

# Reliability, Responsiveness, and Criterion Validity of the Kii Sensor, a New Tool for Assessment of Muscle Function

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**ABSTRACT** Musculoskeletal injuries are a leading cause of disability in both the general population and military, and the ability to effectively quantify musculoskeletal function remains problematic. The aim of the current study is to investigate the reliability, responsiveness, and criterion validity of the kii Sensor for measurement of muscle strength, a key aspect of comprehensive functional assessment. Forty-four (24 male, 20 female) physically active civilian adults (mean [SD] = 21.2 [1.5] years of age) with no history of upper extremity injuries in the last year and no current complaints of pain, weakness, or functional limitation completed two sessions of maximum shoulder external rotation contractions. The forces were measured with a kii Sensor and isokinetic dynamometer. The devices showed strong correlation ( $r = 0.89$ ) and no significant mean difference ( $0.3 \pm 3.3$  lb,  $p = 0.47$ ). Intrasession reliability for both devices was analyzed using intraclass correlation coefficients ( $ICC_{3,1} = 0.96$  [95% confidence interval = 0.93–0.98]), with the kii Sensor having slightly less standard error and trial-to-trial variability. The kii Sensor 7-day reliability was  $ICC_{3,3} = 0.97$  (95% confidence interval = 0.94–0.98). The kii Sensor demonstrates excellent reliability, responsiveness, and validity compared with a gold standard isokinetic dynamometer. Several key attributes contributing to this technology's military relevance are discussed.

## INTRODUCTION

Musculoskeletal injuries are a leading cause of disability in the general population and U.S. military, resulting in enormous direct and indirect costs.<sup>1–4</sup> Prerequisite to any program of injury management, from prevention to rehabilitation, is the ability to effectively quantify the many facets of musculoskeletal function. The World Health Organization defines function at three different levels: the body part function and structure, the whole person, and the whole person in a social context.<sup>5</sup> Disability results from dysfunction at one or more of these levels in the form of impairments, activity limitations, and participation restrictions, respectively. To effectively assess any individual, all three levels must be tested.<sup>6</sup> Although tests of the activity and participation levels are important for estimating daily function, they lack sensitivity to underlying impairments of muscle function allowing potential compensatory movements, which may predispose to future injury. For example, strength impairment of the ankle plantar flexors is a risk factor for development of Achilles tendinopathy.<sup>7,8</sup> However, plantar flexor strength has very low correlation with tests of activity and participation.<sup>9</sup> Thus, assessment at the level of body part must also be considered. Additionally, activity and participation tests provide only limited information to guide the progress of individuals who fail to meet required standards. For instance, an individual who fails to achieve the required proficiency in a push-up test would benefit from knowing if this was related to weakness in the pectoralis musculature, the dynamic stabilizing muscles of the

glenohumeral joint, or the scapulothoracic stabilizers.<sup>10</sup> This is especially critical after injury, as medical and rehabilitative treatment primarily aim to resolve impairments in body part function and structure.<sup>7,11</sup> Therefore, to comprehensively guide decisions for musculoskeletal training either to prevent or rehabilitate injury, specific objective measures at the level of key individual body parts is a necessity, and should be used in conjunction with other functional tests. Objective performance standards serve a number of important purposes, from identifying and reducing injury risk factors, to easing clinical decision-making with legally defensible criteria, to improving efficiency of fitness training and rehabilitation. To develop and administer specific, comprehensive, and validated performance standards, effective methods for measurement of muscle function must be identified.

Despite recent technology advancement,<sup>12</sup> measurement of regional musculoskeletal function remains a complex entity rooted in long-standing paradigms. The most popular methods, which have been in use by clinicians and fitness professionals for decades, all have positive aspects but significant limitations. Manual muscle testing (MMT) is the most widely used method. An examiner applies hand pressure to a body segment as the individual exerts countereffort. The examiner then subjectively rates the maximal exertion of the tested muscle on a 0 to 5 Likert-type scale. This technique is efficient and cost-effective, but unreliable and negatively impacted by human factors such as size and strength of the examiner.<sup>13–15</sup> Additionally, this only provides a single metric of maximal isometric strength. Recent studies show that more complex metrics requiring a force/time curve, such as rate of force development, provide useful information for return to activity decisions.<sup>16</sup> For these reasons, MMT fails to provide adequate data needed to develop performance standards.<sup>17</sup> On the other end of the spectrum are isokinetic dynamometers

