# The Functional Arm Scale for Throwers (FAST)—Part II

# Reliability and Validity of an Upper Extremity Region-Specific and Population-Specific Patient-Reported Outcome Scale for Throwing Athletes

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**Background:** The Functional Arm Scale for Throwers (FAST) is an upper extremity (UE) region-specific and population-specific patient-reported outcome (PRO) scale developed to measure health-related quality of life in throwers with UE injuries. Stages I and II, described in a companion paper, of FAST development produced a 22-item scale and a 9-item pitcher module. Stage III of scale development, establishing reliability and validity of the FAST, is reported herein.

Purpose: To describe stage III of scale development: reliability and validity of the FAST.

Study Design: Cohort study (diagnosis); Level of evidence, 2.

**Methods:** Data from throwing athletes collected over 5 studies were pooled to assess reliability and validity of the FAST. Reliability was estimated using FAST scores from 162 throwing athletes who were injured (n = 23) and uninjured (n = 139). Concurrent validity was estimated using FAST scores and Disabilities of the Arm, Shoulder, and Hand (DASH) and Kerlan-Jobe Orthopaedic Clinic (KJOC) scores from 106 healthy, uninjured throwing athletes. Known-groups validity was estimated using FAST scores from 557 throwing athletes who were injured (n = 142) and uninjured (n = 415). Reliability and validity were assessed using intraclass correlation coefficients (ICCs), and measurement error was assessed using standard error of measurement (SEM) and minimum detectable change (MDC). Receiver operating characteristic curves and sensitivity/specificity values were estimated for known-groups validity. Data from a separate group (n = 18) of postsurgical and nonoperative/conservative rehabilitation patients were analyzed to report responsiveness of the FAST.

**Results:** The FAST total, subscales, and pitcher module scores demonstrated excellent test-retest reliability (ICC, 0.91-0.98). The SEM<sub>95</sub> and MDC<sub>95</sub> for the FAST total score were 3.8 and 10.5 points, respectively. The SEM<sub>95</sub> and MDC<sub>95</sub> for the pitcher module score were 5.7 and 15.7 points, respectively. The FAST scores showed acceptable correlation with DASH (ICC, 0.49-0.82) and KJOC (ICC, 0.62-0.81) scores. The FAST total score classified 85.1% of players into the correct injury group. For predicting UE injury status, a FAST total cutoff score of 10.0 out of 100.0 was 91% sensitive and 75% specific, and a pitcher module score of 10.0 out of 100.0 was 91% sensitive and 75% specific, and several indices between intake and discharge time points.

**Conclusion:** The FAST is a reliable, valid, and responsive UE region-specific and population-specific PRO scale for measuring patient-reported health care outcomes in throwing athletes with injury.

Keywords: outcome; health-related quality of life; baseball; softball; measurement property

The Functional Arm Scale for Throwers (FAST) is an upper extremity (UE) region-specific and population-specific patient-reported outcome (PRO) scale developed to evaluate the health-related quality of life (HRQOL) of baseball and softball players.<sup>17</sup> The FAST comprises 22 items that combine to produce a total score between 0 and 100 points, with a higher score indicating lower HRQOL. In addition, subscale scores can be calculated in 5 domains that include the following: pain, throwing, activities of daily living (ADL), psychological impact, and advancement. A separate 9-item pitcher module is also available to specifically evaluate HRQOL of pitchers since they incur greater forces on

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the UE and have a greater throwing volume. The FAST was designed using a 3-stage scale development process, which is described in this article and in a previously published companion article.<sup>17</sup> During stage I (item generation and initial item reduction), scale items were generated to develop a beta version based on the National Center for Medical Rehabilitation Research disablement domains and to ensure a blend of sport-related and non-sport-related items. An expert panel assessed the importance of each item. Then, a focus group assessed the interpretability of each item, and empirical- and judgment-based processes were used to reduce the number of scale items. During stage II (factor analysis, final item reduction, and construct validity), the FAST was reduced, preserving the variance characteristics, factor structure, and construct validity of the beta version. The reduced 22-item version FAST and 9item pitcher module were determined to have excellent internal consistency and content and construct validity, suggesting they measure HRQOL in a way that is meaningful to throwing athletes.<sup>17</sup> While demonstrating internal consistency and content and construct validity of the FAST is an important step in scale development, additional measurement property testing is required to evaluate the value of the scale for clinical use in throwing athletes. Stage III of scale development required estimates of test-retest reliability, instrument error, and criterion validity in a population of baseball and softball players.

Evaluating the reliability of a PRO scale is essential because it speaks to the consistency of the scale.<sup>14,20</sup> The reliability of a scale may be estimated several ways, such as assessing test-retest reliability or measurement error. High test-retest reliability means that the scores from 1 administration of a scale to another remain stable when health status is unchanged.<sup>14,20</sup> The most common and accepted method to estimate a scale's test-retest reliability is the intraclass correlation coefficient (ICC).<sup>20,21</sup> Measurement error is estimated to determine the error associated with single and multiple administrations of a scale. The standard error of measurement (SEM) is a statistical estimate of the random error in a scale during a single administration, and minimum detectable change (MDC) is used to estimate error following multiple scale administrations. The MDC is the minimal change that falls outside the measurement error of the score for a scale.<sup>5,14,20</sup> While random and systematic errors are inherent aspects of measurement scales, reliability is important to consider for determining the scale's ability to differentiate among patients and to evaluate change over time.

