Are existing outcome instruments suitable for assessment of spinal trauma patients?

A review

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Object. Valid outcome assessment tools specific for spinal trauma patients are necessary to establish the efficacy of different treatment options. So far, no validated specific outcome measures are available for this patient population. The purpose of this study was to assess the current state of outcome measurement in spinal trauma patients and to address the question of whether this group is adequately served by current disease-specific and generic health-related quality-of-life instruments.

Methods. A number of widely used outcome measures deemed most appropriate were reviewed, and their applicability to spinal trauma outcome discussed. An overview of recent movements in the theoretical foundations of outcome assessment, as it pertains to spinal trauma patients, has been attempted, along with a discussion of domains important for spinal trauma.

Commonly used outcome measures that are recommended for use in trauma patients were reviewed from the perspective of spinal trauma. The authors further sought to select a number of spine trauma–relevant domains from the WHO’s comprehensive International Classification of Functioning, Disability and Health (ICF) as a benchmark for assessing the content coverage of the commonly used outcome measurements reviewed.

Results. The study showed that there are no psychometrically validated outcome measurements for the spinal trauma population and there are no commonly used outcome measures that provide adequate content coverage for spinal trauma domains.

Conclusions. Spinal trauma patients are currently followed either as a subset of the polytrauma population in the acute and early postacute setting or as a subset of neurological injury in the long-term revalidation medicine setting. (DOI: 10.3171/2010.5.SPINE09128)

KEY WORDS • outcome measurement • spinal trauma • literature review • spinal cord injury • health-related quality of life

Abbreviations used in this paper: AAOS = American Association of Orthopaedic Surgeons; ADL = activities of daily living; BDI = Beck Depression Inventory; FCI = Functional Capacity Index; FIM = Functional Independence Measure; GOS = Glasgow Outcome Scale; HADS = Hospital Anxiety and Depression Scale; HDRS = Hamilton Depression Rating Scale; HSU = health service use; HUI2 = Health Utilities Index Mark 2; HUI3 = HUI Mark 3; ICF = International Classification of Functioning, Disability and Health; ISS = Injury Severity Score; LBOS = Low-Back Outcome Score; MFA = Musculoskeletal Function Assessment; MVAS = Million Visual Analog Scale; NASS = North American Spine Society; ODI = Oswestry Disability Index; QBPDS = Quebec Back Pain Disability Scale; QOL = quality of life; RMDQ = Roland-Morris Disability Questionnaire; RTW = return to work; SCI = spinal cord injury; SCIM = Spinal Cord Independence Measure; SF-36 = 36-Item Short Form Health Survey; SIP = Sickness Impact Profile; VAS = visual analog scale; WISCI = Walking Index for Spinal Cord Injury.
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logical involvement, represents a minority of all spinal trauma patients.\(^1\) This fact complicates the translation of outcome research performed in these populations to a general spinal trauma population. On the other hand, work in (poly)trauma populations typically contains a subset of spinal trauma patients, leading to similar obstacles when interpreting outcome data and evaluating outcome measures from the spinal trauma perspective.

Furthermore, spinal trauma patients are in a fundamental way dissimilar to patients with nontraumatic chronic back conditions, the population toward which many of the existing “spine” outcome measures have been directed.\(^4^4\)

As there is no consensus on the treatment strategies for many types of spinal injuries, prospective studies are necessary to compare these treatment options. However, validated outcome assessment tools specific to the characteristics of the spinal trauma population are necessary to be able to establish the efficacy of interventions and rationalize management decisions.

For the purposes of this review, we used the WHO's International Classification of Functioning, Disability and Health (ICF) as an expansive theoretical underpinning for newly developed measures targeting, among others, trauma patients.\(^6^4\) This describes, in detail, various health-related QOL domains, which can be used when comparing instruments and assessing their validity, and thus facilitates a more meaningful analysis.

The aim of this review is to evaluate the current state of outcome measurement as applied to spinal trauma patients. To be able to better assess the applicability and validity of existing outcome measures to spinal trauma patients, an overview of recent movements in the theoretical foundations of outcome assessment, as it pertains to spinal trauma patients, has been attempted, along with a discussion of domains important for spinal trauma. This permits an evaluation of the suitability of existing outcome measures to spinal trauma patients. A selected number of widely used outcome measures deemed most appropriate are reviewed and their applicability to spinal trauma outcome is discussed.