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(ID), which provide highly complex and dynamic measures, such as indices of power and work, with excellent reliability and are generally considered the gold standard for muscle assessment.<sup>18,19</sup> The major limitations for IDs include high cost (up to \$50,000 per instrument), nonportability with a large footprint (up to 64 ft<sup>2</sup>), and complex setup and operation.<sup>20,21</sup> The ID instruments are computerized, recording a number of useful metrics based on a torque/time curve, but their high cost and labor-intensive methodology have limited their applicability on a large scale. The most commonly used compromise between MMT and ID devices is handheld dynamometry (HHD). The HHD adds a quantitative force sensor, either spring loaded or digital, to a MMT. This removes the subjectivity of MMT, and provides a quantifiable metric of force output. The devices are cost-effective, generally in the range of \$1,000 to \$2,000, and efficient to operate.<sup>22</sup> Some have wireless technology to expedite data collection, and some have the ability to generate a force/time curve for more complex performance metrics. The major limitation for these devices is that numerous authors find them subject to the same human factors as MMT, such that if the muscle to be tested is stronger than the examiner, the data are no longer reliable.<sup>23–26</sup> A solution to this is to provide external stabilization to the device, which can be cumbersome, time consuming, and adds to the equipment necessary to conduct tests.<sup>27</sup> Recently, tension myometers have become more appealing as strength testing devices (sometimes referred to as pull-type HHD).<sup>28,29</sup> These strain gauges eliminate the examiner from the testing procedure, resulting in reliable strength data. Unfortunately, very little data exist on the measurement properties of myometers. A new device, the kiiro Sensor (Kiiro, Madison, Wisconsin), is a tension myometer that has been validated and shown to be reliable in mechanical laboratory testing, but has not been studied with human subjects (personal communication with Kiiro). Therefore, the purpose of this study is to investigate the reliability, responsiveness, and criterion validity of the kiiro Sensor in comparison to a gold standard ID.

## METHODS

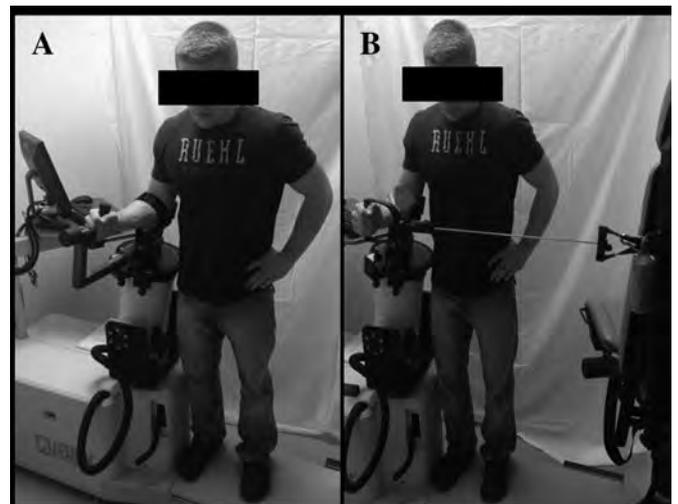
### Participants

Forty-four (24 male, 20 female) civilian adults (age, mean [SD] = 21.2 [1.5] years) with no history of upper extremity injury in the last year and no current complaints of pain, weakness, or functional limitation participated. Males averaged 179 cm tall (range 168–199 cm), with mean weight of 84.1 kg (range 64.4–161.0 kg). For females, mean height was 166 cm (range 159–176 cm), mean weight was 68.5 kg (range 53.0–88.2 kg). Thirty-nine were right-hand dominant based on self-report of hand used for writing. Individuals were recruited from the local campus physical therapy and exercise science departments. All participants reported moderate-to-high levels of average weekly physical activity ( $\geq 5$  on the Tegner Activity Level Scale<sup>30</sup>). Individuals were excluded if

they had any history of cardiovascular disease, neurologic or vascular impairment of the upper extremity, or cervical injury in the previous year. All participants provided informed consent before the study, which was approved by the University of Wisconsin-La Crosse Institutional Review Board.

