spine fracture might prevent SPTD. Agreement (80%) was reached that rigid bracing and longer duration of the bracing of an acute spine injury do not prevent SPTD. 87% agreed that minimally invasive surgery (MIS) for acute spine injury does not prevent SPTD more than open surgery. Monoaxial screws concerning the sagittal profile, no agreement that certain Roussouly types could promote the development of SPTD was reached.

Table 3. Which treatment of an acute spine injury might prevent SPTD

Type of treatment		Yes	No
Does rigid bracing prevent SPTD? *		3	12
Is there an impact of duration of brace in prevention of SPTD? *		3	12
Are there regions that benefit from bracing?		6	9
Which regions benefit from bracing?	*C3 – C7*	*2*	
	C7 – T3	*1*	
	T4 – T10	*3*	
	T11 – L2	*4*	
	L3 – L5	*3*	
Does MIS predispose to SPTD more than open surgery?		5	10
Does MIS prevent SPTD more than open surgery? *		2	13
Is the use of monoaxial screws important in acute management?		11	4

SPTD: spinal posttraumatic deformity; MIS: minimally invasive surgery
* Agreement ≥80% is reached

In Table 4 the preferred treatment per spine region in a neurologically intact patient with an acute unstable spine injury is shown. Agreement was reached (≥ 80%) that the preferred treatment of all spine regions except the subaxial cervical spine region is posterior fixation of the acute injury.

Table 4. What is the preferred treatment per spine region for an acute unstable spine injury in a neurologically intact patient

Spine region	Bracing	Posterior surgery	Anterior surgery	Combined surgery
Subaxial (C3-C7)	1	4	9	4
Cervicothoracic (C7-T3)	1	14*	1	2
Mid-Thoracic (T4-T10)	1	15*	0	0
Thoracolumbar (T11-L2)	1	12*	0	4
Lumbar (L3-L5)	1	14*	0	1

* Agreement ≥80% is reached

A majority of the participants agreed that there was no increased risk on SPTD when using the posterior approach alone for acute spine injury in the CTh region (80%) and the mid-Th region (93%), 20% and 7% said it was a possible risk, respectively. Fracture type was chosen most often by the participants as dependent factor.

Figure 5 shows an overview of different indications for surgical management of patients suffering from SPTD. All experts agreed that an asymptomatic patient should not undergo surgical treatment. Also unanimous agreement was reached that patients with a neurological deficit have an absolute surgical indication.

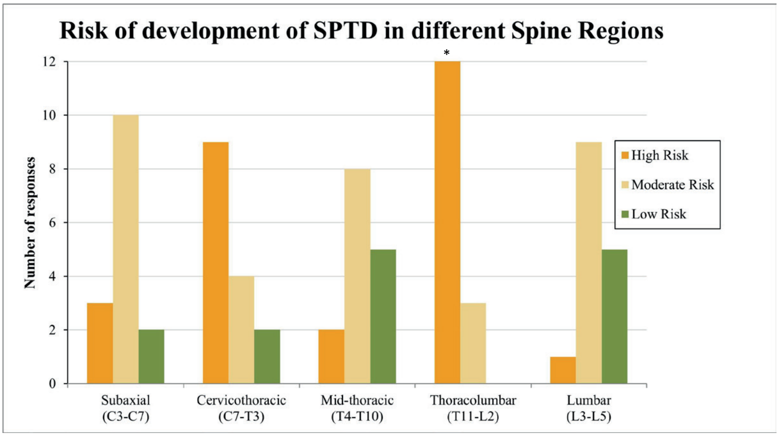

Figure 4: Risk of development of SPTD in the different spine regions. This figure shows the assessment of risk on development of SPTD by the participants, clustered by the various regions of the spine. Risk of SPTD can be classified either low, moderate or high for each spine region. An asterisk (*) indicated consensus, as more than 80% of participants had the same rating.

DISCUSSION

This survey among leading spine trauma experts, was performed to look for possible agreement on diagnosis, risk factors and management of SPTD. Many criteria and factors were subjected to the experts' opinion in this survey. In total 15 questions from this survey reached an agreement of 80% or more. However there remains a great degree of disagreement about other possibly relevant items.

The 'painful' in the definition of Schoenfeld et al is consistent with our survey. We found a unanimous agreement that 'Back pain' needs to be fulfilled in a patient to define SPTD. This is consistent with the findings from the survey of Schoenfeld et al a decade ago. [3] In the literature over the years, back pain was mentioned often in combination or as a surgical indication in patients with SPTD.[11]

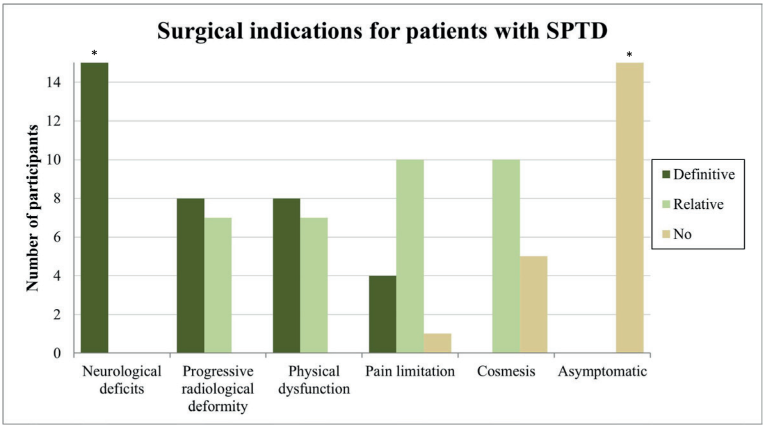

Figure 5: Surgical indications for patients with SPTD. This figure shows different indications of patients with SPTD to qualify for surgical treatment. Participants rated each symptom on being definitive, relative or no indication for surgical treatment. An asterisk (*) indicated consensus, as more than 80% of participants had the same rating.

Our survey found a unanimous agreement on 'Neurological deficits' being an absolute indication for surgical indication in patients with SPTD. The question remains if patients with a known neurological deficit fall in this category as well, or only if they have increasing neurology.

There was full consensus that asymptomatic patients with SPTD have no indication for surgical intervention. This confirms the survey of Schoenfeld et al which stated that there could be patients with an asymptomatic SPTD, but whether this is clinically relevant is unclear.[3]

Chapter 5

General agreement was found that a standing 'full spine CR' is required to support surgeons in diagnosis and treatment decision making. The main reason for this type of CR is to look at the sagittal balance of the patient.[1,4,5] The severity of the sagittal imbalance might point the surgeon to a different type of treatment.[1,12] Interestingly, dependency on sagittal balance to define SPTD was endorsed by only 67% of the experts which did not exceeded the 80% consensus limit. It could be argued that SPTD can exist with a balanced spine and an imbalanced spine.

As a novelty the experts were asked to rate risk factors for the development of symptomatic SPTD from most important (corresponds to number 1) to least important (corresponds to the amount of factors per question) as is seen in Figures 1, 2 and 3. Some convergence among the participants on certain items was observed. For example, the 'kyphotic angulation' item was found most important by five experts but least important by one expert; and the 'spinal curvature', was found most important by one expert and least important by nine experts. However, there is a wide variation in most of the items leading to a lack of clear consensus. They do give an indication on the overall importance per factor.

The disagreement between participants on the majority of the factors is not unexpected. This can be due to current diversity in the definition as found by De Gendt et al. in their recent systematic review of the literature on SPTD.[6] Another reason could be the lack of clarification between a diagnosis and treatment decision in this questionnaire. We decided to set agreement on 80% after review of the available literature on the Delphi process as this was designed as a preparatory survey.[8–10]

There are limitations to this study. First, only the experts from the AO Spine KFT were asked for their opinion. This creates a bias because other spine surgeons were excluded from this survey. The main reason for this was that this study is a part of multiple preparatory studies before we perform a Delphi study amongst the whole spine community. Second, the small number of participants in this study. A single participant may substantially skew the obtained results. As this study is exploratory all different aspects mentioned will be used in the Delphi study to follow the preparatory study. Third, there are many ways the questions of a survey determine the outcomes. We will add more open questions and open fields in the upcoming preparatory studies to follow. The last limitation of the study is that only one scenario was provided to answer the questions of the survey. In retrospect another or more scenarios could have been provided highlighting different aspects of development of SPTD, however that would have made the survey even longer with a chance of less respondents.

This survey showed that there is some consensus among experts in spine trauma on different domains of SPTD. We confirmed the definition stated by Schoenfeld et al over a decade ago, but we suggest that additions to this definition are necessary to provide a clear and clinically relevant definition of SPTD.[3] The additions deemed necessary for diagnosis of SPTD were: kyphotic angulation exceeding normal values, back pain with a VAS of pain >4 and impaired function. The radiological workup in diagnosis and/or treatment should contain a standing local CR, a full spine CR and a MR-scan. These considerations and the previous systematic review are the foundation to conduct a Delphi Study amongst spine surgeons globally through the AO Spine community.[6]

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Supplement: Complete Survey that was sent to the participants

Domain 1: Demographics

What AO region of the world are you from?

- ◯ North America
- ◯ Latin and South America
- ◯ Europe
- ◯ Africa
- ◯ Asia
- ◯ Middle East

How many years have you been in practice?

- ◯ < 5 years
- ◯ 5 - 10 years
- ◯ 11 - 20 years
- ◯ > 20 years

What is your subspeciality?

- ◯ Orthopaedic Spine Surgery
- ◯ Neurosurgery Spine Surgery

What setting do you work?

- ◯ Academic
- ◯ Hospital employed
- ◯ Private Practice

Please indicate the Knowledge Forum to which you belong?

- ☐ KF Deformity
- ☐ KF Trauma
- ☐ Not Applicable

Domain 2: In this section we would like to understand which criteria need to be fulfilled to define a Symptomatic Post-Traumatic Deformity (SPTD).

Should kyphotic angulation outside normative ranges after spinal trauma be fulfilled to define SPTD?	◯ Yes ◯ No
Please specify the relevant kyphotic angulation of fractured vertebra.	◯ >10° ◯ >20° ◯ >30° ((angle between upper and lower endplate of fractured vertebra))
Should global sagittal dysbalance be fulfilled to define SPTD?	◯ Yes ◯ No
Please specify the most relevant parameter in global sagittal dysbalance.	◯ Sagittal Vertical Axis (SVA) >5cm ◯ Pelvic retroversion or other compensation mechanisms
Is back pain an important criterion to define SPTD?	◯ Yes ◯ No
Please specify the relevant Visual Analog Scale (VAS).	◯ >1 Mild pain ◯ >4 Moderate pain ◯ >7 Extreme pain (0=no pain; 1-3=mild; 4-6=moderate; 7-10=severe)
Is impaired function a criterion which should be fulfilled to define SPTD?	◯ Yes ◯ No
Please specify the Oswestry Disability Index (ODI) score.	◯ >20% ◯ >40% ◯ >60% ◯ >80% (The overall ODI score can range from 0% (best health status) to 100% (worst health status))
Please specify free walking distance.	◯ not mobile ◯ < 10 m ◯ < 100 m ◯ < 1000 m ◯ unlimited
Is secondary progression of deformity after treatment (surgical or bracing) a criterion which should be fulfilled to define SPTD?	◯ Yes ◯ No
Is persisting instability or non-union a criterion which should be fulfilled to define SPTD?	◯ Yes ◯ No
Is post-traumatic disc degeneration a criterion which should be fulfilled to define SPTD?	◯ Yes ◯ No
When does SPTD most likely develop after trauma?	◯ 0-2 Months ◯ 2-6 Months ◯ 6-12 Months ◯ after 12 Months ◯ irrelevant
Do you have any other suggestions/comments related to the definition of symptomatic post-traumatic deformity?	______________________________ (Optional)

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Which radiographic exams are needed for SPTD diagnosis?

	Strongly Necessary	Optional
Standing local x-rays	◯	◯
Dynamic x-rays	◯	◯
Full spine x-rays	◯	◯
CT scan	◯	◯
MRI	◯	◯
Bone Quality Assessment	◯	◯

Confidential

Which radiographic exams are needed for SPTD treatment?

	Strongly Necessary	Optional
Standing local x-rays	○	○
Dynamic x-rays	○	○
Full spine x-rays	○	○
CT scan	○	○
MRI	○	○
Bone Quality Assessment	○	○

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Domain 3: Risk Factors - Radiographic/Morphological Parameters
Please rank the following possible risk factors according to their importance to develop SPTD from 'most important'=1 to 'least important'=6.

	1	2	3	4	5	6
Fracture region	○	○	○	○	○	○
Kyphotic angulation	○	○	○	○	○	○
Injury to PLL	○	○	○	○	○	○
AOSpine fracture type	○	○	○	○	○	○
Global sagittal balance	○	○	○	○	○	○
Spinal curvature (Roussouly Classification I-IV)	○	○	○	○	○	○

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Domain 3: Risk Factors-Spine Region
Please rate the following spine regions according to the likelihood to develop SPTD from high risk, moderate risk, to low risk.

	High Risk	Moderate Risk	Low Risk
Subaxial cervical spine (C3-C7)	○	○	○
Cervicothoracic (C7-T3)	○	○	○
Mid-thoracic spine (T4-T10)	○	○	○
Thoracolumbar junction (T11-L2)	○	○	○
Lumbar spine (L3-L5)	○	○	○

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Domain 3: Risk Factors-Patient related parameters

Please rank the following patient related parameters according to their importance to develop SPTD from 'most important'=1 to 'least important'=9.

	1	2	3	4	5	6	7	8	9
Age	○	○	○	○	○	○	○	○	○
Bone quality	○	○	○	○	○	○	○	○	○
Muscle quality	○	○	○	○	○	○	○	○	○
Stiff spine (DISH, Bechterew)	○	○	○	○	○	○	○	○	○
BMI	○	○	○	○	○	○	○	○	○
Psychological disorders	○	○	○	○	○	○	○	○	○
Compliance	○	○	○	○	○	○	○	○	○
Medical comorbidities	○	○	○	○	○	○	○	○	○
Neurological deficits	○	○	○	○	○	○	○	○	○

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Domain 3: Risk Factors-Treatment related parameters
Please rank the following treatment related parameters for spinal injuries according to their importance to develop SPTD from 'most important'=1 to 'least important'=8.

	1	2	3	4	5	6	7	8
Bracing for A3/A4 fractures	○	○	○	○	○	○	○	○
Non-operative treatment of A3/A4 fractures	○	○	○	○	○	○	○	○
Missed follow up	○	○	○	○	○	○	○	○
Missed type B injury	○	○	○	○	○	○	○	○
Open posterior vs MIS surgery	○	○	○	○	○	○	○	○
Short segment (2 segments) vs long (3 or 4 segments) instrumentation	○	○	○	○	○	○	○	○
No anterior support (eg by expandable cage)	○	○	○	○	○	○	○	○
Implant removal	○	○	○	○	○	○	○	○

Do you have any other suggestions/comments related to the risk factors to develop symptomatic post-traumatic deformity? ______________________________

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Domain 4: Management

Will rigid bracing prevent segment or junctional SPTD?	◯ Yes ◯ No
Would the duration of bracing have an impact on the prevention of SPTD?	◯ Yes ◯ No
Are there segments of the spine that will benefit from rigid bracing in the prevention of SPTD?	◯ Yes ◯ No
Please specify the spine regions that would benefit from rigid bracing in the prevention of SPTD	☐ Subaxial cervical spine (C3-C7) ☐ Cervicothoracic (C7-T3) ☐ Mid-thoracic spine (T4-T10) ☐ Thoracolumbar junction (T11-L2) ☐ Lumbar spine (L3-L5)
Does MIS corrective spine trauma surgery predispose to SPTD more than open techniques?	◯ Yes ◯ No
Does MIS corrective spine trauma surgery prevent SPTD more than open techniques?	◯ Yes ◯ No
Is the use of monoaxial screws important?	◯ Yes ◯ No

Chapter 5

Domain 4: Management

Please specify if you would consider surgery for post-traumatic deformity according to the background characteristics outlined below.

	No	Relative	Absolute
Asymptomatic	○	○	○
Pain limitation	○	○	○
Progressive radiological deformity	○	○	○
Physical dysfunction	○	○	○
Neurological deficits	○	○	○
Cosmesis	○	○	○

Confidential

Domain 4: Management

Please indicate your treatment preferences based on the spine regions for a neurologically intact patient with an unstable injury.

	Bracing	Posterior	Anterior	Combined
Subaxial cervical spine (C3-C7)	☐	☐	☐	☐
Cervicothoracic (C7-T3)	☐	☐	☐	☐
Mid-thoracic spine (T4-T10)	☐	☐	☐	☐
Thoracolumbar junction (T11-L2)	☐	☐	☐	☐
Lumbar spine (L3-L5)	☐	☐	☐	☐

Domain 4: Management

Do you think an anterior approach alone would increase the risk for SPTD in the following spine regions?

	Yes	No	Possible
Subaxial cervical spine (C3-C7)	☐	☐	☐
Cervicothoracic (C7-T3)	☐	☐	☐
Mid-thoracic spine (T4-T10)	☐	☐	☐
Thoracolumbar junction (T11-L2)	☐	☐	☐
Lumbar spine (L3-L5)	☐	☐	☐

You have indicated that an anterior approach alone could potentially increase the risk of SPTD in the subaxial cervical spine region. Please specify if the risk for developing SPTD in the subaxial cervical spine region depends on one of the following conditions.

☐ Fracture type
☐ Bone quality
☐ Other

Please specify what you consider under other: ______________________________

You have indicated that an anterior approach alone could potentially increase the risk of SPTD in the Cervicothoracic region. Please specify if the risk for developing SPTD depends on one of the following conditions.

☐ Fracture type
☐ Bone quality
☐ Other

Please specify what you consider under other: ______________________________

You have indicated that an anterior approach alone could potentially increase the risk of SPTD in Mid-thoracic spine region. Please specify if the risk for developing SPTD depends on one of the following conditions.

☐ Fracture type
☐ Bone quality
☐ Other

Please specify what you consider under other: ______________________________

You have indicated that an anterior approach alone could potentially increase the risk of SPTD in Thoracolumbar spine region. Please specify if the risk for developing SPTD depends on one of the following conditions.

☐ Fracture type
☐ Bone quality
☐ Other

Please specify what you consider under other: ______________________________

You have indicated that an anterior approach alone could potentially increase the risk of SPTD in Lumbar spine. Please specify if the risk for developing SPTD in Lumbar spine depends on one of the following conditions.

