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Measurement of Symptoms Following Sports-Related Concussion: Reliability and Normative Data for the Post-Concussion Scale

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It is important to carefully evaluate self-reported symptoms in athletes with known or suspected concussions. This article presents data on the psychometric and clinical properties of a commonly used concussion symptom inventory—the Post-Concussion Scale. Normative and psychometric data are presented for large samples of young men (N = 1,391) and young women (N = 355). In addition, data gathered from a concussed sample of athletes (N = 260) seen within 5 days of injury are presented. These groups represent samples of both high school and collegiate athletes. Data from a subsample of 52 concussed athletes seen 3 times post-injury are presented to illustrate symptom reporting patterns during the initial recovery period. General guidelines for the clinical use of the scale are provided.

Key words: concussion, symptoms, traumatic brain injury, sports

Clinical strategies for the diagnosis and management of concussion have evolved considerably over the past decade. There has been a trend toward more sophisticated and individualized approaches to managing this injury (Collins, Lovell, & McKeag, 1999; Johnston, McCrory, Mohtadi, & Meeuwisse, 2001). More contemporary concussion management strategies have emphasized multiple diagnostic elements including clinical history, sideline evaluation, neuropsychological testing, and neuroimaging, when appropriate.

Concussion has recently been defined as "a complex pathophysiological process affecting the brain, induced

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by traumatic biomechanical forces" (Aubry et al., 2002). Contemporary definitions of this injury assume a neurophysiological rather than neuroanatomical basis for concussion, and traditional neuroimaging procedures are of little value in the detection of injury and monitoring of recovery. Although newer functional brain imaging (fMRI) protocols show promise as a diagnostic technology, fMRI is currently not available for widespread clinical use (Lovell et al., 2004). Therefore, neuropsychological assessment has played an increasingly prominent role in concussion management. Characteristic neuropsychological deficits following concussion in the areas of attentional processes, memory, and neurocognitive speed following concussion have been documented by multiple researchers (Echemendia & Cantu, 2003; Erlanger et al., 2003; Lovell et al., 2004a, 2004b; McCrea et al., 2003). However, in addition to these common deficits that can be documented by standardized neuropsychological assessment protocols, many symptoms reported by injured athletes are of a more subjective nature.

In recognition of the need for better concussion management strategies, the International Ice Hockey Federation (IIHF), in conjunction with the International Olympic Committee (IOC) and the Federation Internationale de Football Association (FIFA), convened in Vienna in October of 2001 to evaluate the current status of concussion management guidelines and to draft practical recommendations for making return-to-play decisions (Aubry et al., 2002). As a prominent piece of the concussion evaluation process, the Concussion in Sport (CIS) group recommended the careful evaluation of individual symptoms following a suspected concussion and further suggested that any report of symptoms should lead to more in-depth evaluation.

The measurement of symptoms is very common in the sport concussion literature (e.g., Echemendia, Putukian, Mackin, Julian, & Shoss, 2001; Erlanger et al., 2003; Guskiewicz et al., 2003; Macciocchi, Barth, Alves, Rimel, & Jane, 1996; Macciocchi, Barth, Littlefield, & Cantu, 2001; McCrea et al., 2003). Although the importance of player symptoms in making return-to-play decisions is almost universally accepted, the availability of formal evaluation scales with known psychometric properties is rather limited, with the notable exception of the Head Injury Scale (Piland, Motl, Ferrara, & Peterson, 2003). In addition, differences in symptom reporting by different groups (e.g., men vs. women, high school vs. college) have not been adequately explored.

This article presents data on the psychometric and clinical properties of a single commonly used concussion symptom inventory—the Post-Concussion Scale (PCS). Normative data will be presented and discussed. In addition, data gathered from a concussed sample of athletes will be presented to illustrate changes in symptom reporting following concussion. General guidelines for the clinical use of the scale will be provided.