### Procedure

Individuals participated in two separate sessions 1 week apart, at the same time of day to maximize consistency of recent activity levels. Both sessions began with a 3-minute warm-up on an upper extremity ergometer, followed by submaximal isometric external rotation (ER) contractions at approximately 25, 50, and 75% of full effort. During the first session, subjects performed a familiarization trial with each device, after which they performed three maximal isometric contractions of standing shoulder ER using both the kiiro Sensor and a Cybex Norm (CSMI, Stoughton, Massachusetts) ID, for a total of six repetitions, all performed with the dominant arm. The instrument sequence was randomized and balanced among participants to eliminate order effects. Participants received standardized instructions to perform at maximal effort, but no verbal encouragement during exertion. They were instructed to inform the investigator of any pain experienced during testing so the procedure could be terminated appropriately. All trials with a single instrument were separated by 1 minute, and participants rested 5 minutes between instruments to minimize the effects of fatigue.<sup>31</sup> Individuals were asked to maintain their current level of physical activity, with no new activities or exercise protocols commencing between test sessions. When participants returned for session two, they performed three maximal isometric contractions of standing shoulder ER with the kiiro Sensor only. For both sessions, all contractions were performed with the shoulder in a position of 30° abduction in the scapular plane (30° anterior to the



**FIGURE 1.** Participant position for data collection with the (A) isokinetic dynamometer and (B) the kiiro Sensor. The sensor is attached inline between the handle and a steel cable anchored to the locked dynamometer seat.

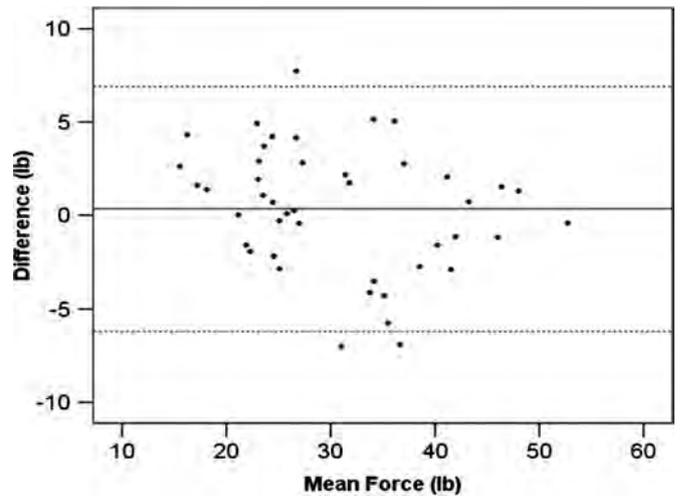
frontal plane), and 0° of rotation (Fig. 1A). The standing position previously provided reliable shoulder measures.<sup>32,33</sup> This position was maintained during use of the kiio Sensor by keeping the participant standing at the dynamometer station, using the elbow rest as a light tactile guide only, the elbow was not strapped in place as it normally would be with use of the dynamometer (Fig. 1B). The ID was calibrated on a weekly basis. The calibration of the kiio Sensor was checked weekly using the same set of weights as the ID, and it maintained accuracy within ±0.1 lb throughout the data collection period without needing recalibration.

**Statistical Analysis**

All data from the ID were collected with Humac2009 software (CSMI) at a sampling rate of 100 Hz, and were entered manually into a spreadsheet. All data from the kiio Sensor were sampled at 80 Hz, transmitted automatically to kiio Flex software (Kiio) running on a Windows tablet (Dell Latitude 10; Dell Inc., Round Rock, Texas), and then exported to the spreadsheet for further analysis. For ID data, torques recorded by the Cybex system were converted to force by measuring the mechanical lever arm from the dynamometer axis of rotation to the handle, and dividing the torque value by this distance. Reliability coefficients (intraclass correlation coefficient [ICC<sub>3,k</sub>] with 95% confidence intervals) and the standard error of measure were calculated for both the kiio Sensor and ID for the three trials within session one.<sup>34</sup> The method error coefficient of variation (CV<sub>ME</sub>) was also calculated for each device, providing a measure of the percentage of variation relative to the mean from trial to trial.<sup>35</sup> Reliability and CV<sub>ME</sub> were also analyzed for the kiio Sensor over the 7-day period between tests, using the pooled data (average of 3 trials) from sessions one and two. Additionally, the minimum detectable difference (MDD<sub>95</sub>) was calculated based on the 7-day data.<sup>35</sup> Criterion validity of the kiio Sensor relative to the ID was analyzed using a Pearson correlation coefficient to evaluate the strength of the linear relationship of the data and a matched pairs *t* test to evaluate for systematic bias.<sup>35</sup> Bland–Altman plots with 95% limits of agreement were constructed to visually examine for systematic discrepancies across the range of forces measured.<sup>36</sup> All statistical analyses were completed with SPSS v22 (IBM, Armonk, New York).