☐ Fracture type
☐ Bone quality
☐ Other

Please specify what you consider under other: ______________________________

Confidential

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Domain 4: Management

Do you think a posterior approach alone would increase the risk for SPTD in the following spine regions?

	Yes	No	Possibly
Subaxial cervical spine (C3-C7)	☐	☐	☐
Cervicothoracic (C7-T3)	☐	☐	☐
Mid-thoracic spine (T4-T10)	☐	☐	☐
Thoracolumbar junction (T11-L2)	☐	☐	☐
Lumbar spine (L3-L5)	☐	☐	☐

You have indicated that a posterior approach alone could potentially increase the risk of SPTD in Subaxial cervical spine region. Please specify if the risk for developing SPTD in Subaxial cervical spine depends on one of the following conditions.

☐ Fracture type
☐ Bone quality
☐ Other

You have indicated that a posterior approach alone could potentially increase the risk of SPTD in Cervicothoracic region. Please specify if the risk for developing SPTD in Cervicothoracic depends on one of the following conditions.

☐ Fracture type
☐ Bone quality
☐ Other

You have indicated that a posterior approach alone could potentially increase the risk of SPTD in Mid-thoracic spine region. Please specify if the risk for developing SPTD in Mid-thoracic spine depends on one of the following conditions.

☐ Fracture type
☐ Bone quality
☐ Other

You have indicated that a posterior approach alone could potentially increase the risk of SPTD in Thoracolumbar junction. Please specify if the risk for developing SPTD in Thoracolumbar junction depends on one of the following conditions.

☐ Fracture type
☐ Bone quality
☐ Other

You have indicated that a posterior approach alone could potentially increase the risk of SPTD in Lumbar spine. Please specify if the risk for developing SPTD in Lumbar spine region depends on one of the following conditions.

☐ Fracture type
☐ Bone quality
☐ Other

Do you have any other suggestions/comments related to the management of symptomatic post-traumatic deformity?

____

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Chapter 5

Domain 4: Management

Please indicate if you see an influence of the sagittal profile to promote SPTD for Roussouly I-IV types?

	Yes	No	Potentially
Type 1	◯	◯	◯
Type 2	◯	◯	◯
Type 3	◯	◯	◯
Type 4	◯	◯	◯

Roussouly classification.
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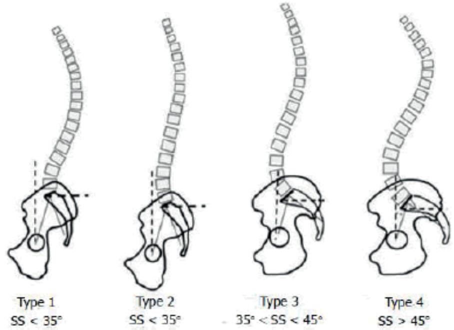

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Chapter 6

The diagnostic process of Spinal Posttraumatic Deformity: an expert survey of 7 cases, consensus on clinical relevance does exist

Erin E A De Gendt, Lorin M Benneker, Andrei F Joaquim, Mohammad El-Sharkawi, Gaurav R Dhakal, Frank Kandziora, Jin Tee, Richard J Bransford, Emiliano N Vialle, Alex R Vaccaro, Eugen C Popescu, Rishi M Kanna, David W Polly, Klaus J Schnake, Pedro Berjano, Sergey Ryabykh, Marko Neva, Claudio Lamartina, Dominique A Rothenfluh, Stephan J Lewis, Sander P J Muijs, F Cumhur Oner.

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Abstract

Study Design. Survey of cases

Objective. To evaluate the opinion of experts in the diagnostic process of clinically relevant Spinal Posttraumatic Deformity (SPTD)

Summary of Background Data. Spinal Posttraumatic Deformity (SPTD) is a potential complication of spine trauma that can cause decreased function and quality of life impairment. The question of when SPTD becomes clinically relevant is yet to be resolved.

Methods. The survey of 7 cases was sent to 31 experts. Case presentation was: medical history, diagnostic assessment, evaluation of diagnostic assessment, diagnosis and treatment options.. Means, ranges, percentages of participants and descriptive statistics were calculated.

Results. Seventeen spinal surgeons reviewed the presented cases. The items' fracture type and complaints were rated by the participants as more important, but no agreement existed on the items of medical history. In patients with possible SPTD in the cervical spine (C) area, participants requested a conventional radiograph (CR) (76-83%), a flexion/extension CR (61-71%), a CT-scan (76-89%), and an MR-scan (89-94%). In thoracolumbar spine (ThL) cases, full spine CR (89-100%), CT-scan (72-94%) and MR-scan (65-94%) were requested most often.

There was a consensus on 5 out of 7 cases with clinically relevant SPTD (82-100%). When consensus existed on the diagnosis of SPTD, there was a consensus on the case being compensated or decompensated and being symptomatic or asymptomatic.

Conclusions. There was strong agreement in 5 out of 7 cases on the presence of the diagnosis of clinically relevant SPTD. Among spine experts there is strong consensus to use CT-scan and MR-scan, a cervical CR for C-cases and a full spine CR for ThL-cases. The lack of agreement on items of the medical history suggest that a Delphi study can help us reach a consensus on the essential items of clinically relevant SPTD.

Keywords: Spinal Posttraumatic Deformity, consensus, spine trauma, diagnosis

INTRODUCTION

Spinal posttraumatic deformity (SPTD) is a potential complication after a spine trauma. Patients with a deformity after spine trauma can suffer from a neurological deficit, functional disability and more commonly back or neck pain.[1–5]

Although all non-trivial spinal injuries result in some deformity, it is not always clear when a patient suffers from a SPTD? In other words when does a posttraumatic deformity become clinically relevant?

Recently the AO Spine Knowledge Forum Trauma (KF Trauma) set up a project in search of a consensus definition of clinically relevant SPTD. In order to construct a consensus definition, a Delphi study will be held among the AO Spine community. Already two studies were completed to gather information for the adjusted Delphi study: a systematic review of the literature and a survey of experts.[6,7] The systematic review showed that there is no clear consensus in the literature about the diagnosis of SPTD, but identified the different domains of the definition or description of SPTD: Radiological parameters, patient factors, Patient Reported Outcome Measurements (PROMs) and indication for surgical intervention.[6]

The survey showed that there was some consensus amongst the 15 spine experts who completed the study. Consensus was reached that pain is an essential criterion for the definition of SPTD. The radiological assessment deemed necessary for diagnosis and treatment was a full-spine conventional radiograph (CR). The only risk factor with a substantial agreement was the factor 'missed B-type injury'. There was no agreement on other risk factors leading to clinically relevant SPTD. Concerning the management, all participants agreed that an asymptomatic patient should not undergo surgical treatment and that neurological deficit is an absolute surgical indication.[7]

However, both studies did not help in understanding the thought process behind the diagnosis of SPTD. SPTD is still an ill-defined clinical problem of patients with a deformity and/or persistent complaints after spine trauma. In order to evaluate this thought process of international spine experts we constructed a case survey with fully anonymized data of patients who had visited our outpatient clinic in the past.

The aim of this survey is to evaluate the opinion of spine-trauma and -deformity experts in the diagnostic process of clinically relevant SPTD. Specifically with the questions of whether consensus exists on the more important parameters of the medical history/physical examination, the necessary radiological assessment and the more important measurements on radiological assessments. Also, whether there is consensus on the diagnosis of SPTD and if this is considered clinically relevant, and whether there is consensus on the preferred treatment. This case survey will aid in the development of a Delphi-study to create a consensus definition of 'clinically relevant SPTD'.

METHODS

Study Design and recruitment of experts

The experts (orthopedic surgeons or neurosurgeons with research experience) were recruited through the AO Spine Knowledge Forum (KF) Trauma and the KF Deformity. The AO Spine Knowledge Forums are expert-driven working groups generating knowledge in different spine pathologies. They are tasked to assess the best evidence for current practices, and formulate clinical studies to advance their field of spine expertise. The development of the case discussion study was based on KF members discussion and the results from the previous systematic review and exploratory survey.[6,7]

Case Survey development

Each case was presented as if the patient presented him or herself at the outpatient spine clinic. The case was deemed eligible if the patient suffered from a spine trauma at least 3 months previously. Seven different cases were used in this study: two cervical spine (C-spine) cases (case 2 and 7) and five thoracic or lumbar spine (ThL-spine) cases (case 1,3,4,5 and 6). The participants were not familiar with the cases and were therefore blinded for the diagnosis and treatment given to the patient. The patients gave permission that their data could be used anonymously for research objectives. The diagnostic process and treatment considerations were investigated with the same seven questions for each case. Table 1 shows an overview of the questions of the case survey and the full case description of Case 1. The full case descriptions of cases 1-7 are available online as Supplement 1, including the key-images of the cases at time of presentation at the outpatient clinic.

Table 1. Course of the Survey; each case had the same questions.

Case	*Anonymous description of the patient visiting the outpatient clinic* Case 1 Female (age 57), 2 years after T11 A2 fracture treated with Jewitt brace. Current clinical presentation: Disabling back pain irrespective of mobilization after pain free period, pain punctum maximum 'bra-strap' and right side of trunk. Physical examination: mild kyphosis at 'bra-strap', no neurological deficit Additional: receives 'Social security insurance' about disability benefits, DEXA-scan showed no osteoporosis.
Q. 1	Which clinical parameters are most relevant in your decision to suspect SPTD? Please rank the parameters accordingly: 1 = most relevant; highest number = least relevant
Q. 2	What type of diagnostic assessment would you perform? And what is your requested information for each of the assessments? Local CR, full spine CR, flexion/extension CR, lateral bending CR, CT-scan, MR-scan, Nuclear imaging and diagnostic injections.
Case	*Description of the assessments and their parameters, also the participants were able to view the radiological assessments described in the description.* Case 1 Trauma CT: T11 A2 fracture, posterior wall intact, no fractures in posterior structures, facets are aligned MRI +2years: no edema in the bone or surrounding structures. Full spine AP and Lat: Cobb (T10-T12): 25°, ThK (T4-T12): 45°, ThL (T11-L1) 30°, LL (L1-L5): 74°, SS: 51°, PT: 25°, PI: 75°, SVA: 15mm, Scoliosis lumbar 11°, some lumbar facet arthrosis.
Q. 3	Which diagnostic parameter is most relevant in your opinion to diagnose SPTD? Please rank the parameters accordingly: 1 = most relevant; highest number = least relevant Case 1 Trauma CT: level of fracture; MR-scan; Full spine: Cobb; Full spine: ThK, ThL, LL; Full spine: SS, PT, PI; Full spine: SVA; Full spine: Scoliosis; Some lumbar facet arthrosis
Q. 4	What is missing (parameter or diagnostic assessment) for your decision to diagnose this case?
Q. 5	Is this a relevant Spinal Posttraumatic Deformity? - Yes (If yes: asymptomatic OR symptomatic; compensated/balanced OR decompensated/imbalanced) - No - Not sure
Q. 6	What type of treatment would you consider? And what would that treatment be? - Conservative treatment - Surgical treatment - Other
Q. 7	Do you have any additional remarks?

Q: Question, CR: conventional radiogram, AP: anteroposterior, Lat: lateral, ThK: thoracic kyphosis, ThL: thoracolumbar segment angle, LL: lumbar lordosis, SS: sacral slope, PT: pelvic tilt, PI: pelvic incidence, SVA: sagittal vertical alignment

The different categories were: Fracture type (history of the trauma and type of fracture), previous treatment, presence or absence of neurological deficit, complaints (pain, functional disability, etc.), physical examination performed, additional aspects (work status, PROMs), medical history (comorbidities) and gender/age. The lowest number corresponded to being most relevant, the highest number to the least relevant.

Question 1. Clinical parameters (ranking question)
After the case description the participants were asked to rank the different aspects according to their relevance.

Question 2. Diagnostic assessment
The presented diagnostic assessments (local CR, full spine CR, flexion/extension CR, lateral bending CR, CT-scan, MR-scan, nuclear imaging and diagnostic injections) were based on the information gathered from the systematic review and the previously conducted survey. [6,7]

Question 3. Diagnostic assessment (ranking question)
After presentation of the different diagnostic assessments including images and measurements the participants were asked to rank the different groups of parameters from most to least relevant. The groups were: trauma (fracture type, configuration), local deformity (Cobb and wedge angles at presentation), global alignment (thoracic kyphosis, thoracolumbar Cobb angle, and lumbar lordosis), sagittal balance (SVA, cervical SVA), and pelvic parameters (pelvic tilt, sacral slope and pelvic incidence) and additional (facet arthrosis, osteophytes, absence of myelopathy).

Question 4. Missing additional information
From the previously held studies and the face-to-face meetings with the KF Trauma it was clear that there is a wide variation on the perceptions of SPTD. We wanted to give the opportunity to add anything that might be important to form their diagnosis.

Question 5. Is this SPTD?
The participants were asked if the patient had SPTD, and if present, if it was asymptomatic or symptomatic SPTD, and if it was compensated or decompensated SPTD. For example, a compensated patient may have a deformity and complaints, but was able to maintain sagittal alignment.

Question 6. Treatment
To evaluate the different treatment options used by the participants, they could choose their preferred treatment for that case and specify what that treatment entailed.

Question 7. Additional remarks
Participants could add any additional remark to specifics of the case or in general to make sure no important details were missing.

Data collection and analysis

The survey was distributed with REDcap (REDCap Software - Version 6.5.2 - © 2020 Vanderbilt University) and the images were anonymized and distributed in Surfdrive (Coöperatie SURF U.A., The Netherlands). Distribution was between 1st of May and 31st of July. The researcher doing the analysis was blinded for the identity of the participants of the survey. R statistical software (R version 3.3.2; R Foundation for Statistical Computing, Vienna, Austria) was used for the analysis of descriptive statistics. The data from questions 1 and 3 were normalized to a 0-100 scale to compare between the cases. Consensus was reached when ≥80% experts agreed.[8–11]

RESULTS

Demographics

In total 31 spine surgeons received the case survey which was completed by 17 (55%). The KF Trauma was represented by 13 participants who completed the full survey and the KF Deformity by 2 participants. Additionally, three surgeons specialized in spine deformity completed the full survey and one spine surgeon completed only the first case. All participants had >5 years of experience as a spine surgeon.

Clinical parameters

The results are depicted in Figure 1. The items fracture type and complaints tended to be rated by the participants as more important. The items additional medical history, gender/age and neurology tended to be rated as less important. All aspects were rated as most and least important at least by one participant. No consensus was reached for the items overall or for the individual cases.

Diagnostic assessment

See table 2 for the results and reasons for requested assessments. For the C-spine cases (case 2 and 7) the majority of the participants requested a cervical CR (76-83%), a flexion/extension CR (61-71%), a CT-scan (76-89%) and a MR-scan (89-94%). A full spine CR (89-100%), a CT-scan (72-94%) and a MR-scan (65-94%) were requested most in the ThL-spine cases (case 1 and 3-6). The imaging was, however, partly requested for surgical planning purposes and not solely for diagnostic purposes.

Diagnostic assessment of imaging parameters

In Figure 2 the results are depicted. The local deformity tended to be ranked as more important, the pelvic parameters and the additional parameters to be less important. All groups were rated at least once as most important and least important by one participant. No consensus was reached overall or in the individual cases.

Additional information wanted for diagnosis

Not all the cases had all the requested assessments available. Four diagnostic assessment were deemed missing in C-spine cases: cervical CR, flexion/extension CR, full spine CR and MRI at time of trauma. In the ThL-spine cases additional information on pain behavior pattern/psychiatric evaluation, diagnostic injections, supine and standing CR's, description of gait pattern, bone quality measurement, lordosis distribution index and Oswestry disability index was wanted by the experts.

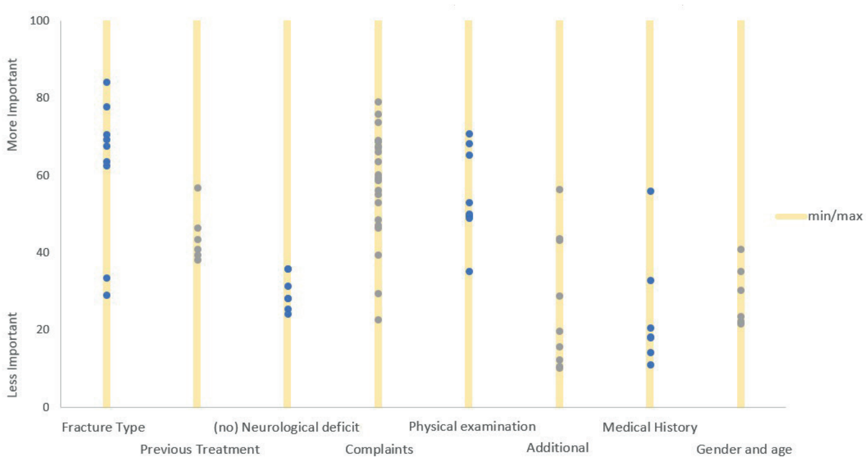

Figure 1. Distribution of the different clinical aspects of the seven cases. This figure shows the distribution of the different clinical aspects of the seven cases. All aspects were rated as most and least important at least by one participant. No consensus was reached for the items overall or for the individual cases.

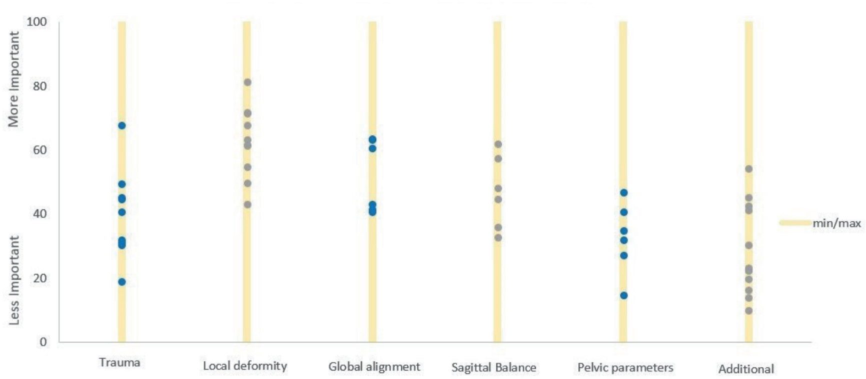

Figure 2. Distribution of the different aspects of the imaging of the seven cases. This figure shows the distribution of the ratings of the different aspects of the imaging assessments. The participants were asked to rank from most to least important. All groups were rated at least once as most important and least important by one participant. No consensus was reached overall or in the individual cases.