METHODS

Participants

Normative data for the PCS were derived from 1,746 high school and university student athletes. All student athletes completed the computerized version of the test, as administered within ImPACT Version 1. The students represented more than 15 high schools and 10 universities. There were 707 high school students and 1,039 university students. The high school sample was comprised of 588 (83.2%) young men and 119 (16.8%) young women. On average, they had completed 10.3 years of school (*SD* = 1.0). The university sample was comprised of 803 (77.3%) young men and 236 (22.7%) young women. On average, they had completed 13.6 years of school (*SD* = 1.3).

A separate clinical sample was comprised of 260 high school and university athletes who were evaluated within 5 days of sustaining a sports-related concussion (*M* = 2.0, *SD* = 1.2) by either a certified athletic trainer or team physician. A concussion was diagnosed based on recent international criteria (Aubry et al., 2002). Prior to the beginning of the study, all athletic trainers were formally trained in the on-field diagnosis of concussion by one of the authors (Drs. Lovell or Collins). A concussion was diagnosed if the athlete reported symptoms such as headache, dizziness, or balance dysfunction, or if he or she exhibited a decline in cognitive functioning as demonstrated by poor performance on a brief mental status examination, which tested aspects of retrograde and post-traumatic amnesia (Lovell, Collins, Iverson, Johnston, & Bradley, 2004).

The majority of the concussed athletes were seen within 72 hours (88%). Their average age was 16.5 years (*SD* = 2.0), and their average education was 10.2 years (*SD* = 1.8). The majority of athletes were in high school (85%). The sample was 83.5% men and 16.5% women. From this sample, a subsample of 52 concussed athletes who were evaluated three times within specified intervals was selected. An athlete was selected from the larger sample, for this subsample, if he or she was evaluated the first time within 72 hours, the second time between 4 and 8 days, and the third time between 7 and 30 days. The time intervals were allowed to overlap slightly to increase the sample size for these analyses. The actual breakdown of mean number of days post- injury for each assessment period was as follows: Time 1 = 1.4 days post (*Mdn* = 1, *SD* = .7, range = 0–3), Time 2 = 5.6 days post (*Mdn* = 5, *SD* = 1.3, range = 4–8), and Time 3 = 11.7 days post (*Mdn* = 11, *SD* = 4.2, range = 7–24).

Measure

The PCS is a 22-item scale designed to measure the severity of symptoms in the acute phase of recovery from concussion (Lovell, 1996, 1999; Lovell & Collins, 1998). This scale was developed in the late 1980s within the context of the Pittsburgh Steelers concussion management program, and variants of this scale have been formally adopted by the National Football League (Lovell, 1996), National Hockey League (Lovell & Burke, 2002; Lovell, Echemendia, & Burke, 2004), by numerous colleges and high schools, and more recently by automobile racing leagues such as the Competitive Automobile Racing League and the Indianapolis Racing League (Olvey, 2002). This scale has been a dependent measure in several published studies (e.g., Collins et al., 2003; Iverson, Gaetz, Lovell, & Collins, 2004a, 2004b; Lovell et al., 2003; Lovell, Collins et al., 2004). The scale is presented in Figure 1.

The PCS was developed to provide a formal method of documenting post- concussion symptoms, as perceived and reported by the athlete. In particular, the goal in developing this scale was to more objectively document the often highly subjective symptoms reported by athletes following concussion by assigning numeric values to each symptom. This scale was developed to provide an adjunct to other tools such as neuropsychological testing. Symptom items were based on earlier experience gathering symptom data

Rate your symptoms over the past 2 days.