**Methods**

A literature search was performed on PubMed and Embase using the Medical Subject Headings (MeSH) terms “Outcome Assessment (Health Care)” and “Spine” and “Spinal Fractures” or “Spinal Injuries” or “Spinal Cord Injuries,” with limits “Humans,” “Clinical Trial,” “Meta-Analysis,” “Randomized Controlled Trial,” “Review,” “English,” “French,” and “German”; 6,090 papers were retrieved. The abstracts were reviewed by 2 authors and if deemed relevant the full-length article was sought. The full-length articles found were then thoroughly evaluated for relevant information on the outcome measurements used. The references of these papers were also manually screened for other potentially relevant articles, as were the related articles lists as generated by PubMed. Articles discussing outcomes in populations including spinal trauma components were included for analysis, with particular attention to those including psychometric data on outcome instruments in these populations. We also sought publications investigating and discussing the implementation of the ICF to spinal trauma. For those measures in which no psychometric/outcomes studies were found pertaining directly to spinal trauma patients as a unified population, the best available evidence was included.

**Results**

Analysis of the literature on spinal injury outcome measurements has led to several important conclusions. Firstly, there is no unanimity regarding which instruments should be used when measuring nonmortality trauma outcomes in general, and spinal trauma outcomes in particular. This fact is evidenced by the plethora of instruments in use.\(^2^3\) Therefore we categorized the different outcome measurements into: QOL physical measures, QOL mental/psychological measures, spinal disability measures, functional measures, and SCI measures. We also chose to draw an additional distinction between specific measurements primarily designed and used for trauma patients and those for SCI patients, due to the significantly different nature and content of these 2 groups of measures. Also, information on validation in spinal trauma was investigated.

Described in Table 1 are 4 QOL physical measures, 5 QOL mental/psychological measures, 8 disability measures, 4 functional measures, and 2 specific SCI questionnaires. These were the most commonly used measures in the literature that we thought relevant and possibly useful in trauma/spinal trauma patients.

Commonly used outcome measures that are primarily used in trauma populations in general and which we identified include the Functional Independence Measure (FIM), the GOS, the SF-36, the EQ-5D (standardized instrument of the EuroQol Group), the Musculoskeletal Function Assessment (MFA), and the Health Utilities Index Mark 3 (HUI 3). The only injury-specific outcome measure we identified is the Functional Capacity Index (FCI).

We found that the SCI patient population, whether the injuries are of traumatic origin or not, is largely treated as a separate and distinct population in the literature. Similar to the trauma outcomes field, there is no consensus about which outcome assessments are to be used in SCI patients. Outcome measures that are frequently used in SCI populations include: the Walking Index for Spinal Cord Injury (WISCI), the Spinal Cord Independence Measure (SCIM), the FIM, the SF-36, and the GOS.

Psychological outcome and well-being measurement is also an important aspect of polytrauma and spinal trauma outcome. The psychological outcome assessments commonly used in both trauma and SCI populations, such as the Hospital Anxiety and Depression Scale (HADS), the Beck Depression Inventory (BDI), and the Hamilton Depression Rating Scale (HDRS), are also discussed here. Components of generic health-related QOL tools (such as the SF-36) also measure psychological well-being. These instruments have been shown to be psychometrically sound, at least in SCI patients.
### TABLE 1: Existing outcome measurements for spinal pathology*