Table 2. Diagnostic assessment who were requested by the participants

Diagnostic assessment	Region	Request percentage	Reasons for request
Local CR	C	76 – 83%	Local deformity/collapse, cervical alignment, K-line, disc damage
	ThL	33 – 47%	Local deformity/collapse, other pathology, instability/progression, instrumentation placement
Full Spine CR	C	24 – 44%	Sagittal & coronal balance, thoracic deformity
	ThL	89 – 100%	Sagittal & frontal balance, pelvic parameters, (progression of) local deformity, regional/global alignment, surgical planning, scoliosis, instrumentation placement
Flexion /extension CR	C	61 – 71%	Stability, mobility fracture, reduction possible, pseudo arthrosis
	ThL	24 – 53%	Stability, mobility fracture, compensation, pseudo arthrosis
Lateral bending CR	C	0%	
	ThL	0 – 6%	Instability
CT-scan	C	76 – 89%	Injury details, fusion/non-union/pseudo arthrosis, surgical planning, bone quality, facet alignment
	ThL	72 – 94%	Bone quality, non-union/pseudo arthrosis/healing, facet joints, anatomy, surgical planning, anatomy, screw integrity and positioning
MR-scan	C	89 – 94%	Compromised neurological structures, PLC-injury, status of discs, stenosis, non-union/healing, other pathology, stenosis
	ThL	65 – 94%	Compromised neurological structures, PLC-injury, status of discs, stenosis, non-union/healing, surgical planning
Nuclear imaging	C	0%	
	ThL	0 – 6%	Bone health
Diagnostic injections	C	0%	
	ThL	0 – 44%	Discern between source of pain: discography to detect disc problems, degenerative pain source.
Other	C	0%	
	ThL	0 – 18%	BMD/DEXA scan

CR: conventional radiograph, C: cervical; ThL: thoracolumbar; PLC: posterior ligamentous complex of the spine

Relevant SPTD

Five out of the seven cases (case 2,3,5,6 and 7) were classified as SPTD (82-100%) and in two other cases (cases 1 and 4) no consensus was reached amongst the participants (35-44%). In the 5 cases in which consensus was reached, there was also consensus on the case being compensated or decompensated and being symptomatic or asymptomatic. Figure 3 shows the opinion of the participants per case on the presence and type of SPTD.

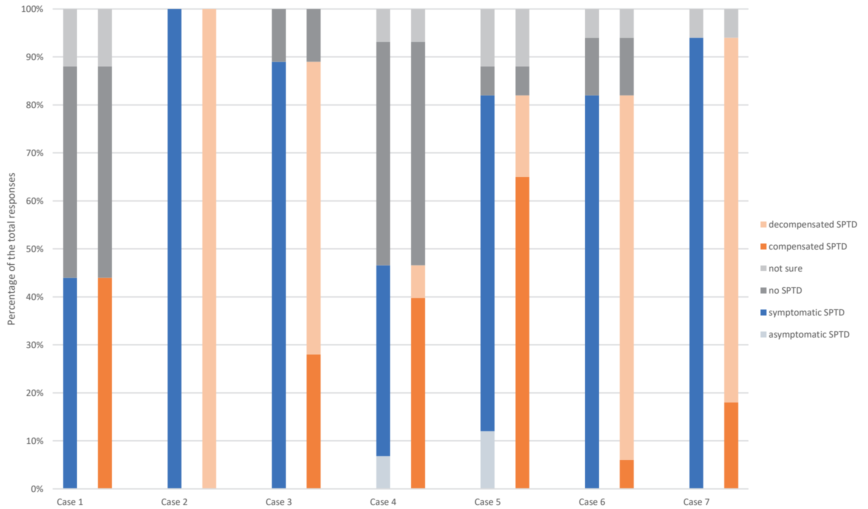

Figure 3. Presence and type of SPTD per case. This figure shows whether the participants diagnosed the patients with SPTD per case. Consensus was present on the case being compensated or decompensated and being symptomatic or asymptomatic, when there was agreement on the presence of SPTD.

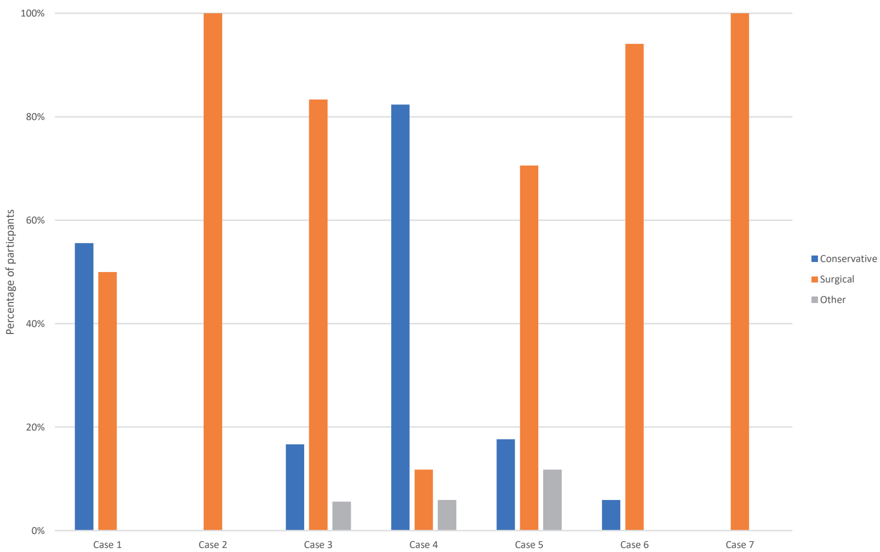

Figure 4. Treatment choices per case. This figure shows the distribution of the treatment choices of the participants per case.

Treatment

The participants unanimously agreed that they would treat both the cervical cases (case 2 and 7) surgically. Only the thoracolumbar cases with a higher agreement towards SPTD (case 3 and 6) would be treated surgically by most participants. There was consensus to treat case 4 conservatively, without agreement on SPTD. Figure 4 shows the distribution of treatments per case.

Other comments

The additional comments were mainly on the treatment contemplations of the cases. Those contemplations depended, for example, on the effect of diagnostic injections before surgery or whether a conservative therapy would be initiated first because of a short time between trauma and presentation of the patient. Also comments on missed fractures were mentioned such as: "this is not SPTD, but B-type injury possibly missed".

DISCUSSION

The current study is unique and innovative in the field of spine trauma and has been set up as a preparatory study for a future Delphi study. This study showed the clinical path of patients with sequels after a spine trauma and the different opinions of spine experts in their diagnosis and treatment. There was strong consensus in 5 out of 7 cases on diagnosis of clinically relevant SPTD. There was also strong consensus on the use of specific imaging assessments. For C-spine cases: cervical CR, CT-scan and MR-scan. For ThL-spine cases: full spine CR, CT-scan and MR-scan.

The diagnostic assessments were requested by the participants for many different reasons (Table 2). When constructing this survey, we decided to split the diagnostic assessment from the treatment considerations. The responses from our participants showed that some imaging modalities serve both diagnostic and treatment planning. In current medical practice, treatment is considered from the moment a patient enters the room of the surgeon. We should strive for the minimum of imaging modalities necessary, but refrain from repeating similar modalities without receiving additional information for the diagnosis or treatment of the patient.

Earlier studies suggested that asymptomatic SPTD can be present in patients after a spine trauma.[6,12] The patients with an asymptomatic SPTD might not seek the advice of the spine surgeon because there are no complaints. However, with increasing age the compensation mechanisms in place might decline and an asymptomatic patient can present with symptoms over time.[13] There was consensus that patients with asymptomatic SPTD should not receive surgical treatment. This was in line with the opinion of Boehm et al.[13] They also stated that patients without complaints should be monitored closely and informed on the possibility of decline of mobility and development of arthrosis.[13]

Our study shows that in most cases unanimous agreement was achieved that the patients exhibited a clinically relevant SPTD. However, the participants did not agree on two ThL-spine cases (case 1 and 4). In the results of those two cases we found differing opinions and wide ranges concerning questions 1 and 4. Subsequently, there was relatively less deformity visible on the diagnostic imaging compared to the cases with consensus on the diagnosis of SPTD. This highlights the problem that disagreement exists on the edges of the spectrum of SPTD, and surgeon variability, preference and available resources are part of this disagreement.

Some specific comments raised questions about a missed fracture without proper treatment. This is an interesting standpoint about the causes of this type of spinal deformity. Is there a categorical difference between missed fractures and fractures which were diagnosed and treated, if they end up in similar symptomatic deformities?

Our study was limited by the number of listed factors of the visit at the outpatient clinic. At the outpatient clinic the patient's history and physical examination were noted by a physician. But not all patients will have the same amount of information noted from the visit. For example, the participants could rank 9 different factors for case 4 and up to 13 factors for case 2. We decided not to create equal amounts of factors because this would mean withholding possible important pieces of information. A complete standardized approach could have led to greater consensus, but if we do not know which parameters are the most essential it is difficult to set up such an approach. To allow comparison the data from the different factors was normalized during analysis to a 0-100 score.

Additional to the case variability, several surgeon specific factors could contribute to the overall disagreement in this study. For example, some variability can be attributed to the resources available to the surgeon, the experience and the preference of the surgeon. This could be prevented by choosing a specific population of surgeons, however, in our aim to create an international consensus definition, we thought it important to include an international group of surgeons.

The strength of our study lies in the fact that this survey was based on real cases as they presented themselves at the outpatient clinic. This strategy enabled us to capture the diagnostic process of the spine surgeon and see how decisions were being made during that process. We highlighted that patients with possible SPTD did not receive the proper treatment at first or that injury was missed. This confirms that SPTD is a preventable complication of spine trauma. To prevent this complication, it is essential to know the risk factors, but to study these, a proper definition of clinically relevant SPTD is necessary.

The findings from this study add to the growing understanding of STPD. Consensus on which imaging assessments to use and consensus on certain cases helps us in the search for a consensus definition of clinically relevant SPTD. Our next steps will be to perform a Delphi study among the global spine community to create this consensus definition of clinically relevant Spinal Posttraumatic Deformity.

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Supplement 1. Case descriptions

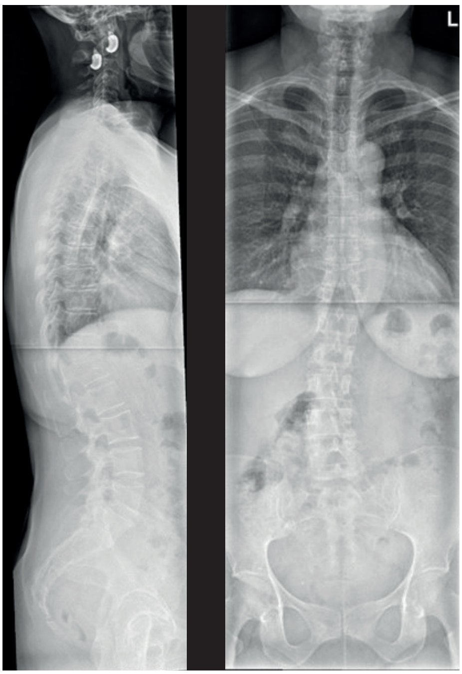
Case 1

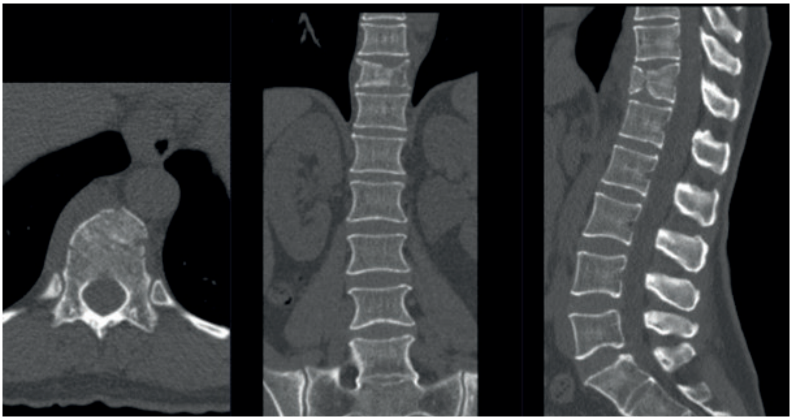
Visit outpatient clinic

- Female, age 57
- 2 years after T11 A2 fracture. Received conservative treatment with Jewitt brace.
- Current clinical presentation: Disabling back pain irrespective of mobilization after pain free period, pain punctum maximum 'bra-strap' and right side of trunk.
- Physical examination: mild kyphosis at 'bra-strap', no neurological deficit
- Additional: receives 'Social security insurance' about disability benefits, DEXA-scan showed no osteoporosis

Radiological assessments and parameters

- Trauma CT: T11 A2 fracture, posterior wall intact, no fractures in posterior structures, facets are aligned
- MRI +2years: no edema in the bone or surrounding structures.
- Full spine AP and Lat: Cobb (T10-T12): 25˚, ThK (T4-T12): 45˚, ThL(T11-L1) 30˚, LL (L1-L5): 74˚, SS: 51˚, PT: 25˚, PI: 75˚, SVA: 15mm, Scoliosis lumbar 11˚, some lumbar facetarthrosis.





Case 2

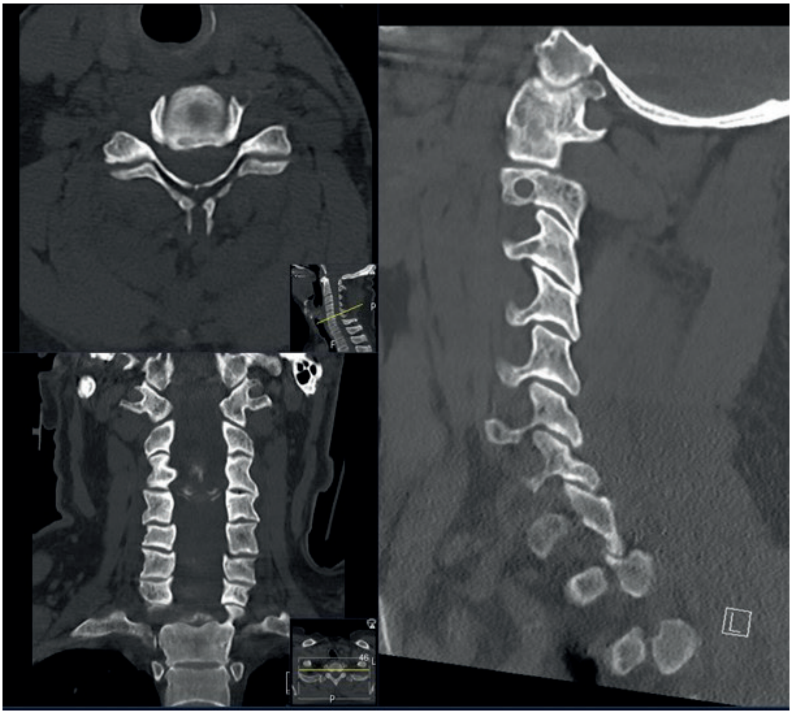
Visit outpatient clinic

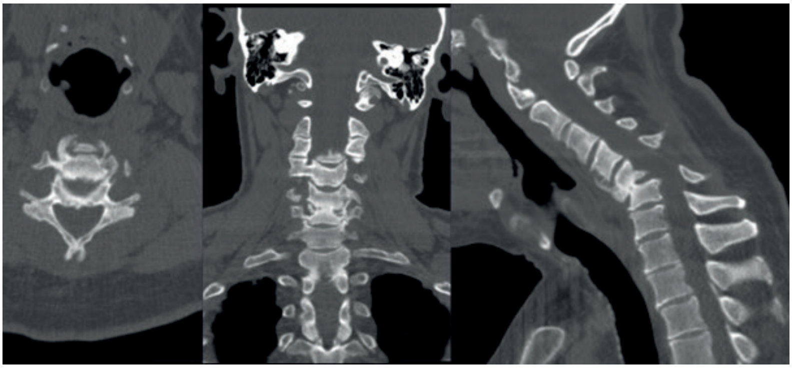
- Male, age 68
- Presentation 6 months after fall from small step on back/neck, with 2 weeks temporary paresthesia in right arm, no injury on trauma CT. Received no treatment except physiotherapy for contusion neck.
- Current clinical presentation: Pain right side of neck and shoulder (NRS pain 7/10), exacerbated by coughing/sneezing, unable to play tennis. Head falls forward.
- Physical examination: pain at level C6, no neurological deficit
- Additional: No medical history. Work: retired, Neck Disability Index: 13 (minimal disability), AOSpine PROST: 79/100 (total)

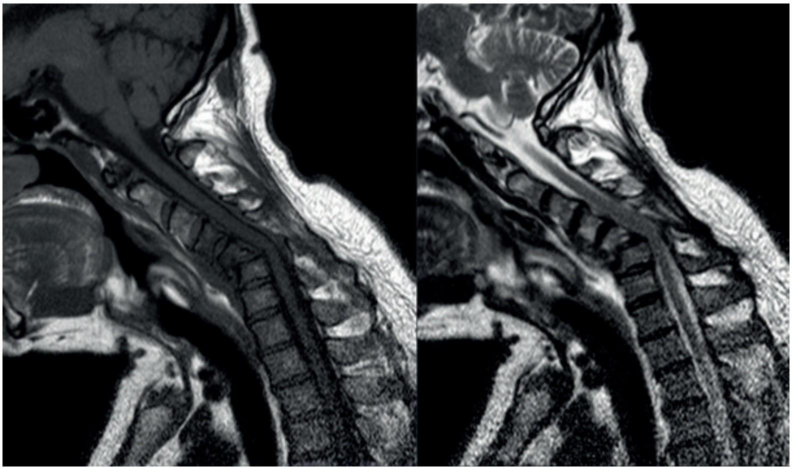
Radiological assessments and parameters

- CT trauma: no evident fracture, enlarged facet joint C5-6 Right>Left

- Cervical radiograph: Cobb (C4-C6): 32°(kyphosis), wedge (C6): 2°, C2-7 L: 21 °(kyphosis), C2-7 SVA: 28mm, T1 slope: 21°
- MRI +6months: injury disc/PLC at level C5-6 with major dislocation/kyphosis, no evident myelopathy
- CT +6months: Major anterior dislocation C5-6, with bilateral dislocation of the facet joints, anterior osteophytes present at C5-6.