Establishing the validity of a PRO is also essential prior to clinical use. Validity is the degree to which an instrument accurately reflects the construct(s) under investigation. The content and construct validity of the FAST were reported during stage II of development,<sup>17</sup> but concurrent and known-groups validity have not been reported. Concurrent validity is a measure of how well a scale correlates with previously validated scales that measure the same construct. To determine concurrent validity, the scale of interest is administered at the same time as a gold standard scale and results are compared. Although there are no gold standards for UE region-specific PRO scales, the Disabilities of the Arm, Shoulder, and Hand (DASH) is widely used for assessment of UE disorders.<sup>3,9</sup> Therefore, the DASH is a reasonable gold standard proxy for assessing HRQOL after UE injury in the general population. The Kerlan-Jobe Orthopaedic Clinic (KJOC) Overhead Athlete Shoulder and Elbow scale is another reliable and valid scale for measuring health status after UE injury.<sup>1</sup> The KJOC was specifically developed for throwing athletes and is also a reasonable proxy for assessing the impact of UE injuries in throwers. Collectively, the DASH and KJOC are appropriate scales for assessing the concurrent validity of the FAST.

Assessing known-groups validity of a scale is important because it speaks to the ability of a scale to differentiate groups that are known to vary on the trait measured.<sup>20</sup> Since the FAST is intended for use in throwing athletes with UE injury, it must be able to differentiate between athletes with UE injury and uninjured athletes. The ability to differentiate athletes by injury status provides guidance on score interpretation. Further, determining scale responsiveness, a measure of longitudinal validity, is important given that an instrument must be able to measure patient change over time to be clinically useful.<sup>15,20</sup> PROs without reported validity estimates have limited clinical value because they provide no sense of confidence in the evaluation or precision of their estimate.

Evaluating HRQOL is fundamental to the provision of whole-person, patient-centered health care. As such, developers of PRO scales must ensure a high-quality scale, and evaluating reliability and validity for the intended population of interest is one way to do that. The broad, long-term objective of developing the FAST was to design a high-quality, region-specific, and population-specific PRO scale based on a whole-person healthcare disablement model to measure HRQOL in high-demand baseball and softball athletes with injuries to their throwing arm. In our 2-part series, we describe the 3-stage process used to develop and validate the FAST for measuring HRQOL in throwing athletes with UE injury. In this article, we describe stage III of scale development, which includes establishing the reliability (test-retest reliability and measurement error [SEM and MDC]), validity (concurrent and known-groups), and responsiveness of the FAST for use in evaluating HRQOL in throwing athletes.

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Ethical approval for this study was obtained from the ATSU, Arizona IRB Committee (#2014-013).

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				Current Status		FAST Version		DASH Total and	
	Sport and Competition Level	Athletes, n	Age, y, Mean $\pm$ SD	Injured	Uninjured	Beta	Final	Arts Module	KJOC
Study 1 <sup>2</sup>	Baseball (192) and softball (77); $HS\left(18 ight)$ and college (251)	Total: 269 PP: 151 P: 118	$19.5\pm1.9$	Yes	Yes	Yes	No	No	No
Study 2 <sup>19</sup>	Baseball (136) and softball (46); HS (133) and college (49)	Total: 182 PP: 129 P: 53	$17.9\pm2.3$	Yes	Yes	No	Yes	No	No
Study 3 <sup>10,18</sup>	Softball; HS	Total: 25 PP: 0 P: 25	$18.3\pm2.0$	No	Yes	Yes	No	Yes	No
Study 4 <sup>7,10</sup>	Baseball; college	Total: 50 PP: 26 P: 24	$19.7\pm0.84$	No	Yes	No	Yes	Yes	Yes
Study 5 <sup>10,11</sup>	Baseball; HS	Total: 31 PP: 11 P: 20	$16.1\pm1.3$	No	Yes	Yes	No	Yes	No

 TABLE 1

 Description of Athletes in Each Study Analyzed<sup>a</sup>

<sup>a</sup>Values in parentheses indicate subjects per subgroup for sport and competition level. All baseball players were male; all softball players were female. DASH, Disabilities of the Arm, Shoulder, and Hand; FAST, Functional Arm Scale for Throwers; HS, high school; KJOC, Kerlan-Jobe Orthopaedic Clinic; P, pitcher; PP, position player.

#### METHODS

#### Participants

A database comprising data pooled from 5 studies (Table 1), each with unique research questions and distinct samples, was used to assess reliability and validity of the 22-item FAST and the 9-item pitcher module. Data were collected from a convenience sample of multiple clinical sites across the United States including high schools, colleges/universities, and orthopaedic clinics. Clinicians at the data collection sites were responsible for inviting eligible baseball and softball players to participate, administering study data collection forms, and returning completed deidentified data to study investigators. The institutional review board approved the use of the pooled database for this study.

Participants were male baseball and female softball players on a roster of an organized baseball or softball team. Participants, except those included in the responsiveness study, were included if they self-reported no change in health, injury, or playing status within 1 week prior to and during the study. Participants were excluded if they selfreported comorbidities, such as current lower extremity musculoskeletal injury or surgery, cardiovascular disease, metabolic disorder, balance disorder, or concussion.