Symptom	None	Mild		Moderate		Severe	
Headache	0	1	2	3	4	5	6
Nausea	0	1	2	3	4	5	6
Vomiting	0	1	2	3	4	5	6
Balance Problems	0	1	2	3	4	5	6
Dizziness	0	1	2	3	4	5	6
Fatigue	0	1	2	3	4	5	6
Trouble Falling Asleep	0	1	2	3	4	5	6
Sleeping More Than Usual	0	1	2	3	4	5	6
Sleeping Less Than Usual	0	1	2	3	4	5	6
Drowsiness	0	1	2	3	4	5	6
Sensitivity to Light	0	1	2	3	4	5	6
Sensitivity to Noise	0	1	2	3	4	5	6
Irritability	0	1	2	3	4	5	6
Sadness	0	1	2	3	4	5	6
Nervousness	0	1	2	3	4	5	6
Feeling More Emotional	0	1	2	3	4	5	6
Numbness or Tingling	0	1	2	3	4	5	6
Feeling Slowed Down	0	1	2	3	4	5	6
Feeling Mentally “Foggy”	0	1	2	3	4	5	6
Difficulty Concentrating	0	1	2	3	4	5	6
Difficulty Remembering	0	1	2	3	4	5	6
Visual Problems	0	1	2	3	4	5	6

Figure 1. Post-Concussion Scale.

from the Pittsburgh Steelers and later from thousands of amateur and professional athletes. Scale items were constructed to reflect actual player reports rather than medical jargon. For instance, the term *fogginess* was employed based on the recurrent report of this symptom by concussed athletes. The original scale was based on a 7-point Likert scale with 0 and 6 reflecting the anchor points. The written instructions that accompany the scale request the athletes to report symptoms based on the severity of each symptom that day. The scale is currently available in paper form through the senior author at no cost and has also been incorporated into the ImPACT computerized neuropsychological program (Lovell et al., 2003; Lovell, Collins et al., 2004; Maroon et al., 2000). The scale has also been suggested as a management tool by other organizations as well (Aubry et al., 2002).

RESULTS

Descriptive Statistics and Normative Data

Descriptive statistics and psychometric analyses are provided in Table 1. The mean, median, standard deviation, range, skewness, and kurtosis of total scores for each sample are presented. As seen from the measures of central tendency (mean and median), skewness, and the ranges, the distributions of total symptom scores are clearly skewed. That is, a large percentage of athletes score between zero and three points at baseline testing. The distribution of scores for the concussed athletes is not severely skewed; it is much more evenly distributed.

There was no significant difference in total symptom scores between the high school students and the university students ($M = 5.31$, $SD = 9.21$, and $M = 5.28$, $SD = 8.36$, respectively). However, there was a significant difference between men and women in both samples. That is, the young women reported more symptoms than the young men in the high school ($p < .03$, Cohen's $d = .33$, small–medium effect size) and the university sample ($p < .001$, $d = .43$, medium effect size). In the concussed sample, there was no significant difference in total symptom scores between high school athletes and university athletes ($M = 24.4$, $SD = 19.5$, and $M = 20.7$, $SD = 21.7$, respectively). In addition, there was no significant difference in total scores for young men versus young women ($M = 23.3$, $SD = 19.4$, and $M = 27.9$, $SD = 22.6$, respectively), although there was a trend towards greater symptom reporting in women.

Given that there were no significant differences between high school students and university students, normative data for the PCS are presented by gender. As previously noted, the distributions of total scores are skewed because healthy young people tend to report few symptoms on this scale. With this degree of skew, forced-normalization of the distributions will (a) distort the true nature of the construct being measured, that is, healthy young people's total symptoms are not normally distributed in the population; and (b) result in in-

Table 1. *Descriptive and Psychometric Analyses for Concussion Symptom Reporting at Baseline and Postconcussion for High School and College Men and Women Athletes*