<table>
<thead>
<tr>
<th>Measure</th>
<th>Description</th>
<th>Validated for Spinal Trauma</th>
<th>Relevant Dimensions for Spinal Trauma</th>
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<tbody>
<tr>
<td><strong>QOL physical measures</strong></td>
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<tr>
<td>SIP[^5^]</td>
<td>pt-oriented 136-item measure of gen health; items: ambulation, mobility, body care &amp; movement, soc interaction, alertness behavior, emot'l behavior, communication, sleep &amp; rest, eating, work, home mgmt, recreation; 2 subscores: phys &amp; psychosoc dysfx range: 0 (perfect health) to 100 (severe disab); 0–3 = little/no disab; 4–9 = mild disab; 10–19 = mod disab; ≥20 = severe disab</td>
<td>no; validated for SCI pts &amp; trauma pts</td>
<td>ambulation, mobility, body care &amp; movement, soc interaction, communication, sleep &amp; rest, eating, working, home mgmt, recreation</td>
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<tr>
<td>SF-36[^6^]</td>
<td>multipurpose, short-form health survey w/ 36 Qs; generic measurement tool w/ 8 difft domains: phys functioning, role limitations phys, bodily pain, soc functioning, gen mental health, role limitations emot'l, vitality, gen health; range 0–100 (perfect health)</td>
<td>no; studied in musculoskeletal trauma, SCI, head injury, polytrauma</td>
<td>phys functioning, bodily pain, soc functioning, mental health, gen health</td>
</tr>
<tr>
<td>EQ-5D[^4^]</td>
<td>standardized generic non–disease-specific instrument describing &amp; evaluating health-related QOL; includes 5 dimensions of health w/ a utility index score &amp; a VAS for current health status; range (utility index): 0 (death) to 1 (perfect health)</td>
<td>no</td>
<td>mobility, self-care, usual activities, pain, anxiety</td>
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<tr>
<td>HU12 &amp; 3[^2^]</td>
<td>HU12: 15-item questionnaire about day-to-day health; measures 7 attributes of health status (sensation, mobility, emotion, cognition, self-care, pain, fertility); HU13: 7 items (hearing, speech, ambulation, dexterity, emotion, cognition, pain); range: −0.36 (worse than dead) to 1.00 (perfect health)</td>
<td>no</td>
<td>mobility/ambulation, emotion, self-care, dexterity, pain</td>
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<tr>
<td><strong>QOL mental/psychological measures</strong></td>
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<tr>
<td>HDRS[^8^]</td>
<td>17 variables to systematically quantify &amp; use expert clin judgment on severity of illness of pts w/ depr; range: 0 (not serious) to 52 (serious)</td>
<td>no; used in SCI pts</td>
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<tr>
<td>BDI[^3^]</td>
<td>21 items: 15 evaluating emot'l status &amp; behavioral changes, &amp; 6 evaluating somatic Sx; each item is scored on a 4-point scale; scores are added; range: 0–63; score &lt;10 min depr, 10–18 mod depr, 19–29 mod–severe depr, &gt;30 severe depr</td>
<td>no; used in pts w/ LBP &amp; orthopedic pts</td>
<td></td>
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<tr>
<td>HADS[^6^]</td>
<td>measure of mood, emot'l distress, anxiety, depr, &amp; emot'l disorder in clin populations w/ Sx of clin disease; 14 items answered on a 4-point verbal rating scale; anxiety (7 items), depr (7 items), emot'l distress (all 14 items); range: 0–24, if &gt;8 in both subscales indication of clinically relevant anxiety or depr is there</td>
<td>no; validated in pts w/ LBP</td>
<td></td>
</tr>
<tr>
<td>SF-36</td>
<td>see above</td>
<td>no</td>
<td>mental health, role emot'l</td>
</tr>
<tr>
<td>HUI</td>
<td>see above</td>
<td>no</td>
<td></td>
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<tr>
<td><strong>disability indices</strong></td>
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<tr>
<td>ODI[^1^]</td>
<td>self-administered tool consisting of sections assessing ADL in 10 difft categories: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, soc life, traveling; range: 0 (no disab) to 100 (compl disab)</td>
<td>no; validated for pts w/ LBP</td>
<td>all categories</td>
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<tr>
<td>MVAS[^4^]</td>
<td>15 subjective variables reflecting severity of back pain, circumstances exacerbating Sx, &amp; impact of problem on lifestyle, recorded asVAS scores; range: 0–10 for each item</td>
<td>no</td>
<td>all categories</td>
</tr>
<tr>
<td>RMDQ[^1^]</td>
<td>health status measure designed to be completed by pts to assess phys disab due to back pain; 24 items relate to phys fx affected by back pain; pts are asked to place a check mark beside statements that apply to them that day; range: 0 (no disab) to 24 (max disab)</td>
<td>no; validated for pts w/ LBP</td>
<td>all categories</td>
</tr>
<tr>
<td>LBOS[^2^]</td>
<td>developed as a quick, practical outcome score in pts w/ lumbar spine disorders measuring pain &amp; disab; range: 0 (very disabled) to 75 (not at all disabled); 4 outcome categories: ≥65 excellent, ≥50 good, ≥30 fair, &lt;30 poor</td>
<td>no; validated for pts w/ LBP</td>
<td>all categories</td>
</tr>
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</table>

(continued)
### TABLE 1: Existing outcome measurements for spinal pathology* (continued)