Case 3

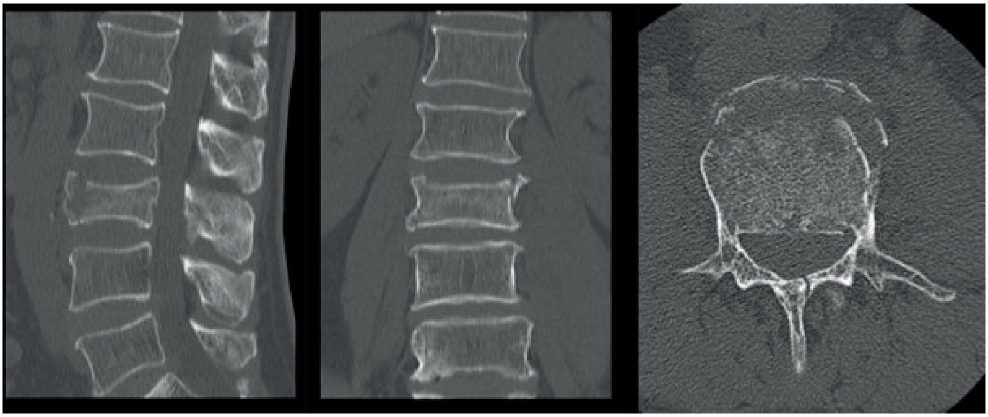
Visit outpatient clinic

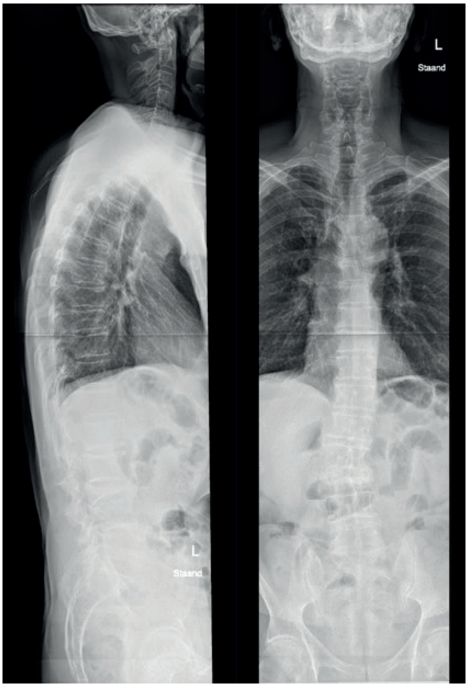
- Male, age 64
- Presentation 4 moths after fall from height(2.5m), L3 A4 fracture. Received conservative treatment with brace for 6 weeks. Also suffered a distal radius fracture.
- Current clinical presentation: After stop brace increasing pain lower back, problems with lifting upper right leg, no incontinence.
- Physical examination: Absent lumbar lordosis, hyperkyphotic spine, MRC 5- left quadriceps, remaining MRC 5, no other neurological deficit
- Additional: No medical history. Work: self-employed builder, unable to work

Radiological assessments and parameters

- CT trauma: L3 A4 fracture, minimal protrusion in the canal
- MRI T2 sag +4 months: no neural compression, relative canal stenosis.

- Full spine AP and Lat: Cobb (L2-L4): 9˚, wedge (L3): 35˚, ThK (T4-T12): 36˚, ThL(T11-L1) 4˚, LL (L1-L5): 24˚, SS: 22˚, PT: 30˚,PI: 52˚, SVA: 67mm, scoliosis Cobb 15˚





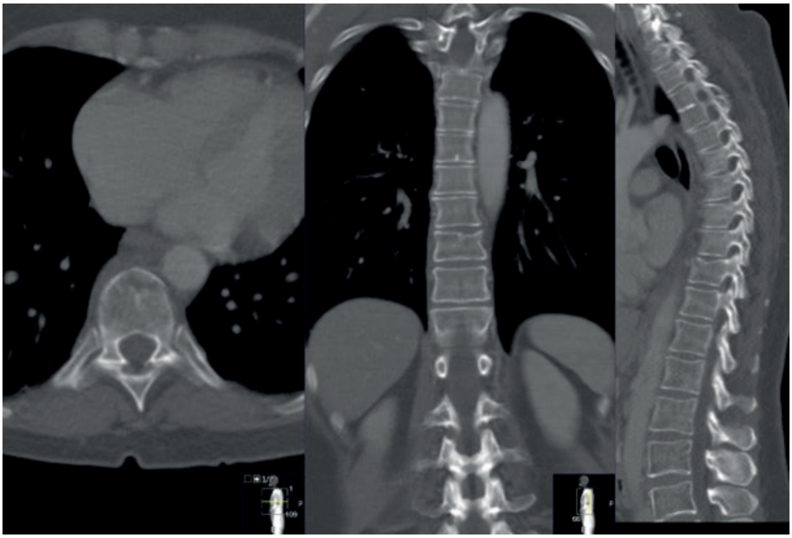
Case 4

Visit outpatient clinic

- Female, age 59
- Presentation 1 year after pedestrian vs car (30 km/h), T10 A2 fracture. Received conservative treatment with mobilization and painkillers. Other injuries: Facial fractures, right subcapital humerus fracture, right sacral and acetabular fracture (all conservatively treated).
- Current clinical presentation: Diffuse back and neck pain mostly after exertion
- Physical examination: Palpation painful mostly paravertebral, no neurological deficit
- Additional: Hypertension, Diabetes Mellitus 2. Work: Social worker psychiatry/ geriatrics

Radiological assessments and parameters

- CT trauma: T10 A2 fracture
- MRI +1month: no ligamentous injury
- Full spine AP + Lat +4months: Cobb (T9-T11): 20°, wedge (T10): 19°, ThK (T4-T12): 46°, ThL(T11-L1) -1°, LL (L1-L5): 60°, SS: 39°, PT: 15°, PI: 53°, SVA: 39mm
- Thoracic and Lumbar spine sag +1 year: Cobb (T9-T11): 20°, wedge (T10): 20°



Case 5

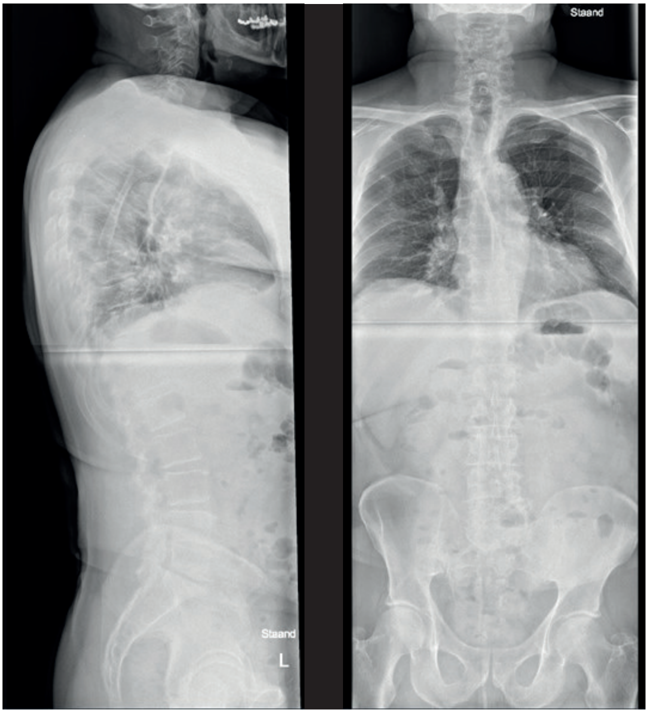
Visit outpatient clinic

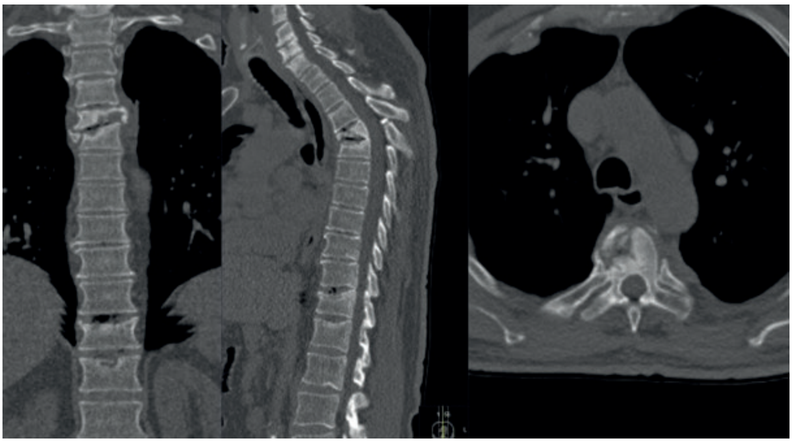
- Male, age 67
- Presentation 4 months after bike accident, radiograph T4/5 compression/burst fractures (no CT-scan of thoracic spine), received conservative treatment with painkillers, mobilization and physiotherapy. Other injury: sternal fracture
- Current clinical presentation: Persistent chest pain, pain between shoulder blades after 30-45min walking/biking.
- Physical examination: No pain on palpation back, evident sternal offset, no neurological deficit
- Additional: hypercholesterolemia. Work: retired (carpenter, still practices)

Radiological assessments and parameters

- Tspine lat: T4 A3, B component cannot be identified

- Full spine AP+lat +4months: Cobb (T3-T5): 46˚, wedge (T4): 23˚, wedge (T5): 22˚, ThK (T4-T12): 57˚, ThL(T11-L1) 12˚, LL (L1-L5): 53˚, SS: 29˚, PT: 16˚, PI: 46˚, SVA: -8mm
- CT +4 months: T4 A4B2, T5 A3, T11 A1, sternal fracture; Vacuum cleft T4 and T5.
- MRI +4 months: no myelopathie, some bone marrow oedema on STIR





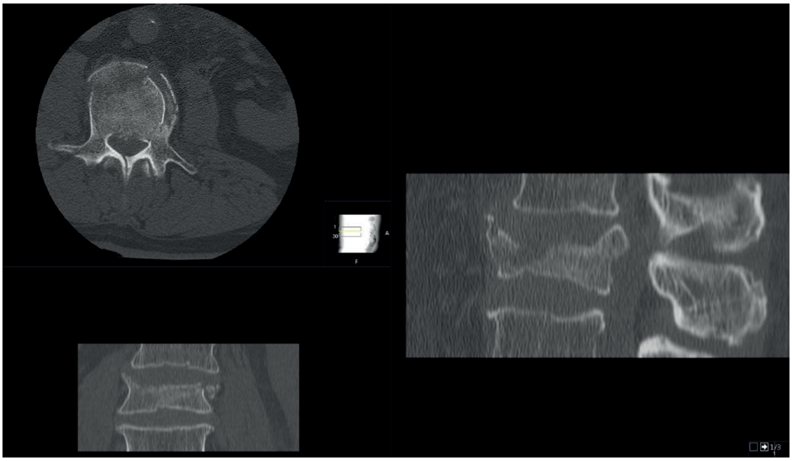
Case 6

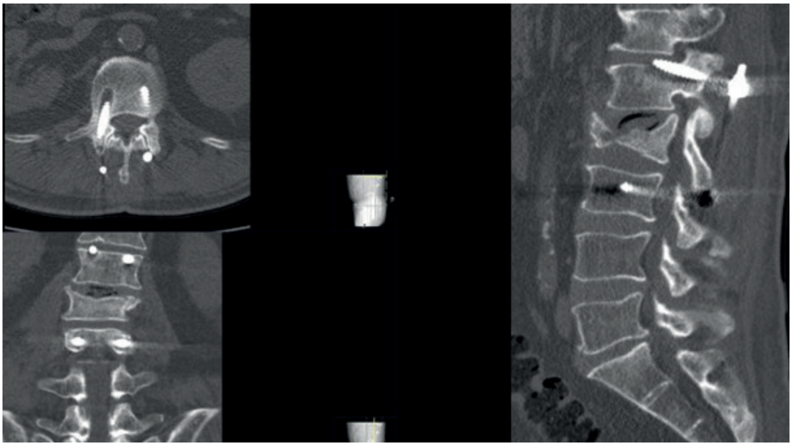
Visit outpatient clinic

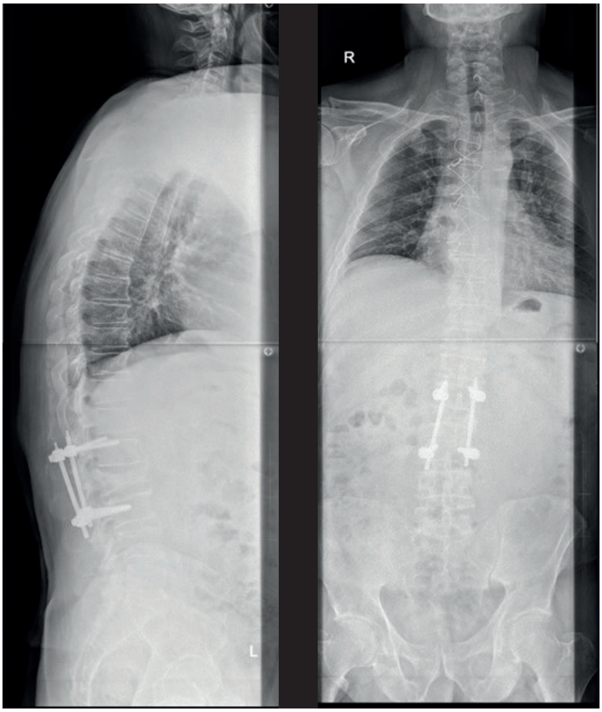
- Male, age 63
- Presentation 6 months after a fall, resulting in L2 A4, received operative treatment spondylodesis L1-3, still uses multiple painkillers
- Current clinical presentation: Disabling progressive lower back pain 6 weeks after surgery, pain while walking
- Physical examination: Painful palpation lumbar spine, all movement is painful, no neurological
- Additional: Diabetes type 2, CABG, intermittent claudication. Work: retired (hospitality)

Radiological assessments and parameters

- CT trauma: L2 A4 fracture, vertebral arch L2 is fractured
- CT +6months: Pull out of superior right screw (L1), vacuum cleft L2.
- Full spine radiograph +6months: Cobb(L1-L3): 14°, wedge (L2): 25°, ThK (T4-T12): 35°, ThL(T11-L1) 6°, LL (L1-L5): 24°, SS: 23°, PT: 24°, PI: 46°, SVA: 78mm







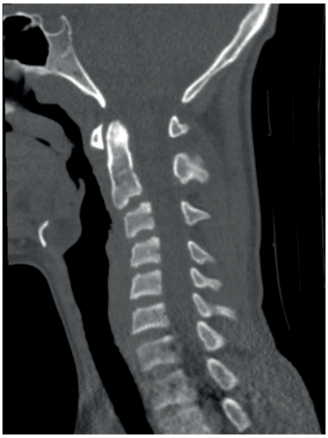
Case 7

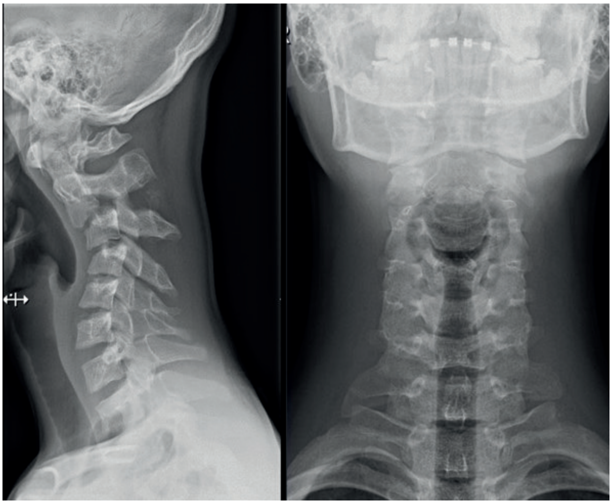
Visit outpatient clinic

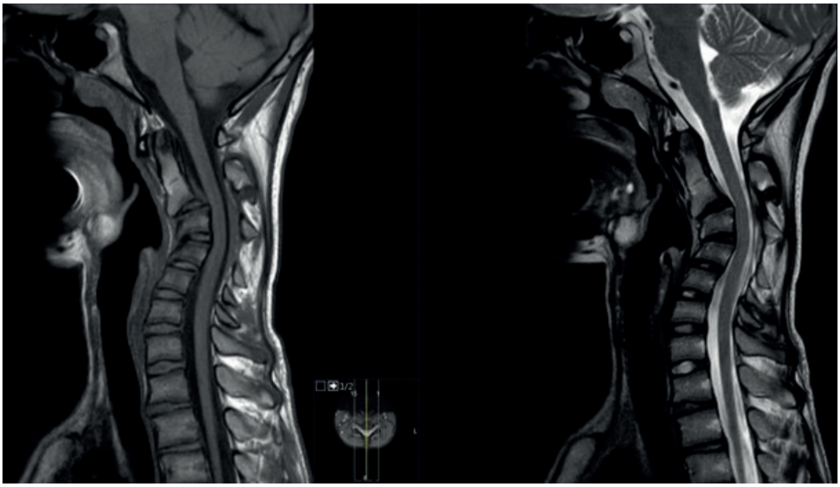
- Male, age 15
- Presentation 5 months after someone hit his neck during PT-class, but CT-scan showed no traumatic injuries. Patient described a temporary funny feeling in both legs. Received conservative treatment of 1 week collar, and was discharged after 1 week from follow-up
- Current clinical presentation: Persistent pain during the day, worse at night.
- Physical examination: Extension, rotation and lateroflexion all partially restricted. No neurological deficit.
- Additional: No medical history. Work: High school, aspires to work in construction

Radiological assessments and parameters

- CT trauma: no traumatic abnormalities, slight kyphosis normal variant or due to pain
- Cervical spine radiograph +5months: major kyphotic Cspine, Cobb (inf C2-C4): 53°, wedge (C3): 13°, C2-7 L: 17° kyphosis, C2-7 SVA: 21mm, T1 slope: 36°
- MRI +5months: Dislocation C2-C3, no myelopathy







7

Chapter 7

Term and Definition of a deformity after a spine trauma: Results of an international Delphi Study

Erin E.A. De Gendt, Sander P.J. Muijs, Lorin M. Benneker, F. Cumhur Oner

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Abstract

Introduction: Deformity of the spinal column after trauma could lead to pain, impaired function, and may sometimes necessitate extensive and high-risk surgery. This 'condition' has multiple terms and definitions that are used in research and clinics. A specific term and definition of this condition however is still lacking. A uniform and internationally accepted term and definition are necessary to compare cases and treatments in the future. Research question: Reach consensus on the term and definition of this deformity after spine trauma using a Delphi approach.