**RESULTS**

Mean (SD) maximal ER force for session 1 was 20.4 lb (6.5). Reliability outcomes are presented in Table I. The Pearson correlation coefficient was *r* = 0.89, and the matched-pairs



**FIGURE 2.** Method comparison with difference calculated by subtracting the maximum force value obtained with the ID from that obtained by the kiio Sensor. The solid line represents mean difference between devices with the dotted lines showing the 95% limits of agreement.

*t* test showed no difference between the two devices (mean difference = 0.3 ± 3.3 lb, *p* = 0.47). Limits of agreement were ±6.6 lb (Fig. 2). Mean (SD) maximal ER force for session 2 was 21.6 lb (6.0), with reliability and responsiveness outcomes in Table I.

**DISCUSSION**

This is the first study to investigate the reliability, responsiveness, and criterion validity of the kiio Sensor for strength measurement in humans. The maximum forces measured, and the high reliability of the gold standard ID in our protocol is in agreement with previous research on shoulder ER isometric strength.<sup>32,37,38</sup> Further analyses indicate that the kiio Sensor provides clinically acceptable data with excellent reliability and responsiveness for human strength assessment that is as good as or better than the ID.<sup>35</sup> This is consistent with previous research with another tension myometer (Mecmesin, West Sussex, United Kingdom), which was used to assess isometric shoulder strength as part of the Constant score, and demonstrated good repeatability with isometric ankle dorsi/plantar flexion strength measures as well.<sup>28,39,40</sup> Bland–Altman analysis of kiio Sensor and ID data shows no evidence of systematic bias over the range of forces measured (Fig. 2). However, the limits of agreement of 6.6 lb are fairly high relative to the maximal forces measured for shoulder ER, and therefore repeated shoulder ER measures on any individual should be performed using the same type of device, rather than using them

**TABLE I.** Reliability and Responsiveness Outcomes

	Within Session			7-Day Reliability			
	ICC <sub>3,1</sub> (95% CI)	SEM (lb)	CV <sub>ME</sub> (%)	ICC <sub>3,3</sub> (95% CI)	SEM (lb)	CV <sub>ME</sub> (%)	MDD <sub>95</sub> (lb)
ID	0.96 (0.93–0.98)	1.3	6.75				
kiio Sensor	0.96 (0.93–0.98)	1.2	6.14	0.97 (0.94–0.98)	1.0	7.17	2.8

interchangeably over time with a single subject. Given the excellent reliability and small percentage of variation from trial-to-trial, low MDD, and strong criterion validity of the kiio Sensor, this device appears to provide a number of potential advantages over currently used methods, warranting further discussion.