<table>
<thead>
<tr>
<th>Measure</th>
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<th>Relevant Dimensions for Spinal Trauma</th>
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<tbody>
<tr>
<td>disability indices (continued)</td>
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<tr>
<td>QBPDS35</td>
<td>20-item scale of phys disab associated w/ pain: refers to simple activities (sleeping &amp; resting, sitting, standing, ambulation, movement, bending &amp; stooping, handling large or heavy objects); 6-point difficulty scale (0 “not difficult at all” to 5 “unable to do”); range: 0 (no disab) to 100 (compl disab)</td>
<td>no; validated for pts w/ LBP</td>
<td>all categories</td>
</tr>
<tr>
<td>NASS-LS13</td>
<td>adaptation of ODI &amp; RMDQ to measure diverse dimensions of impact of lumbar spine problems; 34 items on demographics, medical Hx (14 Qs), body fx (pain, neurogenic Sx; 16 Qs), employment Hx, outcomes of Tx</td>
<td>no</td>
<td>pain, neurogenic Sx</td>
</tr>
<tr>
<td>RADL62</td>
<td>measurement of extent to which a person w/ back pain has resumed his or her usual activities; questionnaire focuses on workers w/ LBP due to “soft tissue injuries;” 12 Qs on resumption of sleeping patterns, sexual activity, self-care, household chores, shopping, socializing, traveling, recreational activities, &amp; employment are rated from 0% (not at all) to 100% (compl resumption)</td>
<td>no</td>
<td>all categories</td>
</tr>
<tr>
<td>LSOQ4</td>
<td>multi-item (56 Qs), self-report questionnaire designed to assess a number of factors in pts w/ LBP: demographics, pain severity, fx'l disab, psych distress, phys Sx, health care utilization, satisfact w/ Tx; range: 0–100 for pain severity, fx'l disab, psych distress, phys Sx</td>
<td>no; validated for pts w/ LBP</td>
<td>pain severity, fx'l disab, psych distress, phys Sx, health care utilization, satisfaction</td>
</tr>
<tr>
<td>functional measures</td>
<td></td>
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<tr>
<td>RTW39</td>
<td>assessing pts' RTW postinjury: in what time span &amp; often characterizing type of work (blue collar/white collar); subdivided into fully employed, fully employed but less-demanding occupation, unable to perform full-time employment, not able to work or unemployed despite normal phys fx</td>
<td>no</td>
<td>RTW after spinal trauma</td>
</tr>
<tr>
<td>FIM59</td>
<td>data set to assess fx'l independence; divided into FIM motor (self care, sphincter control, transfers, locomotion) &amp; FIM cognitive (communication, soc cognition); further subdivided into 18 items; range: 18 (compl dependence) to 126 (compl independence)</td>
<td>no; studied in multiple limb trauma, head injury, gen trauma, spinal injury</td>
<td>sphincter control: bladder mgmt/ bowel mgmt; transfer: bed/ wheelchair; locomotion: walk/ wheelchair/stairs</td>
</tr>
<tr>
<td>FCI37</td>
<td>preference-based, multiattribute fx'l outcome measure that provides 10 dimension-specific scores &amp; 1 overall score that summarizes fx across 10 dimensions (eating, excretory fx, sexual fx, ambulation, hand/arm movement, bending/lifting, vision, hearing, speech, cognitive fx); range 0 (death) to 1 (no limitations)</td>
<td>no; validated for blunt trauma pts, lower-extremity injuries</td>
<td>excretory fx, sexual fx, ambulation, hand/arm movement, bending/lifting</td>
</tr>
<tr>
<td>HSU50</td>
<td>measuring health service use of pts, mostly comparing post-trauma pts w/ healthy population (hospitalization days, placement in extended care services, home care service, physician claims, etc.)</td>
<td>no</td>
<td>health service use after spinal trauma</td>
</tr>
<tr>
<td>SCI measures</td>
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<tr>
<td>SCIM11</td>
<td>disab scale for pts w/ spinal cord lesions; principal areas of fx: self-care (feeding, bathing, dressing, grooming), respiration &amp; sphincter mgmt (respiration, bladder mgmt, bowel mgmt, use of toilet), mobility (mobility in bed &amp; action to prevent pressure sores, transfers bed/wheelchair/tub, mobility for short/moderate/long distances, stair mgmt, transfer wheelchair/car); range: 0 (completely disabled) to 100 (completely independent)</td>
<td>no</td>
<td>feeding, bathing, dressing, grooming, sphincter mgmt, use of toilet, transfers, mobility, stair mgmt</td>
</tr>
<tr>
<td>WISC11</td>
<td>measure of mobility designed for SCI pts; 20-item scale: reflection of walking level, use of devices &amp; phys assistance for a distance of 10 m; range 0 (unable to walk) to 20 (walking w/o braces/assistance/devices for at least 10 m)</td>
<td>yes; SCI pts</td>
<td>walking</td>
</tr>
</tbody>
</table>