Group	*N*	*M*	*Mdn*	*SD*	Range	Skew	Kurtosis	Alpha[1]	SEM[2]	.80[3]
Normative										
High school										
Young men	588	4.8	2	7.9	0–54	2.8	9.7	.89	2.62	3.35
Young women	119	7.7	3	13.7	0–78	3.1	10.8	.94	3.36	4.30
College										
Young men	803	4.5	2	7.5	0–56	2.9	10.6	.88	2.60	3.33
Young women	236	8.0	5	10.3	0–55	2.1	5.2	.88	3.57	4.57
Combined sample										
Young men	1,391	4.6	2	7.7	0–56	2.9	10.2	.88	2.66	3.40
Young women	355	7.9	4	11.5	0–78	2.7	9.2	.91	3.46	4.43
Athletes with concussions										
Young men	217	23.3	19	19.4	0–94	1.1	.8	.93	5.13	6.57
Young women	43	27.9	23	22.4	0–82	.8	–.3	.92	6.34	8.12
Combined sample	260	24.0	19	20.0	0–94	1.0	.5	.93	5.29	6.77

Note. The statistics presented in this table are stratified by concussion status, level of competition, and gender.
[1]Cronbach's Unstandardized Alpha; this represents the lower bound of reliability.
[2]Standard error of measurement.
[3].80 and confidence interval.

creased interpretation error. Therefore, the natural distribution of scores was examined, and classification ranges were created that reflect proportions of normative subjects. Classification descriptors were created that reflect raw score ranges and percentile rank ranges in the natural distribution of scores. For example, in Table 2, 42% of young men obtained a total score of zero on the scale. Thus, a score of zero would be considered "Low–Normal". In contrast, 89% scored 12 or less, so only 11% scored 13 or higher. Thus, scores between 13 and 26 are considered "Very High." The percentile rank values represent the percentage of students who scored at the lower and upper bound of that raw score range. For the "Very High" range, 91% of young men scored 13 or less and 97% scored 26 or less; therefore, scores above 26 are considered "Extremely High."

As seen in Table 3, young women report more symptoms than young men. Approximately 28% obtained a score of zero. The "Broadly Normal" range is from 1 to 9 points, and the "Borderline" range is from 10 to 20 points. Ninety percent of young women scored 20 or less on the scale.

As seen in Table 1, the concussed athletes have high total scores for the PCS. The breakdown of concussed athletes into the total score normative classification ranges is provided in Table 4. The percentages of the normative sample that fall in each classification range are presented for comparison. Combining the two lowest classification ranges provides a "Broadly Normal" range of total scores. For the normative sample, 74% of young men and 73% of young women fell in this range. In contrast, 21% of concussed young men and approximately 26% of concussed young women fell in this range. If the "Very High" and "Extremely High" classification ranges are combined, 10% of healthy young men and 9% of healthy young women fell in this combined category. In contrast, 67% of concussed young men and 51% of concussed young women fell in this combined category.

Table 2. *Classifications, Raw Scores, and Percentile Ranks Based on a Sample of 1,391 Healthy Young Men*

Classification	Raw Scores	Percentile Ranks
Low–normal	0	42
Broadly normal	1–5	49–74
Borderline	6–12	77–89
Very high	13–26	91–97
Extremely high	27+	98

Table 3. *Classifications, Raw Scores, and Percentile Ranks Based on a Sample of 355 Healthy Young Women*

Classification	Raw Scores	Percentile Ranks
Low–normal	0	28
Broadly normal	1–9	35–73
Borderline	10–20	76–90
Very high	21–43	91–97
Extremely high	44+	98

Table 4. *Percentage of Normative Participants and Concussed Athletes Falling in Each Classification Range*

	Normative Sample		Concussed Sample	
Classification	Young Men	Young Women	Young Men	Young Women
Low–normal	42	28	6.5	2.3
Broadly normal	32	45	14.7	23.3
Borderline	15	17	11.5	23.2
Very high	8	7	32.7	25.6
Extremely high	2	2	34.6	25.6

Scale Reliability

Reliability can be viewed as the ability of an instrument to reflect an individual score that is minimally influenced by error. Reliability should not be considered a dichotomous concept, rather it falls on a continuum. One cannot say an instrument is reliable or unreliable, but more accurately should say it possesses a high or low degree of reliability for a specific purpose, with a specific population (Franzen, 2000).