Material and methods: An 'all-rounds invitation' Delphi process was used in this study among a group of international experts. The first round consisted of an online survey using input from preparatory studies, a typical clinical case and ICD-11 codes. The second round showed the results in-person and discussion was encouraged. Participants voted for rejection of certain terms. In the third round the final vote took place. When >80 % of the votes was for or against a term the term was rejected or accepted.

Results: Response rate was high (≥84 %). The 3 Delphi rounds were completed. Unanimous voting led to the acceptance of the term and abbreviation as PSD. Deformity in any plane, pain, impaired function, and neurological deficit, were deemed important to include in the definition of PSD.

Discussion and conclusion: Unanimous consensus was reached on 'Posttraumatic spinal deformity: Condition where a trauma to the spine results in a deformity in any plane and results in pain and an impaired function with or without a neurological deficit.'

Keywords: Posttraumatic spinal deformity PSD Deformity Impaired function Spine trauma

INTRODUCTION

It is well known that some deformity after a traumatic injury to the spine is almost inevitable. Many experts have discussed the size of deformity after trauma and the clinical relevance of it to patients.[1,2] However, when and how much deformity after a spine trauma is a problem for patients resulting in pain, impaired function and in some cases necessitating a (re-)operation is still controversial.

The next step to aid in the research and clinical practice of this condition is the development of a uniform and internationally accepted definition, to enable comparability of future research on this topic. Recent research showed that there is still a big discrepancy in opinions on this topic.[3,4] There is even no agreement on the name of this 'condition' as many different names and terms have been used in the literature. Schoenfeld et al published a definition after sending out a survey to 35 members of the AO Spine community.[2] The term they used for this condition was posttraumatic kyphosis and it resulted in this definition: 'a painful kyphotic deformity after a spine trauma'. This definition is however limited and does not fully depict the condition PSD. The survey was 29-questions long and covered everything from etiology to treatment preferences. This study was however conducted in a time when the participants used different terms for the condition, clouding judgement, and precision of the study. Consequently, the participants did not reach consensus on many factors leading to a limited definition of the condition. A systematic review showed that the most common terms used were: 'spinal posttraumatic deformity', 'symptomatic spinal posttraumatic deformity', 'symptomatic posttraumatic deformity', 'late kyphotic deformity', 'chronic vertebral instability', '(severe) posttraumatic kyphosis', 'posttraumatic deformity syndrome', 'posttraumatic kyphosis' and 'spinal deformity, posttraumatic'.[1]

Many different terms result in many different definitions used in research and clinical practice. The decision making in this condition is challenging because the surgical procedures necessary to correct the deformity are usually very extensive and high risk. The outcome after these procedures is furthermore not always as good as hoped for. [5,6] Different techniques have been reported, and it is therefore important that comparisons can be made. However, there are no uniform term or definition used for this condition of the spine. This results in the incomparability of treatments of patients with a deformity after a spine trauma.

Next to these arguments, a clear definition can aid in identifying patients with a trauma to the spinal column with risk factors for developing PSD in the future. This could result in better treatment decisions at time of trauma to prevent the development of this condition.

This study aims to provide a universal term and definition of posttraumatic spinal deformity using a Delphi approach in the AO Spine Knowledge Forum Trauma. Clear description of the definition will aid in decision making in clinical practice and aids in accomplishing a uniform language in research of this condition.

METHODS

Study team and Participants

A study team was selected to conduct the study. The two members of this team, one researcher (EdG) and one research manager from the AO Spine Knowledge Forum Trauma (KF Trauma), did not take part in de Delphi rounds.

Twenty-four experts from the KF Trauma (orthopedic surgeons and neurosurgeons) with at least 3 years of experience in the treatment of spine trauma were included in this research.

Figure 1 shows a flowchart of the Delphi process. An 'all-rounds invitation' set-up was used for this Delphi study.[7]

First round: collection of relevant factors

First, the information from preparatory studies was collected.[1,3,4] Earlier a preparatory systematic review was performed.[1] This review included 46 articles containing a unique definition or description of a deformity after a spine trauma (Figure 2). The different terms given to the condition were used as input for the first Delphi round. Additional terms used in other preparatory studies were included.[3,4] All the terms can be found in Appendix A.

Second, two typical clinical cases were presented to enhance decision making in the survey. Both patients approved the use of their anonymized data including radiological images. After the presentation of the cases the participants were asked to choose which definition they preferred, or if they wanted to add another definition. The participants were asked to justify their choice of definition. The case descriptions including imaging is provided in Appendix B.

This information was sent to the participants in an online survey comprising of two main questions:

If you look at this clinical case, what do you think the condition should be called using a single unifying term (all mentioned terms were collected from the literature through preparatory studies or do you prefer another term)?

Please select why you prefer this name? Please check all boxes that apply to you.

Multiple options were given to help in the discussion in round 2.

Third, ICD-11 codes were searched for definitions that were related to spinal or posttraumatic pathology. The terminology and systematics used, were identified, and used in the consensus meeting during the discussion (2nd round).

Fourth, an online survey was sent to all participants. The survey consisted of two questions. The first question was multiple choice and based on the most mentioned factors in the literature. Participants could choose as many as they wanted. The second question was an open field where the participants were asked to describe the condition in their own words.

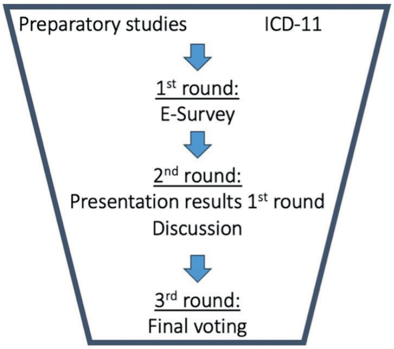


Figure 1. Flowchart of the 'all-round invitation' Delphi process to the definition of posttraumatic spinal deformity

Second Round: discussion

In preparation for the 2nd round the data collected in the first round was analyzed using word clouds and thematic free text analysis. Percentages were given when applicable.

During the second round the results from the first round were presented to the participants at the in-person KF Trauma meeting. Discussion in this round was stimulated by showing the different terms and asking for opinions and why to accept or reject is. Also, example definitions were shown and participants were asked for opinions and reasons to accept or reject certain factors in the definition.

Third round: final voting

In the third round the final voting was done first, per term and second, per factor to be part of the definition. When >80% of the votes was 'Yes' for a factor it was accepted. These factors were than incorporated in a definition which was then voted on until >80% of the votes was 'Yes'.

RESULTS

First round

The first round was started by 19 participants, of which 17 completed the survey. One entry was incomplete, and one participant completed it twice (response rate of 84%).

Term

Symptomatic spinal posttraumatic deformity was chosen by 53% of the participants. Four terms were not chosen by any participants: Chronic vertebral instability, (severe) posttraumatic kyphosis, late kyphotic deformity, and spinal deformity, posttraumatic. The results of the entries and percentages of the different terms are stated in Table 1.

Almost 90% of the participants stated that their choice of term 'explains exactly what the condition is'. In Figure 3 all the different reasons for choosing the specific terms are depicted.

Definition

From the systematic review fourteen different factors were extracted. Figure 4 shows the different factors mentioned in the articles as percentages from the total number of articles.

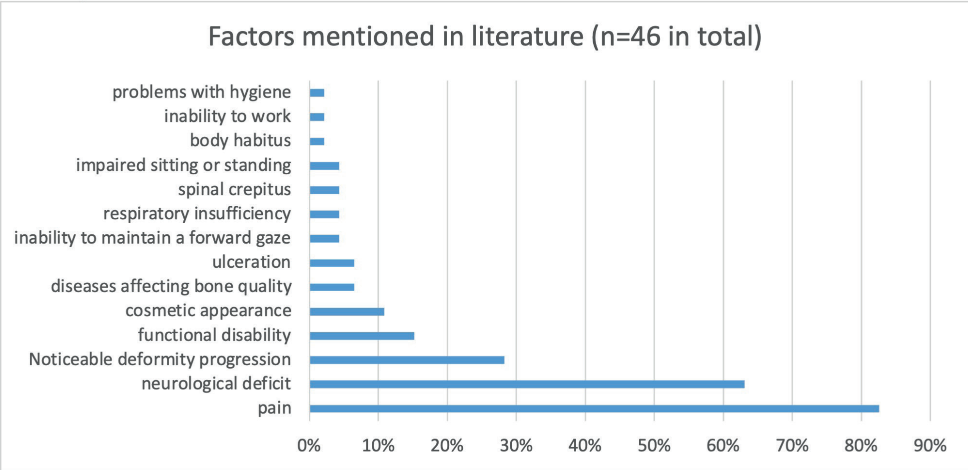


Figure 2. This graph depicts the percentages per factor mentioned in literature on posttraumatic spinal deformity

Table 1. Results of the first Delphi round of the chosen terms.

Possible Index Term	Number of entries	Percentage
Symptomatic spinal posttraumatic deformity	9	53%
Spinal posttraumatic deformity	3	18%
Posttraumatic kyphosis	2	12%
Posttraumatic deformity syndrome	1	6%
Symptomatic posttraumatic deformity	1	6%
Other: Symptomatic posttraumatic kyphosis	1	6%
Chronic vertebral instability	0	
(severe) Posttraumatic kyphosis	0	
Late kyphotic deformity	0	
Spinal deformity, posttraumatic	0	

Two similar definitions were extracted from the ICD-11 codes (Appendix A). The systematics used in the ICD-11 definitions focusses on the pathology, the symptoms, or the cause of the condition/term. This systematics was explained and discussed during the second round and helped structure the final definition in the third round.

In total seventeen participants completed the online survey (response rate of 84%), one completed it twice and one entry was incomplete. The results of the first question are presented in Figure 3. The descriptions of PSD from the second question were processed and presented to the participants as seen in Figure 5.

Second round

All the results from the first round were presented to the participants during the in-person meeting (24 participants were present). Personal and common reasons to include or exclude certain parts of the term and factors of the definition were discussed. All 24 participants voted, none refrained.

Term

The mentioning of 'kyphosis' in the term was discussed as it excluded deformities in other planes that are deemed possible in this condition. The word 'symptomatic' was discussed, with supporters and opponents. Also, the following terms with the least or no votes in the first round were discussed and rejected by >80% of the participants: Posttraumatic deformity syndrome, Symptomatic posttraumatic deformity, Other: Symptomatic posttraumatic kyphosis, Chronic vertebral instability, (severe) posttraumatic kyphosis, Late kyphotic deformity and Spinal deformity, posttraumatic. This resulted in the following terms that were included for voting in the third round: Symptomatic spinal posttraumatic deformity, Spinal posttraumatic deformity, and Posttraumatic kyphosis.

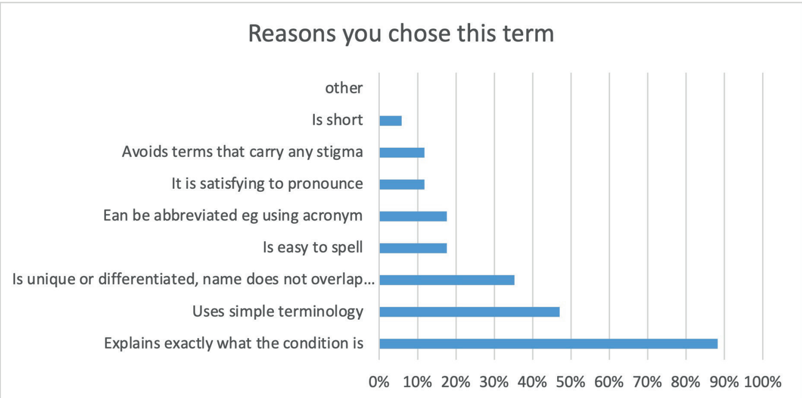


Figure 3. The reasons why participants chose their preferred term given in percentages of total participants (17). Participants could choose more than one.

Definition

There was discussion on the word 'kyphosis', it was stated that also deformity in other planes could be present and that those should not be excluded in the final definition.

Another topic of discussion was whether to add a certain timeframe to the definition. It was decided that this was not applicable because it would limit the possible inclusion of certain patients in the future. The factor 'neurological deficit' was discussed as being not always present but still an important part in this condition and therefore that it should be included in the definition without excluding any patients. It was proposed to add a certain cut-off value of an angular measurement, from the results of the survey >20 or >30 degrees were mentioned by two separate participants. The discussion concluded that no such cut-off value could be added because no consensus existed in current literature or amongst experts.

The following example definitions were presented and discussed: 'Condition where a trauma to the spine results in: a deformity in any plane of the spine (outside normative ranges) and results in pain, an impaired function and can be accompanied with a (increasing) neurological deficit; a malalignment of the spine in any plane, pain, and impaired function.'

Third round

Term

A definitive voting process was started in which the research team posed the terms. In the end a unanimous agreement was reached for the term Spinal Posttraumatic Deformity. No one refrained from voting. Also, with several native English participants present it was decided that the order of the words should be adjusted. And the term: Posttraumatic Spinal Deformity with PSD as abbreviation was unanimously accepted by the participants.

Definition

After the discussion of the second round, >80 % of the participants voted to include the factors: pain, impaired function, deformity in any plane, and neurological deficit in the definition. Using the ICD-11 code systematics a final definition was proposed and voted upon. The final definition of posttraumatic spinal deformity: 'Condition where a trauma to the spine results in a deformity in any plane and results in pain and an impaired function with or without a neurological deficit.'

This definition was unanimously accepted as the new definition of posttraumatic spinal deformity.

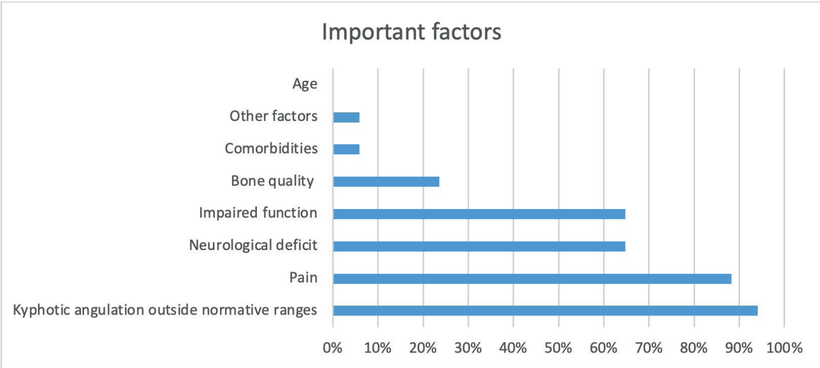


Figure 4. This graph depicts the percentages of respondents that deemed the factors mentioned in literature were important in posttraumatic spinal deformity.

CONCLUSION

When the name and definition of a condition is not unanimously accepted, comparison in treatment, research and outcomes can be difficult. This study focused on the creation of the term and the definition of the condition: a deformity after a spine trauma, through an 'all-rounds invitation' Delphi process. The participants unanimously accepted posttraumatic spinal deformity (PSD) with the definition: 'Condition where a trauma to the spine results in a deformity in any plane and results in pain and an impaired function with or without a neurological deficit.'

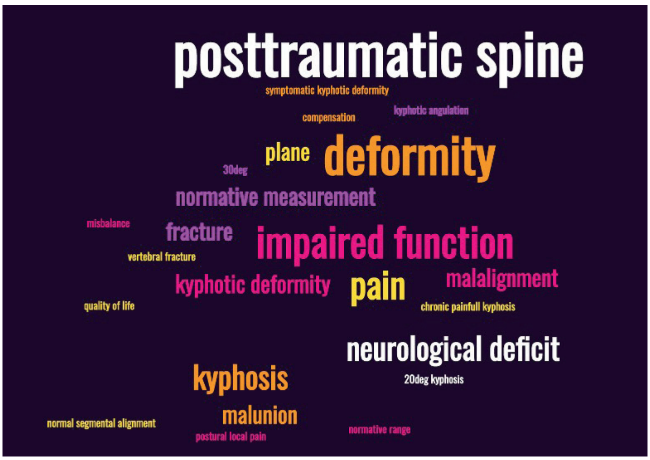


Figure 5. The magnitude of the factors is directly related to the number of times that factor was mentioned by participants.

DISCUSSION

A Delphi study is an ideal format to explore all the different opinions and discuss them in a group of experts. We decided to use an adjusted format of the Delphi study, using preparatory studies as well as an online survey in preparation. This decreased time spent for the participants and enhanced the response rate. We did think it important to have in-person discussion to enhance the quality and acceptance of the new definition. Those who were not able to be present in-person were able to attend through video connection.

An 'all-rounds invitation' was used in this Delphi study. The original set-up of a Delphi study uses only respondents of previous rounds for consecutive rounds. An 'all-rounds invitation' set-up allows participants to join in the consecutive round regardless of their earlier participation. In 2021, Boel et al, researched the difference between the two approaches in an e-Delphi study.[7] They found a lower overall response rate for the original set-up (46%) compared to the 'all-rounds invitation' (61%). No differences were found in the percentages of critical votes or consensus results. Concluding that an 'all-rounds invitation' approach is not inferior to the original set-up and might be beneficial. Our study found a high (17 out of 19 participants) response rate in the first round. And a complete response rate in the second and third round. The second and third round were during the in-person meeting and discussion. There was a possibility of refraining from voting, but no participant chose to refrain from voting.

Schoenfeld et al did great work trying to define this condition.[2] But with an absent uniform defined and specified term this task was difficult, the term Schoenfeld et al choose was: posttraumatic kyphosis. This excludes a group of patients who do suffer from PSD, and have a deformity in another plane of the spine. Also, just one big survey among the experts was not enough to get all different views and experiences on the same page. They reported great variance in opinions and were not able to add other factors to their definition.

A limitation of this study was mostly in the wording of the typical clinical case. It had to be without any implications or judgements and in correct and clear wording. Another limitation came up during one of the discussions in the last round. An adequate abbreviation should be decided because this would limit confusion when the term will be used in future research. An adequate abbreviation of the term 'posttraumatic spinal deformity' could be PTSD, but this is already a widely accepted abbreviation for posttraumatic stress disorder. It was then decided by unanimous voting that PSD was an adequate definition without big associations to other conditions.

In the future our aims are to submit the term posttraumatic spinal deformity and the definition to be included in the ICD-11 codes. When a term and definition are included in the ICD-11 codes, they are internationally accepted and findable for a major public. This will aid in the increased awareness of the condition posttraumatic spinal deformity in research and clinical practices.