* clin = clinical; compl = complete; depr = depression; diff = different; disab = disability; dysfx = dysfunction; emotl = emotional; fx = function; fx'l = functional; gen = general; incl = including; LBP = low-back pain; LSOQ = Lumbar Spine Outcome Questionnaire; mgmt = management; min = minimal; mod = moderate; NASS-LS = NASS Lumbar Spine Outcome Assessment Instrument; phys = physical; psych = psychological; psychosoc = psychosocial; pt = patient; Q = question; RADL = Resumption of Activities of Daily Living Scale; soc = social.
Quality-of-Life Physical Measures

The SF-36 is a widely applied generic measure that has been validated in numerous patient populations and consists of 36 items in 8 health domains. It is not designed for measuring disability and has limitations such as inappropriate items for SCI patients. Additionally, the psychometrics of the SF-36 have not been extensively tested in SCI populations.

The EQ-5D is a self-administered generic health-related QOL measure with 5 dimensions (mobility, self-care, activities, pain, anxiety/depression) and a general health state VAS item. It was developed by the interdisciplinary EuroQol Group. Although initially intended to complement condition-specific measures, it is being used increasingly as a stand-alone measure in spine research. The EQ-5D has the added benefit of being able to generate utilities allowing economic evaluations. The HUI is a “generic multi-attribute preference-based measure of health status and health-related quality of life.” It encompasses both physical and emotional dimensions of health and emphasizes functional potential over performance in order to avoid the assumption that patients always choose to realize their full functional potential and to directly measure impairment. The HUI also allows for economic evaluation. The applicability of the HUI in trauma populations has yet to be tested.

The Sickness Impact Profile (SIP) is a 136-item patient-oriented measurement. It relates to 12 areas of activity with statements that patients are asked to endorse, or patients are asked to check only those that they are sure describes their health on that day. This instrument was developed to detect changes or differences in health status over time and between groups. It is useful for evaluation, program planning, and policy formulation. It is also used in several spine studies on cervical disc herniation, spinal stenosis and back pain, vertebral deformities and osteoporosis, and in evaluating iliac crest donor problems.

Other generic outcome instruments such as the WHO Disability Assessment Schedule and the GOS are not discussed because they are similar and used less often than the generic instruments discussed above, or are not directly applicable to spinal trauma.

Quality-of-Life Mental/Psychological Measures

The SF-36 and HUI both incorporate psychological features. Neither is validated for spinal trauma patients.

The HDRS was developed in 1960 and is one of the questionnaires most used in depression research. It contains 17 variables measured on a 5- or 3-point scale. Important aspects for spinal trauma patients are depressed mood, work and interests, somatic, and genital.

The BDI has 21 items: 15 items evaluating emotional status and behavioral changes, and 6 evaluating somatic symptoms. It has high internal consistency, high content validity, and validity in differentiating between depressed and nondepressed patients, and it is sensitive to change. In a study of the prevalence and severity of depression in 161 orthopedic trauma patients, 55% were classified as having minimal depression, 28% moderate, 13% moderate-to-severe, and 4% severe when the somatic elements of the scale were included. Without the somatic elements, the proportion of patients classified as having moderate, moderate-to-severe, or severe depression was 26%.

The HADS is a self-rating instrument for patients with both somatic and mental problems. It was designed in 1983 to identify anxiety or depression disorders in nonpsychiatric hospital clinics. It is divided into an anxiety subscale (HADS-A) and a depression subscale (HADS-D). It performs well in screening for the separate dimensions of anxiety or depression disorders.

All of these depression outcome measurements are mostly used in SCI patients. There has been a lot of research, but none of the measurements are validated for use in spinal trauma patients.

Disability Indices

The Oswestry Disability Index (ODI) and the Roland-Morris Disability Questionnaire (RMDQ) are 2 widely used condition-specific instruments that assess disability in patients with chronic low-back pain. These instruments are included here as they are illustrative of the outcome measures commonly employed in this related population. The ODI is a self-administered tool consisting of sections assessing ADL. It seems slightly more sensitive to improvements in condition than the RMDQ. It is one of the most widely used outcome measurements for patients with low-back pain. The RMDQ was derived from the SIP and assesses pain and daily function. It has been extensively validated and demonstrates good reliability and consistency in patients with low-back pain. The ODI has been directly compared with the RMDQ in several studies. It seems that the ODI is better at detecting change in more seriously disabled persons, whereas the RMDQ may have an advantage in patients with minor disability. Both of these instruments are designed and mainly used to assess disability associated with chronic low-back pain.