An important aspect of reliability is internal consistency. Internal consistency can be estimated using Cronbach's alpha (Cronbach, 1951). Alpha is believed to represent the lower bound for the true reliability of the scale and is influenced by the number of items on the scale, the average inter-item covariance, and the average item variance (SPSS, 1998).

As seen in Table 1, internal consistency reliability of the PCS ranged from .88 to .94 across the various samples of healthy high school and college students in this study. The standard error of measurement (SEM) is considered an estimate of measurement error in a person's observed test score. SEMs for the different groups also are presented in Table 1. These SEMs were used to create confidence intervals. A confidence interval represents a range or band of scores, surrounding an observed score, in which the individual's true score is believed to fall. For young men, the 80% confidence interval for the total score was ±3.4 points. For young women, the 80% confidence interval was ±4.4 points (i.e., the SEM multiplied by a *z*-score of 1.28).

For the concussed athletes, the internal consistency of the PCS was very high ($r = .93$). The standard error of measurement is 5.3 points, and the 80% confidence interval is 6.8 points.

Individual Symptom Reporting

The frequencies of individual symptom endorsement by level of severity for the concussed athletes are presented in Table 5. The most frequently endorsed symptoms, at a severity of mild or greater, were as follows: headaches, fatigue, feeling slowed down, drowsiness, difficulty concentrating, feeling mentally foggy, and dizziness. These individual symptoms were endorsed by 60–79% of the sample. The least frequently endorsed symptoms were nervousness, feeling more emotional, sadness, numbness or tingling, and vomiting. These individual symptoms were endorsed by less than 25% of the sample.

A sample of 52 concussed athletes was evaluated three times, within 72 hours ($M = 1.4$ days), between 4 and 8 days ($M = 5.6$ days), and between 7 and 30 days ($M = 11.7$ days). Forty-seven of these athletes were men and only 5 were women. Therefore specific data by gender are not presented in this current study. As seen in Figure 2 and Table 6, there was a linear decrease in total symptoms reported across the three intervals. During the first time period, subjects reported numerous symptoms. By the third time period, their symptom reporting was essentially normal. However, as seen by the error bars, there is considerable variability in symptom reporting within each time period. A small percentage of athletes were still quite symptomatic at the third time interval. At 11 days, 15% scored greater than 10 points and 10% scored greater than 17 points. Notably, the significant minority of athletes reporting high levels of symptoms at 11 days probably reflects a selection bias, given that symptomatic athletes are more likely to be seen in follow-up on a third occasion.

The distributions of difference scores were examined to determine if there was a consistent trend toward improvement across all participants. From Time 1 to Time 2, 90.4% of the participants reported fewer symptoms. From Time 1 to Time 3, 92.3% reported fewer symptoms. From Time 2 to Time 3, 84.6% reported the same or fewer symptoms. Therefore, for the vast major-

Table 5. *The Frequencies of Symptom Endorsements for the Post-Concussion Scale in Concussed Athletes*