In the future we would like to progress this research by setting up an international cohort study where patients after a spine trauma are followed using the AO Spine PROST up to ten years with additional radiographs to measure progression or stability. The idea is that we can then see which patients yield a high risk to develop PSD and see which factors they have in common. If those factors are present in a patient who arrives at the hospital after a trauma to the spinal column, we could decide to treat that patient, accordingly, depending on the presence or absence of risk factors for developing posttraumatic spinal deformity in the future.

APPENDIX A

Chronic vertebral instability
Late kyphotic deformity
Posttraumatic deformity syndrome
Posttraumatic kyphosis
(severe) Posttraumatic kyphosis
Spinal deformity, posttraumatic
Spinal posttraumatic deformity
Symptomatic posttraumatic deformity
Symptomatic spinal posttraumatic deformity

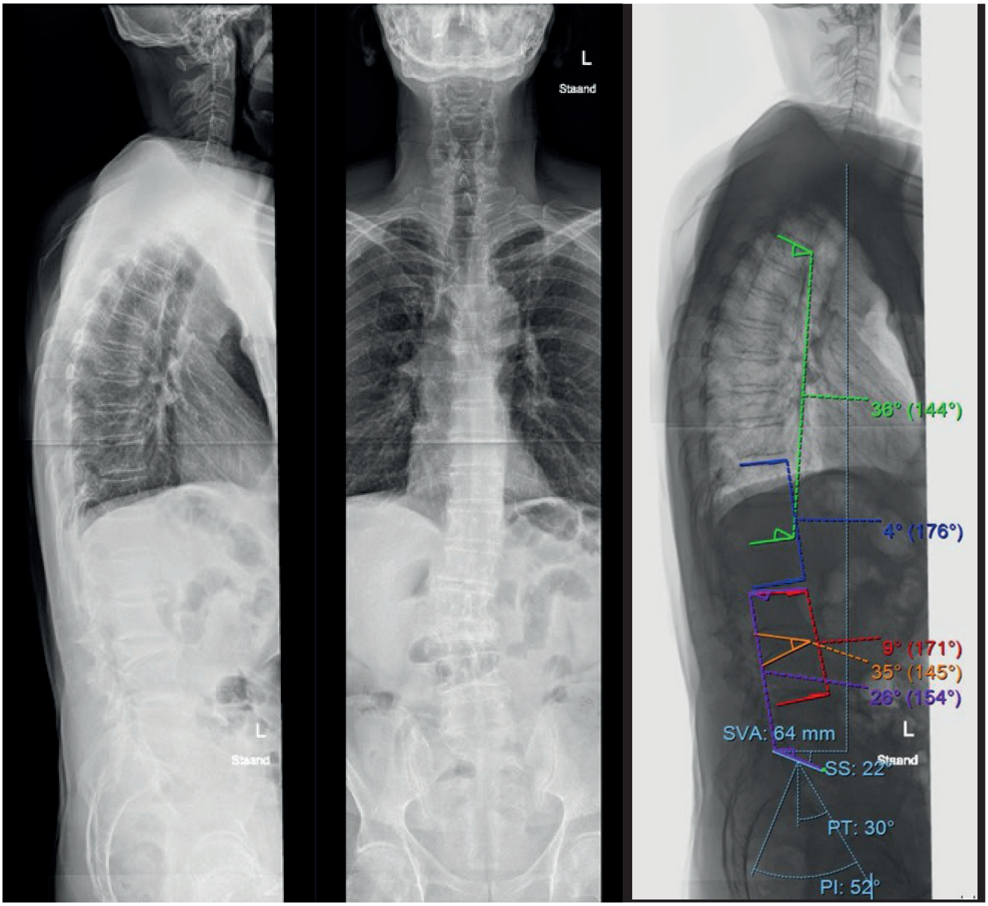
ICD-11 codes

ICD-11 code	Term	Definition
FA70.0	Kyphosis	This is a curving of the spine that causes a bowing or rounding of the back, which leads to a hunchback or slouching posture.
ME 84	Spinal Pain	This is a condition characterised by pain felt in the back that usually originates from the muscles, nerves, bones, joints or other structures in the spine.

APPENDIX B

Case description 1:

- A male of 64 years presents himself at the outpatient clinic. Two years ago he fell from a ladder of about 2,5m height. He suffered from a L3 A4 fracture and was treated with a Hewitt brace for 6 weeks.
- He complains of increasing pain in his lower back over the last year and has increasing problems with lifting his upper right leg. He does not suffer from urine or defecation problems. There are no other neurological complaints.
- Physical examination shows an absent lumbar lordosis and a hyperkyphotic spine
- Neurological examination shows: MRC5- of the left quadriceps also pain related and no other neurological deficits.



Case description 2:

- A male of 35 years presents himself at the outpatient clinic. He suffered from a T9 B2 fracture and T10-11-L1 A1 type fractures. He was treated with 6 weeks of bed rest.
- Patient now complaints of increasing pain in the lower back and more arching forward of his upper back. Physical examination shows a hyperlordosis with maximum pelvic rotation

Acknowledgements to:

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Part III

8

Chapter 8

Posttraumatic Spinal Deformity in patients after spine trauma with decreased health and function outcomes

Erin E.A. De Gendt, Sander P.J. Muijs, Lorin M. Benneker, F. Cumhur Oner

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Posttraumatic Spinal Deformity in patients after spine trauma with decreased health and function outcomes

Purpose: Disability, pain, and decreased function in daily life are very important concerns for patients after a thoracolumbar spine trauma. Recently a new term Posttraumatic Spinal Deformity (PSD) is introduced defined as: condition where trauma to the spine results in deformity in any plane and results in pain and impaired function with or without a neurological deficit. In this study we analyzed radiographic and patient specific factors in a group of PSD patients with significant and lasting impairment.

Methods: a patient cohort with impaired function (ODI>40%) was selected from an existing database of patients after long-term follow-up after spine trauma. Patient factors were collected such as: age, fracture region, type and treatment, comorbidities and work status. Radiographic measurements and PROMs were collected. Descriptive statistics and Spearman's rho for correlation were used.

Results: 31 patients were included with a median age of 52 (IQR 33). A B-type fracture in the thoracic spine was mostly involved. Fulltime employment dropped from 62% to 26%. Strong correlation was seen between the total scores of the ODI and the AO Spine PROST. But a very small correlation was seen between the pain dimensions of the ODI and the AO Spine PROST.

Conclusion: This patient cohort did fit within the newly developed definition of PSD. Amount of measured deformity was variable and did not correlate to impaired function.

Keywords: Posttraumatic spinal deformity, spine trauma, PROST, quality of life, Oswestry disability index

INTRODUCTION

Disability, pain, and decreased function in daily life are very important concerns for patients after a thoracolumbar spine trauma.[1] Multiple patient reported outcome measurements (PROMs) have been used and developed for follow-up and research of these patient. The most commonly used are the Oswestry disability index (ODI), EuroQol 5D-5L (EQ-5D-5L), and SF-36.[2-4] In recent years, the AO Spine Patient Reported Outcome Spine Trauma (PROST) has been validated for short and long-term follow-up of patients after a spine trauma.[5-8] While the ODI was developed for patients with chronic low back pain, it remains the most widely used tool for evaluating these patients. [9]

Patient-reported outcome measures can help quantify a patient's pain and functional disability. However, it is unclear whether decreased PROM outcomes are directly related to more severe spinal deformities in trauma patients. We do know that some degree of deformity occurs after every spinal trauma, but the specific circumstances in which these deformities become clinically relevant remain unknown.[10]

A term and definition for patients with a deformity after a spine trauma were recently determined through a Delphi approach. [11] Prior to this, various terms and definitions were used in clinical practice and the literature to describe the same condition. This is finally defined as Posttraumatic Spinal Deformity (PSD), which is a condition where a trauma to the spine results in a deformity in any plane and results in pain and an impaired function with or without a neurological deficit. [11]

However, to further refine our definition and identify patients more prone to developing posttraumatic spinal deformity, it is necessary to investigate potential contributing factors. Ideally, this would enable determining which patients at the time of initial trauma are at higher risk of developing PSD, potentially warranting more aggressive initial treatment. This study describes a cohort of patients with poor PROMs after a trauma to the spine to analyze them according to the newly developed definition of PSD.

METHODS

Patient selection and study procedures

Patients were selected from a database of patients who were treated either conservatively or surgically, in University Medical Center Utrecht (UMCU) between 2003 and 2018 for a trauma to their thoracic (Th) or lumbar (L) spine.[6] Patients included were native

Dutch speakers, without cognitive impairment, with at least 12 months of follow-up in the outpatient clinic and an ASIA Impairment Scale (AIS) grade C, D, or E. Patients with an initial polytrauma (injury severity score >15) were excluded.

All eligible patients were asked to complete three online surveys: the ODI, the PROST and the EQ-5D-5L. The results of these surveys are published separately. [6] Patients who scored an ODI of 40 or more in this study are considered having a severe disability and became the subject of this study. [12]

Data collection

The following clinical characteristics were extracted from the electronic patient records: age, year of injury, level of fracture, number of fractures, type of treatment received, American Spinal Injury scale (ASIA) grade at time of trauma and at follow-up, overall follow-up, current comorbidities (osteoporosis, cardiovascular disease, lung disease, cancer, diabetes, neurological), employment before and after trauma, complications after treatment and additional spine surgery.

Radiological data

The radiographs and CT-scans at time of trauma and radiographs at least at one-year follow-up were available. Fractures were classified using the AO Spine Trauma classification on CT-scans at time of trauma. Multiple measurements were performed to assess alignment of the spine, when full radiographs where available: Cobb-angle, wedge-angle and when possible on standing full radiographs Th kyphosis, L lordosis, sagittal vertical alignment with C7 line and spinopelvic parameters (sacral slope, pelvic tilt and pelvic incidence).[11]

Patient reported outcome measurements

The ODI comprises 10 dimensions (pain, self-care, lifting, walking, sitting, standing, sleeping, sex life, social life, and traveling) which are scores on a six-point scale ranging from 0 (no problems) to 5 (extreme problems) and are subsequently calculated as a percentage of disability. This percentage leads to a five-scale disability index, ranging between 0% (no disability) to 100% (completely disabled). [12]

The EQ-5D-5L is a commonly used tool to measure overall non-specific health. The five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) of the EQ-5D-5L are rated on a five-point scale. [13]

AO Spine Patient Reported Outcome Spine Trauma is a survey comparing function after trauma to pre-trauma on 19 different dimensions. Scores vary between 0 (I do not function at all) and 100 (I function as well as before the accident). The total score is calculated using the sum of all completed items, divided by the number of completed items.

Both pain scores of the ODI and the AO Spine PROST will be included in a single analysis.

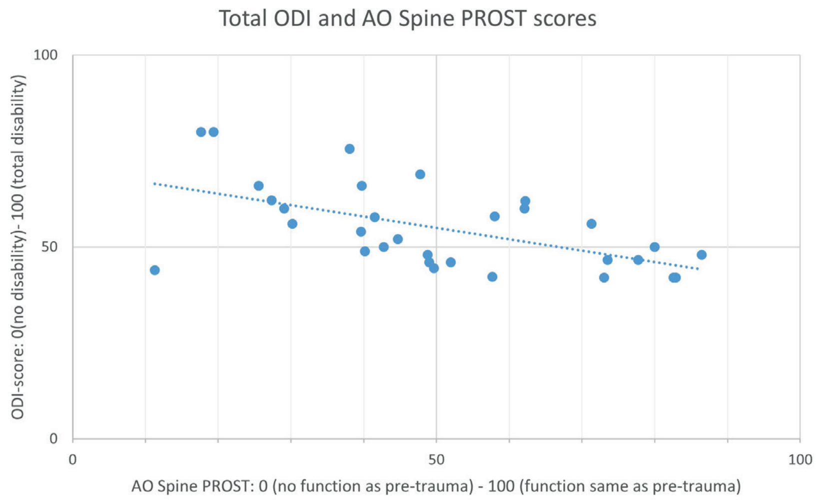

Figure 1. This figure shows the scatterplot of the total Oswestry Disability score (ODI) versus the AO Spine Patient Reported Outcome Spine Trauma score (PROST). They show a negative significant correlation.

Statistical analysis

Descriptive statistics will be used. Because of the expected small patient sample the median and interquartile ranges will be reported. Visual analysis with scatterplots will be reported. The correlation between the different PROMs will be analyzed using the Spearman's rho test (IBM SPSS Statistics version 29.0.1).

Ethical Statement

This study was approved by the Medical Ethical Board of the UMCU (19-457). No funding was received for this study. We used the STROBE cohort checklist when writing our report. [14]

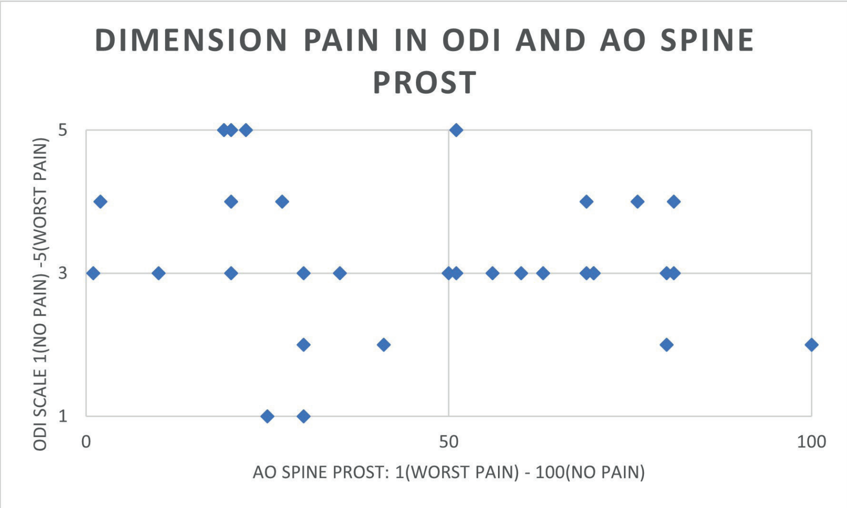

Figure 2. This figure shows the scatterplot of the dimension pain of the Oswestry Disability score (ODI) versus the dimension pain of the AO Spine Patient Reported Outcome Spine Trauma score (PROST). They show no significant correlation.

RESULTS

Baseline characteristics

In total 31 patients were included in this study out of the 224 patients included in an earlier study from a database of 768 patients.[6] The median age at time of trauma was 52 years (IQR 33) and 52% was female. Nineteen patients (62%) had a fulltime employment, six had a parttime employment and six patients did not work or were already retired at time of trauma. More than one spinal fracture was present in 58% of the patients. The region of the spine mostly afflicted was the thoracic spine (Th1-Th12, 52%), followed by the lumbar spine (L1-L5, 29%) and 19% of the patients had fractures in both regions. The majority of the patients was neurologically intact (AIS E, 81%), and only one patient was AIS C.

Radiological follow-up

The median overall available radiographical follow-up of patients in time was 35 months (IQR 22,5). The median wedge angle was 10° (IQR 11°) at trauma and 8,5° (IQR 13,5°) at the last follow-up point. With a median wedge difference of 0° (IQR 7,75°). The full range was -14° – 14°

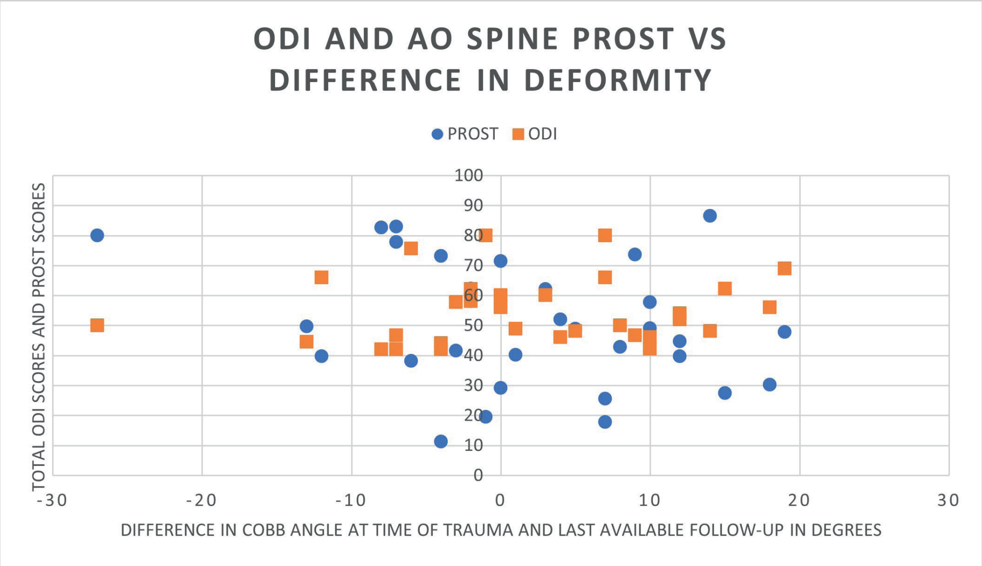

Figure 3. This figure shows the total Oswestry Disability score (ODI) and the AO Spine Patient Reported Outcome Spine Trauma score (PROST) plotted against the difference in Cobb angle at time of trauma and last available follow-up in degrees.

The median Cobb angle was 11° (IQR 22,25°) at trauma and 17,5° (IQR 25,75°) at the last follow-up point. With a median Cobb difference (Δ-Cobb) of 0,5° (IQR 13,75°). The full range was -27° – 19°.

In only 38% a full spine radiograph was available (12 patients). The median thoracic kyphosis (Th1-Th12) was 58,5°, the median lumbar lordosis (L1-L5) was -45,5°. The total range was respectively 30°-118° and -83° - -20°. The median thoracolumbar angle (upper endplate Th12- lower endplate L1) was 8,5° (range -9°- 44°). The pelvic tilt was 19,5°, the sacral slope was 28,5°, and the pelvic incidence 49,5°. The ranges were: PT 11°-41°, sacral slope 22°-51° and pelvic incidence 42°-92°.

Follow-up at time of the survey

The median age at completion of the follow-up survey was 63 years (IQR 34). The median follow-up time in months of the survey was 100 months (IQR 69).

Work status

Eight patients (26%) had a fulltime employment, nine patients (29%) had a parttime employment and eleven (35%) patients did not work or were retired. Furthermore, three patients (10%) were unemployed due to health reasons.

Comorbidities

In total two patients did not respond to this question. Eighteen patients did not have any comorbidities (62%), six were treated for osteoporosis (20%), four had a form of cardiovascular disease and four a form of lung disease. Two patients reported two or more comorbidities.