The Million Visual Analog Scale (MVAS) consists of 15 questions, with a VAS for each. It is not as widely used as the ODI or RMDQ and is not validated for spinal trauma.

The Low-Back Outcome Score (LBOS) was developed by Greenough and Fraser as a quick score for assessment of disability and pain. It is used in spinal trauma patients, but has not been validated.

The Quebec Back Pain Disability Scale (QBPDS) is validated for patients with low-back pain. In comparison between the QBPDS and the ODI, the ODI showed higher test-retest reliability and responsiveness.

Another interesting questionnaire is the Resumption of Activities of Daily Living Scale (RADLS). As previously mentioned, most questionnaires fail to take into account what was “normal” or “usual” prior to injury. Also, patients’ perceptions of readiness to return to work may not agree with clinicians’ judgments.

The AAOS/NASS spine questionnaires are adaptations of the ODI and the RMDQ. They differ from the ODI and RMDQ in that they are applied as preoperative and follow-up modules. There are specific questionnaires for the cervical and lumbar spine. In addition to the features found in the ODI and the RMDQ, the AAOS/NASS
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disease-specific questionnaire contains a comorbidity index (14 questions) and questions on physical health and pain (16 questions), treatment expectations (5), satisfaction with symptoms (1), neurogenic symptoms (6), and pain/disability (11). Normative values have been published.33

An analogous instrument, the Neck Disability Index, is used for similar purposes in patients with cervical spine disorders.56,58

Functional Measures

The practice of measuring a single meaningful parameter of outcome has also been implemented as a way to expedite the outcome assessment process. Measures of work status or unidimensional measures of mobility are often included in the commonly used generic and functional outcome measures, but they are also applied independently.

The return to work (RTW) measure represents an interesting construct in that it is a meaningful outcome from a societal as well as an individual point of view and it can serve as an indirect proxy for the domain of participation as well as function. Of course it also reflects the other domains of impairment and activities, making it a complex as well as a useful construct.8,53 The RTW has been used as a primary outcome in a patient population that underwent surgery for spinal fractures resulting from high-energy trauma.41 The presence of neurological symptoms was found to be a major predictor of RTW status at follow-up.

The FCI has been validated in major trauma populations.37,38 It is a “preference based, multi-attribute functional outcome measure that provides 10 dimension specific scores and one overall score that summarizes function across the 10 dimensions.”37 The dimensions include “eating, excretory function, sexual function, ambulation, hand/arm movement, bending/lifting, vision, hearing, speech and cognitive function.”53 It does not assess psychosocial outcomes and is targeted mainly toward measuring outcome in general trauma patients, reflecting the domains pertinent to that group. It merits inclusion here as it is one of the only outcome measures designed specifically for trauma populations.51

More comprehensive functional outcome measures such as the FIM and SCIM incorporate a mobility domain. The FIM is a well-established functional outcome assessment score that also relies on the patient’s ability to perform ADL.56,59 Although initially designed for stroke patients, it has been extensively used in the assessment of trauma outcome and is likely the most widely used functional outcome measure for the SCI population, with demonstrated validity and reliability in that specific population.48,63

Although the use of the FIM has merit in spinal trauma patients, it is not free of limitations. Briefly, the FIM scoring aggregation creates a masking effect in that unequal ordinal items are simply summed. Moreover, the FIM measures a narrow set of domains reflecting impairments that are primarily specific to SCI.30,40 Other limitations are that the FIM is usually administered by a certified therapist, it is largely designed for hospitalized patients, and it is not a patient-directed questionnaire. A “phone FIM” instrument is now also available, however, so direct patient contact is not necessary.

The measure of health service use (HSU) is similar to the RTW in that it is a complex but also useful and important construct for assessing injury outcome. The complexity and multifactorial nature of this measure have been established but not adequately explored in trauma patients, let alone spinal trauma patients.50 Like the RTW, it is an important measure from an economic and social point of view, but any inferences drawn from it about the efficacy of treatment are tenuous at best.