#### Instrumentation

*FAST*. The FAST is a UE region-specific and populationspecific PRO scale to evaluate the HRQOL of baseball and softball players with UE injury. As previously described,<sup>17</sup> the FAST was developed using an empirical 3-stage process. At completion of stage I, a 54-item beta version of the FAST was created that included 5 subscales (pain, impairment, functional limitation, disability, and societal limitation) and a 9-item pitcher module. The beta version of the FAST was used in preliminary studies<sup>18</sup> evaluating the HRQOL of throwing athletes. After completion of stage II, the FAST was reduced to 22 items with the 9-item pitcher module.<sup>17</sup> For the 5 studies included in this analysis, either the 54-item beta version of the FAST or the 22-item final version of the FAST was used.

The 22-item version of the FAST comprises 5 subscales: pain (6 items that span the other 4 subscales), throwing (10 items), ADL (5 items), psychological impact (4 items), and advancement (3 items).<sup>17</sup> The separate 9-item pitcher module, specifically for pitchers, remained unchanged between the beta (stage I) and final (stage II) versions of the FAST. Each item in the FAST is answered using a 5-point Likert-type scale. The FAST total score, 5 subscale scores, and pitcher module score are individually calculated to produce a score that ranges between 0 and 100 points, with higher scores indicating lower HRQOL. The formula for scoring the FAST and the pitcher module has been reported previously.<sup>17,18</sup>

In stage III of FAST development, data from 3 of the smaller studies were obtained from the FAST beta version; data from 2 of the smaller studies were obtained from the final FAST version. For data from the beta version, only scores on the 22 items in the final version and the 9 items in the pitcher module were used to establish reliability and validity, so the 22 items used to evaluate reliability and validity were identical across the 5 studies

DASH. The DASH is a widely used UE region-specific PRO scale that evaluates the impact of UE disorders on physical disability and symptoms.<sup>9</sup> A total score is produced from 25 disability and 5 symptom items.<sup>3</sup> The DASH also includes a sports/performing arts module (4 items) to determine the impact of a UE injury on the patient's ability to play a sport or instrument.<sup>9,12</sup> The DASH has been found to be valid, reliable, and responsive to change.<sup>3</sup>

In stage III of FAST development, data from the DASH total and DASH sports/performing arts module gathered from participants in 3 of the smaller studies were used.

*KJOC Overhead Athlete Shoulder and Elbow Score.* The KJOC scale evaluates the functional status of the UE in overhead athletes.<sup>1</sup> It includes 10 items in 3 categories: impact of injury on function and athletic performance (5 items), UE symptoms (4 items), and interpersonal relationships related to performance (1 item).<sup>1</sup> The response format for the scored items is a visual analog scale, where a mark is placed along a 10-cm line indicating the athlete's current level of physical function as it relates to the shoulder or elbow injury during game and practice conditions. The KJOC's score ranges from 0 to 100 points, with lower scores indicating greater disability.<sup>1</sup> The KJOC has demonstrated acceptable measurement properties for validity, reliability, and responsiveness to changes in health status in professional and collegiate baseball athletes.<sup>1</sup>

In stage III of FAST development, participants from one of the smaller studies completed the KJOC. Prior to administration, the format of the KJOC was converted from a 10-cm visual analog scale to a 5-point Likert-type scale (0-, 2.5-, 5.0-, 7.5-, 10.0-point option for each item) to facilitate ease of completion and clinician friendliness and to enable scoring on a 100-point scale for comparison in the same direction as the FAST and DASH.

#### Procedures

Throwing athletes who consented to participate in each of the 5 studies represented in the larger pooled database completed a standard 29-item questionnaire (6 demographic, 6 playing history, 10 injury history, and 7 pitcher-specific questions) and either the 54-item beta version or the 22-item final version of the FAST, including the 9-item pitcher module, where appropriate. All data were collected anonymously.

*Reliability*. Reliability analyses were conducted using data from 1 study (Table 1, study 2). Baseball and softball players (n = 154; pitchers, n = 43) completed the FAST on 2 separate days separated by at least 2 days and no more than 7 days. The FAST and pitcher modules were completed by participants on day 1. On day 2, participants completed the FAST and the pitcher module again and were asked to self-report whether a change in health, playing, or injury status occurred since the first administration. Participants who self-reported a change in status between repeat administrations (n = 13) and those who did not complete the second administration (n = 15) were excluded in the test-retest reliability analyses.

*Concurrent Validity.* Data from throwing athletes in 3 of the smaller studies (n = 106) were used to assess concurrent validity of the FAST score, 5 subscale scores, and the pitcher module score compared with DASH (total and sports/performing arts module scores) and KJOC scores. Data were collected in a single session. Baseball and softball players from studies 3 and 5 (n = 56; pitchers, n = 45) completed the FAST and pitcher module and the DASH total and sports/

performing arts module. Baseball players from study 4 (n = 50; pitchers, n = 24) completed the FAST and pitcher module, DASH total and sports/performing arts module, and KJOC.

Known-Groups Validity. Baseball and softball players from all 5 studies (n = 557) were included in the knowngroups validity analyses. Self-reported current injury status was obtained from responses on the standard questionnaire, and the data were used to categorize participants into 1 of 2 groups: UE injured (n = 142) or uninjured (n = 415).