		Mild		Moderate		Severe	
Symptom	**None**	**1**	**2**	**3**	**4**	**5**	**6**
Headache	21.5	14.6	16.5	18.5	15.0	11.2	2.7
Fatigue	30.8	21.5	12.3	11.9	13.1	6.9	3.5
Feeling slowed down	33.1	19.6	20.0	14.6	6.9	3.8	1.9
Drowsiness	33.8	18.8	15.0	10.8	11.2	6.5	3.8
Difficulty concentrating	34.2	16.9	15.0	18.1	8.1	6.2	1.5
Feeling mentally “foggy”	37.7	18.1	16.2	15.8	5.4	4.6	2.3
Dizziness	38.8	20.4	20.8	10.0	6.2	3.1	0.8
Difficulty remembering	45.0	20.0	18.1	5.4	5.8	4.6	1.2
Sensitivity to light	46.2	16.2	13.1	9.2	4.2	8.1	3.1
Balance problems	50.8	21.2	14.2	9.6	2.7	1.5	—
Nausea	53.8	21.9	12.3	8.1	2.7	1.2	—
Sensitivity to noise	54.2	15.0	8.5	8.1	7.3	6.5	0.4
Irritability	61.2	11.2	14.6	6.5	2.7	1.9	1.9
Trouble falling asleep	65.4	8.1	8.5	6.2	6.9	2.7	2.3
Sleeping more than usual	66.2	8.5	6.2	6.2	7.3	3.5	2.3
Visual problems	70.4	11.5	6.9	6.9	1.9	2.3	—
Sleeping less than usual	75.0	6.2	6.2	4.2	2.7	4.6	1.2
Nervousness	78.8	9.6	6.5	1.9	1.9	1.2	—
Feeling more emotional	82.3	7.7	2.7	5.8	0.8	0.8	—
Sadness	85.0	6.2	4.2	2.3	1.5	0.8	—
Numbness or tingling	85.4	7.7	2.7	3.5	0.8	—	—
Vomiting	91.2	6.2	2.3	0.4	—	—	—

Note. $N = 260$.

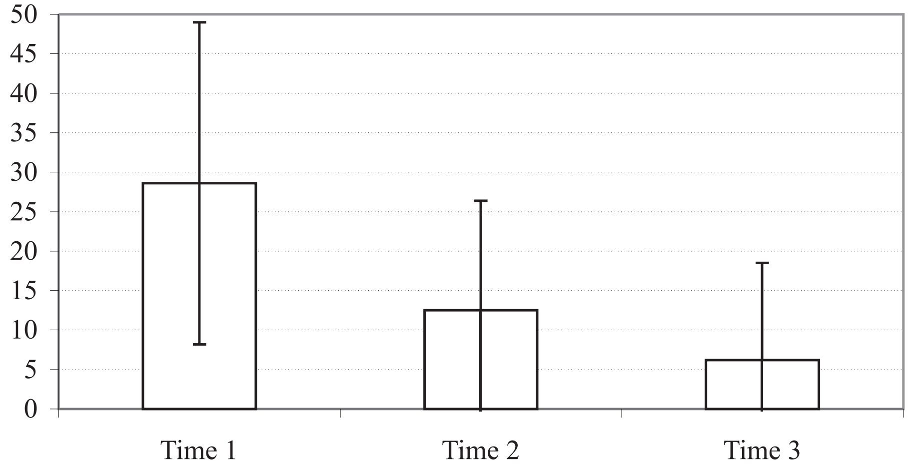

Figure 2. Total symptoms reported at approximately 1, 5, and 11 days post injury (*N* = 52). The bars represent the mean and the error bars represent one standard deviation. Median scores were 26, 8, and 1 for the three time periods, respectively.

ity of athletes, there was steady improvement across the test intervals. Worsening in symptoms was very uncommon across these time intervals. From Time 1 to Time 2, only one participant (2%) reported a worsening by 5 or more points. From Time 1 to Time 3, 3 participants (5.8%) reported a worsening by 5 or more points. From Time 2 to Time 3, 4 participants (i.e., 7.7%) reported a worsening by 5 or more points.

Table 6. *The Frequencies of Serial Symptom Endorsements for the Post-Concussion Scale in Concussed Athletes*