The kiio Sensor provides efficient, objective quantification of muscle force/time, eliminating the problems of subjectivity, rater bias, and single data points encountered with the MMT and most HHD methods. The ID and other tension myometers also solve some of these problems, but the kiio Sensor does so at a fraction of the cost. Current list prices of approximately \$1,000 are roughly 2% of an ID, and less than 50% of the Mecmesin myometer. The kiio Sensor is also very portable, being smaller and lighter than other tension myometers on the market, while the ID fails to be portable in any way. Thus, widespread use may be more easily achievable in various settings, from rehabilitation clinics, to fitness training facilities and beyond. The attachment of the kiio Sensor is adaptable to various implements (e.g., static straps, steel cable, elastic bands), and anchor points, allowing for wide-ranging use in both static and potentially dynamic test applications. Although the ID is the only device capable of standardizing joint rotation velocities, the ability of the kiio Sensor to provide kinetic measures throughout a range of motion with force/time data enables the possibility of collecting more complex metrics of body part function. This is an area of study with ample room for innovation, as the clinical use of rate of force production and joint acceleration and deceleration are only beginning to be investigated.<sup>16,41</sup> Additionally, there may be ways to incorporate the device into the other levels of functional assessment, gaining more quantitative data from activity and participation tests. Perhaps the most important attribute of the kiio Sensor is its wireless connectivity. This allows for data to be quickly and seamlessly transmitted to a tablet, which worked reliably throughout this study. According to the manufacturer, this device can communicate with both computers and mobile devices, and integrates with a secure cloud database. This capability enables collection of mass quantities of information in a cost-effective manner, enabling large-scale analytics to identify trends having significant implications for prediction and prevention of injury or reinjury. In the military environment, this type of device represents a means to gather muscle performance data on large numbers of active duty members efficiently with limited expense. Data can be collected in various settings, without the need for extensive protocol training, specialized equipment, or dedicated testing locations. Consider the implications of attempting this with isokinetic technology, including the time, equipment, and space requirements, and the need for new assessment tools at the level of body part structure and function is clear. With tension myometers, it is feasible to assess multiple muscles on an individual in a matter of minutes, with automated generation of databases contributing to musculoskeletal injury prevention and rehabilitation initiatives.

Despite these advantages, the kiio Sensor has two limitations. The first is sampling rate that is limited to 80 Hz. Although this is sufficient for most clinical analysis, it is significantly slower than other devices. New Biodex IDs (Biodex Medical Systems, Inc., Shirley, New York), with appropriate auxiliary outputs, are capable of sampling rates up to 2,000 Hz, and the Mecmesin device can achieve 5,000 Hz.<sup>20,39</sup> The significance of this may be minor, however, as some studies have shown that a sampling rate as low as 50 Hz results in negligible differences in force data when compared to frequencies up to 1,000 Hz.<sup>42,43</sup> The second limitation is maximum load. The kiio Sensor is rated up to 250 lb, whereas IDs, such as the Cybex device in this study, are commonly tested for accuracy up to 500 lb of force. The Mecmesin myometer is capable of measuring up to 225 lb, whereas other tension myometers have various ranges. This range may limit the kiio Sensor's ability to assess some muscles on some individuals, but it is possible to connect multiple sensors in parallel, increasing the capacity to at least 500 lb. Therefore, this limitation is likely to be rarely encountered. Considering its overall capabilities, the addition of some key tests of body part function using technologically advanced tools such as the kiio Sensor could provide a significant increase in usable data with which to manage musculoskeletal injury prevention and rehabilitation. Because of the efficiency and cost-effectiveness of such instruments, the relative effort of incorporating these measures is small in comparison to the scope and financial impact of musculoskeletal injuries.

## LIMITATIONS

A methodological limitation likely added some small element of error to the data. In order to convert torques recorded with the ID to forces for comparison with the kiio Sensor, the moment arm of the ID needed to be measured manually. The investigators made every effort to keep this measurement as consistent as possible, thereby minimizing impact on the data. Of greater importance, this study was restricted to healthy individuals for shoulder ER only, which limits generalizability to patient populations and other body regions. Additionally, the individuals were civilians, which raises the question of whether the results apply to military populations. Although the population studied may have characteristics in common with some segments of active duty members, this study only represents a first step in the process. Now that reliability and criterion validity of this device in asymptomatic individuals are established, the effort and cost of future study are warranted. This includes the investigation of various body regions, various populations (i.e., military, healthy, injured, wider age ranges), and the usefulness of more complex data available from the kiio Sensor (e.g., rate of force production, area under the force/time curve) for both static and dynamic tests. Once accomplished, meaningful objective performance standards can then be established and prospectively validated.

## CONCLUSIONS

Current methods of muscle assessment are limited in their ability to objectively quantify impairments of localized muscle function, rendering them impractical for widespread augmentation of comprehensive functional testing. The Kiio Sensor demonstrates excellent reliability, responsiveness, and validity compared with a gold standard ID in a group of healthy participants. Because of several key attributes, this technology may be an excellent tool for muscle assessment in widespread settings, and with additional study could assist in the establishment, validation, and administration of objective performance standards. Although this study is limited to the measurement of isometric shoulder ER, the device appears readily applicable to the measurement of more complex metrics for many muscle groups, efficiently increasing the quantity of useful data for the prevention and rehabilitation of musculoskeletal injuries.

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