Responsiveness. A separate sample of injured baseball players (n = 18) being treated for a UE sport-related injury was recruited after the initial validation work was completed to provide data for determining scale responsiveness. Patients completed the FAST when care was initiated (intake) and again at discharge. At discharge, patients also completed a global rating of change to indicate their perceived level of change in health status between discharge and intake.

#### Data Analysis

Descriptive statistics (mean, standard deviation, and interquartile range [25th-75th percentiles]) were calculated for self-reported playing and injury history; FAST total score, 5 subscale scores (pain, throwing, ADL, psychological impact, advancement), and pitcher module score; DASH total and sports/performing arts module scores; and KJOC scores. All results for the FAST are presented based on the factor structure of the reduced 22-item final version of the FAST and the 9-item pitcher module.<sup>17</sup> The  $\alpha$  was set a priori at 0.05, and SPSS version 22 (IBM Corp) was used for all analyses.

*Reliability.* Test-retest reliability was analyzed using data from baseball and softball players who self-reported no change in injury, health, or playing status between days 1 and 2 of testing (n = 154). ICCs were used to examine the test-retest reliability of the FAST total score, 5 subscale scores, and pitcher module score. ICCs were interpreted as follows: 0.0 to 0.25, little or no relationship; 0.25 to 0.50, fair relationship; 0.50 to 0.75, moderate to good relationship; and >0.75, good to excellent relationship.<sup>14</sup>

Measurement error was examined by calculating the SEM<sub>95</sub> of the FAST total score, 5 subscale scores, and pitcher module score.<sup>21</sup> Calculations for the MDC used each SEM value and a 95% confidence interval (MDC<sub>95</sub>). Smaller SEM and MDC values indicate less error and more reliability in the measure.<sup>5,14,20</sup>

*Concurrent Validity.* ICCs were used to evaluate concurrent validity based on data from baseball and softball players who completed the FAST and pitcher module, DASH total and sports/performing arts module, and KJOC scales. The same ICC ranges defined above were used.<sup>14</sup>

Known-Groups Validity. Known-groups validity of the FAST total score, 5 subscale scores, and the pitcher module score were each analyzed by testing their ability to differentiate between baseball and softball players who self-reported their injury status as currently having a UE injury (n = 142) or being currently uninjured (n = 415). Canonical linear discriminant function analyses were conducted, along with receiver operating characteristic (ROC) curve analyses, to determine whether the FAST total score,

5 subscale scores, and the pitcher module score were able to differentiate between known groups of UE injured and uninjured athletes. ROC curves are plots of sensitivity and 1 - specificity values, where the upper left-hand portion of the ROC curve represents sensitivity and 1 – specificity at their maxima,<sup>6</sup> indicating the optimal cut-point between baseball and softball players with UE injury and those who are uninjured. Each cut-point also has associated sensitivity and specificity values. Area under the curve (AUC) values and 95% CIs were used to estimate the probability that the FAST total score, 5 subscale scores, and the pitcher module score would correctly classify the injury status of baseball and softball players. The range of the AUC is 0.5 to 1.0, and interpretation for the diagnostic ability of measurements was as follows: >0.90, high; 0.70 to 0.89, satisfactory; and 0.50 to 0.69, low.<sup>4,6,16</sup>

Floor and Ceiling Effects. The potential floor and ceiling effects were evaluated for FAST total score and 5 subscale scores by examining the percentage of injured participants who reported the minimum and maximum possible scores.

*Responsiveness.* Responsiveness of the FAST total score was evaluated using a number of complimentary indices, including a test for differences in scores between intake and discharge (Wilcoxon signed rank test), the standardized response mean (mean change in score divided by the standard deviation of the change in scores), effect size (mean change in scores divided by the standard deviation of the baseline score), correlation of the change score with global rating of change scale, and the AUC, calculated using an ROC curve analysis to discriminate between patients who had improved and those who had not improved. Global rating of change was measured using a 7-point Likert-type scale, ranging from "a great deal worse" (1) to "a great deal better" (7). Patients were classified as improved if they endorsed "somewhat or a great deal better" and not improved if they endorsed any other score at discharge.

For Spearman rho correlations, 0.40 to 0.59 was interpreted as a moderate correlation, 0.6 to 0.79 as strong, and 0.8 to 1 as very strong. (http://www.bmj.com/about-bmj/resourcesreaders/publications/statistics-square-one/11-correlationand-regression). Following Hosmer and Lemeshow,<sup>8</sup> we classified an AUC between improved and not improved patients of 0.8 to 0.9 as excellent discrimination and an AUC greater than 0.9 as outstanding discrimination.

# RESULTS

#### Descriptive Data

Descriptive data and PRO scale scores of the studies used for reliability and validity are presented in Table 2.

# Reliability

The FAST total score, 5 subscale scores, and the pitcher module score all demonstrated excellent reliability (Table 3). The time between repeat administrations of the FAST was 3 to 7 days (mean,  $4.5 \pm 2.4$  days). The SEM<sub>95</sub> and MDC<sub>95</sub> for the FAST total score were 3.8 and 10.5 points,

respectively. The 5 subscale scores demonstrated acceptable measurement error during a single administration, with SEM<sub>95</sub> values ranging from 4.3 points for the ADL subscale to 6.1 points for the advancement subscale. They also demonstrated acceptable measurement error during repeated administrations, with MDC<sub>95</sub> values ranging from 11.9 points for the ADL subscale to 17.0 points for the advancement subscale. The SEM<sub>95</sub> and MDC<sub>95</sub> for the pitcher module score were also acceptable at 5.7 and 15.7 points, respectively.