Table 1. Baseline characteristics

	Overall (n = 31)
Age at trauma in years, median (IQR)	52 (33)
Gender (%)	
Male	15 (48%)
Female	16 (52%)
Pre-trauma employment (%)	
Fulltime	19 (62%)
Parttime	6 (19%)
Unemployed (other reason)	6 (19%)
Unemployed (health reason)	0
Total number of fractures / patient (%)	
1	13 (42%)
>1	18 (58%)
Fracture region (%)	
Thoracic (Th1 -Th12)	16 (52%)
Lumbar (L1-L5)	9 (29%)
Both	6 (19%)
Fracture main type (%)*	
Type A	12 (39%)
Type B	18 (58%)
Type C	1 (3%)
Treatment (%)	
Conservative	8 (23%)
Surgical	23 (77%)
ASIA impairment grade at time of trauma (%)	
C	1 (3%)
D	5 (16%)
E	25 (81%)

*According to AO Spine Classification System

Patient Reported Outcome Measurements

The median ODI-score was 52% (IQR 16) with a range of 42-80%. The median of the VAS-health of the EQ-5D-5L was 55.5 (IQR 37.25) with a range of 15 – 83. One patient did not complete the VAS-Health score. The median AO Spine PROST score was 49 (IQR 33), with a range of 11-86. Visual analysis of the total ODI compared to the total AO Spine PROST scores showed a trend, see Figure 1. This was confirmed with a strong correlation of r = -0,568.

The median score of the dimension Pain of the ODI was 3 (IQR 1). The median score of the dimension Pain of the AO Spine PROST was 50 (IQR 48). Visual analysis showed no trend in the Pain scores of the ODI compared to the Pain scores of the AO Spine PROST. See Figure 2 for the plotted results. This was confirmed by a very small correlation of r= -0,219.

The ODI-scores and PROST-scores per patient compared to the Δ-Cobb angle at time of trauma and last available follow-up and were visualized by scatterplots. See figure 3. No significant correlations between the Δ-Cobb angle and the ODI and PROST-scores were found, r= 0,184 and r= -0,247 respectively.

DISCUSSION

This study investigated a patient cohort with reported disability and decreased health outcome after suffering a spine trauma. Long-term follow-up of this patient population is rare, and this study is to our knowledge the first one to compare these patients to the newly developed definition of Posttraumatic Spinal Deformity (PSD).

The main type of injuries were B-type injuries (58%), according to the AO Spine Classification System. When looking at the previously published database results of which this is a subgroup, the main type of injury is an A-type injury (61,2%).[6] This might indicate that patients with a more unstable injury (B-type) are more prone to develop PSD. The more unstable types of spine injury in this subgroup is confirmed by the fact that 77% of patients were treated surgically, compared to the total patient cohort previously published (56,7% treated surgically). This is also comparable to a recent study on the decision making of expert clinicians for treatment on the different AO Spine fracture types. They found a preference for surgical treatment of B-type fractures in the algorithm and in real life. [15]

In this patient cohort a big decrease in fulltime employment was seen between pre-trauma and follow-up (from 62% to 26%). This was partly declared by 3 patients who were unable to work because of health reasons, some worked parttime now and some went into retirement. These numbers of not returning to work are much higher than reported by others. Which reported a return to work of 78% in patients after spine injuries. [16]

Table 2. Radiological outcomes

Overall radiological follow-up in months, median (IQR)	35 (22,5)		
	Trauma	**Last available follow-up**	**Difference**
Wedge angle (upper and lower endplates of most fractured vertebra)	10° (IQR 11°) Min-max: -13° – 23°	8,5° (IQR 13,5°) Min-max: -7° – 24°	0° (IQR 7,75°) Min-max: -14° – 14°
Cobb angle (upper endplate of 1 vertebra above and lower endplate of 1 vertebra below)	11° (IQR 22,25°) Min-max: -35° – 35°	17,5° (IQR 25,75°) Min-max: -33° – 38°	0,5° (IQR 13,75°) Min-max: -27° – 19°
Number of Full spine radiographs	12 (38%)		
	Median	**IQR**	**Range**
Thoracic kyphosis (Th1-Th12)	58,5°	25,75°	30°-118°
Lumbar lordosis (L1-L5)	-45,5°	31,5°	-83°- -20°
Thoracolumbar angle (Th12-L1)	8,5°	19,75°	-9° - 44°
Pelvic tilt	19,5°	10,5	11° - 41°
Sacral slope	28,5°	14°	22°- 51°
Pelvic incidence	49,5°	11,5°	42°-92°
SVA (mm)	54	75,25	-26 – 112

Table 3. Follow-up results

	Overall (n = 31)
Age at completion of PROMs, median (IQR)	63 (34)
Overall PROMs follow-up in months, median (IQR)	100 (69)
Employment at follow-up PROMs (%)	
Fulltime	8 (26%)
Parttime	9 (29%)
Unemployed (other reason: e.g. retirement)	11 (35%)
Unemployed (health reason)	3 (10%)
Comorbidities (% of 29 patients who responded to this question)	
No	18 (62%)
Osteoporosis	6 (20%)
Cardiovascular disease	4 (14%)
Lung disease	4 (14%)
No response	2
Oswestry Disability Index median (IQR)	52% (16)
Min - max	42% – 80%
Pain	3 (1); min-max 1-5
Visual Analogue Scale of health median (IQR)*	55,5 (37,25)
Min-max	15 – 83
AO Spine PROST median (IQR)	49% (33)
Min - max	11 – 86
Pain	50 (48); min-max 1-100

*n=30, 1 missing value

The most used radiological measurements in PSD are the Cobb and wedge angle, even though the description on how exactly the angle was measured is often unclear. [11,17,18] However, not all fractures have severe "deformity" initially. For example, a stiff spine with a B3 fracture will not always show an increased Cobb or wedge angle. These angles for follow-up might not be informative to assess the deformity.

Interestingly, some patients did not exhibit substantial deformities, measured using the Cobb and wedge angles at time of trauma and last available follow-up, but did report an impaired function.

Our study showed that the overall ODI and AO Spine PROST scores were strongly correlated, but that the dimensions of pain from both surveys only had a low correlation. This discrepancy can possibly be explained by the different type of questions asked in the surveys. In the ODI the patient is asked to answer which amount of pain applies to them that day. Compared to the AO Spine PROST where the patient is asked to compare the pain to pre-trauma level. Compared to earlier validation studies a much lower correlation was found in this specific patient group. [7,8] Future patient follow-up should be done with a patient-specific PROM such as the specially developed AO Spine PROST. Even though, some patient reported an impaired function, but rated their Visual Analogue Scale of perceived health fairly positive (maximum results 83/100). It is unclear why these discrepancies exist.

A limitation of this study is the small number of patients (n=31) and the heterogeneity in the group. The age range at time of trauma was between 19 and 86 years. This results in different expectations of function in life and after a longer follow-up more risk of decreased functional and health outcomes in the elderly due to natural decline. However, this heterogeneity is an example of the daily clinical practice.

A limitation of this study is the inconsistent follow up period and incomplete radiographic documentation which is explained by the retrospective design of the study. This study is, however, the first combining the newly developed term and definition and the quality of life after a spine trauma. In order to progress this research we think it is necessary to setup a study in which patients after any spine trauma are followed in an international, natural case cohort study.

For future research we suggest that the PROST is completed at set time points in normal follow-up including low-dose full spine radiographs at the same time for at least 1 year after trauma. Only the AO Spine PROST can be sufficient in consecutive follow-up, and can serve as a red-flag to indicate problems.

In conclusion, when looking at the newly developed term PSD and definition (condition where trauma to the spine results in deformity in any plane and results in pain and impaired function with or without neurological deficit) this patient cohort classifies as having PSD. They have a history of spine trauma, report pain and impaired function, some have a neurological deficit, and they all have a varying degree of deformity. As in other studies we observed no strong correlation between the amount of deformity and loss of function.

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Chapter 9

Summary, general discussion and future perspectives

Our knowledge of traumatic spine injuries has grown substantially in the last decades, resulting in new classification systems to standardize the distinction between various fracture patterns, leading to better treatment algorithms. [1-4] These classification systems have been incorporated in current clinical practice and research. However, there is still a great diversity of treatment schemes. Next to the fracture morphology, location of the injury can in certain fracture types determine which treatment the patient will receive. [5]

Historically, treatments evolved from Hippocratic ladders and boards to plaster cast and bed rest to current minimal invasive internal fixation with direct postoperative weightbearing. Fortunately, the mortality of serious trauma dropped dramatically but that means also that more patients are confronted with the long-term functional consequences of these traumatic injuries. This warrants the need to have standardized spine trauma specific follow-up systems utilizing both patients' and clinicians' perspectives, to address problems and establish an expected 'normal' recovery. The AO Spine PROST and the AO Spine CROST were specifically developed for these goals. [6,7]

Ideally, we would like to be able to predict which spine trauma patients are at risk of developing problems in the future. Preferably we want to be able to predict this in the emergency room, before the decision on the treatment is made. But then we have to define first, what these problems might be and how we recognize and describe them.

In this thesis we studied the consequences of spine trauma and the following recovery process from the patients' and clinicians' perspectives. It provides the long-term follow-up results of the reliability of the AO Spine Patient Reported Outcome Spine Trauma (AO Spine PROST) and the clinicians' view to the clinically tested AO Spine Clinician Reported Outcome Spine Trauma (AO Spine CROST). Next, we studied the consequences when the recovery process does not go as expected. We tried to reach a uniform and internationally accepted term and definition for a clinically relevant deformity after a trauma to the spine utilizing an extensive Delphi process. Finally, we analyzed a patient cohort who have apparently not reached a full recovery and fulfill the criteria for our newly developed definition of 'Posttraumatic Spinal Deformity' in order to understand if any specific factors could be determined at the time of trauma which would have predicted this outcome.

FOLLOW-UP OF FUNCTION AND HEALTH OF SPINE TRAUMA PATIENTS

In Chapter 2 the long-term psychometric properties of the AO Spine PROST, a disease-specific outcome measure for spine trauma patients are studied. This was the first study investigating the outcome after more than 13 months of follow-up. Patients were asked to complete multiple questionnaires including: work status pre- and post-trauma, comorbidities, the AO Spine PROST, EQ-5D-5L, ODI, and in case of a cervical fracture the NDI. In total 224 patients participated in this study, with the majority having an A-type spine fracture and ASIA E neurology at time of trauma, with the majority of the fractures in the thoracolumbar spine. In total, 56% of the patients was treated surgically. For the test-retest reliability 49 patients from the total cohort were included for repeated measurements.

The study found strong internal consistency and test-retest reliability, as well as good concurrent validity compared to the EQ-5D-5L, ODI, and NDI. It also identified the presence of comorbidities and increased duration of return to work as significant determinants of worse AO Spine PROST outcomes. While limited by its cross-sectional design and single-center approach, this study provides valuable insights into the long-term evaluation of spine trauma patients using the validated AO Spine PROST measure.

A variety of questionnaires is commonly used in the follow-up of spine trauma patients in clinical settings and research studies. [8] Most of these were not specifically designed for spine patients in general and the more specific questionnaires were not developed for spine trauma patient. The recently developed AO Spine PROST was shown to be valid and reliable in follow-up of these patients. Validation of the AO Spine PROST for the longer-term follow-up was essential for improved usability in the future and to compare it to earlier outcomes. With the valid and reliable long-term results presented in this thesis, it provides stronger evidence to promote its use in clinical practice. A decline in AO Spine PROST score during follow-up can warrant further investigation into why the patient is experiencing problems in their own perspective.

The perspective of the clinician during the follow-up of the patient was investigated in Chapter 3. This study examined the validation of the AO Spine Clinician Reported Outcome Spine Trauma (AO Spine CROST). The current study was performed in an actual clinical setting including seeing patients face-to-face in the outpatient clinic after inclusion, a previous validation study only included online cases [9]. The multicenter study performed in this thesis included 92 patients from four different hospitals in different world regions through the AO Spine Knowledge Forum Trauma network.

Excellent feasibility and acceptable internal consistency results were found. Analysis per CROST item showed very good exact agreement, but varying Kappa values, potentially skewed by the high number of 'no concerns' responses on the dichotomous scale (yes/no concerns). When 'no concerns' were expressed by the surgeon a trend was seen. CROST scores had a moderate to strong correlation. Remarkably, no specific association or correlation was found between the AO Spine PROST and CROST.

The validation results of the AO Spine CROST suggest that the questionnaire is a good tool to evaluate the patient in the outpatient clinic from the clinicians' point of view. However, caution is advised when using the AO Spine CROST. The patient may report problems and not be satisfied with the recovery, but the clinician can still have a 'no concerns' score on the AO Spine CROST. This study highlighted the discrepancy between clinicians' and patients' perspectives on health and functioning after spinal trauma. Surgeons rely on clinical and radiological parameters, but their assessments may differ substantially from patients' perceptions.[9]

CREATING A UNIFORM TERM AND DEFINITION

A systematic literature review on the posttraumatic spine deformity examined all the domains discussed in Chapter 4. The review was unique as international efforts resulted in inclusion of all relevant literature in any language by native or highly competent readers. Four different domains were identified: terms/definitions, radiological factors, PROM's and surgical indications.

Previous efforts to establish a consensus on defining a clinically relevant deformity of the spine after a trauma were less successful, and we believe this may have stemmed from the absence of standardized terminology.[10] This was confirmed by the systematic review. This review reflects the evolving concepts of a deformity of the spine after a trauma over the last decades. For example, more recently, PROMs are used increasingly in evaluation of patients. Another striking point was the radiological assessments used to diagnose or describe the deformity of the spine. In the second half of the 20th century, some imaging techniques were not widely available and were thus not incorporated into the initial descriptions. The way we diagnose and treat spinal trauma evolved throughout the last decades, which also influences the meaning of a deformity of the posttraumatic spine. The evolving perspective on a deformity of the spine after trauma could partly explain the differences in descriptions throughout the years. The review resulted in multiple terms and different dimensions of the post trauma spine patient and how clinicians view the problem.

In Chapter 5 the second preparatory study of the Delphi process was discussed. In this study a survey was sent to multiple spine surgeons through the AO KF Trauma network. The survey contained questions derived from the systematic review (Chapter 4) and discussions during meetings on this topic. All possible factors and patient characteristics were included. This survey showed that there is some consensus among experts on different domains of a deformity after a spine trauma. (SPTD) The definition stated by Schoenfeld et al [10] over a decade ago was confirmed, but this study suggested that additions to this definition are necessary to provide a clear and clinically relevant definition of SPTD. The additions deemed necessary for diagnosis of SPTD were: kyphotic angulation exceeding normal values, back pain with a Visual Analogue Scale of pain >4, and impaired function. The radiologic workup in diagnosis and/or treatment should contain a standing local radiograph, a full-spine radiograph, and a Magnetic Resonance-scan. However, there was hardly consensus on the specific risk factors for developing SPTD.

Chapter 6 shows a case survey to see if spine traumatologists could reach consensus when presented with multiple cases with posttraumatic spine in the diagnostic work-up in the outpatient clinic. This study was unique and first-of-a-kind in this field and was part of the preparatory studies for the Delphi process. This study showed the clinical path of patients with complaints after a spine trauma and the different opinions of spine experts in their diagnosis and treatment. There was strong consensus in 5 out of 7 cases on diagnosis of clinically relevant SPTD. As with the previous study in Chapter 5 there was strong consensus on the use of certain imaging modalities. For C-spine cases: cervical CR, CT-scan and MR-scan. For ThL-spine cases: full spine CR, CT-scan and MR-scan. There was consensus that asymptomatic spinal post-traumatic deformities should not receive surgical treatment but should be monitored closely. The study found disagreement on the edges of the SPTD spectrum, likely due to surgeon variability, preferences, and available resources.

All the preparatory studies led to the final study in Chapter 7, which describes the Delphi process to determine a uniform term and definition of patients with a deformity after a spine trauma. During the process of the previous studies the decision was made that the first goal was to determine a uniform term and definition. The problem of deformity after a spine trauma is very complex and multifactorial, and it was of the utmost importance to start with discussing the problem using the same accepted terminology. In this defining study, a short online survey using all the available information was used to explore expert opinions and enhance the response rate. The next round was an in-person discussion to improve the quality and acceptance of the new term and definition. An 'all-rounds invitation' approach was employed, which allowed participants to join in consecutive rounds regardless of prior participation and resulted in high response rates. Unanimous consensus was reached on the definition of clinically relevant 'Posttraumatic Spinal Deformity' as: 'Condition where a trauma to the spine results in a deformity in any plane and results in pain and an impaired function with or without a neurological deficit.' During the last round it became clear that an abbreviation was necessary, and after thorough discussion there was unanimous consensus on the term 'PSD'.

Earlier research from Schoenfeld et al [10] tried to incorporate too many aspects of PSD, resulting in low-consensus and a limited definition. This thesis stresses the complexity of PSD and the factors involved. The future will hopefully result in the use of this uniform term and more understanding of the risk factors involved in the development of PSD.

Finally, we returned to the patients after spine trauma with impaired function in Chapter 8. From the cohort of patients for the validation of the AO Spine PROST a subgroup with an ODI-score of >40, meaning severe disability was selected. Numerous parameters were collected to see if there were any patterns or risk factors in this subgroup. This subgroup of patients with impaired function was selected as it was a new important factor in the definition of PSD in Chapter 7. We hypothesized that patients with impaired function may have a symptomatic deformity of the spine following trauma, and thus potentially exhibit clinically relevant Posttraumatic Spinal Deformity. PSD is something we would like to prevent at time of trauma or diagnose and treat if it is present.

Long-term follow-up of this population is rare, and this is the first study to compare these patients to the new definition of PSD. The main injuries in this group with impaired function were B-type, suggesting that more mechanically unstable injuries are prone to develop PSD. 77% of this subgroup were treated surgically, consistent with a preference for surgical treatment of B-type fractures. This cohort had a substantial decrease in full-time employment, much higher than the 78% return to work reported elsewhere. [11]

Radiological measurements like Cobb and wedge angles may not fully capture the meaning of 'clinically relevant deformity', as some patients without severe deformities reported impaired function. The ODI and AO Spine PROST scores were strongly correlated overall, but pain dimensions had low correlation, likely due to differences in questions in each survey. ODI is specifically designed for degenerative low back pain while PROST is a measure of 'functioning' after trauma.