Spinal Cord Injury Measures

The SCIM is a recently developed disability measure designed and validated for patients with spinal cord lesions.41 It measures a patient’s ability to perform daily tasks and demonstrates good reliability and validity in the SCI population subset. Specifically designed for patients with substantial neurological damage, it would not be suitable for use in a spinal trauma population with no or varying degrees of neurological involvement. Nevertheless, it still warrants mention because it is an excellent tool for assessing the spinal cord–related functional outcome component of spinal injury.25

The WISCI is also a recently developed measure of mobility designed for SCI, with demonstrated high sensitivity.43 It is validated for SCI patients with good correlation.55

The ICF and Spinal Trauma

The ICF framework reflects a biopsychosocial model of health and functioning. It is generic in nature and not designed with any particular patient group in mind. As such, the practice of selecting a subset of ICF domains and constructs to generate condition-specific “ICF core sets” has emerged to take better advantage of the ICF in specific patient groups.7 This approach has been applied both to the SCI population and to patients with acute and postacute musculoskeletal conditions.9,14,49,55 For acute musculoskeletal injuries, a consensus conference selected 47 ICF categories for inclusion into a “core set.”27 The core set emphasizes the integrity and function of musculoskeletal structures. By comparison, for longer-term follow-up of these patients, emphasis was placed on activities/participation.

The target patient population did not include SCI trauma patients, who were lumped into a different core set, namely that of acute and postacute neurological patients.57 This population includes patients with head injury, cerebrovascular diseases, and CNS neoplasms. A large number of the categories selected for this population would be tangential to both SCI and non-SCI spine trauma.

The postacute core sets as they are described above seem to be more applicable to outcome assessment, as the acute core sets include assessments of the current state of patients in the acute setting (for example, temperature and electrolyte levels). These categories are not meant as outcomes but rather as classification and prognostic aids. The postacute core sets discussed here were generated for
trauma and neurological injury populations, and while spinal trauma patients form subsets of both populations, parts of both core sets are not relevant to spinal trauma populations.

Table 2 presents a list of spinal trauma–relevant ICF criteria that we have generated to evaluate how effectively frequently used outcome instruments address spinal trauma outcome domains.

**Discussion**

This review sought to assess the current state of outcome measurement in spinal trauma patients and to address the question of whether this group is adequately served by current disease-specific and generic health-related QOL instruments. Several overarching trends were found to be significant to the spinal trauma outcome field.

While the SF-36 and other widely used generic instruments provide normative data that allow for demographically adjusted approximations of preinjury scores and comparisons between populations, these instruments were not designed for any specific population. This “one-size-fits-all” approach may be a source of methodological limitations (ceiling and floor effects, large minimally clinically important difference, and low responsiveness) if they are relied on too heavily as primary measures in spinal trauma. Indeed, the applicability of generic health-related QOL assessments as primary outcome measures in SCI studies has come under question recently, as measures of function might be more meaningful and sensitive in discriminating between different treatment modalities.57

Spine-specific (low-back or cervical) outcome measures, on the other hand, may theoretically have limited applicability to spinal trauma patients in the sense that the domains they measure and the relative weighting of each in the scoring do not correspond to the domains perceived to be important in spinal trauma patients, a fundamentally different population. For instance, chronic pain is probably a lesser issue in trauma patients, including spinal trauma victims, than in chronic cervical or lumbar pain syndromes.2 Although pain may be relevant for SCI patients,34 the lower incidence and lower pain scores in spinal trauma patients after the acute phase make the emphasis placed on pain measures in the instruments used in chronic patients potentially misplaced in the spinal trauma population. Additionally, the high psychometric quality of the ODI and RMDQ in patients with low-back pain might not apply to the very different spinal trauma patient group (because of ceiling and floor effects and responsiveness issues, for example).

Concerning the functional outcome measurements, the literature shows that after 12 months of follow-up, the FCI does not correlate with the initial FCI or initial trauma severity, indicating that the FCI may not be a suitable tracker of outcome progression over time.51 While outcome measures like the WISCI might be useful in populations with substantial SCI, they are too narrow to form the basis of evidence-based decisions in spinal trauma patients with a broad spectrum of neurological involvement and disability.

Our literature search identified only 1 outcomes paper dealing directly with acute trauma patients as a single population, and the authors of that paper used the FIM.1 The study showed that FIM scores improved significantly

**TABLE 2: Overview of ICF criteria measured in selected outcome instruments**

<table>
<thead>
<tr>
<th>Domain†</th>
<th>SF-36</th>
<th>EQ-5D</th>
<th>HUI</th>
<th>ODI</th>
<th>RMQD</th>
<th>FCI</th>
<th>WISCI</th>
<th>FIM</th>
<th>SCIM</th>
<th>RTW</th>
<th>HSU</th>
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<tr>
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<td>+</td>
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<tr>
<td>sensory &amp; pain</td>
<td>+</td>
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<td>++</td>
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<td>interpersonal relationships</td>
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<td>support &amp; relationships</td>
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</table>