#### **Concurrent Validity**

The FAST total score, 5 subscale scores, and the pitcher module score all demonstrated moderate-to-excellent concurrent validity with the DASH total score, DASH sports/ performing arts module score, and KJOC score (Table 4). The FAST total score had the highest ICC values between the DASH total score (0.74), DASH sports/performing arts module score (0.72), and KJOC score (0.78). The 5 FAST subscale scores demonstrated fair-to-excellent concurrent validity, ranging from little or no relationship (ICC, 0.47) between the advancement subscale score and DASH total score to a good-to-excellent relationship (ICC, 0.81) between the throwing subscale and KJOC score. The pitcher module score demonstrated the highest (ICC, 0.70) concurrent validity with the KJOC score and lowest (ICC, 0.49) with the DASH total score.

# Known-Groups Validity

Mean FAST total scores for UE injury (n = 142) and uninjured (n = 415) baseball and softball players were  $33.5 \pm$ 18.5 points and  $7.3 \pm 10.4$  points, respectively (Table 2). The FAST total score was able to classify 85.1% of players into the correct injury group (canonical correlation, 0.66; P < .001). A leave-one-out cross-validation analysis also correctly classified 85.1% of players.

AUC for the FAST total score was 0.91 (95% CI, 0.89-0.94; P < .001), demonstrating high diagnostic ability for detecting the presence or absence of UE injury. A FAST total cutoff score of 10.0 points was 91% sensitive and 75% specific for predicting UE injury status.

Mean FAST subscale scores for UE injury and uninjured players are provided in Table 2. Stepwise entry of the 5 subscales indicated the throwing, advancement, and ADL subscales yielded a canonical correlation of 0.68. Each of these subscales was predictive of injury status (P < .001). Using these 3 subscales, 85.0% of baseball and softball players were correctly classified in the full dataset and in a leave-one-out cross-validation. AUCs for FAST subscale scores ranged between 0.78 and 0.90 (P < .001), demonstrating satisfactory to high diagnostic ability.

Mean FAST pitcher module scores for current UE injured (n = 62) and uninjured (n = 163) pitchers were  $52.8 \pm 35.0$  and  $7.2 \pm 14.2$ , respectively (Table 2). The pitcher module (canonical correlation, 0.68; P < .001) correctly classified 86.2% of players in the full dataset and in a leave-one-out cross-validation. AUC for the pitcher module was 0.91 (95% CI, 0.87-0.95; P < .001), demonstrating high

	Reliability <sup>19</sup>	Validity <sup>10</sup>			
Variable	Test-Retest and Measurement Error	Concurrent	Known-Groups		
Study analyzed	Study 2	Studies 3-5	Studies 1-5		
Age, y, mean $\pm$ SD	$17.9 \pm 2.3$	$18.2\pm2.1$	$18.8 \pm 2.2$		
Experience, y, mean $\pm$ SD	$9.7\pm3.8$	$10.1 \pm 4.7$	$10.7\pm3.9$		
Sport and level of competition	Baseball and softball,	Baseball and softball,	Baseball and softball,		
	HS and college	HS and college	HS and college		
Position, n	Total: 162; PP: 115; P: 47	Total: 106; PP: 37; P: 69	Total: 557; PP: 317; P: 240		
Current status, n	Injured: 23	Injured: 0	Injured: 142		
	Uninjured: 139	Uninjured: 106	Uninjured: 415		
FAST total score	Injured: 34.4 ± 19.4 (19.3-51.2)	Uninjured: $10.1 \pm 12.7 (0-14.3)$	Injured: $33.5 \pm 18.5 (18.2-47.7)$		
	Uninjured: $6.4 \pm 8.9 (1.1-7.4)$		Uninjured: $7.3 \pm 10.4$ (1.1-9.1)		
Pain subscale score	Injured: 27.9 ± 18.7 (12.5-37.5)	Uninjured: 8.3 ± 11.7 (0-12.5)	Injured: $29.0 \pm 19.0 (12.5-37.5)$		
	Uninjured: $5.5 \pm 10.2 (0-6.3)$		Uninjured: 6.1 ± 9.9 (0-8.3)		
Throwing subscale score	Injured: 45.1 ± 23.0 (28.8-65.0)	Uninjured: $13.5 \pm 15.4 (0-21.7)$	Injured: $42.0 \pm 23.4 (22.5-57.5)$		
	Uninjured: $9.5 \pm 12.3 (2.5-12.5)$		Uninjured: $10.2 \pm 13.0 (0-15.0)$		
ADL subscale score	Injured: 17.9 ± 18.2 (5.0-25.0)	Uninjured: 7.6 ± 11.5 (0-10.0)	Injured: 21.8 ± 17.8 (5.0-30.0)		
	Uninjured: $5.1 \pm 9.4 (0-5.0)$		Uninjured: $5.3 \pm 9.6 (0-5.0)$		
Psychological impact subscale score	Injured: 18.1 ± 8.7 (12.5-31.3)	Uninjured: $5.8 \pm 11.8 (0-6.3)$	Injured: 16.5 ± 17.7 (0-25.0)		
	Uninjured: $1.8 \pm 5.5 (0-0)$		Uninjured: $3.4 \pm 9.9 (0-0)$		
Advancement subscale score	Injured: 48.0 ± 35.8 (12.5-83.3)	Uninjured: 9.1 ± 18.7 (0-8.3)	Injured: 44.3 ± 35.5 (8.3-83.3)		
	Uninjured: $4.7 \pm 12.2 (0-0)$		Uninjured: 5.8 ± 14.5 (0-0)		
FAST pitcher module score	Injured: 56.5 ± 39.1 (25.0-100)	Uninjured: $9.4 \pm 17.2 (0-11.1)$	Injured: $52.8 \pm 35.0 (18.8-94.2)$		
	Uninjured: $4.3 \pm 7.4$ (0-5.6)		Uninjured: 17.2 ± 14.2 (0-8.3)		
DASH total score	N/A	$4.8 \pm 6.8 \ (0.0-7.5)$	N/A		
DASH sports/performing arts module		$10.1 \pm 17.1 \; (0.0\text{-}12.5)$			
score					
KJOC score		$78.2 \pm 23.3 \ (61.9 \hbox{-} 98.1)$			