This cohort meets the PSD definition, with spine trauma history and impaired function with varying degrees of deformity. As in other studies, deformity alone did not strongly correlate with functional loss.

FUTURE PERSPECTIVES

In this thesis the long-term follow-up of the patients' health and functional outcome and the follow-up of the clinicians' view of spine trauma patients is reported. In the second part an extensive Delphi process with multiple preparatory studies was performed, resulting in a uniform term and definition: Posttraumatic Spinal Deformity: 'Condition where a trauma to the spine results in a deformity in any plane and results in pain and an impaired function with or without a neurological deficit.' Finally, a specific patient cohort with decreased health and function outcomes was investigated for the presence of Posttraumatic Spinal Deformity (PSD).

The development of uniform follow-up of patients who suffered a spine trauma is essential in creating more accurate predictions and better treatment algorithms. It can also help in determining risk factors for development of PSD and possibly the means for mitigating these.

Chapter 5 already showed consensus, that the follow-up of patients with a trauma to the spine should consist of a local CR (Conventional Radiograph) and a full-spine radiograph. Both these radiographs are feasible in most clinics globally.

Another important development outlined in Chapter 4 is the rise of the use of PROMs in the evaluation of the spine trauma patient. This thesis showed that the AO Spine PROST is a valid tool to use in the long-term follow-up (Chapter 2), next to the already know validity in the short term. [6,7]

Combining the patients' view with the PROST and the clinicians view with the standardized radiographs in normal follow-up will aid to detect small changes in both perceptions and treatment can be adjusted accordingly. Normal follow-up should be standardized until at least one year after trauma, and ideally every consecutive year the patient should complete an AO Spine PROST to detect differences. When a large decrease in PROST score is detected, the patient can be invited to the outpatient clinic for a check-up. For a real long-term perspective on spine trauma, these patients can be asked every 5 consecutive years for a (preferably) low dose full spine radiograph. Additionally, this extensive data can be used in research. When patients consent at the beginning of their recovery, that their data can be used in research in the future, it will result in an extensive database.

The Natural Experiments Study group (NEXT study group) aims to improve research in emergency and orthopedic trauma patients. In 2022 het NEXT study group published an article explaining how natural experiments can be implemented in the field of orthopedic trauma research. They state that natural experiments are a form of observational studies in which treatment allocation is determined by factors outside the control of the investigators. This can possibly resemble experimental randomization. [12] It is essential that different regions, countries and clinics start working together to combine their natural experiments in the same fashion such as mentioned above for the follow-up of spine trauma patients. Use of universally accepted standards for diagnostics and outcome measurements will facilitate the development of this kind of valid methodologies for research in surgical fields.

This combination of multiple databases of spine trauma patients and their follow-up can potentially uncover risk factors for developing PSD. In the end this can lead to a predictive model on which clinicians can decide to treat patients more aggressively in the beginning than risk high-risk surgeries later. This can also prevent unnecessary initial surgeries when the risk of developing PSD is low.

It can also help identify clinically relevant PSD and asymptomatic deformities. The last category will have an evident deformity but is able to compensate and function reasonably. So next to risk factors, also protective factors can be taken into account in treating patients with spine trauma. Hopefully this will also help in determining the patients with high risk of developing PSD and to take measures to reduce the incidence of symptomatic posttraumatic spine deformity.

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Chapter 10

Nederlandse Samenvatting

De laatste decennia is onze kennis over traumatische wervelletsels aanzienlijk gegroeid. Dit heeft geresulteerd in een goed systeem om wervelletsels te classificeren en zijn de behandelingen hierop verder aangescherpt. Deze systemen helpen om dezelfde taal te spreken in de kliniek en in het onderzoek.

Ondanks deze uitgebreide kennis over wervelletsels zijn er nog steeds veel verschillende manieren van behandelen van deze letsels. De behandelingen van wervelletsels zijn geëvolueerd vanuit de Griekse Oudheid middels Hippocratische ladderborden naar gipsverbanden en bedrust, tot de huidige minimaal invasieve interne fixatie technieken die de patiënt in staat stellen gelijk te kunnen bewegen. Daartegenover staat dat meer patiënten te maken krijgen met de langdurige functionele en gezondheidsbeperkingen na een wervelkolomtrauma, omdat de sterfte drastisch afnam. Dit maakt het monitoren en begeleiden van deze patiënten noodzakelijk, en hiervoor is gestandaardiseerde opvolging specifiek voor wervelkolomtrauma nodig. Belangrijk voor deze opvolging is dat, zowel het perspectief van patiënten als dat van clinici benut wordt. Zo kan een 'normaal' herstel gemonitord worden en kunnen problemen erkent worden. De AO Spine Patiënt Reported Outcome Spine Trauma (AO Spine PROST) en de AO Spine Clinician Reported Outcome Spine Trauma (AO Spine CROST) zijn specifiek voor deze doelen ontwikkeld.

Idealiter wil je voorspellen wie er in de toekomst problemen ontwikkelt na een werveltrauma. En het liefst bepaal je dit op het moment dat iemand zich presenteert op de Spoedeisende Hulp, waarbij je behandeling kan aanpassen aan de risico's of beschermende factoren die iemand heeft.

Dit proefschrift bestaat uit 3 delen:

Het eerste deel bespreekt de lange termijnresultaten en de betrouwbaarheid van de AO Spine PROST. Daarnaast bespreken we de resultaten van de betrouwbaarheid en de validiteit van de AO Spine CROST.

Het tweede deel beschrijft de zoektocht naar een uniforme en internationaal geaccepteerde term en definitie voor een misvorming na een trauma aan de wervelkolom. Deze uitgebreide onderzoeken resulteerden in de term Posttraumatische Spinale Deformatie (PSD) met de definitie: een aandoening waarbij een trauma aan de wervelkolom zorgt voor misvorming van de wervelkolom in elk vlak met functionele beperkingen, met of zonder neurologische symptomen.

Tot slot, in deel drie, wordt een specifieke patiëntengroep geanalyseerd met functionele en gezondheidsbeperkingen op de aanwezigheid van posttraumatische spinale deformatie.

Opvolging van Functie en Gezondheid bij Wervelkolomtrauma Patiënten

De lange termijn psychometrische eigenschappen (betrouwbaarheid, validiteit en test-hertest) van de AO Spine PROST werden getest in Hoofdstuk 2. Verschillende vragenlijsten worden gebruikt in de opvolging van wervelkolomtrauma patiënten in klinieken en onderzoek, maar deze zijn meestal niet specifiek ontwikkeld voor deze doelgroep. De AO Spine PROST is specifiek ontworpen en gevalideerd voor wervelkolomtrauma patiënten tot een opvolging van 13 maanden.

De AO Spine PROST is een specifieke vragenlijst ontwikkeld voor patiënten na een wervelkolomtrauma om hun functionele en gezondheidsbeperkingen te evalueren. Dit is de eerste studie die de psychometrische eigenschappen en uitkomsten na meer dan 13 maanden opvolging onderzocht. In totaal namen 224 patiënten deel. De meesten patiënten hadden een A-type wervelkolomfractuur en het overgrote deel had geen neurologische afwijking net na het trauma. Iets meer dan de helft van de patiënten (56%) werd geopereerd. De studie toonde aan dat de AO Spine PROST een zeer goede interne en test-hertest betrouwbaarheid heeft, evenals goede overeenkomstige validiteit vergeleken met 1 algemene vragenlijst (EQ-5D-5L) en 2 vragenlijsten specifiek voor degeneratieve wervelaandoeningen(ODI en NDI).

Ook bleek dat comorbiditeiten en een langere tijd tot terugkeer naar werk belangrijke voorspellers waren van een slechtere uitkomst op de AO Spine PROST. Deze studie, hoewel beperkt door het cross-sectionele ontwerp en de single-center aanpak, biedt waardevolle inzichten in de lange termijn beoordeling van wervelkolomtrauma patiënten met de gevalideerde AO Spine PROST.

Deze studie laat zien dat de AO Spine PROST een betrouwbare en valide vragenlijst is voor het opvolgen van patiënten na een werveltrauma ook op de lange termijn. Een daling in de AO Spine PROST score gedurende de opvolging, bijvoorbeeld, kan aanleiding geven tot verder onderzoek naar de problemen zoals gerapporteerd door de patiënt.

Hoofdstuk 3 onderzocht betrouwbaarheid van de AO Spine CROST op de polikliniek tijdens de opvolging van patiënten na een werveltrauma. Het onderzoek werd uitgevoerd in vier ziekenhuizen wereldwijd via het AO Spine Knowledge Forum Trauma en includeerde 92 patiënten. De resultaten toonden uitstekende uitvoerbaarheid en acceptabele interne consistentie. Per CROST-item werd een goede overeenstemming gevonden, hoewel de Kappa-waarden varieerden, waarschijnlijk door het hoge aantal 'nee'-antwoorden. Opvallend was dat er geen specifieke correlatie werd gevonden tussen de uitkomsten van de AO Spine PROST en CROST.

De validatie van de AO Spine CROST suggereert dat deze vragenlijst geschikt is voor het evalueren van de patiënt vanuit het perspectief van de arts in de kliniek. Wel is de discrepantie tussen de ervaringen van de patiënt en die van de arts opvallend. Een patiënt kan ontevreden zijn over zijn herstel en beperkingen in functioneren ervaren, terwijl de arts op de AO Spine CROST toch 'geen zorgen' kan scoren. Dit onderzoek benadrukt het verschil tussen de perspectieven van de arts en de patiënt met betrekking tot gezondheid en functioneren na een wervelkolomtrauma. Artsen baseren hun oordeel vooral op klinische en radiologische gegevens, maar deze kunnen aanzienlijk afwijken van hoe de patiënt zijn of haar herstel ervaart.

Nieuwe term en definitie

Eerdere studies die zochten naar consensus over een definitie voor een misvorming na wervelkolomtrauma waren niet succesvol omdat er in essentie meerdere termen voor dezelfde aandoening werden gebruikt. Hoofdstuk 4 beschrijft een systematisch literatuuronderzoek dat vier domeinen identificeert rondom posttraumatische wervelkolomafwijkingen: termen/definities, radiologische factoren, patiënt gerapporteerde uitkomsten (PROM's) en chirurgische indicaties. Uit de literatuur bleek dat er veel verschillen termen worden gebruikt en dat er meerdere factoren een rol spelen, tevens was het moeilijk om verschillende behandelingen/operaties te vergelijken omdat iedereen net andere definities gebruikte.

Hoofdstuk 5 beschrijft een enquête onder ervaren wervelkolomchirurgen die werd gebruikt om factoren te identificeren die belangrijk zijn voor de diagnose van een posttraumatische wervelkolomafwijking. Hieruit bleek dat bepaalde criteria, zoals toename van vervorming van de wervelkolom (hyperkyfose), pijn (>4 uit 10) en verminderde functionaliteit, noodzakelijk zijn voor een klinisch relevante diagnose van posttraumatische wervelkolomafwijking. Daarnaast was er consensus over de uit te voeren radiologische onderzoeken in de diagnose en behandeling namelijk: een röntgenfoto van de volledige wervelkolom en het specifieke deel, en een MRI-scan. Helaas werd er geen consensus bereik over specifieke risicofactoren.

In Hoofdstuk 6 werden 7 casus gepresenteerd via een online enquête aan ervaren wervelkolomchirurgen. Ze beoordeelden een online enquête waarbij het verhaal van verschillende patiënten met klachten na wervelkolomtrauma en de radiologische onderzoeken de revue passeerden. Ook moesten ze uiteindelijk aangeven of er sprake was een symptomatisch of asymptomatische posttraumatische wervelkolom vervorming. Consensus werd bereikt over 5 van de 7 casussen, waarbij alle 5 klinisch relevante posttraumatische wervelkolom vervorming werden geacht te hebben. Net als de voorgaande studie werd consensus gevonden over het uit te voeren radiologische onderzoek. Tevens was er consensus dat asymptomatische posttraumatische wervelkolom vervorming niet geopereerd hoeft te worden. De meningen lagen ver uit elkaar bij de niet evidente gevallen van posttraumatische wervelkolom vervorming. Dit kan komen door de voorkeuren van de wervelkolomchirurgen, waar en door wie ze zijn opgeleid en welke mogelijkheden er zijn in hun klinieken.

De voorbereidende studies leidden tot Hoofdstuk 7, waarin het Delphi-proces wordt beschreven. Na analyse van de voorbereidende studies werd duidelijk dat het noodzakelijk was consensus te bereiken over de term en definitie van een vervorming na wervelkolomtrauma. Middels meerdere rondes werd eerst aanvullende informatie verzameld en werd er consensus bereikt over de term en definitie: "Posttraumatische Spinale Deformatie (PSD): een aandoening waarbij een trauma aan de wervelkolom zorgt voor misvorming van de wervelkolom in elk vlak met functionele beperkingen, met of zonder neurologische symptomen." Deze term en definitie werden unaniem geaccepteerd. Met name het onderdeel over de functionele beperkingen is een toevoeging aan eerder gevonden definities en neemt ook het perspectief van patiënten naast dat van de arts mee.

In het laatste deel van dit proefschrift koppelen we de wetenschap weer terug aan de kliniek. Dit werd gedaan door een subgroep van het onderzoek van Hoofdstuk 2 met verminderde functionaliteit beter te bekijken.

Deze subgroep bleek vaker B-type wervelfracturen te hebben (ernstiger dan A-type), en werd vaker geopereerd dan de totale groep. Wat opviel is dat weinig patiënten weer terugkeerden naar hun voorgaande voltijd baan, dit was tegengesteld aan andere literatuur.

Op röntgenfoto's werden meting gedaan om de vervorming van de wervelkolom te kwantificeren. Het bleek echter dat niet alle patiënten evidente forse vervormingen hadden, ondanks dat ze wel functionele beperkingen rapporteerden.

Daarnaast toonde de totale scores van twee vragenlijsten de ODI en de AO Spine PROST wel een sterke correlatie, maar hun dimensies 'Pijn' toonde een lage correlatie. Dit komt mogelijk door de manier waarop de vraag aan de patiënten wordt gesteld.

Concluderend voldoet deze subgroep wel aan de definitie van PSD: een wervelkolomtrauma in de voorgeschiedenis, pijn, een beperkte functie en soms neurologische afwijkingen, echter is er een grote variatie in vervorming. En net als in andere studies was de vervorming niet direct gecorreleerd aan de functiebeperking.

De bevindingen van dit proefschrift benadrukken het belang van een uniforme terminologie en lange termijn opvolging bij patiënten met een wervelkolomtrauma om het ontstaan van functionele beperkingen beter te begrijpen en, indien mogelijk, te voorkomen.

Toekomst perspectieven

Het goed controleren van patiënten na een wervelkolom trauma is essentieel in het maken van goede behandelstrategieën. Dit proefschrift onderstreept de betrouwbaarheid van de AO Spine PROST als patiënt specifieke vragenlijst voor patiënten na een wervelkolom trauma om ze lange termijn op te volgen. Daarnaast is er een goede betrouwbaarheid in de AO Spine CROST voor het perspectief van de arts. Ook is gebleken dat er consensus is over de uit te voeren radiologische onderzoeken: namelijk een detail röntgenfoto en een röntgenfoto van de volledige wervelkolom. Deze onderzoeken zijn ook wereldwijd uit te voeren op een gestandaardiseerde manier.

In een ideale wereld willen we PSD voorkomen. Dit betekent dat het nodig is om aan de poort duidelijk te hebben wie er meer of minder risico loopt op het ontwikkelen van PSD. Om deze risico-/ en beschermende factoren uit te zoeken is het lange termijn gestandaardiseerd opvolgen van veel patiënten met wervelkolom trauma noodzakelijk.

Dit kan eventueel worden gedaan via 'natuurlijke experimenten'. Dit betekent dat patiënten in het ziekenhuis waar ze behandeld worden volgens de daar gebruikelijke methode en kennis, maar wel op een gestandaardiseerde manier opgevolgd worden met vragenlijsten en röntgenfoto's. Patiënten geven dan wel toestemming dat ze meedoen aan het onderzoek maar worden niet in specifieke behandelplannen ingedeeld. Als meerdere (internationale) centra meedoen aan dit natuurlijk experiment hoeven ze hun huidige behandelingen niet aan te passen en dit geeft dan ook een goede weerspiegeling van de huidige Internationale behandelingen.

Uit deze database kan dan hopelijk blijken welke factoren beschermen tegen, of risico geven op PSD. En zo kan uiteindelijk aan de poort een evident betere behandelkeuze worden gemaakt.

A

Appendices

List of publications
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List of publications

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Chapter 2:
Buijs GS, de Gendt EEA, Sadiqi S, Post MW, Muijs SPJ, Oner FC. Long-Term Reliability and Validity of the AO Spine PROST (Patient-Reported Outcome Spine Trauma). Spine (Phila Pa 1976). 2022 Sep 1;47(17):E562-E569. doi: 10.1097/BRS.0000000000004379. Epub 2022 Jul 14. PMID: 35853155.

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Curriculum vitae

Erin De Gendt was born on March 5th 1991 in Amsterdam, The Netherlands. After graduating high school in Amsterdam in 2009 (Vossius Gymnasium) she started medical school at the University Utrecht. After obtaining her Bachelor's degree in 2012 she decided to take a gap year to travel the world after working in home care and as a general practitioners assistant. During her Master's study she participated in the board of the Rugbyende Utrechtse Studenten for one year. During her study she participated in multiple research projects under the supervision of Prof. Dr. F.C. Oner and Prof. Dr. J.J. Verlaan at the Orthopedics department of the University Medical Center Utrecht.

After receiving her medical degree in February 2017, she started as a non-training resident at the department of Surgery in the Amphia Hospital in Breda and one year subsequently at the department of Orthopedics at the IJsselland Hospital in Rotterdam. In 2019 she had the opportunity to start a new research project as full-time researcher under the supervision of Dr. S.P.J. Muijs and Prof. Dr. F.C. Oner at the department of Orthopedics at the UMC Utrecht. The research project was performed in close collaboration with the AO Spine 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 January 2021 she started working as a resident in training at the department of Surgery in the Amphia Hospital in Breda. Subsequently she started her orthopedics rotations on July 2022 in the Reinier HAGA Orthopedic Center in Zoetermeer under the supervision of Dr. Gerald Kraan, and since February 2024 in the Erasmus Medical Center under the supervision of Dr. Koen Bos.

She currently lives in Rotterdam with her son Seb and husband Bas. In her free time she loves to be outside, running and speedskating. They love to hike and ski in the mountains.