Symptoms	Time 1	Time 2	Time 3
Headache	88.5	61.5	32.7
Difficulty concentrating	82.7	51.9	23.1
Feeling slowed down	78.8	40.4	19.2
Dizziness	78.8	30.8	17.3
Nausea	77.3	21.2	15.4
Fatigue	76.9	50.0	21.2
Feeling mentally “foggy”	75.0	46.2	19.2
Drowsiness	73.1	48.1	17.3
Difficulty remembering	69.2	50.0	23.1
Sensitivity to light	57.7	40.4	17.3
Balance problems	55.8	26.9	11.5
Sensitivity to noise	50.0	40.4	15.4
Trouble falling asleep	45.0	25.0	15.4
Irritability	38.5	36.5	11.5
Sleeping more than usual	34.6	28.8	9.6
Visual problems	32.7	19.2	7.7
Sleeping less than usual	30.8	15.4	7.7
Nervousness	30.8	15.4	7.7
Feeling more emotional	19.2	11.5	7.7
Sadness	19.2	7.7	5.8
Numbness or tingling	15.4	7.7	1.9
Vomiting	11.5	7.7	1.9

Note. $N = 52$.

DISCUSSION

Preliminary psychometric data and information regarding the clinical interpretation of the PCS has been previously reported (Iverson & Gaetz, 2004; Iverson, Lovell, & Collins, 2003). This article provides comprehensive normative data and additional psychometric data for the inventory. This scale was originally developed to provide information to athletes, physicians, and athletic trainers regarding post-concussive symptoms and their resolution over time. Although the normative and psychometric work that has been completed thus far has been limited to the English language version, this inventory is currently available in Spanish, French, Russian, and Czech, and research studies are underway to study its utility in other cultural groups.

The measurement of subjective symptoms represents an important component in the evaluation of the concussed athlete. Resolution of post-concussion symptoms, in combination with normal neuropsychological test results, is generally regarded as a requirement for return to play (Aubry et al., 2002; Echemendia & Cantu, 2003). Although all self-report scales are subjective in nature, it is hoped that the investigation of psychometric properties of this scale will provide clinicians and researchers with additional information regarding the significance of symptom reporting following sports-related concussion.

The internal consistency reliability of the PCS is very high in healthy and concussed adolescents and young adults. There is no baseline or post-concussion difference in total symptom scores between high school students and university students. There is a difference, however, in baseline symptom reporting between young men and young women; healthy young women tend to report more symptoms. Therefore, normative data for the PCS were provided by gender (see Tables 2 and 3). It is interesting to note that although the samples of men and women differed with regard to report of symptoms at baseline, these differences were not significant following injury. However, there was a trend towards greater symptom reporting in the group of women. In another recent study, Broshek, Kaushik, Freeman, Erlanger, Webbe, and Barth (2005) did find significantly higher post-injury symptom reporting in a group of high school and collegiate women athletes, compared to a group of men. Therefore, this issue continues to warrant further exploration.

An advantage of the PCS is that it is a "state" measure of perceived symptoms. It is designed to provide an estimate of symptoms experienced on that day. As such, it can be used over short retest intervals (in contrast to other scales which require the respondent to rate symptoms over the past week, 2 weeks, month, or in general). As a state measure, however, the scale can reflect an unusually good or unusually bad day for the athlete, which might mislead the clinician. This can occur during the preseason evaluation or during post-injury evaluations. Moreover, people with depression, anxiety, life stress, or pain report very similar symptoms. Potential comorbid factors or frank differential diagnoses influencing symptom reporting are essential to consider in athletes with protracted recovery periods. The authors have seen athletes with presumed slow recoveries from concussions whose primary problem several months post-injury was a pre-existing anxiety disorder that appeared to be mimicking a post-concussion syndrome. The PCS is simply a tool that can be used to quantify symptoms; it should not be used in isolation. Rather it should be used within the context of a thorough clinical evaluation.

One limitation of this study is that we did not conduct a direct comparison of the concussed group who were tested three times post-injury with a non-injured control group who also underwent multiple assessments. The addition of this component to future studies would help to determine variability in symptom reporting in non-injured ("normal") athletes. In addition, through future studies we intend to examine the factor structure of the scale and determine whether reliable subscales can be identified. If so, these subscales will be normed. In addition, we will evaluate the reliability of the subscales and provide information regarding how to interpret statistically reliable and clinically meaningful change.

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