 
 TABLE 2

 Demographic Information and Patient-Reported Outcome Scale Scores of the Studies Used for Reliability and Validity Analyses<sup>a</sup>

<sup>*a*</sup>Point values for scores are reported as mean ± standard deviation (25th-75th interquartile range). ADL, activities of daily living; DASH, Disabilities of the Arm, Shoulder, and Hand; FAST, Functional Arm Scale for Throwers; HS, high school; KJOC, Kerlan-Jobe Orthopaedic Clinic; N/A, not applicable; P, pitcher; PP, position player.

TABLE 3 Reliability of the Functional Arm Scale for Throwers  $(FAST)^a$ 

Item	Test-retest, ICC	SEM	MDC <sub>95</sub>
FAST total	$0.97^b$	3.8	10.5
Pain subscale	$0.95^b$	4.4	12.3
Throwing subscale	$0.96^b$	5.1	14.1
Activities of daily living subscale	$0.93^b$	4.3	11.9
Psychological impact subscale	$0.91^b$	4.6	12.7
Advancement subscale	$0.97^b$	6.1	17.0
FAST pitcher module	$0.98^b$	5.7	15.7

 $^{a}$ ICC, intraclass correlation coefficient; MDC<sub>95</sub>, minimal detectable change; SEM, standard error of the mean.

 ${}^{b}P < .001.$ 

diagnostic ability. A pitcher module cutoff score of 10.0 was 87% sensitive and 78% specific for predicting injury status.

#### Floor and Ceiling Effects

The FAST total score indicated neither floor nor ceiling effects, with none of the injured participants achieving a

 $\begin{array}{c} {\rm TABLE~4}\\ {\rm Concurrent~Validity~of~the~Functional~Arm~Scale~for~Throwers}\\ {\rm (FAST)~Compared~With~the~DASH~and~KJOC~Scales^a} \end{array}$ 

FAST Item	DASH Total	DASH Sports/Performing Arts Module	KJOC
FAST total	$0.74^c$	$0.72^c$	$0.78^c$
Pain subscale	$0.78^c$	$0.68^c$	$0.74^c$
Throwing subscale	$0.63^{c}$	$0.69^c$	$0.81^{c}$
Activities of daily living subscale	$0.82^c$	$0.70^c$	$0.73^{c}$
Psychological impact subscale	$0.69^{c}$	$0.63^c$	$0.62^c$
Advancement subscale FAST pitcher module	$\begin{array}{c} 0.47^b \\ 0.49^b \end{array}$	$0.59^c$ $0.66^c$	$\begin{array}{c} 0.67^c \\ 0.70^b \end{array}$

<sup>a</sup>Values reported are intraclass correlation coefficients. DASH, Disabilities of the Arm, Shoulder, and Hand; KJOC, Kerlan-Jobe Orthopaedic Clinic.

 ${}^{b}P < .05.$ 

 $^{c}P < .001.$ 

minimum (0) or maximum (100) score. For the subscale scores, the percentages of injured participants achieving minimum and maximum scores, respectively, were: pain

 $(4.3\%,\,0\%),$  throwing  $(0\%,\,0\%),$  ADL  $(12.9\%,\,0\%),$  psychological impact  $(27.3\%,\,0\%),$  and advancement  $(15.1\%,\,12.9\%).$  For the pitcher module, 3.2% achieved a minimum score and 21.0% achieved a maximum score.

#### Responsiveness

Eighteen injured baseball players (age,  $20 \pm 2.2$  years) provided data for the FAST responsiveness analysis. All players received treatment and rehabilitation for postsurgical (n = 2) or nonoperative/conservative care (n = 16)and reported a variety of injuries, including soft tissue and bone contusions, rotator cuff strains, and a SLAP lesion. Their treatment intervals (intake to discharge) ranged from 12 to 96 days (median, 27.5; interquartile range [IQR], 9.3-55.5). At intake, the median FAST total score was 43.8 (IQR, 22.5-52.0), and at discharge, 16.2 (IQR, 8.2-29.0). The median change in the FAST total score during treatment was -21.0 (IQR, -34.1 to -4.3) (Z = 2.7, P = .007). The standardized response mean for the change score was -0.79; the effect size was -0.99. The correlation between the FAST total change score and the global rating of change was strong (r = -0.68, P < .01). The AUC for discrimination between improved and not improved patients was outstanding at 0.946.