* This table provides a rough indication of which topics relevant to spinal trauma are addressed in the instruments analyzed. It indicates only their presence or absence and does not address the quality of these items in the measurement instruments. Definition of symbols: + = included in outcome measurement; ++ = emphasized in outcome measurement; ± = mentioned in outcome measurement.
† Putative spinal trauma domains.
Outcome instruments in spinal trauma

in survivors at 12 months posttrauma. Additionally, no correlation was found between results of the FIM administered on admission and results obtained 1 year postinjury. The authors also did not find a significant correlation between the Injury Severity Score (ISS) and 1-year FIM outcome. Interestingly, a different study performed in spinal trauma patients with polytrauma did find a correlation between the ISS and 1- and 2-year FIM scores.29 This discrepancy is possibly related to the study populations and/or the differing statistical methods applied. The study investigating spine patients with polytrauma further found that the severity of spinal injuries was the most important predictor of disability as measured by the FIM, although the authors acknowledge that this finding may relate to the spine bias of the FIM.29 Nonetheless, this result again suggests the importance of spinal trauma in mid- to long-term disability and emphasizes the selection of outcome measures.

The 2 single-item outcomes, RTW and HSU, are interesting in that they produce a single economically significant outcome measure directly dependent on multiple parameters spread over many health domains. Assessments using these measures are easy to conduct, but one should use caution in analyzing and interpreting the results because they depend on a poorly defined collection of multiple patient-related factors.

The available outcome research was assessed in the trauma and SCI fields in an attempt to extract and synthesize relevant conclusions about the state of outcome research in spinal trauma, an approach necessitated by the paucity of research specifically involving the spinal trauma patient population. This is a further indication that outcomes in spinal trauma patients might not be adequately measured with existing instruments; most of the outcome analysis was being performed in the general (multi)trauma population and/or the SCI population, with spinal trauma patients sometimes constituting a subset in the trauma studies. Conversely, in SCI outcome studies a large proportion of the patients have SCIs of traumatic etiology and therefore represent a subset of spinal trauma patients.

On the other hand, patients with chronic lumbar or cervical pain constitute a distinct population in which much outcome research is being conducted. Although many studies use these outcome measurements for spinal trauma patients, there is actually little overlap between these patients with chronic conditions and the patients with acute spinal trauma.

Identifying those ICF criteria relevant to spinal trauma and evaluating in a summary form which domains were measured in the outcome tools are important issues in the discussion on this subject. The putative ICF domains that we selected as likely to be relevant to spinal trauma demonstrate that no single outcome measure adequately addresses all the major domains likely to be relevant to spinal trauma. After reviewing both the most commonly used outcome measures and current consensus on the underlying domains, we have come to the conclusion that the outcome tools in current use are not adequate for assessing spinal trauma patients as a specific population. It seems that the ICF criteria pertinent to the spinal trauma group could be more or less completely covered by a combination of generic and condition-specific trauma and SCI outcome assessments. The most inclusive approach would be to select a combination of measures, but this would also lead to a significant amount of redundancy, as well as creating the possibility of psychometric issues.

The lack of tools designed for the spinal trauma population and the lack of research into the applicability and validity of existing tools to the spinal trauma population produce a situation in which the efficacy of interventions targeting this group cannot be readily evaluated. Thus the status quo, in which spinal trauma patients are effectively split between trauma patients and SCI patients, is suboptimal, leading to psychometric limitations and redundancy. Additionally it would be desirable to treat spinal trauma patients as a single unified group because of the commonality of SCI and non-SCI patients, and to employ a single psychometrically validated instrument specifically tailored to the unique dynamics of spinal trauma.

A proper spinal trauma injury outcome tool should probably be a combination of already-existing questionnaires and, in our opinion, focus on resumption of activities in comparison with pretrauma level of functioning. Computer adaptive tests or item response theory can be helpful in combining relevant domains and activities for spinal trauma patients to create an outcome instrument for spinal trauma patients with or without SCI.27,28,34

Conclusions

Outcome instruments currently in use fail to capture many of the domains relevant to spinal trauma patients. There is currently very little work that evaluates these patients as a single specific population. In this study, an evidence-based preliminary list of domains has been generated to serve as the basis for further discussion of which domains are pertinent to spinal trauma patients.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following. Concept and design: Öner, Holtslag. Acquisition of data: Stadhouder, Buckens. Analysis and interpretation of data: Stadhouder, Buckens. Drafting the article: Stadhouder, Buckens. Critically revising the article: Öner, Holtslag. Reviewed final version of the manuscript and approved it for submission: all authors.

References

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