#### DISCUSSION

The majority of UE PRO scales were developed for the general population and lack relevance to the activities important to high-functioning populations, such as throwing athletes. Therefore, we created a region-specific and population-specific PRO scale to better evaluate the impact of injuries in this population. A necessary step in instrument development is evaluation of the scale's measurement properties to ensure that it performs well in the population of interest. The results of this study indicated the FAST is a reliable, valid, and responsive region-specific and population-specific PRO scale that assesses a broad spectrum of disablement and is a valuable and appropriate scale to evaluate HRQOL in throwing athletes with UE injury.

#### Reliability

Test-retest reliability is an important characteristic of a PRO scale because it reflects the consistency in responses associated with repeated administrations of the scale. The ICCs for the FAST were excellent (>0.90), suggesting that the FAST is a reliable scale. The test-retest reliability for the FAST total score was 0.97, for the 5 subscales it ranged from 0.91 to 0.97, and for the pitcher module it was 0.98. There were, on average, 4.5 days (range, 3-7 days) between repeat administrations of the FAST. It is unknown whether this time frame was long enough to eliminate effects of recall. These excellent test-retest reliability values for the FAST total score, 5 subscale scores, and pitcher module suggested that repeated measurements yield consistent scores when health status of the patient remains constant.

The measurement error of a scale should also be considered when interpreting the score. For the FAST total score and pitcher module score, the SEM<sub>95</sub> was 3.8 and 5.7 points, respectively, and the  $MDC_{95}$  was 10.5 and 15.7 points, respectively. Overall, the estimate of random error, represented by SEM<sub>95</sub>, for the FAST was relatively low. Thus, a clinician can assume that random error in the FAST accounts for 4 points in the total score and 6 points in the pitcher module score. The MDC<sub>95</sub> represents the minimal change needed in a FAST score from one administration to another to be confident that the change is greater than measurement error. For example, when a patient is evaluated 2 or more times with the FAST or pitcher module, a change of less than 11 or 16 points, respectively, from one administration to the next is likely error associated with the measurement and not true change in the patient's health status.

The test-retest reliability for the DASH (ICC, 0.96) in a general, nonthrowing population is reportedly excellent.<sup>3</sup> The error values on single and multiple day scores for the DASH are similar to the FAST, with an SEM of 4.6 points and MDC<sub>95</sub> of 12.8 points.<sup>3</sup> The DASH is a reliable PRO scale for UE conditions in a general population; however, its reliability in a throwing population is reported to be lower (ICC, 0.83).<sup>1</sup> Reports of the KJOC test-retest reliability (ICC, 0.88) in a small sample of college and professional baseball athletes (n = 18) are similar to the DASH.<sup>1</sup> Compared with the DASH and KJOC, the test-retest reliability of the FAST is higher, although all the instruments had good to excellent reliability.<sup>14</sup> Based on a moderately sized sample of baseball and softball players aged 14 years and older, the test-retest results of the FAST indicated that it is an appropriate scale for measuring HRQOL in throwing athletes with UE injury. Furthermore, results suggested it is stable because reproducible scores were obtained when a patient's condition remained unchanged.

#### Validity

Our results indicated that the FAST has good-to-excellent concurrent and known-groups validity, suggesting it captures what it is intended to measure and can differentiate between injured and uninjured athletes. Because the FAST and DASH are both UE PROs that evaluate more than 1 domain of health and use the same calculation to generate a score, we determined concurrent validity between the FAST and DASH. Furthermore, because the FAST and KJOC address pain and function in baseball athletes with UE injury, a comparison between these measures was also appropriate. By correlating the FAST total score, 5 subscale scores, and pitcher module with the DASH total score, sports/performing arts module score, and the KJOC score, we could evaluate validity and establish the FAST as a unique and relevant UE region-specific and populationspecific PRO scale.

Our concurrent validity results demonstrated the FAST and pitcher module serve an important role in providing a holistic, multidimensional scale for measuring HRQOL in throwing athletes with UE injury. Furthermore, it is fast and easy for athletes to complete and clinicians to score. The FAST total and pitcher module scores were highly correlated with the KJOC score (ICC, 0.78 and 0.70, respectively), and most of the FAST subscale scores correlated most strongly with the DASH total score. The strong correlations of the FAST total and pitcher module scores with the KJOC score can be explained by the similarity in questions related to pain and function while throwing. Both scales include items that are relevant to throwing athletes with UE injury. However, the FAST also contains subscales that specifically address ADL, psychological impact, and advancement domains, which more closely relate to the general health questions included in the DASH. While the FAST and pitcher module correlated with the DASH and KJOC, none of the correlations were greater than 0.82, an overlap in variance of  $67.2\% (0.82^2)$ . Therefore, even though the FAST and pitcher module correlated with these other scales, the correlations did not approach 1.0, suggesting the FAST and pitcher module capture information that is unique.

The FAST had good-to-excellent known-groups validity. Using the FAST, a clinician could classify a throwing athlete currently experiencing a UE injury from an uninjured throwing athlete with an estimated 85.1% accuracy. Furthermore, the high AUC value for the FAST (0.91) indicated high diagnostic ability to differentiate between an injured and uninjured throwing athlete. We also estimated that throwing athletes who scored 10 out of 100 on the FAST total score were likely to have a UE injury (sensitivity, 91%; specificity, 75%). The ability of a PRO scale to distinguish between groups is clinically beneficial. For example, clinicians can use this information as ancillary or corroborative evidence about their patient's health status, which should enhance the management of care for throwing athletes. Our estimate of a cut-off score to differentiate injured from uninjured athletes is similar to that used in the KJOC. In a study of professional baseball athletes, Kraeutler et al<sup>13</sup> found KJOC scores greater than 90 out of 100 indicated a healthy athlete and scores less than 90 suggested the athlete was injured or experiencing pain. Descriptive information, such as the cutoff scores for injured versus uninjured patients, supports the clinical utility of these scales.

Although our results are similar to those of the KJOC, the methods by which these cutoff scores were determined are different. Baseline scores for the KJOC were based on descriptive analyses using mean values as the guide to distinguish patients who were injured and uninjured. The FAST cutoff score was determined using discriminative analyses, which are more rigorous and recognized as an appropriate standard for establishing measurement properties.<sup>20</sup> Furthermore, the study population used to calculate the KJOC baseline score was based on a small group (n = 44) of healthy professional baseball pitchers, <sup>13</sup> limiting its generalizability to a larger population of throwing athletes, such as position players, softball players, and throwing athletes playing at different levels of competition (ie, youth, high school, and college). Even though the FAST data contained a larger proportion of baseball and college players, its data represent a wider spectrum of throwing athletes. Therefore, clinicians using the FAST can be more confident in using the 10-point cutoff score for identifying baseball and softball players at multiple levels of play who may be experiencing pain or injury and the resulting diminished HRQOL.

# Floor and Ceiling Effects

The analysis of floor effects indicates that a portion of injured respondents reported no problems with ADL (12.9%), psychological impact (27.3%), or concerns about advancement (15.1%). The FAST was developed to assess the impact of throwing-related injuries on high-functioning athletes, including those who experience significant symptoms and functional limitations only with full-effort throwing. Operationally, this translates into addressing the ceiling effects that occur when variance in the measured construct no longer registers. This makes discrimination among respondents who peak at the upper end of the scale impossible. In fact, among injured pitchers, 21% achieved the maximum score. Inspection of the items on the pitcher module indicates that, if a pitcher is "unable to pitch," he or she will achieve a maximum score on the pitcher module, so on this dimension, these pitchers have truly "ceilinged," and there is no more variance to measure.

#### Responsiveness

Our complementary responsiveness analyses indicate the FAST total score is responsive and is able to capture changes in patient health status. There was a 21.0-point change in the FAST total score between intake and discharge, indicating overall improvement in HRQOL at the time of discharge. This change in the FAST total score was strongly correlated with the patient's perception of improvement as indicated by the global rating of change in addition to an outstanding ability to discriminate between subjects who had improved and those who had not improved.

In addition to determining responsiveness of the FAST, it is important to consider how FAST responsiveness compares with similar scales, such as the DASH and KJOC. Comparing responsiveness of PRO scales is somewhat challenging given differences in analyses and populations used to report responsiveness. A responsiveness study for the DASH contained effect sizes and standardized response means using a sample of shoulder and wrist/ hand patients.<sup>3</sup> The overall effect size for the DASH was 0.59, and the overall standardized response mean was 0.78.<sup>3</sup> For the FAST, the effect size was -0.99, and the standardized response mean -0.79, indicating the ability of the FAST to detect change in response to treatment exceeds that of the DASH, one of the most commonly used PROs for UE injuries.

The responsiveness of the KJOC was estimated somewhat unconventionally.<sup>15</sup> They calculated the effect sizes (mean/SD of change scores) for their "no improvement" (n = 13) and "improvement" (n = 11) groups as -0.13 and 1.69, respectively.<sup>1</sup> Analogous computations for the FAST total score yield values of 0.87 and 1.66, respectively. Based on these values, both the FAST and KJOC show similar responsiveness to improvement; however, given differences in how "improvement" was operationalized between the studies, the scales cannot be directly compared. The authors of the KJOC defined improvement as returning to play without pain and no improvement as continuing to report functional impairment.<sup>1</sup> The authors of the current article defined improvement as endorsing "somewhat or a great deal better" on a global rating of change scale at discharge and not improved as any other response at discharge. Overall, the large effect size and standardized response means found for the FAST demonstrate its responsiveness, suggesting the FAST responds to change at a level that matches or exceeds other commonly used UE PROs.

#### Limitations and Future Research

There are limitations to the present study. Our sample was recruited primarily from secondary school and collegiate settings, and results may not be generalizable to older, recreational, or professional throwing athletes. While our sample included high school athletes and female softball players, their representation was less than college athletes and male baseball players. None of the participants who completed the KJOC were injured, so the range of their scale scores is substantially truncated, which almost certainly led to a conservative estimate of the concurrent validity between the FAST and KJOC. A larger and more diverse sample of overhead throwing athletes with upper extremity injury for establishing responsiveness is needed to more fully generalize the ability of the FAST to capture true and meaningful changes in health status over time.

# CONCLUSION

Our findings suggest the FAST is a reliable, valid, and responsive UE region-specific and population-specific PRO scale that is valuable for measuring patientreported health care outcomes in a broad range of throwing athletes with UE injury. Clinicians and researchers should consider using the FAST as a PRO scale in clinical practice to evaluate the HRQOL of baseball and softball players with UE injuries.

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